NEWS

bmj.com
Trust tells woman she cannot have her stored ovary tissue

Cameron riles doctors by excluding critical voices from summit on controversial NHS changes

Zosia Kmietowicz LONDON

The prime minister emerged from his summit on Monday 20 February with supporters of the coalition's changes to the NHS proclaiming that choice for patients, with GPs at the helm, was resulting in better care.

The summit became notorious even before it took place for its exclusion of groups that have called for the Health and Social Care Bill to be withdrawn, including the BMA, the Royal College of General Practitioners, the Faculty of Public Health, and the Royal College of Nursing.

Those invited included the Royal College of Surgeons, the Royal College of Physicians, the Royal College of Paediatrics and Child Health, and the NHS Confederation—all of which have remained open to negotiating amendments to the bill to see it passed into law.

At the summit David Cameron reiterated the messages that he has been stating since the bill was laid before parliament in January 2011: that the NHS was safe in his hands and that competition would provide better care for patients.

Mr Cameron said the meeting was "constructive and helpful" and that there were "quite a few myths that we need to bust about this reform."

He said, "Choice for patients is a good thing: making sure that doctors and nurses, not bureaucrats, are making decisions, that's a good thing.

"I also heard how, on the ground, where some of the reforms are already taking place, you are actually seeing better health outcomes, GPs doing more things for their patients, people living healthier lives as a result of these changes."

A letter from 650 healthcare professionals and taken to number 10 during the summit accused Mr Cameron of being "profoundly antidemocratic" by excluding groups opposed to the bill.

Sue Slipman, chief executive of the Foundation Trust Network, was among those invited to the summit

STEFAN WERMUTH/PA

The letter, which was coordinated by the campaigning group Keep Our NHS Public, said, "Your stubborn disregard for these considered and well founded criticisms . . . is breath-taking.

"If you were serious about safeguarding and improving the NHS you would listen to these critical voices. Instead you have called together a group of 'yes-men' who will allow you to claim that you have significant professional support for your bill when you have no such thing."

It concluded, "Your attempt to split the profession while ignoring their voice is profoundly antidemocratic. This bill will not succeed when the majority of healthcare workers oppose it."

In a statement the Royal College of General Practitioners said that it was disappointed not to have been invited to the meeting. "It is our Members who will have to implement the changes if the Bill goes through so it is very important that we are part of any discussions on the way forward," it said.

Hamish Meldrum, chairman of council of the BMA, said that one of his biggest concerns was that the increasing bureaucracy and focus on competition in the bill will hinder progress, such as reducing emergency admissions.

He added, "It is extremely disappointing that the government seems increasingly to be indulging in selective listening. We want to find a way to make sure patient care continues to improve. If the government shares this objective, it has to recognise that NHS reform must have the support of these—and all other—health professionals."

Cite this as: *BMJ* 2012;344:e1294

Row erupts over effect of plain packaging on prevalence of smoking

Ingrid Torjesen LONDON

A report from the Adam Smith Institute claiming that government plans to introduce plain packaging of cigarettes will not reduce the prevalence of smoking has been hotly contested by the antismoking charity Action on Smoking and Health (ASH).

The institute's report says that there is no evidence that the colour and logos on a packet of cigarettes encourage people to start smoking and that packaging design has little effect on smoking rates.

It warns that plain packaging could actually have detrimental effects, such as increasing the trade in counterfeit cigarettes, because the packaging will be easier to replicate. This would make cheap tobacco more readily available, the institute says, and lure young customers.

ASH argues that tobacco companies' glitzy packaging is designed to attract young smokers and that there is now a large body of evidence from around the world to show that plain packs are less appealing and strengthen the impact of the health warnings.

Deborah Arnott, chief executive of ASH, said, "It [the institute] should be more transparent about its association with 'Big Tobacco.'"

Cite this as: *BMJ* 2012;344:e1269

Chain of 30 kidney transplantations sets record

Nigel Hawkes London

A new record for chained kidney transplantations has been set in the United States. It involved 30 transplantations across the country between August and December last year, which linked living donors to recipients whom they were unlikely ever to meet.

