NEWS

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bmj.com
Infertile woman, aged 24, accuses trust of age discrimination over IVF

Allow mitochondrial disorders to be prevented, report says

Nigel Hawkes LONDON

Techniques that prevent the transmission of mitochondrial disorders are ethically acceptable, even though they involve permanent changes to DNA that would be transmitted down the generations, says the Nuffield Council on Bioethics.

But the treatment would first have to be shown to be safe, carried out as part of a clinical trial; and parents considering it would have to be offered full information and support.

A new report by a working group chaired by the medical journalist and broadcaster Geoff Watts concluded that the balance of the argument lies on the side of permitting such treatments so long as the conditions are met.[1]

It acknowledged that it would be a germline therapy involving permanent changes to inheritable DNA and that hitherto such therapies have been deemed unacceptable. But special circumstances make mitochondrial DNA an exception, the report argues.

The DNA that controls mitochondria does not determine identity, appearance, or any personal traits and is located outside the nucleus of the cell. It is inherited unchanged down the maternal line. Defects in mitochondrial DNA cause disorders of varying complexity that cannot easily be treated.

But in vitro fertilisation can repair such defects if the mitochondrial DNA is replaced by that from an unaffected donor. This would prevent the disorder in a child and subsequent generations. It would enable affected women, now forced to consider surrogacy, egg donation, or adoption, to have healthy children genetically related to them.[2 3]

These advantages outweigh the risk that altering germline DNA would involve "a slippery slope," said Watts at a London press conference. "The genes are few in number, separate in location, and affect only mitochondrial function. We didn't look at other germline therapies."

Children born after such therapies would have a biological connection to their parents and the donor of the mitochondrial DNA. But it would be wrong to describe them as having "three parents" or "two mothers," because the genetic contribution from the donor is just 0.1% of the DNA.

Cite this as: *BMJ* 2012;344:e4089

Public's satisfaction with NHS shows largest dip in 30 years

Ingrid Torjesen LONDON

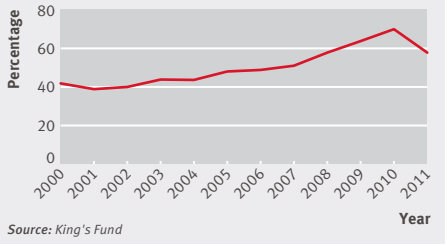
Last year saw the largest dip in satisfaction with the NHS since public attitudes on its performance first began being assessed by the British Social Attitudes Survey almost 30 years ago.

The figures, published on 12 June by the King's Fund, which sponsors the health questions in the wide ranging survey since the Department of Health scrapped funding for them last year,[1] show that public satisfaction "with the way in which the NHS runs nowadays" fell from a peak of 70% in 2010 to 58% in 2011. This drop of 12 percentage points is the largest since the survey began in 1983 and follows almost a decade in which satisfaction with the NHS crept up steadily.[2]

However, despite the fall, current public satisfaction with the NHS is still the third highest since the survey began.

The latest figures appear in the King's Fund report *Public Satisfaction with the NHS and its Services* and are based on the views of more than 1000 people surveyed between July and November 2011.[3] This period came in the first year in a four year freeze in NHS spending in real terms and was a time when the government had to justify to the public its proposed NHS reform programme after sustained criticism from professional medical bodies and the media.

Proportion of British public very or quite satisfied with "the way in which the NHS runs"



Source: King's Fund

The King's Fund believes that the dip in satisfaction has resulted from a combination of these factors and also the public's growing expectations of what the NHS can provide and wider dissatisfaction with the incumbent government, rather than from a deterioration of NHS services.

John Appleby, chief economist at the King's Fund, told a press briefing in London: "There really isn't any hard evidence of the sort of change in the quality of service that would really account for such a big fall in satisfaction." Healthcare acquired infections have continued their "downward trend," he said, and waiting times remained "broadly stable."

"In the end I think it is a combination of things—rhetoric used to justify the reforms by ministers, concern about the reforms themselves that is undeniable . . . and I think reaction to the funding squeeze."

