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bmj.com Government may leave some patients out of 18 week target

Court upholds GMC decision over Sally Clark case pathologist

Clare Dyer *BMJ*

Alan Williams, the consultant pathologist whose failure to disclose the results of microbiological tests on one of Sally Clark's two baby sons led to the quashing of her murder convictions, lost his High Court appeal last week against a finding of serious professional misconduct.

Mrs Clark was convicted in 1999 of killing babies Christopher and Harry but was cleared on appeal in 2003 after spending three and a half years in prison. She died earlier this year at the age of 42. A coroner ruled this week that the cause of her death was acute alcohol intoxication.

A General Medical Council fitness to practise panel found Dr Williams, aged 58, guilty of serious professional misconduct in 2005 for not disclosing the results of tests on her second son, Harry, at or before her trial. Dr Williams was banned from doing Home Office forensic pathology or coroners' work for three years, although he was allowed to continue working as a consultant histopathologist at Macclesfield General Hospital, in Cheshire.

His lawyers appealed on a range of issues, including delays in bringing his case before the GMC.

Dr Williams had not considered the tests to be relevant

But Mr Justice Davis ruled last week, "In my judgment this appeal fails on essentially every ground advanced. There was no procedural unfairness giving rise to injustice; nor were the findings and conclusions of the panel wrong."

Mrs Clark was cleared after a second appeal, when previously unreported microbiological results came to light. They showed the presence of *Staphylococcus aureus* at eight sites of the baby's body, including cerebrospinal fluid, raising the possibility that Harry died from natural causes.

Dr Williams told the GMC panel that he had not considered the tests to be relevant and that if the defence had wished to see them, they should have asked for them.



Members of the British Association of Physicians of Indian Origin protest in March at visa changes

MARK THOMAS

International graduates win High Court challenge

Clare Dyer *BMJ*

Guidance from the Department of Health that makes it harder for doctors who trained abroad to compete with UK medical graduates for NHS training posts was ruled "unlawful and of no effect" by the Court of Appeal last week.

Lords Justices Sedley, Maurice Kay, and Rimer ruled that a government department could not impose restrictions unsanctioned by parliament which went further than the immigration rules.

The guidance to NHS employers was that doctors on the highly skilled migrant programme (HSMP) whose leave to remain in the United Kingdom was due to expire before the end date of any training post on offer, should be offered the post only if there were no suitable UK or

EU candidates. The guidance was first challenged earlier this year but rejected (*BMJ* 2007;334:333).

A spokeswoman for the Department of Health said that it was considering its next move. But the ruling means that employers will be unable to apply the guidance to the January recruitment exercise as planned. Even if the House of Lords agreed to hear an appeal, there is almost no chance that it could be dealt with in time.

The court heard that one of the main reasons for the change was the increase in the number of students graduating from UK medical schools. Allowing foreign doctors to obtain training posts at previous levels would have meant that significant numbers of UK medical graduates would be unable to complete their

training, and the investment in them would have been wasted.

Anthony Robinson of the law firm Linder Myers, who brought the challenge on behalf of the British Association of Physicians of Indian Origin (BAPIO), said, "As is widely acknowledged, the NHS has for many years relied upon the contribution of doctors from overseas, and in particular the Indian subcontinent, to provide a quality service in times of shortage of UK doctors."

Ramesh Mehta, president of BAPIO, said, "We are absolutely delighted that at last justice seems to help overseas doctors, who have had an absolutely traumatic time for the last 18 months. We are glad that it was the unanimous verdict of three judges that the Department of Health guidelines were wrong and illegal."

IN BRIEF

Obese women should lose weight before fertility treatment: Guidelines from the British Fertility Society published in the journal *Human Fertility* say that treatment should be deferred if an obese woman's body mass index (BMI) exceeds 35 (2007 Nov 7 doi: 10.1080/14647270701731290). Women younger than 37 should aim to reduce their BMI to less than 30 to maximise the effectiveness and reduce the risks of treatments.

