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Study linking CFS with retrovirus is partially retracted

Anna Sayburn LONDON

The authors of a controversial paper published in *Science* that linked chronic fatigue syndrome to a mouse retrovirus have partially retracted their findings, admitting that some of their samples were contaminated. At the same time new research casts further doubt on the original findings.

However, the study's authors, led by Vincent Lombardi at the Whittemore Peterson Institute in Reno, Nevada, say that their research (*Science* 2009;326:585) didn't rely solely on the data they are retracting.

The paper created much interest when it was published in 2009. It seemed to show that 67% of a group of patients with chronic fatigue syndrome but only 3.7% of healthy controls showed signs of infection with xenotropic murine leukaemia virus related virus (XMRV).

The study was welcomed by patients' groups, who saw it as a validation of the clinical basis for the syndrome and as an area for researching a cure.

But before long, researchers were questioning the study's validity. Attempts to find XMRV in other groups of patients with chronic fatigue syndrome, including one paper in the *BMJ* (2010;341:c1018), failed. Other studies pointed to the possibility that the strain of XMRV picked up by Lombardi and colleagues' study was created inadvertently during work on a mouse cell line to investigate prostate cancer and had subsequently contaminated laboratories and reagents (*BMJ* 2010;341:c7358).

In June this year the editors of *Science* published an "editorial expression of concern" after asking the authors to retract their paper, which they declined to do (*BMJ* 2011;342:d3505).

In their partial retraction (doi:10.1126/science.1212182) the authors say that some of their samples were contaminated with XMRV plasmid DNA. The editors of *Science* say they are now "discussing next steps" with the authors.

A new study casts further doubts on the validity of the research (*Science* doi:10.1126/science.1213841). The multi-laboratory analysis of blood samples from the 2009 research found that only two out of nine laboratories—those involved in the 2009 research—found XMRV and that their findings were not consistent.

Cite this as: *BMJ* 2011;343:d6097

Trusts are told to prioritise high risk general surgical patients

Jacqui Wise LONDON

The high rate of complications and deaths after major abdominal surgery could be radically cut if hospitals prioritised high risk emergency cases over elective cases, says a new report from the Royal College of Surgeons of England.

The report points out that death rates of 15% to 20% are typical, and the rate can be as high as 40% in the oldest patients. Death rates for general surgery are up to three times those for cardiac surgery, where there has been a much greater focus on outcomes. Complications and death rates vary significantly between hospitals and even within the same hospital, depending on the time of day, the report says.

Norman Williams, president of the Royal College of Surgeons, said, "The focus on reducing waiting times for elective procedures has resulted in a large group, of mostly elderly patients, becoming seriously underprioritised to the point of neglect in some NHS hospitals."

The report, from the royal college and the Department of Health's working group on perioperative care of the higher risk surgical patient, makes a number of recommendations:

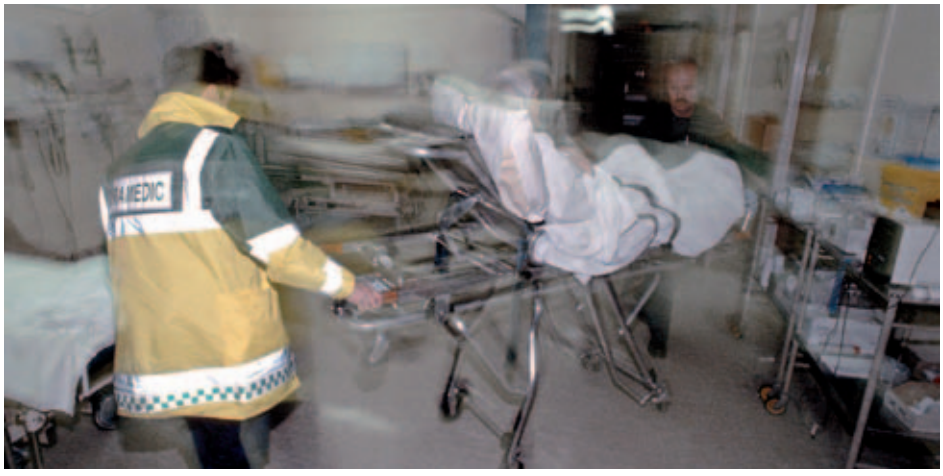
- Every general surgical patient should undergo routine risk assessment and tailored management
- Patients at highest risk should be treated under the direct supervision of consultant surgeons, anaesthetists, and intensivists.
- Hospitals should provide fast access to operating theatres within defined time periods, with patients at highest risk getting priority over elective operations, where necessary
- Patients at highest risk should be routinely admitted to critical care after surgery
- Postoperative care, including treatment of severe infection, should be improved, with the rapid involvement of senior doctors when needed, and
- Hospitals should carry out routine audits of emergency cases to improve outcomes.