Chained transplantations start with a single altruistic donor. If this donor's kidney is used to help a recipient who has been denied a transplant from a relation who was willing to donate but was unable to do so because of immunological incompatibility, then the chain can continue if that relation remains willing to donate anyway. That kidney goes to the next recipient in the chain, who also has a willing but incompatible relation, prepared once more to reciprocate the gift by donating onwards. Technically such a chain need not end, but people are excluded who have no relation or partner who is willing to keep the chain going.

The 30 strong chain in the US has been anatomised by the *New York Times* in a meticulous reconstruction that traced and identified all but one of the 60 people involved (www.nytimes.com/2012/02/19/health/lives-forever-linked-through-kidney-transplant-chain-124.html). The chain began with a single altruistic donor, Rick Ruzzamenti, 44, of Riverside, California, who decided one day to give a kidney to a needy kidney patient—any needy kidney patient. He attributed this spur of the moment decision to his Buddhist beliefs and to the recession, which had reduced his work as an electrical contractor and given him time to spare.

Rick Ruzzamenti started the chain because of his Buddhist beliefs

His kidney was flown across the country to Livingston, New Jersey, where it was transplanted into a 66 year old man. His niece had offered him her kidney, but it did not match, so in recognition of Mr Ruzzamenti's gift she gave it anyway, and it was shipped to the University of Wisconsin Hospital in Madison and transplanted into Brooke Kitzman, 29. In reciprocity Ms Kitzman's former partner, David Madosh, 46, donated one of his kidneys, in spite of the fact that he and Ms Kitzman had just had an acrimonious break up.

And so it went on, until the 30 transplant chain terminated with Donald Terry, 47, in Joliet, Illinois, who had nobody in his family willing or able to donate a kidney. Overwhelmed by his good fortune, he began to feel guilty that he would be last in the chain. "Is it going to continue?" he asked his transplant surgeon. "I don't want to be the reason to stop anything."

He was reassured that as one chain stops, another begins. The process is made possible by a registry of would-be donors and their intended recipients started by Garet Hil, a business executive

TIM SOAR

Doctors at Kentish Town Health Centre (above), London, are happy with the new arrangement

BMA warns of "private sector kicking GPs out of their surgeries" as NHS company takes over

Helen Mooney LONDON

GPs are being warned to prepare for higher costs and uncertainty over their surgery premises and the legal status of their leases.

After the Department of Health's announcement last month that it would set up a government owned company responsible for owning and managing the estate of the primary care trusts after the organisations are abolished in April 2013, local medical committees and the BMA are warning GPs to ensure that their property documentation is up to date.

They are concerned that the establishment of the new company, NHS Property Services, could mean that new landlords take a much more commercial view of the use of GP premises. The company will take over more than 150 properties in the NHS estate.

Laurence Buckman, chairman of the BMA's General Practitioners Committee, told the *BMJ* that he was "naturally suspicious" of the new arrangements.

He said, "As yet we don't know how much impact it will have, but my worry is that premises development will stop completely if there is no money or that they will be privatised . . . We could see the private sector kicking GPs out of their surgeries."

He said that all GPs who did not own their premises urgently needed to check their ownership licences and leases.

Paddy Glackin, secretary of the Londonwide Local Medical Committees, which represent GPs in London, warned that most general practices in the capital that were based in a primary care trust health centre did not have formal lease arrangements in place.

"There is huge worry that GP premises will be handed over to community foundation trusts, who will hive them off to the private sector."

Health department guidance issued last year said that aspirant community foundation trusts could acquire primary care trust properties where the trust occupies most of the building and where the asset is deemed to be "service critical clinical infrastructure."

Dr Glackin said that his organisation was in discussions with London primary care trust clusters and NHS London (the strategic health authority) in a bid to draw up "model" leases for general practices, as well as an agreed list of "reasonable" service charges that GPs should pay to landlords.

Some practices are happy with the new arrangements, however. Roy Macgregor, partner in the James Wigg practice in Kentish Town Health Centre, north London, was happy that partial ownership of the premises, which is 20% owned by the local primary care trust and 20% by the Department of Health, would go to the new company. He said, "As tenants to the PCT [primary care trust] we are pleased with the solution that the NHS share of these premises remains at 40% of the private-public partnership in LIFT. Holding the 20% PCT portion of ownership alongside the existing NHS share of 20% is one piece of good news for the NHS."

