For the full versions of articles in this section see bmj.com

Nigeria files criminal charges against Pfizer

Jeanne Lenzer BOSTON

Officials in Nigeria have filed criminal and civil charges against Pfizer for its role in the deaths and disabilities of children who were treated with an experimental drug during a meningitis outbreak in Kano in 1996.

The charges, filed by government prosecutors in Nigeria, follow three attempts by families of the children to sue in US courts. All three attempts were denied after Pfizer successfully argued that the US courts were not an appropriate forum.

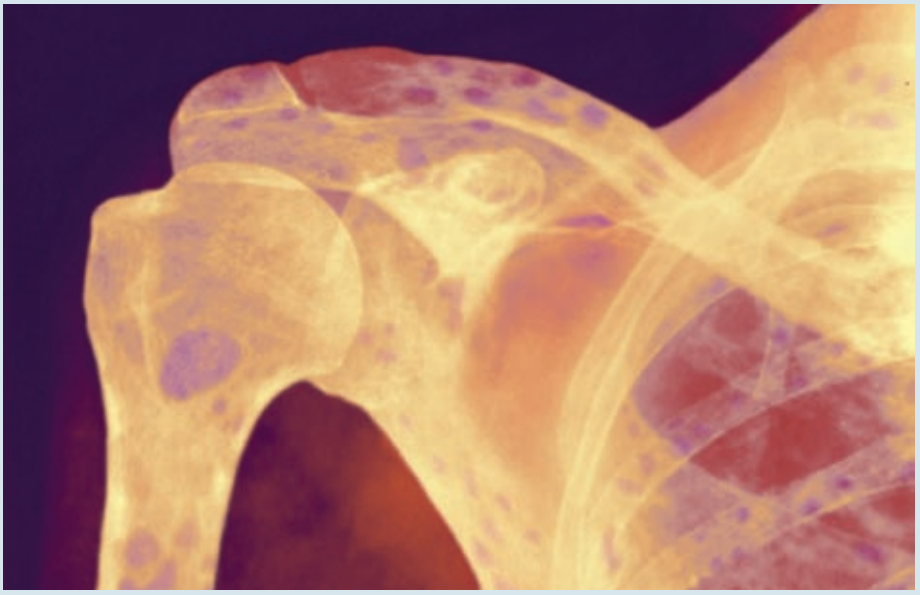
Four separate legal actions have been filed in Nigeria, including 31 criminal counts against 10 people, according to the *Washington Post* (www.washingtonpost.com, 2 Jun, "Pfizer faces new charges over Nigerian drug test"). The plaintiffs also seek a total of $9bn (£4.5bn; €7bn) in civil suits.

The charges stem from Pfizer's test of its unlicensed drug, trovafloxacin (Trovan) to treat 100 children with meningitis. A comparator group of 100 children were treated with a low dose of ceftriaxone. Suits on appeal in US courts charge Pfizer with causing harm to the children in both arms of the trial, alleging that a number of the children either died or were left deaf, mute, or brain damaged.

The families allege that the company failed to tell them that their children were being enrolled in an experimental drug trial and that free, effective treatment was available from Médecins Sans Frontières at the same hospital. Five children in the trovafloxacin arm and six in the ceftriaxone arm died, according to Pfizer.

Pfizer issued a statement in response to the charges, saying "Pfizer continues to emphasise—in the strongest terms—that the 1996 Trovan clinical study was conducted with the full knowledge of the Nigerian government and in a responsible and ethical way consistent with the company's abiding commitment to patient safety.

"Any allegations in these lawsuits to the contrary are simply untrue."



SCIENCE SOURCE/SPL

All patients with multiple myeloma (above) will get the chance to see if the drug works well for them

Drugs "refund" scheme proposed by NICE

Susan Mayor LONDON

The drugs advisory body for England and Wales has recommended a "refund" scheme in which the manufacturer of bortezomib (Velcade) would reimburse the NHS for the cost of the drug in patients who do not respond to treatment.