Tighten alcohol laws to prevent serious health problems: The UK government should make alcohol more expensive and reconsider its 24 hour availability to reduce the serious health problems related to heavy drinking, says a report from the Nuffield Council of Bioethics (www.nuffieldbioethics.org). A new coalition of 24 organisations, the Alcohol Health Alliance UK, is also calling on the government to act to prevent alcohol related diseases.

Fewer assaults seen against NHS staff: NHS staff were physically assaulted 55 709 times in England in 2006-7, a drop of nearly 3000 from 2005-6. Staff working in mental health and learning disability settings bore the brunt of the violence, with more than 41 500 assaults this year. The biggest drop was seen in assaults against staff in primary care.

Measures brought in to control cholera in Congo: The United Nations High Commissioner for Refugees has stepped up efforts to curb the spread of cholera in five refugee camps in the Democratic Republic of Congo. In October there were 439 suspected cases—189 between 24 and 28 October. New admissions fell to 135 in the first week of November.

New scientific facilities badly managed: Teams who plan and develop large scientific facilities in the United Kingdom often lack the project management and commercial skills to deliver them on time and within budget, says a report from the Public Accounts Committee (www.parliament.uk/pac).

Hallmark apologises for inappropriate card: A promise last year by the greetings card maker Hallmark to ban a birthday card that made fun of people with acromegaly has backfired. The company mistakenly reprinted the card and sold it in stationers WH Smith. This week the company apologised, destroyed the cards, and donated £5000 (€7200; \$10 500) to the Pituitary Foundation charity (www.pituitary.org.uk).



Most trusts will not meet chlamydia screening target

Caroline White LONDON

Most trusts in England will not meet their 2008 chlamydia screening target, the director of the national screening programme admitted last week.

Speaking at the fourth annual conference of the national chlamydia screening programme, in London, Mary Macintosh said that great progress had been made.

"Last year only 25% of [primary care trusts] were screening [for chlamydia]. Now 78% are screening, and a further 23% will be [doing so] by the end of the year," she said.

But the government target for all strategic health authorities to have offered 15% of 15-24 year olds a test for the infection between March 2007 and April 2008 was unlikely to be met, she said. "It won't be reached by all. But some will."

Figures presented to the conference showed that projections by the health authority had fallen well below the actual numbers reported to the Health Protection Agency for the first six months up to September 2007.

The average coverage in England has reached 1.5%, up from 0.6% of the target population in the first three months. But the best performing strategic health authority reached only 2.5%.

Dr Macintosh added that the target was not an endpoint. "It's a stepping stone to getting high volume," she said. "Fifteen per cent is not going to be adequate. But it's not just about the numbers; it's about how we do it."

In a bid to boost coverage, the programme announced a new strategy to raise sexual health awareness among men under the age of 25. About only one in five men come forward for chlamydia testing at the moment.

But community contraceptive services, which account for almost a third of tests offered, have been under increasing financial pressure as cash strapped trusts have struggled to balance their books this year.

GPs are not given a cash incentive under the quality and outcomes framework to offer the test.

Danish men consult GPs less than women

Roger Dobson ABERGAVENNY

Men of all ages have less contact with their family doctor than women, with the gap narrowing with age, and they are more likely to be admitted to hospital and have a greater mortality, according to a study of more than 30 million contacts with GPs and hospital admissions in Denmark in one year (*Journal of Public Health* 2007 Nov 2 doi: 10.1093/pubmed/fdm072).

"This is compatible with a scenario in which men react later to severe symptoms than women so that

they are more likely to be hospitalised for or die from these conditions," say the authors.

They say that population based studies indicate that in many aspects men have better health than women—men are stronger, report fewer diseases, and consistently report better health status than women.

"A prominent hypothesis is that men seek medical advice very late, and the stereotype is that men over-react to small symptoms and under-react to severe symptoms.

US drug company to pay \$5bn in rofecoxib claims

Fred Charatan FLORIDA

The US drug company Merck announced last week that it will pay \$4.85bn (£2.3bn; €3.3bn) to settle 26600 lawsuits, representing 47000 plaintiffs, in addition to 265 possible class action cases, arising out of the use of rofecoxib (Vioxx).