Cite this as: *BMJ* 2012;344:e1241

whose daughter was saved by a kidney donated by one of his nephews. With his wife, Mr Hil set up the National Kidney Registry and created an algorithm to match pairs and create chains.

Mr Hil's pool consists of up to 350 donor-recipient pairs, making possible a huge series of different possible chains. The programme eliminates those matches that are immunologically impossible and creates viable combinations, which are then ranked by the number of transplantations they would enable, with weight given to chains that find kidneys for patients who are hard to match or who have waited for a long time. Last year Mr Hil's registry arranged 175 transplantations, including the 30 in the record breaking chain. "We've just scratched the surface," Mr Hil told the *New York Times*.

Chained donations, which take place over several months, have not occurred in the United Kingdom, but "pooled" donations, which are carried out simultaneously on the same day, have. There is no legal obstacle to chained donations in the UK, and from the beginning of this year would-be altruistic donors have been able to choose to donate into a pooled scheme rather than to the next suitable patient on the national transplant waiting list.

Lisa Burnapp, lead nurse for living donation at NHS Blood and Transplant, said, "The story of the 30 long chain shows the future potential for what is possible in living donor kidney transplantation.

"In the UK we've just embarked on introducing altruistic donor chains into our established national living donor kidney sharing schemes. We've chosen to build on the strengths of our existing paired and pooled donation scheme to extend the benefits of altruistic donation, by creating the potential for a single donation to benefit more than one recipient [by starting a chain].

"We recognise the importance of considering all possible options that extend the benefits of transplantation for patients, and once we've established the principles of altruistic donor chains we can consider different approaches and we will look to international expertise and experience as a benchmark for future developments."

Cite this as: *BMJ* 2012;344:e1304

SEE PICTURE OF THE WEEK

Regulation of UK medical devices is criticised by manufacturers and by doctors who implant them

Geoff Watts LONDON

Medical device regulations were criticised last week by manufacturers who make devices and doctors who use them.

At a recent press briefing, manufacturers said the regulations were unnecessarily cumbersome, while doctors criticised them for being inadequate and subject to conflicts of interest.

At the briefing organised by the independently funded Science Media Centre, Stephen O'Connor, who works for a medical equipment manufacturer, pointed out that it can take 18 months to get approval for a study. Clinical trials must be agreed by national and local ethics committees, NHS research and development departments, an NHS medical devices committee, and the Medicines and Healthcare Products Regulatory Agency.

The agency then delegates the decision to a so called "notified body."

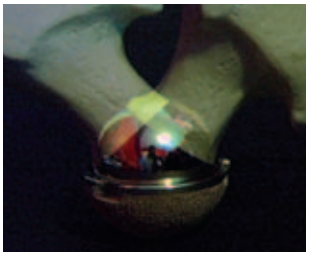
"All these people are reviewing the same thing in different ways," said Dr O'Connor.

Peter Wilmshurst, a consultant cardiologist with Shrewsbury and Telford Health Authority, is concerned about licensing standards. "I don't understand why, when I implant devices in people's hearts," he said, "the standard for licensing is lower than for drugs." There are more than 70 notified bodies with, he claimed, differences in standards and in rigour. "There are suggestions that companies will shop around for the notified body that will give them the easiest ride."

On conflicts of interest he said, "You get clinicians doing trials on devices that they've invented. They may even own shares in the company." Also, doctors' poor record on reporting adverse events is exacerbated in the case of devices. "If you've put the device in and you report a problem someone may well say that you're the problem. You put it in badly."

Defending himself and his organisation, the chief executive of the Medicines and Healthcare Products Regulatory Agency, Kent Woods, said he welcomed any public debate that might help people to understand how regulation works.

With 2-3 million people in the UK having some form of implantable device, Professor Woods views this branch of medicine as a success story. The task of regulating devices is quite different from that of regulating drugs, he insisted. Devices are subject to many minor improvements. You can't do a randomised trial on each one. "The system has to rest on post-marketing vigilance as well as pre-market assessment."