The refund scheme, proposed by the National Institute for Health and Clinical Excellence (NICE), could signal a way for the NHS to cope with funding the rapidly growing range of new and expensive drugs. It was suggested by the company making bortezomib, Janssen-Cilag, as part of its appeal against NICE's previous recommendation that the drug was not cost effective.

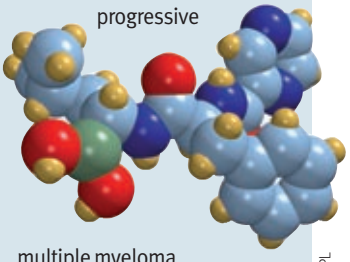
NICE's independent advisory committee agreed and recommended in draft guidance published this week that all suitable patients with progressive multiple myeloma should be offered bortezomib. Patients who show a full or partial response should continue treatment, with the costs of treatment being met by the NHS. Patients showing a minimal or no response after four cycles should stop treatment, and the manufacturer will refund the costs of the drug to the NHS.

Andrew Dillon, chief executive of NICE, said, "We are aware of the challenge that the NHS faces in ensuring that patients can access expensive but potentially effective treatments for life threatening conditions such as cancer." Bortezomib costs about £9000 (€13 000; $18 000) for a course of three cycles of treatment per patient, with eight cycles costing about £25 000.

"If the drug's manufacturer accepts the proposals we are consulting on, it will mean that when the drug works well the NHS pays, but when it doesn't the manufacturer should bear the cost. All patients suitable for treatment will get the chance to see if the drug works well for them," said Mr Dillon.

The draft guidance recommends bortezomib as an option for people with progressive multiple myeloma who have received at least one previous treatment and who have had, or are unsuitable for, bone marrow transplantation. The response to bortezomib must be measured using serum M protein (a protein produced in vast excess in multiple myeloma) after a maximum of four cycles of treatment.

The draft guidance is at www.nice.org.uk.



MARK J WINTER/SPL

Questions over HPV vaccine in the US and Australia

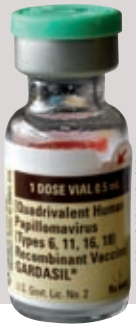
Janice Hopkins Tanne NEW YORK

Questions have emerged in the United States and Australia about the possible side effects of Gardasil, the vaccine for human papillomavirus.

In the US, three deaths closely time related to immunisation with the vaccine were among 1637 adverse reactions reported by Judicial Watch, a public interest watchdog. Judicial Watch obtained the reports from the Food and Drug Administration using the Freedom of Information Act. The reports were filed through the FDA's vaccine adverse event reporting system.

In Australia, 25 girls at a Catholic high school in Melbourne who had just received their first injection of the vaccine on 22 May experienced headache, nausea, and dizziness, the *Age* reported. Four were sent to hospital and two were admitted overnight. All were discharged. One expert called it mass hysteria. Shares of the vaccine's Australian developer, CSL, fell after news reports of the incident (www.theage.com.au, 25 May, "Why are we experimenting with drugs on girls?").

The FDA approved the vaccine in June 2006, and an advisory committee of the Centers for Disease Control and Prevention unanimously voted to recommend it for girls aged 11 and 12 years. It is effective against human papillomavirus types 6, 11, 16, and 18, which cause most cervical cancers and genital warts.



HARRY CABLUCK/AP

The vaccine has been controversial because some parents objected to state mandates to give it to young girls, preferring to encourage their daughters to abstain from sexual activity until marriage (*BMJ* 2007;334:721-3).

Judicial Watch reported on 23 May that the three deaths included one poorly documented death from a blood clot three hours after receiving the vaccine and two deaths in young women with existing heart or clotting problems.

See: Fainting schoolgirls wipe $A 1bn off the market value of Gardasil producer, p 1195

Reed Elsevier to stop hosting arms exhibitions after wide protests

Nayanah Siva LONDON

Reed Elsevier, the global publisher that owns the *Lancet*, has announced that it will no longer take part in organising arms fairs.

For more than three years Reed Elsevier has owned the company Spearhead Exhibitions, which has hosted some of the largest international defence exhibitions. This connection has angered some members of the medical and scientific community.