The agreement is to cover cases filed in federal and state courts, and depends on 85% of all plaintiffs dropping their cases. The money will be paid into a settlement fund for claims that qualify. In a statement the company said,

“This is not a class action settlement. Claims will be evaluated on an individual basis.”

Chris Seeger, one of six lawyers for the plaintiffs who helped to negotiate the settlement, said that it was the largest ever in the drug industry.

Rofecoxib was approved by the US Food and Drug Administration in 1999 for the relief of the symptoms of osteoarthritis, management of acute pain in adults, and treatment of menstrual pain. The company withdrew the

drug from the market in 2004, when a study that it had funded showed that patients taking rofecoxib had twice the risk of heart attack and stroke (*New England Journal of Medicine* 2005;352:1092-102; see *BMJ* 2004;329:816).

In February 2005 the FDA concluded that rofecoxib and similar drugs posed cardiovascular risks but that they could remain on sale. Later that year, in the first Vioxx trial, a Texas jury awarded \$253.4m (later reduced to about \$26m) to

the widow of a man who had died in May 2001. Other legal cases followed, some of which resulted in millions of dollars in damages awarded to the plaintiffs (*BMJ* 2005;331:471) and others ruling that Merck had not been responsible for heart attacks experienced by people taking rofecoxib (*BMJ* 2005;331:1101).

To qualify for part of the settlement, applicants must have filed their claims by Thursday 8 November 2007 and show that they have not had a heart attack or stroke.

Cost of US soldiers' health care could reach \$650bn

Bob Roehr WASHINGTON, DC

The lifetime health care of soldiers deployed to Iraq could cost the United States \$650bn (£310bn; €440bn), more than has been spent on operations in Iraq, according to projections in a report published last week.

The report, *Shock and Awe Hits Home*, was written by Evan Kanter, a staff psychiatrist at the post-traumatic stress disorder (PTSD) outpatient clinic of the Department of Veterans Affairs, Puget Sound Health Care System, in Washington state, for the Nobel peace prize winning group Physicians for Social Responsibility. It was presented to sympathetic members of Congress on 8 November. “Every day of continued fighting adds to the terrible price that we are



A US army helicopter medic leaves a wounded soldier at the 28th Combat Support Hospital, Beirut

paying,” the report says, before calling for an end to the war.

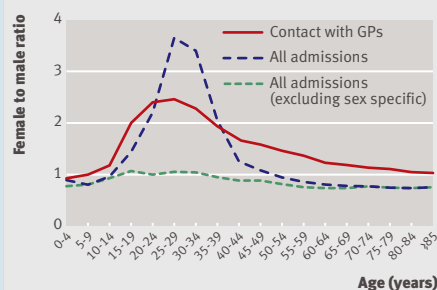
One reason for the huge cost is that fewer soldiers are dying in combat from their wounds than in past wars because of better body armour, battlefield medicine, and rapid evacuation. The torso is protected, the report said, but there is greater polytrauma, particularly brain injury and injuries that require limb amputation. The ratio of wounded to dead soldiers has changed from 2:1 in the second world war, to 3:1 in Vietnam, to 8:1 in Iraq.

Earlier in the week, during a presentation at the annual meeting of the American Public Health Association, Dr Kanter said, “A study of the first 100000 veterans [of Iraq and Afghanistan] seen at facilities of the Department of Veterans Affairs showed that 25% of them were diagnosed as having mental health problems. Of these, 56% had two

or more mental health conditions. The most common were PTSD, substance abuse, and depression.” He added, “The younger the veterans, the more likely they are to have mental health conditions.” There also was “a dose response” effect of multiple deployments increasing the likelihood and severity of mental health problems.

Evaluation of soldiers immediately on return from deployment indicated that 5% of staff on active duty and 6% of reserve personnel had a noteworthy mental health problem, but this increased to 27% and 42% when they were reassessed 3-6 months later. Dr Kanter said soldiers initially lied because they wanted to get back to their families and feared that answering yes to mental health screening questions might delay that. *Shock and Awe Hits Home* is available at www.psr.org/site/DocServer/ShockandAwe.pdf?docID=3161.