More than 70 notified bodies assess implantable devices

Cite this as: *BMJ* 2012;344:e1202

NHS picks up the bill for caring for private patients fitted with PIP implants

ROB PINNEY/DEMOTIX/PA

Women protest against the government's decision to allow PIP implants to be used in the UK

Ingrid Torjesen LONDON

Almost 3000 women who had breast augmentation surgery done privately with implants made by the discredited French manufacturer Poly Implant Prosthèse (PIP) have been seen by the NHS, more than a third have been investigated, and a small group of women have already had the implants removed, figures from the Department of Health for England show.

The British Association of Aesthetic Plastic Surgeons estimates that the NHS has already spent hundreds of thousands of pounds seeing and treating private patients who had come forward, who represent only a small proportion of the number of women who have received these implants privately. The association has accused private clinics of failing in their "moral obligation" and "ethical duty" to treat patients.

The health department figures show that 2860 women who had their implant surgery done privately have been referred to NHS specialists by their GPs. More than 1100 of these women have undergone scans, 67 women have decided to have their PIP implants removed, and 12 of these procedures have been carried out so far.

But these figures could escalate substantially because only 522 of these 2860 women have completed the process: the remainder are still being investigated or deciding what course of action they want to take. Many more of the 40 000 UK women who had PIP implants fitted privately could also come forward.

The health minister Anne Milton said women choosing not to have their implants removed seems to show that they were being reassured from speaking to an expert or having a scan.

Cite this as: *BMJ* 2012;344:e1259

IN BRIEF

Breastfeeding rate climbs in England while smoking in pregnancy falls: The proportion of new mothers initiating breast feeding in England was 74.1% in October to December 2011, up from 73.7% in the same period in 2010, Department of Health figures show. Women breast feeding at 6-8 weeks rose from 45.7% to 47%. In the last three months of 2011 the percentage of mothers smoking at delivery was 13.4%, slightly lower than the 13.5% at the end of 2010.

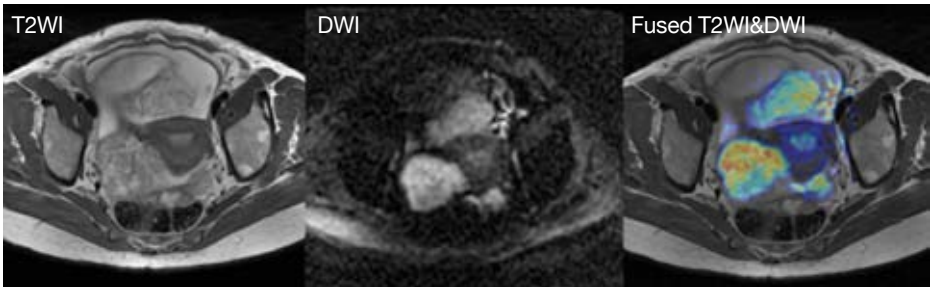
Call for more BRCA1 testing in breast cancer: Women under 50 with triple negative breast cancer (which does not express oestrogen receptor, progesterone receptor, or HER2) should be offered testing for faults in the BRCA1 gene, says a report published in the *British Journal of Cancer* (doi:10.1038/bjc.2012.31). NICE recommends testing if the likelihood of detecting a mutation is greater than 20%. The researchers estimate that more than one in three women with triple negative breast cancer caused by BRCA1 mutations would not have been tested under current criteria.

Measles outbreak is declared on Merseyside: A measles outbreak has been declared on Merseyside after six people required hospital treatment. The Health Protection Agency said that there had been 13 confirmed and 16 suspected cases of measles in the first six weeks of 2012. This compares with one confirmed case in the same period in 2011.

Australian government is urged to create a food ministry: Public health experts have called on the Australian government to create a Ministry of Food to ensure a "whole of government" approach to food policy that deals with health, equity, and environmental concerns. The Public Health Association of Australia (www.phaa.net.au) says that the minister for food should sit in cabinet.

Authors of papers on asbestos declare conflicts of interest: The journal *Inhalation Toxicology* has issued a correction notice covering four articles on asbestos. The notice is written by a coauthor of all four papers who is also an employee of Georgia-Pacific, an industrial giant that sold asbestos and is still embroiled in litigation over health effects. The notice states that two other authors are expert witnesses for the company and that the research was commissioned by Georgia-Pacific for use in court.