Sir Crispin Davis, chief executive officer of the company, said last week, "Our defence shows are quality businesses which have performed well in recent years. None the less, it has become increasingly clear that growing numbers of important customers and authors have very real concerns about our involvement in the defence exhibitions business.

"We have listened closely to these concerns and this has led us to conclude that the defence shows are no longer compatible with Reed Elsevier's position as a leading publisher of scientific, medical, legal, and business content."

Reed Elsevier's involvement has been severely criticised by numerous journals, even including its own *Lancet*. Staff at the journal, which was founded in 1823, were unaware of their owner's connection with the arms trade until 2005, when they expressed their concerns in an editorial (*Lancet* 2005;366:868).

"We reject completely any perceived connection between the journal and the arms trade, no matter how tangential it might be . . . We respectfully ask Reed Elsevier to divest itself of all business interests that threaten human, and especially civilian, health and well being," the editorial said.

An editorial in the *BMJ* in March called for medical societies to look elsewhere for publishers, for journal editors to express their disgust, and for researchers to refuse to submit their high profile randomised controlled trials to Reed Elsevier (*BMJ* 2007;334:547-8, 17 March)

More opposition to Elsevier's participation in arms exhibitions was expressed in a letter to the *Times* newspaper in March signed by several literary authors, including Ian McEwan, Will Self, and Nick Hornby. "We call upon Reed Elsevier to end its involvement in a dirty and damaging business," the letter said (www.timesonline.co.uk, 1 Mar, "The London book fair, democracy in action, shoot first").

Peter Hall, chairman of Doctors for Human Rights, criticised Reed Elsevier for refusing to take any action earlier, in the face of two years of criticism.

CAMPAIGN AGAINST ARMS TRADE

Demonstrators protest outside the annual general meeting of Reed Elsevier in London in April

JESSICA RINALDI/REUTERS

A doctor gives a shot of Gardasil, the vaccine against HPV, to a 14 year old in Dallas, Texas

System for detecting side effects can beat regulatory agency

Bob Roehr WASHINGTON, DC

A new approach to pharmacovigilance developed by doctors in Chicago can identify adverse drug reactions up to six years before the Food and Drug Administration or monitoring programmes run by the drug industry, researchers say (*Archives of Internal Medicine* 2007;167:1041-9).

The scheme, the research on adverse drug events and reports (RADAR) project, was developed by Charles Bennett and colleagues at the Northwestern University Feinberg School of Medicine, in Chicago, and launched in 1998.

Dr Bennett told the *BMJ* that other pharmacovigilance programmes are based on epidemiology and databases. The RADAR approach is based on considering whether there is a theoretical reason why a drug might have an adverse side effect, and looking at that, he said.

The project has started 80 investigations and issued 30 reports. It focuses on incidents such as those requiring major surgery or organ transplant, and deaths. "We work actively, we are not waiting passively for all of these reports to show up in databases, we're calling people on the phone. We have a strategy to look to see if it is interesting or not and make an early decision" in terms of a full investigation.

Dr Bennett cites the example of the antiplatelet drug clopidogrel. "We were able to get that [evidence about its adverse effects] out to the FDA and into the public's hands within six months of the drug receiving approval." Clopidogrel was approved in 1997 and the adverse reaction that the RADAR system identified was thrombotic thrombocytopenia.

"That side effect occurred at the rate of four per one million, so it is not common, though it is fatal. That would take seven years with the FDA." Clopidogrel has a chemical structure similar to another drug with the same side effect, which allowed the doctors to form and test the risk hypothesis.

Emphasis is on the quality rather than quantity of data, with gathering and analysis carried out by a group that does not have a stake in the outcome. "We've shown with this project that people who have a basic science background and who are interested from a scientific standpoint can add a lot to the field by working with… very complete reports, and a collaborative network."

"We are not waiting passively for all of these reports to show up in databases"

Dr Bennett says that one weakness of the FDA reporting system is that because much of it is voluntary the data are shallow and incomplete. "I think you get what you pay for," he says. He describes it as "essentially a bunch of statisticians waiting for the data to generate a signal."