DANISH HOSPITAL ADMISSIONS AND CONTACT WITH GPs, 2005



Source: *Journal of Public Health*

Conflicting guidelines on same topics cause doctors confusion, MPs tell NICE officials

Lisa Hitchen LONDON

Clinicians in England and Wales are confused when different sets of guidelines are published at the same time on the same topic, a parliamentary committee heard at an inquiry into the National Institute for Health and Clinical Excellence (NICE).

Richard Taylor, MP, health select committee member, said that for two topics NICE and the Department of Health had recently published recommendations one soon after the other. One was about venous thromboembolism and the other on the use of alcohol in pregnancy.

NICE's clinical guidelines on the prevention of venous thromboembolism in patients having orthopaedic surgery and the Department of Health's report of the independent expert working group on the prevention of venous thromboembolism in patients admitted to hospital were both published in April.

"What clinicians are bothered about is when they get two substantially different



**Chief Executive of NICE,
Andrew Dillon**

bits of advice," said Dr Taylor.

Michael Rawlins, chairman of NICE, said that the department's guidance was an interim document and that NICE produced full guidance on venous thromboembolism.

But the department's report was delayed by nine months, noted Dr Taylor, and its interim status was never made clear.

Dawn Primarolo, minister for public health, agreed that the process of simultaneously publishing guidance from the Department of Health and NICE needed to be handled with "care and clarity." "This is a really

complex area, and I can say that the Department of Health is looking very carefully at how they manage that," she said.

On the use of alcohol in pregnancy, updated health guidance for pregnant women came from the department in May telling women who are pregnant or trying to conceive that they should abstain from alcohol altogether.

NICE's draft clinical guideline on antenatal care followed in September and is to be published as final guidance in March 2008. Its draft recommendation is that pregnant women should limit their alcohol intake to less than 1.5 units per day.

Ms Primarolo said that NICE's final guidance, when it comes out next year, should be accepted as the definitive advice.

Sandra Gidley, MP, wanted to know if NICE could work faster, as the Scottish Medicines Consortium seemed to do.

Andrew Dillon, chief executive of NICE, explained that NICE could only reach its decisions more quickly if it

dropped its consultation and appeals processes. "About 30% of our technology appraisals go to appeal and this adds further time," he said.

Identifying which new drugs to look at and which patient groups they are useful for also differentiated NICE from the Scottish consortium, he said. "We have a very different process and are producing a different product."

She asked what would happen if NICE focused on more useful products and spent less time on treatments that were known to be ineffective.

NICE had attempted to do this using Cochrane reviews, replied Mr Dillon. "The health service does not indulge in things that are not working to an extent. What we have found in some circumstances is some things that are being overused, and we could stop some of these."

What was needed was more selective use, added Professor Rawlins.

The oral evidence to the House of Commons' Health Select Committee is available at www.parliament.uk.

Charity warns of proposed restrictions to asylum seekers'



Helen Mooney LONDON

Failed asylum seekers in the United Kingdom could be refused access to primary care services, under proposals being considered by the Home Office, a human rights charity has warned.

The Medical Foundation for the Care of Victims of Torture says that it is concerned that the government is considering proposals to refuse unsuccessful asylum seekers still living in the UK the right to access primary health care.

Under current regulations, failed asylum seekers have a discretionary entitlement to use primary care, including GP visits, dental care, and midwife support, although some restrictions are imposed on the secondary care services that they are entitled to receive.

Lunar House, the headquarters of the UK immigration department in Croydon



MIRAMAX/VEVRETT/REX FEATURES

A scene from the film *Dirty Pretty Things*, which featured illegal organ donation

WHO reports on the growing commercial trade in transplant organs

Roger Dobson ABERGAVENNY

Travelling abroad for organ transplants provided on a commercial basis—so called transplant tourism—may now account for at least one in 20 of all transplants, according to a report from the World Health Organization (*Bulletin of the World Health Organization* 2007 Nov 1 doi: 10.2471/BLT.06.039370).