The report says that an objective risk assessment should be carried out before and after surgery. A high risk patient is defined as one whose estimated mortality risk is greater than 5%. Patients undergoing major gastrointestinal or vascular surgery who are over 65 years old are classed as high risk, as are patients over 50 who have comorbidity such as diabetes or renal impairment. These patients should have active input of consultants into the diagnostic, surgical, anaesthetic, and critical care elements of their care pathway.

Routine admission of high risk patients to critical care would reduce rates of complications and subsequent admission to intensive care units, the report says.

The Higher Risk General Surgical Patient: Towards Improved Care for a Forgotten Group **is at www.rcseng.ac.uk/publications/docs/higher-risk-surgical-patient.**

Cite this as: *BMJ* 2011;343:d6168



SHOUT/ALAMY

Death rates for general surgery are up to three times those for cardiac surgery, the report says

Cost of cancer treatment does not reflect benefits, say experts

JEFF MORGAN 14/ALAMY

Patients' advocates who campaign for expensive drugs, such as Herceptin (trastuzumab), should challenge the manufacturers about the high prices they seek for their products, says NICE

Nigel Hawkes LONDON

Care of patients with cancer has become "a culture of excess" in rich countries, says a team of specialists assembled by the *Lancet*. "We overdiagnose, overtreat, and overpromise. We are heading towards a crisis in medical-care delivery," they say.

The report of the 37 strong commission, headed by Richard Sullivan from King's Health Partners Integrated Cancer Centre in London, is uncompromising (*Lancet Oncology* 2011;12:933-80). It says that expensive new drugs often contribute modest benefits while imposing huge cost burdens.

Surgery, the mainstay of cancer care, is going the same way, with the increasing use of robot assisted surgery that drives costs up with no clear evidence of better outcomes or quality of life. Imaging has hugely improved diagnostic accuracy but at much higher operating costs, which are often not reimbursed.

The burden of cancer is likely to rise, with more cases being diagnosed in an ageing population and costs of treatment continuing to rise. By 2030, the commission estimates, there will be 27 million new diagnoses a year. "The challenge to developed countries is how to collectively deliver reasonably priced cancer care to all citizens—that is, make cancer care affordable to individuals and society," it says.

No drug companies agreed to take part in the commission's work, despite repeated requests. In a comment accompanying the report, *Lancet Oncology*'s editor, David Collingridge, laments their absence (2011;12:923-4). A reticence to participate did not come from the clinicians or scientists within the organisations but from the legal teams worried about company self interest, he writes.

However, the commission's view is that involvement of drug companies is needed and that policy makers should seek to ensure their continuing viability.

Between 1980 and 2010, it says, anticancer drugs increased the life expectancy of the average cancer patient by a year, at an average cost in the United States of $6500 (£4180; €4800). This may seem a small gain, but it is cost effective.

The commission suggests that in the future value based pricing of cancer treatments may be a way to ensure that benefits and costs are in step.

In another comment on the report Michael Rawlins, chairman of the UK National Institute for Health and Clinical Excellence (NICE), and his colleague Kalipso Chalkidou sound a dissonant note (*Lancet Oncology* 2011;12:931-2). The commission, they charge, has not adequately explained why costs of anticancer drugs have ballooned.

They argue that clinical trial costs could be cut by 40% to 60% without damaging their quality and that—rather than criticising NICE for declining reimbursement for drugs on grounds of cost effectiveness—clinicians and patients' advocates should start challenging the manufacturers about the high prices they seek for products with modest benefits.

Cite this as: *BMJ* 2011;343:d6220

Expert criticises US decision to stop using bevacizumab for AMD

Nigel Hawkes LONDON

A decision by the US Department of Veterans Affairs to stop using the anticancer drug bevacizumab (marketed as Avastin) to treat wet age related macular degeneration after reports of infections apparently caused by contaminated syringes was criticised as unnecessary by a leading specialist in the eye disease.

Bevacizumab is unlicensed in the United States for treating age related macular degeneration but has been widely used because it is much cheaper and has the same mode of action as the licensed drug ranibizumab (Lucentis). At the end of August the US Food and Drug Administration reported a cluster of infections in the Miami area linked to a pharmacy in Hollywood, Florida, which had repackaged bevacizumab into syringes suitable for injection into the eye.

Patients from two Veterans Affairs hospitals—one in Nashville, Tennessee, and the other in the San Fernando valley, Los Angeles—are also reported to have become infected after injections of bevacizumab. Many lost their remaining sight; and the family of one man treated in Nashville has issued a claim for $4m (£2.6m; €3m) in damages for loss of sight and brain damage as a result of an infection.