Raymond Woosley is president of the Critical Path Institute, based at the University of Arizona. It is a non-profit making partnership with the FDA that advances modernisation of the drug development and monitoring process.

He says that when electronic medical records are completely implemented, and that will take years, they will help the identification of adverse events from approved drugs.

Chinese court sentences former drug chief to death

Jane Parry HONG KONG

A court in Beijing has handed down a death sentence on Zheng Xiaoyu, the former head of the Chinese State Food and Drug Administration. He was found guilty of taking ¥6.5m (£0.4m; €0.6m; $0.9m) in bribes and gifts and of dereliction of duty for failing to ensure the safety of drugs and devices that were approved during his tenure.

Court documents quoted by China's state news agency, Xinhua, say that Mr Zheng pleaded guilty to charges that he "sought benefits" from eight domestic drug companies in exchange for approval of drugs and medical devices between June 1997 and December 2006. In addition, six drugs granted approval on the basis of false documents between 2001 and 2003 were found to be fake.

"[Mr Zheng's acts] greatly undermined the integrity of an official post and the efficiency of China's drug monitoring and supervision, endangering public life and health, and had a very negative social impact," a court statement said.

Mr Zheng was director of the regulatory agency since its formation in May 2003 until mid-2005. Before that he was head of the State Pharmaceutical Administration from 1994 to 1998 and head of the State Drug Administration from 1998 to 2003.

Until 2002 all drugs distributed in China required approval from the State Drug Administration and then from its successor, the State Food and Drug Administration. He was investigated by the Communist Party of China's Central Commission for Discipline Inspection in December 2006 and was expelled from the Communist Party in March this year.

CDIC/REUTERS

Zheng Xiaoyu faces a death sentence

Bush's nominee for surgeon general opposed

Bob Roehr WASHINGTON, DC

The nomination of James Holsinger to be surgeon general of the United States is drawing mounting opposition from AIDS and gay groups. That may lead to particularly contentious confirmation hearings because the leading Democratic candidates Hillary Clinton and Barack Obama sit on the Senate health committee that will review the nomination.

President George Bush nominated Dr Holsinger (below) on 24 May. His paper credentials make him eminently suitable for the position of chief public health officer—a medical degree from Duke University; a masters degree in hospital financial management from the University of South Carolina; a 25 year career with the Veterans Health Administration, rising to a senior management position; and subsequent work for the University of Kentucky and the state healthcare system.

PATTI LONGMIRE/AP

He also strongly identifies as a Christian, and it is his actions as a Christian that are proving controversial in the United States. Dr Holsinger served as the head of the nine member Judicial Council of the United Methodist Church, which in June 2004 defrocked Beth Stroud, a lesbian minister in Philadelphia.

The council claimed that she might serve had she remained celibate, but sex outside of marriage is not allowed, and gay people are not allowed to marry. So, Reverend Stroud's long term relationship with her partner was considered to be immoral.

The pressure group AIDS Action has taken the strongest position of any organisation to date, opposing the nomination. Its deputy director, Ronald Johnson, told the *BMJ* that the group will write to senator Ted Kennedy, Senate health committee chairman, and to Mike Enzi, the most senior member of the opposition party on the committee, spelling out its opposition to the nomination, which must be confirmed by the entire US Senate.

"We feel this is another distressing signal and message that this administration—this president—does not either understand or take seriously the domestic epidemic."

Indian doctor held under controversial antiterrorism law

Owen Dyer LONDON

Demonstrators in six Indian cities last week called for the release of a paediatrician arrested under controversial antiterrorism laws in the central Indian state of Chhattisgarh.

Binayak Sen, a noted civil rights activist, was arrested on 14 May accused of using prison visits to pass a message between two prisoners accused of involvement in local Maoist rebel groups.

"Activists in India are arrested all the time on such charges, which give wide, arbitrary powers to police"

Chhattisgarh is one of several Indian states troubled by a longstanding insurgency led by disparate Maoist guerrilla groups, known as Naxalites, after the town of Naxal where the movement originated. The Naxalites have support among local indigenous communities in remote areas of the state.