Cite this as: *BMJ* 2012;344:e1208



RADIOLOGY

The images demonstrate the increased sensitivity of diffusion weighted MRI for detecting the effects of treatment on ovarian tumours. From left, they are: the traditional T2 weighted image, the corresponding diffusion weighted image (DWI), and then a fusion of the two images

Water molecule movement may be key to monitoring ovarian cancer treatment

Susan Mayor LONDON

Magnetic resonance imaging (MRI) that measures the movement of water molecules in tumours may be the best way to monitor the response to treatment of women with advanced ovarian cancer, shows a study that compares different types of imaging in this group of patients.

The study compared three different MRI techniques and found that diffusion weighted MRI was the most effective for detecting the effects of treatment on primary ovarian tumours and on tumours that had metastasised to surrounding tissues (*Radiology* doi:10.1148/radiol.11110175).

Computed tomography has traditionally been used to assess whether patients with ovarian cancer should continue with chemotherapy after their first round of treatment. But this type of scanning measures changes only in the size of tumours, not in their structure.

Serum CA-125, a cell surface protein that is increased in ovarian cancer, is also used as a biomarker of overall response to treatment, but it integrates responses from responding and non-responding tumours.

Researchers from Addenbrooke's Hospital, Cambridge, compared three types of imaging in assessing the primary ovarian mass and tumours at two distant sites in 21 women with advanced ovarian cancer being treated with platinum based chemotherapy: diffusion weighted MRI (which measures the movement of water molecules in tissues), dynamic contrast material enhanced MRI (which uses a contrast agent to make tissues easier to see), and hydrogen-1 MR spectroscopy.

Results showed that diffusion weighted MRI was the most effective imaging technique. Evis Sala, lecturer in radiology at the University of Cambridge and the study's lead author, said, "Diffusion weighted MRI . . . [makes] it easier to determine which patients are benefiting most from the treatment."

Cite this as: *BMJ* 2012;344:e1229

Bird flu research is likely to be published within a year

Robin McKie VANCOUVER

Controversial research into the H5N1 bird flu virus is likely to be published in full within a year. The editors of *Science* and *Nature* announced on Friday 17 February that they both expected that the work would appear in their journals once a safety review of the flu research laboratories that are likely to use the data contained in the papers had been conducted.

Earlier that day the World Health Organization in Geneva had recommended that there be a delay in publishing while it held more discussions on finding ways to ensure safe publication. It also proposed that a safety review of laboratories carrying out flu research be implemented as a priority.

"We are going to delay publication until that review is carried out," said Bruce Alberts, editor of *Science*, at a press conference at a meeting of the American Association for the Advancement of Science in Vancouver. "The aim, after that, would be to publish the full version of the research, most likely within the year."

BNL

Bruce Alberts (left), editor of *Science*, and Philip Campbell, editor of *Nature*, hope to publish the research in full

The H5N1 research that *Nature* and *Science* wish to publish is controversial because it shows that the virus could mutate, fairly easily, into a form that could spread rapidly among the human population. Scientists want to

Israel bans graduates of Al Quds University from taking exam to enable them to work in Israel

Sophie Arie LONDON

The Israeli Medical Association has called on Israel's health ministry to allow Palestinian doctors who graduate from Al Quds University to practise in East Jerusalem, the disputed territory at the heart of the Israeli-Palestinian conflict.

Since the first batch of medical students graduated from Al Quds in 2002 they have not been allowed to take the licensing exam that foreigners take to be able to practise in the Israeli health system. Israel says that because the university has facilities in East Jerusalem, which is under Israeli control, and in the West Bank, which is Palestinian territory, it is not technically a foreign university so its graduates cannot sit this exam. However, if they have not passed the exam they cannot work in Israel or Israeli controlled areas such as East Jerusalem. They are entitled to work in Palestinian areas not under Israeli control, such as the West Bank and Gaza.

Last June, 35 graduates who are all residents of East Jerusalem and wish to work there appealed through the Israeli courts for the health ministry to allow them to take the exam. In 2005 a similar group of graduates won the right to sit the exam after a court case, but the ruling did not lead to a blanket change of policy. So far the 35 graduates are still awaiting a court hearing.