But Philip Rosenfeld of the University of Miami

Moorfields is to host trial of human stem cells

Geoff Watts LONDON

Moorfields Eye Hospital in London is to carry out a clinical trial of human embryonic stem cells in the treatment of Stargardt's disease, a form of macular degeneration. The phase 1 and 2 trial, which is due to begin in a few months, is said to be the first in Europe to test stem cells of this kind in patients.

The trial will be conducted by the retinal surgeon James Bainbridge. Describing his hopes for the new treatment in this and other forms of macular degeneration, he said, "There is real potential that people with blinding disorders of the retina . . . might benefit in the future from the transplantation of retinal cells."

The team will inject epithelial cells derived from stem cells directly into the patients' retinas. "Whilst principally a safety study," said Chris

told the *New York Times* that the recent incidents seemed to have stemmed from careless procedures by pharmacies and should not discourage the use of bevacizumab. "It took six years for something like this to happen," he said, adding that there had been more than two million injections of the drug into the eye since the practice began in 2005.

A study in *Retina* in 2008 (28:1395-9) by a team from Barnes Retina Institute in St Louis, Missouri, that compared the incidence of endophthalmitis, a dangerous infection, after 12 585 injections of bevacizumab and 14 320 of ranibizumab found that the incidence of infection was the same—three cases (0.02%)—in each group.

Defending its decision, a spokesman for the Department of Veterans Affairs said that it had stopped the use of bevacizumab in the eye while an investigation was undertaken. "Once the investigation is complete, VA will assess how Avastin and similar therapies may be made available for ophthalmologic use and will issue further guidance," the department said in a statement.

Meanwhile in Europe four organisations, one of which is supported by the drug industry, and the drug company Novartis, which markets ranibizumab outside the US, warned that the true extent of the problem was not known and that there were likely to be unreported cases, because when a drug is used for unlicensed indications there is no formal mechanism for reporting adverse events.

Jim Thomson, chairman of the European Alliance for Access to Safe Medicines, which coordinated the statement, said, "We strongly believe that unlicensed and off-label medicines should only be used when a licensed product is unavailable, and there should be a mandatory adverse reporting system in place."

His statement was backed by the European Federation of Neurological Associations, the European Men's Health Forum, and the European Depression Alliance.

The European Alliance for Access to Safe Medicines is supported by the drug industry and includes among its funding partners Novartis. The two directors of the alliance listed on the registry of companies at Companies House are Mr Thomson and Mary Baker, who is also president of the European Federation of Neurological Associations. Ian Banks, director of the European Men's Health Forum, is also a member of the alliance's board, and Mr Thomson is a former chief executive of the UK Depression Alliance.

Mr Thomson said, "Our position is clear and, I believe, clearly stated. It is certainly not the result of any undue influence exerted upon the EAASM [European Alliance for Access to Safe Medicines] or its board. Happily we are protected from that by our governing documents and structure."

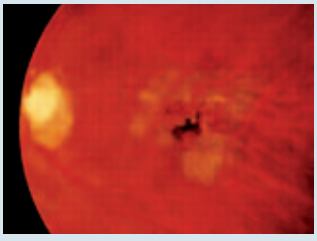
Novartis said it did not know any details of the statement, as the alliance determines its own work streams and projects.

In April the alliance published a report, *When is a Medicine not a Medicine?* (www.eaasm.eu/), which warned that reformulating the drug increased the risk of contamination.

Cite this as: *BMJ* 2011;343:d6169

Mason, chair of regenerative medicine bioprocessing at University College London, "it will significantly add to the growing core of knowledge on cell therapies, thus helping advance the entire field."

The new treatment has been devised by Advanced Cell Technology, a company in Massachusetts that specialises in regenerative medicine. Plans for the current trial received the go ahead when the UK Medicines and Healthcare Products Regulatory Agency granted permission to test the treatment on patients with advanced disease.



Stargardt's disease, which is currently untreatable, is a major cause of blindness in young people

Stargardt's disease, a juvenile form of macular dystrophy, first appears between the ages of 10 to 20 and affects roughly one in 10 000 young people. Patients with Stargardt's have a gene mutation that interferes with energy transportation to and from the photoreceptors. The retinal pigment epithelium degenerates, photoreceptors are lost, and vision deteriorates progressively. Currently untreatable, Stargardt's disease is the world's leading cause of blindness in young people.

News of the trial has been greeted with enthusiasm by stem cell researchers eager to see tangible benefits from a form of therapy that has been widely anticipated for more than a decade. The new trial would follow a similar one carried out in California in June.