Chhattisgarh's state government has encouraged the growth of an armed civilian militia to counter these groups, known as the salwa judum in the Gondi language—or "peace mission." About 45 000 people have been swept out of their forest villages into guarded camps since the militia was created in June 2005. Reports of serious human rights abuses by both sides are commonplace.

Dr Sen worked on behalf of indigenous communities for 30 years. He helped to found a cooperative hospital for mine workers, the Shaheed hospital, and played a big part in evolving a statewide programme of training community health workers.

He also became active in monitoring human rights violations, and in the past two years has reported numerous abuses by civilian militia and state police. Dr Sen is the general secretary of the Chhattisgarh unit of the People's Union for Civil Liberties, one of India's leading human rights organisations.

The police allege that Dr Sen passed a letter from one inmate of Raipur jail to another while visiting prisoners in his capacity as a human rights observer. He was detained under the provisions of the Chhattisgarh Special Public Security Act, 2005, which allows detention without charge for up to seven years, without judicial remedy, bail, or appeal, of anyone suspected by police of aiding the Maoist insurgency.

Amnesty International has taken up his case, demanding that he be freed or charged with a recognised criminal offence. On 25 May, he was charged under the Indian penal code with criminal conspiracy, conspiracy to wage war against the state, and sedition.

Ramesh Gopalakrishnan, of Amnesty International, told the *BMJ* that the organisation is still calling for his release. "These offences allow sweeping interpretations of criminal intent. Activists in India are arrested

Germany may tighten laws on sports medicine after doping incidents

Annette Tuffs HEIDELBERG

Doctors and politicians in Germany are demanding stricter laws for sports medicine after three doctors were discovered to have given performance enhancing drugs to professional cyclists.

Two of the three doctors, from Freiburg University Hospital, were suspended last week by the university when they admitted doping professional cyclists. In separate statements, Lothar Heinrich and Andreas Schmid said that they gave the blood cell stimulating hormone erythropoietin to the cycling team of the German telephone company Deutsche Telekom, now T-Mobile.

The confessions were made after several cyclists had recently publicly admitted to taking drugs for performance and accused the doctors of involvement.

"I admit that I supported doping individual cycling professionals from the mid-1990s," Dr Schmid said in a statement released by his attorney. Previously, he and his colleague had denied any wrongdoing.

Freiburg prosecutors are investigating and the university has also promised a full independent investigation into the past 20 years of its participation in sports medicine.

The incident had spread to amateur ranks a few days later when another doctor from the Freiburg

GURINDER OSAN/AP

Writer Arundhati Roy attends a rally for Binayak Sen

all the time on such charges, which give wide, arbitrary powers to police," he said.

Joel Almeida, a friend of Dr Sen who recently organised a small protest outside the Indian High Commission in London, said, "Dr Sen is a champion of peace and fair play and an internationally respected medical doctor who has devoted his whole life to peaceful service of the poorest people. He should be released immediately."

Dr Sen is currently being held at Raipur jail, where supporters report he is reasonably comfortable.

Researcher accused of breaching research ethics faces GMC

Owen Dyer LONDON

A former senior lecturer at the UK Institute of Psychiatry repeatedly breached research ethics guidelines and lied to study sponsors while building an international reputation as a leading researcher, according to charges laid by the General Medical Council.

The GMC's fitness to practise committee heard that Tonmoy Sharma, who left the Institute of Psychiatry as a clinical senior lecturer in 2001, falsely claimed to have sought and received approval from ethics committees for several studies.

He is also accused of recruiting patients by telephone without informing their carers; offering financial inducements to research subjects; breaching agreed research protocols; lying in a job application; posing as a professor; and threatening a patient with withdrawal of treatment if she left a study.

Dr Sharma "was a man who paid little more than lip service to ethical rules in research"

Joanna Glynn, counsel for the GMC, told the hearing that Dr Sharma "was a man who paid little more than lip service to ethical rules in research."