The health minister Simon Burns said, "Our own polling of the general public, undertaken independently by MORI, shows that satisfaction with the NHS is broadly stable at around 70%."

Cite this as: *BMJ* 2012;344:e4091

WPA/GETTY IMAGES

The fall in satisfaction came at a time when "the government had to justify . . . its proposed NHS reforms"

IN BRIEF

Dying Dutch patients are treated for too long: Dutch doctors continue intensive treatment of dying patients for longer than is desirable or in patients' best interests, say almost two thirds of respondents in a survey of more than 700 doctors carried out by the Dutch Medical Association journal, *Medisch Contact*. Doctors, the respondents believe, are simply inclined to offer treatment.[1]

Germans are to be asked regularly about organ donation: All Germans over 16 years old will regularly be asked to declare their wishes on organ donation after death, says an amendment of the German transplant law passed by the German parliament on 25 May. "The regulation allows for people not wanting to decide at a particular point in time," said the health minister Daniel Bahr.

Disney adopts healthy eating guidelines: The Walt Disney Company is to ban junk food advertising on its television channels and websites from 2015. All food and drink advertisements will have to adhere to the company's own nutrition guidelines, which are aligned with federal standards, and state, for example, that breakfast cereal must contain less than 10 g of sugar per serving. Disney will introduce a "Mickey check" labelling system so that consumers can identify nutritious food items.

Portuguese doctors to go on two day strike: Doctors in Portugal are to hold two days of national strikes on 11 and 12 July in protest at government plans to put out to tender around 2.5 million locum work hours in hospitals and primary care health centres (equivalent to around 1700 doctors working full time) to private medical recruitment companies. Medical unions said that the tender would destroy "collective hiring and medical careers" and the quality of care.

Monthly malaria drugs prevent cases in children: In parts of Africa where malaria is a major problem for only a few months of the year during and after the rainy season, giving young children courses of a cheap antimalarial drug combination (sulphadoxine-pyrimethamine and amodiaquine) once a month prevents about 80% of severe and uncomplicated malaria cases, even if they sleep under bed nets treated with insecticide, a study has found.[2] The main countries that could benefit are Nigeria, Niger, Burkina Faso, and Mali.

Cite this as: *BMJ* 2012;344:e4037

New scoring charts for GPs are too crude, say doctors' leaders

Adrian O'Dowd LONDON

GPs and their practices are to be scored out of 10 for how their patients rate their experiences under new data being published in England for the first time.

Doctors' leaders, however, have described the data as too simplistic, lacking detail, and creating a risk of overwhelming patients with information.

From 7 June, the Department of Health will be publishing data online about various issues such as appointments, communication skills, and waiting times at GP practices in England.

This patient experience information, which has been gathered from patients' responses to the annual GP Patient Survey, will be available on the NHS Choices website (www.nhs.uk/Pages/HomePage.aspx), and the idea is that it will allow patients to make easy comparisons between different GP practices in their area so they can choose which practice they wish to use.

Data on more than 8000 GP practices will be used to form a new measure of patient experience for each surgery based on several areas including convenience in securing an appointment; length of time patients have to spend waiting in reception; opening hours; and skill of doctors and nurses at explaining things and listening to patients.

Each GP surgery will be scored out of 10. The health department claims the system will help to drive up standards within the profession by helping practices to identify problems.

In addition to the new patient experience measure, new data and an analytical tool will be published on the NHS Information Centre website (www.ic.nhs.uk/) to support GPs and the NHS to make improvements.

These developments are described by the department as part of the government's commitment to opening up data about health services and are in line with the aims of its information strategy The Power of Information[1] published in May.

The new data are additional to the existing 260 clinical measures of GP surgeries that were first published on the NHS Information Centre and Department of Health websites in December last year.

Health minister Earl Howe said: "This data will not only help patients choose the right GP surgery for them but will also give GP surgeries and the NHS new information they can use to make fresh, innovative improvements."

A BMA spokesman said doctors welcomed the opportunity for patients to give feedback on care they received.

The government's new approach, however, was crude, the spokesperson added: "Reducing surgeries to a score out of 10 fails to allow patients to give detailed responses. The rating would also fail to take into account the differing challenges that each GP practice may face, especially in terms of resources, which are increasingly being squeezed."