Advertising of package deals that include a transplant—for example, a package costing £16 000 (€23 000; \$34 000) for a kidney transplant in Pakistan—is flourishing, and the trade in organs is growing, the report found. “The results suggest that the international

organ trade no longer represents sporadic instances in transplant medicine,” it says. “The total number of recipients who underwent commercial organ transplants overseas may be conservatively estimated at around 5% of all recipients in 2005.”

Reliable information on numbers and clinical outcomes is scarce, the report noted, but it reviewed information from media reports, journal articles, conference papers, reports from health ministries, national transplant registries, and other documents to assess the scale of the problem.

The most common way in which organs are traded across national borders is by potential recipients travelling abroad to undergo transplantation, but there are other strategies. “In some cases, live donors have reportedly been brought from Republic of Moldova to the United States, or from Nepal to India. In other cases, both recipients and donors from different countries move to a third country,” the review says.

The report found that organs from donors living in India are regularly transplanted to foreigners. The Voluntary Health Association of India estimates that about 2000 Indians sell a kidney every year. In Pakistan, as many as two thirds of the 2000 renal transplants performed in 2005 were estimated to have been for foreigners, according to the Sindhi Institute of Urology. In the Philippines, data from the National Kidney Transplant Institute show that 110 of the 468 kidney transplants in 2003 were for patients from abroad.

British paediatricians help Palestinians with training

Owen Dyer LONDON

Doctors from the UK Royal College of Paediatrics and Child Health and workers in child health from Gaza and the West Bank recently attended a ceremony for seven doctors and two nurses who received Palestinian certificates in child health. The presentation, given by the college’s president, Patricia Hamilton, in a ceremony in the West Bank, marks the culmination of seven years’ work to offer a course in child health to Palestinian doctors and nurses. The training was put together by the college and offered partly by distance learning.

The paediatrician Tony Waterston, of Newcastle University, who leads the college’s project, says the certificate is loosely modelled on the diploma in child health, which is offered to British GPs. “It’s not quite that standard, but it is a high standard.” Unlike the UK diploma, the Palestinian certificate is offered to nurses as well as doctors.

The college hopes to extend the course to 20 students next year, he said, and ultimately aims to enrol 50 students a year in the West Bank and a further 30 in Gaza.

Modules are taught by British and Palestinian paediatricians, and students also have

The Palestinian certificate is offered to nurses as well as doctors

access to a password protected website for distance learning, said Dr Waterston. The students use facilities provided by the Palestinian Medical Relief Society.

“We got the original invitation from the Ministry of Health. They felt that the quality of care in primary care clinics, particularly in child health, was poor, because most of the doctors had been trained in European countries and weren’t prepared for the kinds of situations they were facing in the West Bank and Gaza.”

The ministry has already agreed that graduates of the course will have increased professional status, but “we’re still working on getting them improved pay,” said Dr Waterston. The current health minister of the Palestinian National Authority, Fathi Abu Maghli, “is in fact one of our trainees from our original attempt to set this up back in 2002,” he added.

The college has organised less advanced courses in child health for Iraqi GPs, and also runs similar projects in Africa.

access to care

The charity has warned that the government is considering curbing access to primary care, however, which it says if implemented could have “irreparable consequences.”

In March the Home Office published a document, *Enforcing the Rules: A Strategy to Ensure and Enforce Compliance with our Immigration Laws*, and announced a joint review with the Department of Health on access to the NHS by foreign nationals.

Angela Burnett, senior clinician at the foundation, warned that the restrictions, both current and proposed, denied vulnerable and destitute individuals the chance to have serious and sometimes life threatening conditions identified that needed treatment.

University drops plagiarism case against academic

Zosia Kmiotowicz LONDON

A senior Croatian academic and obstetrician has escaped punishment over allegations of plagiarism in his published work by Zagreb University's "court of honour" because the alleged offences took place some years ago and he retired in August.