Dusko Ilic, senior lecturer in stem cell science at King's College London, describes it as among the most eagerly awaited clinical trials in the history of regenerative medicine. "Demonstrating safety and tolerability of hESC [human embryonic stem cells] derived cell therapy in a trial like this would open a new age in regenerative medicine," he said.

In choosing to arrange this clinical trial in London, said Professor Mason, Advanced Cell Technology is endorsing the United Kingdom's position as a world leader in stem cell therapies.

Cite this as: *BMJ* 2011;343:d6124

WILL WINTERCROSS/TELEGRAPH SYNDICATION

Was Richard Scott's discussion with his patient appropriate and sensitive? The case continues

Patient is encouraged to give evidence in Christian GP case

Clare Dyer BMJ

A Christian GP accused of "crossing the line" in discussing religion with a vulnerable patient won a temporary reprieve when the General Medical Council adjourned the case against him to make another attempt to persuade the patient to give evidence.

The GMC had proposed giving Richard Scott a warning about his behaviour, but he refused to accept it and opted instead for an oral hearing before its investigations committee.

On 23 September the committee adjourned "to make a further attempt to secure the attendance of Patient A," who has so far refused to appear before the committee. His absence prevented Dr Scott's lawyer cross examining him to challenge his account of what happened at the consultation in August 2010.

GMC guidance says that doctors may not impose their personal or religious beliefs on patients and that if such issues are raised this must not be done "insensitively."

The committee heard that Dr Scott had seen the 24 year old man at his surgery in Margate, Kent, after his mother had said that he was "suicidal." Paul Ozin, for the GMC, said, "[Dr Scott] suggested that Jesus or Christianity—his own religion—offered something exclusive and superior to that offered by the patient's own religion. It is a matter of record that Patient A subsequently complained about Dr Scott and said he was very upset about the consultation and he was offended by what he saw as the belittling of his own religion."

Paul Diamond, for Dr Scott, did not accept this portrayal of events.

The Christian Legal Centre, which represents Dr Scott, said it would consider applying for judicial review if the GMC went on with the case.

bmj.com **Lobby Watch: Christian Medical Fellowship (*BMJ* 2011;343:d4586)**

Cite this as: *BMJ* 2011;343:d6158

The PFI scheme at North Bristol NHS Trust (above) represents "good value for money"

Trusts deny Lansley's claims over problems caused by PFIs

Adrian O'Dowd LONDON

Several NHS trusts have denied claims by England's health secretary, Andrew Lansley, that they are facing serious financial problems caused by the private finance initiative (PFI) schemes.

A row broke out after Mr Lansley was interviewed and quoted by the *Daily Telegraph* newspaper on 22 September as saying that he had been contacted by 22 trusts that run more than 60 hospitals between them to raise concerns that their "clinical and financial stability" was under threat because of the costs of their PFI contracts (http://tgr.ph/omk2tO).

However, several of those trusts have now denied the claim, and one said that not only was it in good financial health but that its PFI repayments were factored into financial plans and these were completely "affordable."

Mr Lansley's political opponents have claimed that the figures have been issued to try to distract attention from problems being caused by the government's controversial changes in the Health and Social Care Bill currently going through parliament. The list of trusts was put together in April.

Under PFI projects, first introduced by the Conservatives under John Major in 1992 and expanded when Labour came to power in 1997, private companies build hospitals, with NHS trusts repaying them, typically over 30 years. A total of £12.6bn (€14.4bn; $19.5bn) in PFI contracts exists in the NHS.

Mr Lansley announced the financial problems through the Conservative Central Office and not the Department of Health.

He said that up to 22 trusts had said that their PFI contract could act as a "barrier to achieving clinical and financial sustainability" and securing foundation trust status.

Several trusts took issue with Mr Lansley's claims. Ruth Brunt, chief executive of North Bristol NHS Trust, another of the trusts listed, said, "Our PFI deal represents good value for money which equates to yearly repayments of less than 7% of our overall annual turnover. PFI was the only route available for us to build the new acute hospital facilities that patients in Bristol and the surrounding areas so desperately need. The repayments have been factored into our long term financial plans, so we know they are affordable."

Cite this as: *BMJ* 2011;343:d6133

NHS boss ended type of gallbladder surgery at Stafford Hospital

Clare Dyer BMJ

The medical director of the NHS in England stepped in to stop one type of surgery at Stafford Hospital after getting a "unique" phone call from a senior surgeon brought in to review the hospital's surgical unit, the public inquiry into failings at North Staffordshire NHS Foundation Trust has been told.