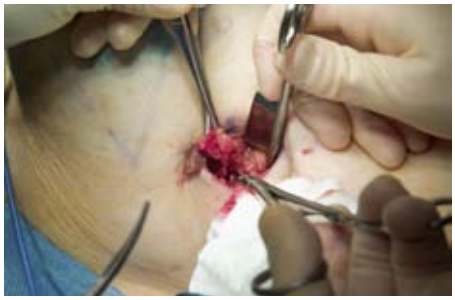
Cite this as: *BMJ* 2012;344:e3988

A fifth of patients with breast cancer have a recurrence

Susan Mayor LONDON

Just over one in every five people with diagnosed breast cancer has a recurrence of their cancer, show figures from a UK follow-up study reported this week.

Researchers retrospectively studied 1000 consecutive patients who were given a new diagnosis of invasive breast cancer in Leeds primary care trust between 1 January 1999 and March 2002. They were followed up for at least 10 years or until death if this occurred sooner.



DR BARRY SLAVEN, VISUALS UNLIMITED/SPL

The median disease free survival to first recurrence of breast cancer was just over three years

The study used local cancer records to track breast cancer recurrence and progression, and information was cross referenced against data from the Northern and Yorkshire Cancer Registration and Information Service.

Preliminary results, reported at the Joint UK Association of Cancer Registries and National Cancer Intelligence conference on 14-16 June, showed that 22.6% of the patients (214; 54 were lost to follow-up) developed a recurrence of breast cancer. The median disease free interval to first recurrence was 39.9 months.[1] Patients with a first recurrence had a median overall

GMC chief executive Niall Dickson says patients often have misplaced expectations of the council

GMC launches new tribunal service to decide fitness to practise of UK doctors

Clare Dyer BMJ

A new tribunal service to decide doctors' fitness to practise was launched on 11 June, in the biggest shake up of medical regulation in the United Kingdom since the General Medical Council was set up more than 150 years ago.

The Medical Practitioners Tribunal Service (MPTS), headed by a judge, will be part of the GMC but will operate separately from it and be accountable to parliament. The GMC will continue to investigate and prosecute cases.

The move paves the way for reforms of the fitness to practise procedures expected to come into force over the next few years.

Pre-hearing case management, better framing of charges, and more use of legally qualified people to chair fitness to practise panels are expected to cut delays and do away with the lengthy hearings that have bedevilled the GMC in recent years.[1] The hearing in the case of Andrew Wakefield, the doctor who made a spurious link between the measles, mumps, and rubella vaccine and autism and sparked a worldwide scare, ran for 217 days before he was struck off the medical register.[2]

GMC fitness to practise panels, which have been strongly criticised for flawed reasoning in three recent High Court appeals, will be given better training and performance assessment.

In one case, quashing the decision to erase Wakefield's colleague John Walker-Smith from the register, Mr Justice Mitting said, "It would be a misfortune if this were to happen again."[3]

David Pearl, the judge and former legal academic who chairs the MPTS, said, "One of my earliest priorities is to make improvements to the way that panellists are trained and performance managed through regular appraisal and quality assurance, which will bolster the quality of decision making."

This year the GMC plans to pilot a proposed new system of consensual disposal, which would allow a doctor to avoid a public hearing by accepting a suggested sanction. The doctor would attend a meeting to explain the circumstances and put forward mitigation at an early stage.

There are also plans to pilot face to face meetings with patients who complain, once at the beginning and once at the end of the process, rather than just send legalistic letters. "Often there is a mismatch of expectations," said the GMC's chief executive, Niall Dickson.

The regulator will be deploying regional liaison officers later this year to liaise with employers and back up the responsible officers in charge of five yearly revalidation of doctors, with the aim of spotting and dealing with underperforming doctors early.

The reforms were welcomed by the NHS Employers organisation. Bill McMillan, its head of medical pay and workforce, said, "Safeguards will be as strong as ever, but this new process aims to resolve cases more quickly, while evidence is fresh and participants still have a good recall of events. It is a significant step away from the cumbersome processes that could result in doctors being suspended for several years awaiting hearings and decisions."