The allegations against Asim Kurjak were originally made in the *BMJ* by Iain Chalmers of the James Lind Library in Oxford last year (2006;333:594-6).

In the late 1980s Dr Chalmers noticed that the text and data in a 1974 paper on epidural anaesthesia, coauthored by Professor Kurjak, were identical to those in a paper by another group of authors that had been published three years earlier.

He reported his observations to the editor concerned and to Professor Kurjak's university. Both wanted this handled discreetly.

But 14 years later Dr Chalmers was prompted to write the *BMJ* article when he discovered that Professor Kurjak had continued to plagiarise. A 2002 report showed that he had taken material from a Norwegian doctoral thesis and published it as a chapter in a book on fetal neurology under his own name.

This week the University of Zagreb's court of honour admitted that Professor Kurjak had behaved unethically in writing both pieces, but judged that the apologies submitted to those concerned were "adequate measures, concordant with the common practice for the breaches of the Code of Teachers' Ethics."

Since Professor Kurjak retired from the university on 13 September, before the case was heard on 25 October, the court of honour decided that the case should be dismissed.

Dr Chalmers said, "This is a sad day for Croatian scientists who wish to promote honesty and to outlaw misconduct and cynicism within academia."

Fiona Godlee, editor of the *BMJ*, commented, "Until the dean of Zagreb's medical school, Nada Cikes, shows that she takes Kurjak's offences seriously, the scientific integrity of the whole institution is in question and a cloud will remain over Croatia's research community" (*BMJ* 2007;335:10 November [editor's choice]).



Croatian academic
Asim Kurjak

Medical care is inadequate for landmine

John Zarocostas GENEVA

Land mines and other explosive remnants of war, including cluster munitions, claimed 5751 casualties—including 1367 people killed and 4296 injured—in 68 countries in 2006. Civilians made up three quarters of all victims, a global report says.

Overall, children—almost all boys—accounted for one third of civilian victims. In some places

"In Afghanistan, children accounted for 59% of casualties, Palestine 67% and Somalia 66%"

most casualties were children. In Afghanistan they accounted for 59% of casualties, Palestine 67%, Somalia 66%, Ethiopia 62%, Nepal 53%, Mozambique 49%, Vietnam 44%, the Democratic Republic of Congo 42%, and Laos 41%.

One quarter of casualties were military staff. "Deminers," carrying out clearance activities, accounted for 1%. The report estimates the current global number of survivors at 473 000, "with many needing life long care."

Last year's total is a 16% drop on 2005, and fewer than half the 11 700 new casualties reported in 2002, it says, and attributes the drop to the positive effect of the 1997 global treaty to ban mines and efforts of pressure groups.

But the report also cautions that the 2006 total refers only to recorded casualties, adding that the actual total number "is unknown but certainly higher . . . as data collection is inadequate in many countries."

The largest number of casualties was in Colombia, with 1106 (1112 in 2005), Afghanistan 796 (996), Pakistan 488 (214), Cambodia 450 (875), Somalia 401 (276), Burma 243 (231), Lebanon 207 (22), and Nepal 169 (197).

The report by the International Campaign to Ban Landmines, titled *Landmine Monitor Report 2007*, says that despite many programmes, help for survivors is inadequate in those countries having the greatest need for medical care, rehabilitation, and other services to survivors.

The campaign, a coalition of more than 1000 organisations in 72 countries, which won the Nobel peace prize in 1997, says that, overall,

Website tracks progress towards UN millennium goals

Janice Hopkins Tanne NEW YORK

A website (www.mdgmonitor.org) will monitor how well nations around the world are meeting the United Nations millennium development goals for 2015, which were established at a UN summit in 2000. It will allow countries to compare themselves with others.

The millennium goals are to decrease global poverty and hunger, to increase primary school education, to promote sexual equality, to reduce child mortality, to improve maternal health, to combat HIV/AIDS and malaria and other diseases, to ensure environmental sustainability, and to develop a global partnership for development.

The website will provide information for policy makers and development experts, who can learn from each other's successes and setbacks. It will also increase public access and attention to whether the goals are being met.