Both Arabs and Jews claim East Jerusalem as theirs; and although Israel has controlled the territory since 1967, Palestinians still see it as the capital of Palestine. It has a large Palestinian population and, the Israeli Medical Association has reported, an acute shortage of doctors.

"The best medical treatment can be offered only by a local resident who is deeply familiar with the local culture and inhabitants," wrote the chairman of the association, Leonid Eidelman, in a letter to the director of the health ministry.

"I beseech you to use all your powers and recognise the university graduates as eligible to attend the Israeli certification exams," Dr Eidelman wrote in the letter dated 30 January.

Haaretz newspaper reports that East Jerusalem has a shortage of doctors because it is not a desirable place for Israeli medical professionals to work. Many Palestinians believe that Israel is deliberately blocking Al Quds medical graduates from obtaining a licence to practise in East Jerusalem as part of its attempt to discourage Palestinians from living and working there.

The health ministry says that the problem is a bureaucratic one, related to the cross border nature of Al Quds University. The university has been advised to become two entities.

"We cannot recognise the graduates until the university has completed the procedure of separating its entities," said Amir Ofek, press attaché at Israel's embassy in the UK. The procedure normally takes about three years to complete.

Cite this as: *BMJ* 2012;344:e1265

RINA CASTELNUOVO/THE NEW YORK TIMES/EYEVINE

Medical students from Al Quds University cannot take the qualifying exam for overseas students because it has a site in East Jerusalem, but without the exam the medical graduates cannot work in the city

use these data to prepare vaccines in the event of such mutations occurring.

At present the H5N1 virus is not easily transmitted between humans, so it has had a limited impact so far. However, research by Dutch and US scientists last year found that this low transmission rate could change fairly easily as a result of mutations of the virus, and *Nature* and *Science* announced that they were preparing to publish papers on this research.

However, this move was blocked by the US National Science Advisory Board for Biosecurity (*BMJ* 2012;344:e840, 2 Feb). It asked the journals to redact sensitive parts of the research. The request caused an outcry among scientists who believed the move to be an infringement of academic liberty. Others warned that redaction would hamper the work of researchers seeking to prepare vaccines against mutated viruses.

Cite this as: *BMJ* 2012;344:e1268

BMA and ambulance service call for delays to NHS 111

Ingrid Torjesen LONDON

The BMA and the Ambulance Service Network have asked the government to put back the April 2013 deadline for the universal roll out of the non-emergency telephone number NHS 111 across England.

NHS 111 is intended to be a 24 hour helpline for urgent but not life threatening health problems and is being piloted in three areas: County Durham and Darlington; Luton; and the East Midlands (Nottingham and Lincolnshire). The telephone number is due to be rolled out nationally by April 2013, when it will replace NHS Direct.

In a letter to the health secretary for England, Andrew Lansley, the BMA makes it clear that it supports the principle behind NHS 111—that patients should have an easily accessible telephone number for urgent health problems—but points out that it has misgivings about the speed of roll out and that GPs have raised a number of serious concerns about the use of the number.

The BMA says that adequate time is needed to evaluate the pilots and resolve GPs' concerns, that the procurement of providers to run NHS 111 in non-pilot areas is being rushed through without careful reference to the pilot schemes, and that decisions on NHS 111 and its procurement are not being driven by clinical commissioners, who will ultimately be responsible for NHS 111 in their areas.

Ambulance services have backed the BMA's call for a delay in roll out until the pilots have been properly evaluated. Jo Webber, director of the Ambulance Service Network, said the current timeframes are just too tight.

Cite this as: *BMJ* 2012;344:e1204

Obama's plan to include contraception in healthcare provision provokes opposition from Catholics

Bob Roehr WASHINGTON, DC

A religious war of words over contraception has broken out in the United States. The flashpoint has been the Obama administration's decision to include contraception as an essential component of preventive health services for women that must be included in every health insurance plan.

The US Conference of Catholic Bishops has led the charge in calling this an attack on religion, saying that life begins at the moment of conception. They want a "conscience provision" that provides an exemption.