NHS Employers has published new guidance for employers on supporting doctors in difficulty.

Cite this as: *BMJ* 2012;344:e4060

survival of 17.9 months (13.1 to 22.7 months) and their one year survival rate was 63%.

The lead author, Lucy Walkington, clinical fellow and specialist registrar in medical oncology at St James Institute of Oncology, Leeds, said, "This is the first study to assess breast cancer recurrence rates systematically in an unselected group of patients and is part of a larger study assessing the costs of recurrence and planning related services." UK cancer registries routinely collect information on initial diagnosis, management, and overall survival of most cancer patients but do not track recurrence.

Walkington explained, "The aim of this study is to begin to understand more about how long patients with breast cancer survive without recurrence, how long they survive if their cancer does return, the cost of each stage of cancer treatment, and how we can best plan services."

Cite this as: *BMJ* 2012;344:e4085

Young Jehovah's Witness who refused a blood transfusion is allowed to die

Clare Dyer BMJ

A 22 year old Jehovah's Witness with sickle cell anaemia has recently been allowed to die in the United Kingdom after refusing a blood transfusion, the lawyer advising the NHS trust caring for him has announced.

Robert Tobin, a partner in the law firm Kennedys, was consulted because doctors were reluctant to let the man, who was in a sickle cell crisis, die when such a simple procedure could have saved his life.[1] He revealed details of the case on his firm's website.

Doctors "looked into the possibility of alternative products, but the only thing that would work was a human blood transfusion," said Tobin. "It was very difficult for the doctors. The whole thing took about three weeks in the end. He was gradually deteriorating, every day dragged on, and he eventually died."

Tobin said that the initial concern was that the man's mother, also a Jehovah's Witness, who was sitting by his side when he died, and an elder from his church were unduly influencing him. But a doctor from a neighbouring trust assessed that he had full capacity and was making the decision on his own.

Lawyers drew up an advance decision for the man to sign in case he lost capacity before he died, "to save the family from retrospectively suing on the grounds we weren't acting in his best interests if he lost capacity," Tobin added.

Cite this as: *BMJ* 2012;344:e4097

Trust seeks legal advice to stop private firms selling GP practices

Tom Foot LONDON

NHS officials have admitted they were powerless to stop a US health giant from suddenly selling a Camden GP surgery to another private firm. The surgery closed less than a year later, leaving 4700 patients looking for a new GP.[1]

Tony Hoolaghan, associate director of North Central London NHS Trust, described how the trust lost control of Camden Road Surgery and that he was seeking legal advice to stop a similar situation happening again. He was speaking on 31 May at an inquiry into the closure of the surgery held by Camden Council.

Camden Road Surgery is one of three GP practices that were contracted out by the primary care trust to the giant US healthcare company UnitedHealth in 2008. But in April 2011 UnitedHealth sold its shares in the three practices, including Camden Road, to The Practice plc, describing it as a "management transfer."

The transfer shocked patients, who were not informed about the deal until after it was done. Managers at North Central London NHS Trust, a cluster of five primary care trusts, had not vetted or approved the new operators.

By February 2012 Camden Road Surgery had closed, triggering the public inquiry in Camden Town Hall.

Speaking at the inquiry, Hoolaghan said: "We took legal advice at the time and we were informed that what had happened was legal. We couldn't prevent it from happening. There was no change to what the new deliverer had to do—no change in the performance monitoring [hence no illegality]." He added: "We are seeking legal protection for next time."

Cite this as: *BMJ* 2012;344:e3993

Pressure on beds in Scotland is affecting patient care, college says

Bryan Christie EDINBURGH

Care of patients is being compromised at hospitals across Scotland because of pressure on specialist beds and medical staffing, the Royal College of Physicians of Edinburgh warned on 12 June.

It is resulting in patients who need treatment on specialist wards being "boarded out" to other wards where less specialist care can be provided. This used to be a problem confined to the busier winter months but is now becoming the norm all year, said the college.