Bruce Keogh said that Robert Greatorex, who led the review of the surgical unit at the trust's request in 2009, was so concerned by the findings that he broke confidentiality—something that was "entirely consistent with good medical practice and professionalism"—to alert Professor Keogh.

"He said in all his time of doing these reviews he had never seen a more dysfunctional surgical unit anywhere," Professor Keogh told the inquiry. There were particular problems with laparoscopic cholecystectomy.

Professor Keogh said that although he had no authority to stop a foundation trust doing a particular type of surgery, he phoned the medical director and a senior surgeon and advised stopping the procedure.

The surgeon, who happened to be good at doing that procedure, had asked him by what authority he could stop it. "I made it clear . . . I would have spoken to the chairman of the trust," Professor Keogh told the inquiry.

Government announces end of NHS IT programme—again

Michael Cross LONDON

For the second time in a year the UK government has announced the end of the £12bn (€13.7bn; $18.5bn) programme to computerise the NHS in England.

However, the announcement offers no detail on how the Department of Health will extricate itself from troubled information technology (IT) contracts. It also implies that large parts of the programme will remain intact.

In a statement apparently leaked to daily newspapers the department said that the government "had announced an acceleration of the dismantling" of the NHS National Programme for IT. It noted that the programme "was created in 2002 under the last government" and that a review by the Cabinet Office's new Major Projects Authority had concluded that the programme is "not fit to provide the modern IT services that the NHS needs."

The review was launched after a devastating report by the National Audit Office into the most troubled aspect of the national programme, the long delayed effort to create electronic patients' records in acute units (*BMJ* 2011;342:d3125, 17 May).

But the government had already announced, in September 2010, that the programme's "centralised national approach is no longer required" (*BMJ* 2010;341:c4988).

This week's statement, made on the eve of the Labour Party conference, seems to reflect political frustration at the lack of progress. The main new development is that control of the project has moved from a health department board to the Cabinet Office, which is responsible for central government's IT policy. Francis Maude, the Cabinet Office minister, said, "We now need to move faster to push power to the NHS frontline and get the best value for taxpayers' money."

However, the statement also said that the review had identified "substantial achievements" in many parts of the programme. These include the central data spine, the Choose and Book electronic booking service; the secondary uses service for extracting research and management data from patients' records; and the picture archiving and communications service's electronic imaging project. These central infrastructure elements, along with summary care records available throughout the NHS, are likely to be preserved under a new IT strategy expected to be announced in November.

The new statement contains no update on the most problematic elements of the national programme, the so called "local service provider" contracts to install standard systems across large geographical regions. The health department is still trying to renegotiate contracts worth nearly £3bn with the supplier Computer Sciences Corporation and to resolve a £700m dispute with Fujitsu.

Cite this as: *BMJ* 2011;343:d6125

Professor Keogh, a former cardiac surgeon, said that the Royal College of Surgeons, which puts forward the names of senior surgeons to do rapid response reviews at the request of trusts, had learnt from the experience. The college now included a provision in contracts with trusts that if "something bad" was found it would alert regulators, and the Academy of Medical Royal Colleges was working on making that a universal practice among the colleges.

Tom Kark QC, counsel to the inquiry, said that some people might want to ask, "Why didn't the medical director of the NHS know about the appalling things that were happening at the trust in 2007-8 as the [Healthcare Commission] investigation was going on?" Professor Keogh said that he was unaware of the magnitude of the problems until he saw the final report.

"At various points in this chain where I and others asked the Healthcare Commission, 'Is any intervention required?' the answer was always 'no,' because there was an expectation that things were improving," he said.

In terms of delivering quality, he said, it was neither the Care Quality Commission, the local primary care trust, nor the strategic health authority that treated patients badly at the trust, "it was individual clinicians, largely." There needed to be a significant focus on professionalism.

Under the new commissioning arrangements for the NHS he expected GPs "to actually walk the wards, to speak to the medical director, to meet with the chief executive." In the existing structures he suspected that "GPs were simply just a bit remote."

Cite this as: *BMJ* 2011;343:d6154

PROPOSED CHANGES TO THE NATIONAL PROGRAMME FOR IT IN ENGLAND

Components likely to be phased out:
NHS Connecting for Health (the central IT agency)
Local service provider contracts to supply standard electronic patient records to acute hospitals in geographical regions:
- Northwest England and West Midlands (contractor: Computer Sciences Corporation (CSC))
- Northeast England (CSC)
- East England (CSC)
- London (BT)

Components whose future is uncertain:
N3 (NHS data network) (BT)
NHSmail (email) (BT)

Infrastructure components likely to survive:
The national "spine," connecting all NHS units to:
- Summary care records
- Choose and Book
- Electronic prescribing service

Other national components expected to remain:
Secondary uses service, which extracts anonymised data for research and commissioning
Picture archiving and communications service

New infrastructure components expected to be announced:
Finance spine

First NHS club drug clinic opens its doors after successful pilot

Current services are not equipped to deal with the problems seen among users of newer "club drugs"

Jacqui Wise LONDON

The number of people experiencing problems after taking club drugs such as ketamine and mephedrone is rising, says the founder of the first NHS clinic in the United Kingdom set up specifically to tackle the issue.