In four studies, he claimed that his research had ethical permission from the Bethlem and Maudsley Ethical Committee, when none had been given, the charges allege. In another case he is alleged to have falsely told the Alzheimer's Society that he had ethics clearance from the Institute of Psychiatry. On another occasion, he allegedly told Novartis that the Alzheimer's Society was sponsoring his research when it was not.

Dr Sharma is accused of telling both Novartis and Sanofi-Synthelab that studies he was carrying out on their behalf were being carried out at the Institute of Psychiatry with ethics committee approval, when in fact they were carried out at private facilities. He is also accused of using proprietary Novartis data in another study.

In 1999 Dr Sharma was offered the chair in psychiatry at the department of psychiatry and behavioural sciences at University College, London, subject to completion of his doctorate thesis. He allegedly told superiors for two years that he was handing in chapters, when he had never done so.

He described himself as "Tonmoy Sharma MD PhD" on the website of his company, Psychmed, despite having never obtained a doctorate degree. In 2002 he was invited to speak as a "visiting professor" at Pittsburgh University. From this point he styled himself Professor Sharma, contrary to British academic convention, the GMC alleges.

Dr Sharma's career began to unravel in 2001, said Ms Glynn, when he was suspended from the Institute of Psychiatry after a complaint from the drug company Sanofi-Synthelab. "After the suspension a picture emerged of a doctor who knew the rules of medical research but deliberately took short cuts," she added.

Dr Sharma denies the charges of unethical, misleading, dishonest, and unprofessional conduct.

sports medicine department admitted giving performance boosting testosterone to riders as far back as 1980.

The third doctor, Georg Huber, was suspended by both German cycling authorities and the University of Freiburg. Two former cyclists had triggered his resignation, naming him in a newspaper story and claiming that doping in amateur German cycling was widespread long before team Telekom.

Several representatives from doctors' organisations such as Klaus Bittmann, chairman of the NAV Virchow-Bund, demanded that active doping should be punished with the withdrawal of the licence to practise medicine.

Meanwhile, the German government is planning to tighten antidoping laws by establishing a task force and punishing the possession of doping drugs.

PETER DEJONG/AP/PA

IN BRIEF

Commission to visit trusts unannounced: The Healthcare Commission will be carrying out unannounced inspections at 120 NHS trusts over the coming year to check compliance with the government's hygiene code. The code was introduced to tackle healthcare associated infections, such as methicillin resistant *Staphylococcus aureus* and *Clostridium difficile*.

Bush backs extra spending on AIDS: The US president, George Bush, asked Congress to double the initial $15bn (£7.5bn; €11bn) to fight HIV/AIDS to $30bn for another five years. The president's emergency plan for AIDS relief, which expires in September 2008, has supported treatment for 1.1 million people in 15 targeted countries, including one million people in Africa.

Health care for people with learning difficulties under investigation: The UK Department of Health has set up an inquiry into access to health care for people with learning disabilities. It follows the publication of a report by Mencap, *Death by Indifference*, in March showing that six people with learning disabilities had died in the NHS through apparent neglect. See www.mencap.org.uk.

Scottish elders take part in mental test: A mental ability test carried out in Scottish schools 60 years ago may help explain the secrets of healthy ageing. A thousand volunteers, now in their 70s, will take the test devised by the University of Edinburgh and funded by the charity Help the Aged to determine the life events and background factors that help or harm mental health.

Study on whooping cough wins award: A study published in the *BMJ*, alerting doctors to the signs of whooping cough in school age children, has beaten 30 other academic papers to win the 2006 Royal College of General Practitioners and Merck, Sharp, and Dohme research paper of the year award (*BMJ* 2006;333:174-7).

Flaming cocktails should be banned: Burns specialists have urged an end to the practice in many UK bars of serving flaming spirits. They report four cases, including that of a 17 year old woman who sustained 25% burns to her left arm, leg, chest and abdomen, and warn that 24 hour drinking may increase prevalence (*Burns* 2007 May 24 doi: 10.1016/j.burns.2006.11.008).