It conducted a survey among 1356 of its fellows in Scotland, mostly senior hospital consultants, to determine the extent of the problem. Of the 290 who replied (21%), just under three quarters (71%) said that they believed levels of boarding out in Scotland to be high and going up, and 99% believed that boarding out had a negative effect on the quality of care. Most respondents believed that boarding out increases readmission rates and length of stay, while contributing to higher death rates.

President Neil Dewhurst: boarding is poor practice

The Scottish health department has said that it took the concerns very seriously and announced that the country's chief medical officer, Harry Burns, is to meet the college to discuss the findings.

A small scale study published last year in the *Scottish Medical Journal* found that 74% of doctors would refuse to be boarded out themselves and that 92% would not accept this for a relative.[1]

The college said that there has been a significant and sustained rise in the number of seriously ill patients admitted to Scottish hospitals at a time when the consultant workforce has remained static and the number of acute beds has reduced. The number of acute hospital beds in Scotland fell from just over 18 000 in 2002 to 16 700 in March 2011. Average throughput per bed rose over this period from 45 to 56 patients a year.

The college's president, Neil Dewhurst, said that pressure on beds meant that in most hospitals consultants have no alternative but to move seriously ill patients to less specialised wards. "There is strong evidence that this reduces quality of care for patients and increases their length of stay. Boarding, in effect, creates a vicious circle, delaying treatment and discharge for patients and adding considerably to the workload of the healthcare teams caring for them.

"What this survey shows is that boarding is becoming the norm in Scottish hospitals on a year round basis. We believe this is poor practice, places patients at risk, and is unacceptable."

The Scottish government says that Scotland is the only part of the UK to look at the issue of boarding on a national level. It asked health boards to report on winter boarding levels from 2009, since when levels have been falling.

Derek Bell, professor of acute medicine at Imperial College London and a member of the Scottish government's advisory group on unscheduled care, said, "Boarding has always been recognised as poor practice, but now in the work that has been driven by the Scottish government we have the potential to measure the adverse impact."

Cite this as: *BMJ* 2012;344:e4067

GP practice shed vulnerable elderly patients to save money

Churchill Medical Centre was investigated after local GPs complained about taking on older and vulnerable new patients at short notice

Clare Dyer BMJ

A GP practice run by one of the most vocal supporters of the UK government's health reforms removed older and disabled care home patients from its list for financial reasons, an NHS investigation has found.

Churchill Medical Centre in Kingston, Surrey, has been found in breach of contract by NHS South West London after delisting 48 patients at Kingston Care Home last year "predominantly for financial reasons."

Charles Alessi, a prominent supporter of the NHS reforms and chair of the National Association of Primary Care, was senior partner at Churchill until he retired at the end of March after 26 years. In June last year, according to documents obtained by the *Surrey Comet*,[1] the practice wrote to the care home saying it could not continue to look after the 48 patients "as a result of significant funding constraints in this financial year."

The decision to delist the patients followed a review of PMS (personal medical services) GP contracts by NHS Kingston. Churchill told South West London primary care managers in an email that its action was taken because of "very significant cuts to our practice budget as a result of the PMS review." It

Funding agencies "are standing in way of open access to research results"

Nigel Hawkes LONDON

The bodies that fund scientific research are the main remaining obstacle to the open publication of results in a form that everyone can access, traditional journal publishers say.

Denying that they were standing in the way of open access, representatives of Nature Publishing Group, Elsevier, and Springer suggested at a briefing at the Science Media Centre in London on 8 June that any delays were due to the reluctance of funding agencies to commit themselves to the model.

Philip Campbell, editor in chief of *Nature*, said that the free availability of all scientific information to everybody was "very compelling" because it made possible new techniques such as data mining and because the public, having paid for the research, had a moral right to access its results.[1]

But there was a cost attached, in editing, checking, and arranging for peer review, and this had to be paid. In open access, subscriptions are replaced by payments by the authors and thus, indirectly, by the funding agencies. "My understanding at the moment is that they can't promise to fund it," he said.

Wim van der Stelt, Springer's executive vice president for corporate strategy, agreed. His company was ready for open access. "But almost nobody is ready to pay yet. This is the major issue that has to be solved," he said.