The Club Drug Clinic in west London opened its doors this week to deal with problems associated with excessive use of drugs such as ketamine, mephedrone, GHB (γ-hydroxybutyric acid) and GBL (γ-butyrolactone), crystal methamphetamine, ecstasy, and the growing number of "legal highs." The founders of the clinic say that current drug services primarily focus on crack cocaine and heroin use, which is actually in decline.

Owen Bowden-Jones, a consultant psychiatrist at Imperial College London and a founder of the clinic, said, "Patterns of drug use in the UK are changing, and over the last two or three years we have continued to see an increase in the use of club drugs. The health risks associated with excessive use of club drugs are underestimated by many people, and little is known about the potential problems of the newer drugs."

He added, "Drug services were set up to treat heroin and crack, but this group of patients are not using those. Many people experiencing club drug problems do not see current treatment services as well equipped to help them."

The clinic has been open as a pilot scheme for five months and so far has had 70 referrals by word of mouth. Dr Bowden-Jones said that these people had been a mix of clubbers, students, and professionals.

One was a 31 year old single woman who had started to take ketamine when clubbing but then increasingly used the drug regularly at home. By the time she came to the clinic she was spending £600 (€690; $930) a month on the drug, and her work performance had deteriorated. She had developed ulcerations on her bladder, had blood in her urine, and may need to have her bladder removed.

Another patient, a 27 year old gay man, started using GHB at clubs but now needed to take 2 ml of the drug every hour, setting his alarm clock through the night, to avoid withdrawal symptoms.

Dr Bowden-Jones said, "Many GPs, A&E [accident and emergency] staff, and other health professionals have a lack of awareness and understanding of club drugs. For example, many may not know that if someone has blood in their urine it could be a sign of ketamine misuse."

Anne Lingford-Hughes, professor of addiction biology at Imperial College, agreed. "There is a huge training gap in all areas of addiction. Things are moving at such a fast pace in this field. We need to see much better education."

One problem emerging over recent years is the growth in use of legal highs. Existing banned drugs are altered slightly so that they fall outside current legislation. These can then be sold legally, often over the internet. Such drugs are continuously being developed, and as a result the authorities are always playing catch up. In 2010 41 new substances were recorded, and in just the first four months of 2011 the number was 20.

The new clinic hopes to become a centre for research on these new emerging drugs and the problems associated with excessive use. It accepts referrals nationally through GPs and other professional health services and self referrals.

See www.clubdrugclinic.com.

Cite this as: *BMJ* 2011;343:d6201

IN BRIEF

Dutch hospitals need to improve safety of acute care patients: An investigation by the Dutch Healthcare Inspectorate into the safety of patients outside regular consulting hours has found an increased risk in all hospital acute care settings and, in particular, higher perinatal mortality at evenings and night time (www.igz.nl). The agency has warned all hospitals to try to reduce risk factors such as "poor availability of sufficiently qualified staff."

Prevalence of hunger is underestimated: Hunger and malnutrition need to be better monitored, says the International Federation of Red Cross and Red Crescent Societies in its 2011 world disaster report. United Nations data indicate that household surveys in some countries may underestimate the number of hungry people by a factor of three, it says.

US doctors believe that patients are overtreated: Nearly half (42%) of 627 US primary care doctors who responded to a survey believe their patients receive too much medical care, while only 6% think they receive too little care (*Archives of Internal Medicine* 2011;171:1582-5). More than a quarter of doctors (28%) said that they personally were practising more aggressively than they would like. "Per capita US healthcare spending exceeds, by a factor of two, that of the average industrialised nation and is growing at an unsustainable rate," say the authors.

Man is charged with contaminating Nurofen Plus: A 30 year old man from south London, Christopher McGuire, has been charged with contaminating packs of Nurofen Plus that were found to contain the antipsychotic drug quetiapine and the antiepilepsy drug gabapentin. The manufacturer, Reckitt Benckiser, recalled the packets of the painkiller and stopped their distribution on 26 August (*BMJ* 2011;343:d5628).