The site tracks progress toward the goals in a number of categories in almost every country. The UN says that the site gives the most current data available from many sources in developing indicators of public health, educa-



The data on Somalia, showing achievement to date by easy to recognise symbols

tion, and women's empowerment.

The UN developed the website in cooperation with Google and Cisco Systems to provide updated information on efforts to fight malnutrition, poverty, and disease. Visitors to the site can also zoom in and use Google Earth to explore places where work is being done to meet the goals. Cisco contributed \$150 000 (£71 000; €102 000) and technical expertise to the initiative, and Google ensured all the monitor's data were available on Google Earth, which can be accessed through www.mdgmonitor.org.

victims, says report

adequate advances were made in only 11 countries, with most progress reported by Albania and Tajikistan.

On a positive note, the report points out that in Cambodia last year 60% of new casualties received medical care within 30 minutes of their injury and that the fatality rate was reduced to 14% compared with 19% in 2005.

The study asserts that more than 160 million land mines are still stockpiled by nations not party to the 1997 treaty, with the bulk belonging to China, Russia, and the United States. Of the treaty's 155 members 145 have no stockpiles and collectively have destroyed about 42 million land mines.

Last year, international funding for mine action increased to a record level of \$475m (€320m; £230m). But the campaign's analysts noted that about 80-90% of this was for mine clearance and only a small proportion was to support survivors.

Meanwhile mine risk education reached 7.3m people in 63 countries in 2006/7, says the report, an increase on the previous year.

The *Landmine Monitor Report 2007* is available at www.icbl.org.



Land mines' legacy: an Afghan boy affected by a land mine explosion. Of the \$475m for mine action less than 10% was used to support survivors.

BERND OBERMANN/VOXWORKS/TIME LIFE PICTURES/GETTY IMAGES

Bayer withdraws heart surgery drug as trial results show increased risk of death

Annette Tuffs HEIDELBERG

The German drug company Bayer has suspended worldwide marketing of Trasylol (aprotinin), its antifibrinolytic drug, after the requests of the drug regulating authorities in Germany and Canada and the advice of the Food and Drug Administration in the United States. Infusions of aprotinin have been used to stop excessive bleeding during heart surgery.

A recent Canadian trial known as the BART trial (blood conservation using antifibrinolytics: a randomised trial in high risk cardiac surgery patients), coordinated by the Ottawa Health Research Institute, was stopped because

preliminary results showed an increased risk of death from the drug. The trial was started in 2001 and includes 3000 patients undergoing heart surgery.

Initial results had shown that Trasylol had lessened bleeding but the drug was linked to increased risk of death from all causes compared with patients taking two other antifibrinolytics—aminocaproic acid or tranexamic acid.

Bayer has announced that the suspension is temporary, until the final results from the BART trial are available, which is not likely to be until the end of 2008. The FDA issued a statement that because “there are not many treatment options for patients at risk of excessive bleeding

during cardiac surgery” the FDA was “working with Bayer to phase Trasylol out of the marketplace in a way that does not cause shortages of other drugs used for this purpose.” However, the German Federal Institute for Drugs and Medical Devices insisted on an

Preliminary results showed an increased risk of death from the drug

immediate suspension because alternative drugs were available in Germany.

Trasylol was registered by the FDA in 1993 and was given in 2006 to about 200 000 patients worldwide, 110 000 of them in the US, with total sales amounting to about €150m (£110m; \$220m) a year.

The BART study was the

latest in a series of worries about Trasylol's safety in past years. In 2006 a study published in the *New England Journal of Medicine* showed increased risks of kidney failure, heart attack, and stroke (2006;354:353-65).

As a result, safety warnings for Trasylol were strengthened in 2006, and approval for use was limited to patients who were having heart bypass graft surgery and were at increased risk of blood loss and blood transfusion during the operation.

In October 2006 international drug regulators' worries heightened when it became known that Bayer had failed to disclose to the agencies or their advisory panels the results of an unpublished study that had been sponsored by Bayer.