Alicia Wise, director of universal access at Elsevier, said that while publishers had been resistant to open access in the past, that had changed. "We're happy to work with anyone, and we [can] adapt fast," she said.

Cite this as: *BMJ* 2012;344:e4062

LAURENT DUBRULE/REUTERS

Anticounterfeiting agreement will hinder trade in generic drugs, protesters say

Matthew Limb LONDON

Several thousand people took to the streets in Germany and Belgium (above) on Saturday 9 June to protest against proposed new anticounterfeiting controls, which they say will harm the production of generic drugs across the world and consequently reduce poor people's access to them.

The day of action, which was organised to stop the implementation of the Anti-Counterfeiting Trade Agreement (ACTA), also produced demonstrations in London, Brussels, Vienna, the Netherlands, and Sweden.

Protestors said that the "undemocratic" agreement would harm fundamental rights and curb access to essential, affordable drugs in Europe and in developing countries that have not participated in negotiations.

Tessel Mellema, a spokeswoman for Health Action International Europe, which backed the demonstrations, said, "We trust that these voices calling for the protection of EU citizens' rights over those of private companies will be taken into account and reflected in the European parliament's final vote scheduled for early July."

Supporters of the agreement said that it will not bar access to drugs but will instead help countries to tackle the trade in counterfeit goods, which costs Europe billions of euros a year and endangers consumers.

Cite this as: *BMJ* 2012;344:e4073

gave the care home 28 days' notice of the delisting, saying the move was unavoidable "given the high demand for GP services from the care home" and the "decision of the primary care trust to remove funding for this specialist service."

But while the review reduced the monthly payments under the contract, it did not amend the service requirements or reduce funding for a specific service, according to the investigation's report, obtained under the Freedom of Information Act. The provision of services to the care home was "not a specialised service."

The contract bans doctors from removing patients from their list on grounds of age, disability, medical condition, or need for specific treatments, and patients cannot be removed unless, during the previous 12 months, they have been given a written warning that they are at risk of removal, with reasons.

The patients, some with dementia, were distributed among six smaller practices, including a single handed practitioner. The investigation was launched after the other local GPs objected to having to take over the care of older and vulnerable patients at short notice.

Alessi did not respond to a request for comment that the *BMJ* asked NAPC to forward to him. Churchill Medical Centre said in a statement that it was "disappointed" with the investigation's conclusions but was "confident lessons have been learned by all parties." It added: "These events took place after a protracted and polarised contractual dispute between the practice and the PCT [primary care trust] and at a time of transition . . . The practice believes these were significant contributory factors to the events."

A spokesperson for NHS South West London said: "We've issued a formal notice to the practice which states that they can't repeat the activities that have put them in breach of contract, and we continue to monitor the practice closely. We took action to ensure that all the affected patients from Kingston Care Home were allocated a new local GP as soon as we were alerted to this issue."

Cite this as: *BMJ* 2012;344:e3998

Finland tops European table for child safety

Zosia Kmietowicz LONDON

National governments need to do more to prevent children injuring themselves and dying from drowning, falls, burns and scalds, poisoning, and choking or strangulation, according to an assessment of child safety policies in 31 countries across Europe.

The Netherlands leads Europe with the lowest rate of deaths from injury among children and adolescents in 2010 or the most recent year available (4.99 deaths from injury per 100 000 children aged 0 to 19), followed by Sweden (5.02) and the UK (6.01).[1]

DANIEL VRABEC/ALAMY

Only 13 out of 31 countries have a law requiring children to wear a helmet while cycling and just eight fully enforce it

The worst performing country is Lithuania (23.91 deaths per 100 000), followed by Bulgaria (17.37), Romania (17.2) and Latvia (16.06). The report covers 27 EU states plus Croatia, Iceland, Israel, and Norway.

"A child dies every hour of every day in the EU as a result of an injury," said Joanne Vincenten, director of the European Child Safety Alliance, which has produced the report. "Consistent use of proven prevention strategies across the EU could save most of these lives. It would also save billions of euros spent each year on treating injuries and would allow children and adolescents to grow up to be healthy and active contributors to future economic growth in Europe."