MSD launches scheme to reduce maternal deaths: The drug company MSD is putting $500m (£320m; €370m) into a 10 year initiative called "Merck for Mothers" to help ensure that no woman has to die from complications of pregnancy and childbirth (merckformothers.com). The programme aims to develop new technologies, improve public awareness, and promote policies and private sector activities that reduce maternal mortality, especially that caused by postpartum haemorrhage and pre-eclampsia.

Cite this as: *BMJ* 2011;343:d6157

US Supreme Court may have to settle dispute over patenting DNA sequences

Clare Dyer BMJ

The US Supreme Court may be asked to rule on whether isolated sequences of DNA can be patented, in a challenge to a controversial patent conferring a US monopoly on testing for gene mutations that increase women's risk of developing breast and ovarian cancer.

The American Civil Liberties Union and the Public Patent Foundation brought the lawsuit in 2009, together with the Association for Molecular Pathology, doctors' organisations, patient advocacy groups, and individual doctors and patients. They argued that patents covering the BRCA1 and BRCA2 genes, granted in 1998 to the biotechnology firm Myriad Genetics and the University of Utah, were unlawful and should not have been granted.

The lawsuit claimed that Myriad's sole rights to the genes and its diagnostic analysis prevented women from obtaining a second opinion and that some women could not afford the test.

The plaintiffs initially succeeded in a federal court, winning a ruling in March 2010 from US district judge Robert Sweet that the genes were products of nature, which cannot be patented (*BMJ* 2010;340:c1870).

But last July that decision was overturned by a three judge panel of the Court of Appeals for the Federal Circuit. The judges ruled 2-1 that isolated DNA molecules with sequences corresponding to those found in nature can be patented. They concluded that isolated DNA claims in the patent relate to molecules that "are markedly different—have a distinctive chemical identity and nature—from molecules that exist in nature."

The judges held that only one of the more than 20 plaintiffs, a doctor who stated that he would immediately offer BRCA testing if the patents were invalidated, actually had standing to sue, but one is enough. The plaintiffs petitioned the court for a rehearing by the same panel on some issues, but the petition was denied.

Annual mammography after breast cancer may improve survival

Jacqui Wise LONDON

Regular mammographic surveillance of women who have had breast cancer is likely to improve their survival, a new study concludes.

The researchers point out, however, that the evidence base is relatively weak and that more research is needed in this area (www.hta.ac.uk/1709).

The United Kingdom has 45 000 new cases of breast cancer each year, and the cancer reoccurs in about a quarter of these women. Most of these recurrences are found in the first three years after treatment.

There is currently debate about how best to detect a recurrence and how often women should be followed up. Recurrent breast cancer can be found through mammography, self examination by the women themselves, or examination by a clinician. The surveillance regimens used vary widely around the country.

The study concludes that surveillance is likely to improve survival and that a strategy of mammography alone every 12-24 months seems to have the highest net benefits. The research was funded by the National Institute for Health Research's health technology assessment programme.

The study's leader, Fiona Gilbert, professor of radiology at the University of Aberdeen, said, "The results of our research demonstrate that mammographic surveillance is an effective and cost effective way of detecting new growths. Our research has the potential to influence the way in which follow-up appointments are organised in the future."

The researchers conducted two systematic reviews and surveyed breast surgeons and radiologists to determine current practice and to estimate cost effectiveness. They also modelled patient data from a number of sources, including the West Midlands Cancer Intelligence Unit's breast cancer registry.

They received responses from 183 of the 1048 clinicians surveyed (17%). Two thirds were surgeons and a third were radiologists, and they were based in 105 NHS trusts across the UK. The survey found considerable variation in the combinations of start, frequency, and duration of and discharge from surveillance mammography, with more than 50 different regimens reported. Annual surveillance mammography was the most commonly reported for women after breast conserving surgery (72%) or after mastectomy (53%).

The health technology assessment programme has issued a call for proposals on surveillance regimes after early breast cancer. For more information see www.hta.ac.uk/funding/standardcalls/index.shtml. The deadline for applications is Thursday 6 October.

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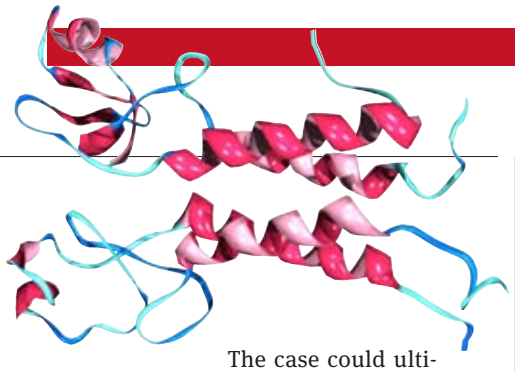

DR MARK J. WINTER/SPL

The case could ultimately go to the US Supreme Court, which has discretion over whether or not to accept it. In December the Supreme Court will hear legal argument in another closely watched patent case.