Doctors advise women not to drink alcohol during pregnancy

Lisa Hitchen LONDON

Women who are pregnant or trying to conceive should not drink any alcohol, guidance from the BMA recommends.

Complying with the guidance would eliminate fetal alcohol spectrum disorders, which include fetal alcohol syndrome and can lead to learning and physical disabilities and behavioural problems, notes the report.

Fetal alcohol syndrome is the most clinically recognisable type of fetal alcohol disorder and is characterised by abnormal facial features, growth deficiency, intellectual disabilities, and hyperactivity. In 2002-3 a total of 128 cases were recorded in England. However, there is no reliable evidence on the incidence of fetal alcohol spectrum disorders in the United Kingdom, something which needs to change, says the BMA.

The report calls on all UK health departments to routinely collect data on fetal alcohol syndrome and for further research to establish the full extent of fetal alcohol spectrum disorder.

"You can manage [fetal alcohol spectrum disorders] but you can never cure them"

Raja Mukherjee, a consultant psychiatrist for people with learning disabilities at the Surrey and Border Partnership NHS Trust, said, "You can manage [fetal acohol spectrum disorders] but you can never cure them, and if you compare this to the potential that these children could have had, there is a deficit that, unlike a genetic condition, is 100% preventable."

The report calls on doctors and other health professionals to take careful histories of women during pregnancy. "People should be more prepared to make the diagnosis, not just of [fetal alcohol syndrome] but of the spectrum of disorders," said Vivienne Nathanson, the BMA's head of science and ethics. "It is a diagnosis of exclusion, but it is a really important one to help the woman and the baby."

Healthcare staff should monitor all pregnant women with suspected or confirmed history of alcohol consumption at low to moderate levels and offer them brief intervention counselling early on, the report recommends. Those known to be at high risk of drinking larger amounts should be referred to specialist services.

The BMA guidance is in line with the latest advice from the Department of Health in England.

But it differs from that given by the Royal College of Obstetricians and Gynaecologists, which says, "There is no evidence of harm from low levels of alcohol consumption, defined as no more than one or two units once or twice a week."

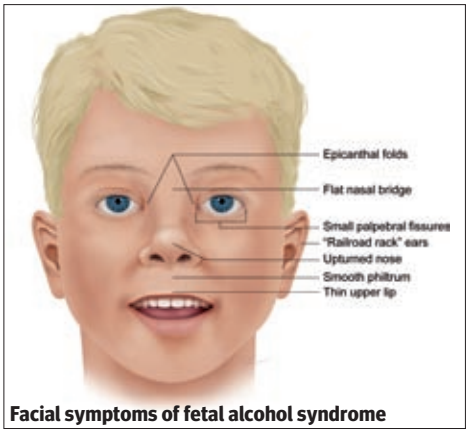
"The difference [between the two sets of guidance] is more apparent than real," pointed out Sir Charles George, chairman of the BMA board of science. Both are advising not to drink alcohol at all, but the royal college guidance states there is no evidence of harm for less than two units per week, he said.

However, there is a danger that the lack of evidence will be misinterpreted, said Professor Nathanson. Because many people are unaware how many units they are actually drinking and because of stronger drinks and pubs serving larger measures, women can end up drinking more than they intend, she said.

The UK's binge drinking culture and high rates of teenage pregnancy also indicate that many women are continuing to drink during early pregancy without being aware of the harm they are doing to their baby.

The BMA spent a year compiling the report only to have it pre-empted by the Department of Health's recommendations 10 days earlier. The department did not consult the BMA before putting out its revised guidance.

"We are not unhappy with what they have said," said Professor Nathanson, but she added that the goverment should go further. All healthcare professionals should have fully funded training to pick up and manage fetal alcohol spectrum disorders and health departments should produce guidance on its identification.



Facial symptoms of fetal alcohol syndrome

STR NEWS/REUTERS

Andrew Speaker, who has extensively drug resistant tuberculosis, stands with his bride at their wedding

Tuberculosis case shows flaws in international public health

Janice Hopkins Tanne NEW YORK

The ease with which a man infected with extensively drug resistant tuberculosis (XDR TB) flew on several international flights exposes flaws in international public health systems. The asymptomatic US lawyer flew on two transatlantic flights and several European flights for his wedding and honeymoon.