The alliance has compiled child safety report cards for 31 countries in Europe that score them on adopting, implementing, and enforcing over 100 strategies and policies proved to prevent unintentional injury. These show that, overall, countries have worked harder to implement policies related to transport than those related to preventing injuries in the home.

To date no country has adopted all the recommended safety measures, and scores range widely—from 45 points out of a possible 60 for Finland to 14.5 points for Greece. Behind Finland were Iceland (44.5), the Netherlands (43.5), the Czech Republic (43.5), and Poland (43.5). With 37.5 points Scotland was ranked 16th, England 17th (36 points), and Wales 24th (31 points).

England's scorecard, for example, says that it could do more to prevent falls by enforcing national standards for playground equipment and banning baby walkers.

This is the third round of report card assessments by the alliance, with 18 countries participating in 2007, 26 in 2009, and now 31 in 2012. There has been a substantial improvement in scores, with some of the greatest improvements in countries with the greatest investments to prevent injuries in the last five years, such as the Czech Republic, Finland, Hungary, Scotland, and Spain. The report says a decrease in Greece's score since 2009 probably reflects the economic crisis there.

The report says that:

- Only 13 countries (42%) have a law requiring use of a bicycle helmet while cycling and just eight fully implement and enforce it.
- No country has a law requiring children to use a rear facing child passenger restraint to age 4, although this is normal practice in Sweden, where child passenger deaths in this age group have been reduced to almost zero.
- Only seven countries (23%) have a law requiring barrier fencing for private pools, but only France implements it.
- Only 15 countries (48%) have a law requiring child resistant medicine packaging.
- Only 16 countries (52%) have a law to prevent children from falling out of windows (such as through use of window guards).

Cite this as: *BMJ* 2012;344:e4008

Anticoagulants cause the most serious adverse events, finds US analysis

Jeanne Lenzer NEW YORK

A report by a watchdog group has concluded that prescribed medicines are "one of the most significant perils to human health resulting from human activity." The group based its conclusion on its analysis of the US Food and Drug Administration's database of serious adverse events.

The report was published on 31 May in *QuarterWatch,* a publication of the Institute for Safe Medication Practices, a non-profit organisation based in Horsham, Pennsylvania.[1] It calculated that in 2011 prescription drugs were associated with two to four million people in the US experiencing "serious, disabling, or fatal injuries," including 128 000 deaths.

According to the US Centers for Disease Control and Prevention, 48% of the US population were taking a prescription medicine in any given month and 11% were taking five or more prescribed medicines.

The FDA estimates that the number of reports it receives represent only the "tip of the iceberg," and the report authors based their estimates on 179 855 reports of serious injuries, including 30 385 deaths submitted to FDA in 2011. Of those reports, 88% were written and submitted by manufacturers and 12% were submitted by health professionals and patients. The authors considered 30% of the death reports to be "nearly useless" since the only event information supplied was the single term, "Death." Ninety nine per cent of the low quality death reports were submitted by manufacturers, which omitted critical patient information such as the cause of death or age of the patient.

DR P MARAZZI/SPL

Bleeding from warfarin (above) topped the list of drug side effects

The top five drugs most often reported by healthcare providers and patients were (in order of frequency) the anticoagulant drugs warfarin and dabigatran; the antibiotic levofloxacin; the cancer drug carboplatin; and the antihypertensive lisinopril.

David Cundiff, lead author of a Cochrane review of anticoagulant treatment for venous thromboembolism, told the *BMJ* that deaths from anticoagulation associated internal bleeding have been ignored for too long—a point underscored by the report authors, who write that "In the sobering arithmetic of anticoagulation, warfarin prevents ischemic strokes in approximately 1% of high risk patients a year, but causes major bleeding in an estimated 3%."

George Lundberg, former editor in chief of *JAMA,* told the *BMJ* that he was not surprised to see anticoagulants topping the list. He said that overprescribing is partly to blame and that "a balance needs to be reached between the benefits and harms of anticoagulants."

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