In a lawsuit that started seven years ago the Mayo Clinic, Rochester, Minnesota, is appealing against a federal appeal court ruling upholding patents for two diagnostic methods held by Prometheus Laboratories. The patents, which the Mayo Clinic is accused of infringing, cover methods for measuring patients' metabolite levels to determine the optimal dosage of drugs to treat stomach disease.

The Mayo Clinic argued in its application to the Supreme Court that the correlation between a type of drug treatment and the natural body metabolism resulting from that treatment was "unquestionably a natural phenomenon."

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Medical research bodies urge EU to reform regulation of clinical trials

Susan Mayor LONDON

Medical research organisations are urging the European Union to review the regulation of clinical trials because they say that excessive bureaucracy is hampering research into new treatments without enhancing the safety of patients.

Sixteen research organisations, including the European Organisation for Research and Treatment of Cancer, Germany's KKS Network of Clinical trials in Germany, and the UK Medical Research Council, have sent a joint statement to the European Commission and members of the European parliament. It outlines how the European Clinical Trials Directive—which sets out the legal requirements for conducting clinical trials throughout the European Union—should be revised to streamline the process of approval of clinical trials.

The Clinical Trials Directive 2001/20/EC provides a standardised framework setting out how clinical trials that investigate the safety or effectiveness of a medicinal product in humans must be conducted throughout the EU. Its aims were to protect people taking part in clinical trials, ensure the quality of trials, and harmonise regulation and conduct of clinical trials throughout Europe.

But the group says that the directive is interpreted differently throughout Europe and that groups undertaking trials are going above and beyond the requirements to ensure that they comply. "This can cause unnecessary bureaucracy and makes it increasingly difficult for researchers to undertake multinational trials," it warns.

This has led to a significant increase in the average cost and time it takes for trials to get up and running. Figures from Cancer Research UK comparing 2003 and 2007 (when the directive had taken effect) showed a 65% increase in the time it took researchers to get approval for studies and a 75% increase in administrative costs.

The statement is at http://bit.ly/noTT2z.

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Spread of polio to China and Africa threatens eradication

John Zarocostas GENEVA

The global campaign to eradicate polio has received a boost with major advances towards wiping out the disease in India, one of the four remaining countries where it is endemic, and a donation to the World Health Organization of a strain to make vaccines.

But the campaign, spearheaded by WHO, Rotary International, the US Centers for Disease Control and Prevention, and Unicef, also faces serious setbacks. These include an increase in numbers of cases this year in the other three countries where it is endemic—Afghanistan, Pakistan, and Nigeria—and imports of the disease into formerly polio free China and some African countries.

On 20 September WHO said that a strain of wild poliovirus type 1, genetically linked to a virus currently circulating in Pakistan, had been confirmed in China's westernmost Xinjiang province.

China, which recorded its last case of endemic polio in 1994, has reported a total of nine cases this year, the first since the importation in 1999 of one case from India.

Chris Maher, WHO's acting director for polio operations and research, told the *BMJ*, "Unfortunately this is the phenomenon we have seen fairly often in the last decade as the number of countries in the world with endemic transmission decreases."

Pakistan has seen 89 cases of polio so far this year, which compares with 52 at the same time in 2010.

Similarly Afghanistan has recorded 27 cases so far in 2011, up from 15 in the same period last year. In 2010 as many as a quarter of the target population for vaccination, children under the age of 5 years, missed out on vaccination, although this has now fallen to 10%, said Dr Maher.

The good news is that India has reported only a single case of polio this year, compared with 36 over the same period in 2010, says WHO.

"We're cautiously optimistic that India has done the job," Dr Maher said.

The global campaign received a boost with the donation on 20 September by Sanofi Pasteur to WHO of the original viral seed used to produce large quantities of oral polio vaccines against type 3 poliovirus.

Dr Maher said there was still residual transmission of poliovirus type 3 in Pakistan, the only case detected in Asia this year. However, there is still endemic transmission of type 3 virus in northern Nigeria, and there have been two new outbreaks this year, one in eastern Chad and one centred on Ivory Coast.

CHRISTOPHER WOLFF/WHO

China has responded to nine cases of polio this year with an aggressive immunisation campaign

So far this year 401 cases of polio have been detected around the world (down from 663 in 2010), of which 147 were in countries with endemic disease. By comparison, in 1988 more than 125 countries had endemic polio and more than 350 000 cases were reported.

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