It also led to an international search for passengers who may have been exposed to this almost incurable disease.

Local public health officials in the United States could not prevent him from travelling; the US Centers for Disease Control and Prevention (CDC) failed to contact him; a "no fly alert" did not prevent him from flying; and a border alert to detain him was ignored.

The good news, said Julie Gerberding, head of the CDC, was that the risk of transmission was low.

Mario Raviglione, director of the Stop TB programme at the World Health Organization, told the *BMJ* that "if the International Health Regulations, 2006, had been in place, the relevant procedures outlined would have been followed correctly. [The regulations] will come into effect on 15 June worldwide and 17 July in the US [United States].

The US man, Andrew Speaker, a 31 year old lawyer from Atlanta, Georgia, is now in isolation at the National Jewish Medical and Research Center in Denver, under a detention order from Denver health officials.

The CDC is investigating a possible link to his father in law, Robert Cooksey, a microbiologist at CDC who works on multidrug resistant tuberculosis. Dr Cooksey said that he has always tested negative for tuberculosis.

The problem began when Mr Speaker had a chest x ray in January for a rib injury. It showed an infiltrate that indicated tuberculosis. A sputum test for tuberculosis was negative, but a more sensitive culture test was positive.

Further tests were under way when Mr Speaker left for his wedding. He and his fiancée flew from Atlanta to Paris, and then to Athens, Mykonos, and Rome.

Mr Speaker was told to turn himself in to Italian health officials, but the couple left their Rome hotel before a CDC representative arrived, flew to Prague, and then to Montreal. From Montreal they drove to the United States.

European agency names six biggest threats to health

Rory Watson BRUSSELS

The first epidemiological report produced by the European Centre for Disease Prevention and Control identifies six important communicable diseases that pose a threat to Europe.

The analysis is based on national data for 2005 from the 25 European Union countries at the time and from Norway, Iceland, and Liechtenstein. Zsuzsanna Jakab, the centre's director, said that the report would "give a major input to policy makers on where they need to invest in public health."

Heading the list are micro-organisms that have become resistant to antibiotics, which are a rapidly growing problem in hospitals. Every year some three million people in the EU catch a healthcare associated infection. Of these about 50 000 die.

In second place comes HIV infection. In 2005 just more than 28 000 new cases were reported in the EU, bringing the total number of people with HIV in the union close to 700 000.

Pneumococcal infections are responsible for high death rates among young children and elderly people, and hundreds of thousands of people in the EU fall seriously ill every winter as a result of seasonal influenza. The fifth most dangerous threat is tuberculosis, with some 60 000 cases identified in the EU in 2005. The disease continues to rise in vulnerable groups, such as migrants and people with HIV. Cases of drug resistant tuberculosis are now appearing, particularly in the Baltic states.

Finally, the report draws attention to two further diseases—chlamydia and campylobacteriosis.

Heart survival rates published

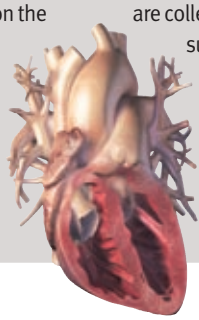
Andrew Cole LONDON

A new NHS website has been launched that will, for the first time, allow parents of children with congenital heart disease to compare the performance of the United Kingdom's specialist children's heart centres before they decide on treatment.

The website, run by the NHS Information Centre and based on figures provided by clinicians and hospitals to a central cardiac database, gives detailed information on the procedures carried out by the 16 centres and survival rates for the most common treatments.

The overall survival rate for neonates (up to 30 days) rose from 96.9% in 2000-1 to 97.8% in 2004-5, the last year for which there are collected statistics. The survival rate for infants (31 days to one year) rose from 94.3% to 96.8% in the same period.

See www.ccad.org.uk/congenital.



ZYGOTE MEDIA/NEWSCOM