One key goal of health reform legislation passed by Congress in 2010 was to strengthen prevention, both as its own good and with the hope of reining in the long term costs of healthcare. It wrote into the law a provision that all health insurance must offer a basic package of prevention services at no additional costs or copayments to beneficiaries.

However, Congress left it to the Department of Health and Human Services to determine exactly what was to be included in that basic package. The department in turn commissioned a report by the Institute of Medicine on what to include.

The institute recommended eight interventions in its report last July, including contraception and family planning services, and the department adopted them on 20 January as regulations that will take effect next year (*BMJ* 2011;343:d4668).

That was when the bishops stepped in, with a massive campaign on the internet and in newspaper advertising (http://usccb.org/issues-and-action/religious-liberty/conscience-protection/index.cfm).

The scope of exemption that they seek is considerable. They argue that the exemption should apply not only to churches themselves (which will continue to be exempt under the regulation) but also to separately incorporated religious affiliated groups such as schools and hospitals and to all their employees. A spokesman for the bishops went so far as to say that, as a matter of conscience and religious principles, the owner of a fast food outlet, for example, should be excluded from having to provide contraception services as part of health insurance.

ANDREW MEDICHINI/AP/PA

Timothy Dolan, president of the bishops' conference, led opposition to Obama's policy

"This type of rhetoric is not about protecting religious freedom. It is about imposing a particular religious doctrine on those who don't share it," wrote the commentator Andrew Sullivan in the magazine *Newsweek*.

Citing studies showing that 98% of Catholic women of childbearing years have used some form of contraception at some point in their lives, he said that the bishops were trying to enlist the government to impose practices that they could not convince their own adherents to follow.

President Obama announced a change in policy on 10 February whereby insurance companies would pay for contraception coverage from the savings generated by such coverage.

"We didn't see much sign of any compromise on what was issued," said Timothy Dolan, the Archbishop of New York and president of the bishops' conference, who was recently elevated to cardinal.

But it was a compromise that affiliated groups such as Catholic Charities and the Catholic Health Association chose to accept. Stephen Schneck, director of the Catholic University of America's Institute for Policy Research and Catholic Studies, told the *Washington Times* that Catholics have been paying for these types of services for decades through their taxes and other health plans.

"We have been told by our bishops that because of the very remoteness of our participation in those contraception offerings, we were not in any way morally compromised," he said. He saw President Obama's compromise in a similar light, but the bishops continue to call it "unacceptable."

Evangelical Christians and social conservatives have joined in the campaign as part of their broader attack on the health reforms that they have labelled "Obamacare."

Cite this as: *BMJ* 2012;344:e1267

Congressmen demand faster publication of trial data after *BMJ* campaign

Bob Roehr WASHINGTON, DC

Three members of the US House of Representatives have written to the National Institutes of Health and the Food and Drug Administration expressing concern that the results of clinical studies are not being published in a timely manner, as prescribed by law, after widespread delays to publication were highlighted in the *BMJ*.

"Researchers and pharmaceutical companies routinely fail to publish data from clinical drug trials in a timely fashion," they wrote, citing a *BMJ* research paper that appeared earlier this year (*BMJ* 2012;344:d7373). "This study raises concerns about whether the FDA is adequately enforcing the law requiring such reporting.

"We are also concerned that these publication delays may allow ineffective or dangerous drugs to remain on the market, resulting in significant harm to patients and waste to the healthcare system."

The Congressmen were led by the Democrat Henry Waxman from Los Angeles, the senior Democrat on the House Committee on Energy and Commerce, which has jurisdiction over the two agencies. The other two Congressmen were fellow Democrats Edward Markey of Massachusetts and Diana DeGette of Colorado.

The *BMJ* study showed that only a fifth (22%) of all registered trials reported their results within one year of completion, as the law requires. A paper that looked only at studies funded by the National Institutes of Health found that results of nearly half (46%) were published within 30 months and two thirds (68%) within 51 months (*BMJ* 2012;344:d7292).

Although fines of up to $10 000 (£6300; €7500) a day can be levied for failure to publish data promptly, Mr Waxman and his colleagues said, "We are unaware of any enforcement action related to these apparent violations."

Cite this as: *BMJ* 2012;344:e1217