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NEWS

Queen's speech presages independent board for the NHS

Adrian O'Dowd LONDON

Increased power for health professionals and patients in the running of the NHS is to be introduced under the new government's legislative plans for the next 18 months.

In the Queen's speech delivered this week, Prime Minister David Cameron set out his plans contained in 22 bills and one draft bill.

Under the Health Bill, the government aims to give health professionals and patients more say over decision making in the NHS. This bill will also create an independent NHS board to allocate resources and provide guidance to allow GPs to commission services; strengthen the role of regulator the Care Quality Commission; axe some health quangos; cut some centrally set targets; and focus more on the problem of health inequalities.

Sales of alcohol below the actual cost to retailers will be banned under a Police Reform and Social Responsibility Bill, which does not go as far as the call for a minimum pricing on units of alcohol from the BMA, Royal College of Physicians and outgoing chief medical officer Liam Donaldson.

The day before the Queen's speech, it became clear that the NHS had survived the worst of public spending cuts announced this week by Chancellor George Osborne and chief secretary to the treasury David Laws.

The government gave details of how it planned to make £6.2bn (€7.3bn; $9bn) of savings in the current financial year to start tackling the UK's £156bn deficit.

Although frontline NHS services will not be affected directly by the cuts, reductions in spending on consultancy fees and information technology as well as a freeze on civil service recruitment will affect the health service.

Mr Osborne said the Department of Health's overall spending would not be reduced in the current financial year so that frontline services in health were protected and any efficiency savings would be recycled. Speaking at a treasury press conference this week, he said all government departments would have to experience cuts apart from health, defence, and international development.

Cite this as: *BMJ* 2010;340:c2822

TIM IRELAND/PA

Andrew Wakefield continues to attract support despite the GMC's verdict

Wakefield is struck off for the "serious findings against him"

Zosia Kmietowicz LONDON

Andrew Wakefield, the British gastroenterologist who sparked a worldwide scare over the measles, mumps, and rubella (MMR) vaccine, has been found guilty of serious professional misconduct and struck off the medical register by the General Medical Council.

In its summation of the case against Dr Wakefield the GMC fitness to practise panel concluded that erasing Dr Wakefield's name from the medical register was "the only sanction that is appropriate to protect patients and is in the wider public interest, including the maintenance of public trust and confidence in the profession and is proportionate to the serious and wide-ranging findings made against him."

Dr Wakefield now has 28 days to appeal against the judgment before he is officially struck off.

In January Dr Wakefield was found guilty of dishonesty and irresponsibility by the GMC, the UK's regulatory body. The fitness to practise panel held that Dr Wakefield abused his position, subjected children to intrusive procedures such as lumbar puncture and colonoscopy that were not clinically indicated, carried out research that flouted the conditions of ethics committee approval, and brought the medical profession into disrepute (*BMJ* 29 January 2010;340:c593).

After the GMC's verdict the *Lancet* retracted the 12 year old paper (*BMJ* 2 February 2010;340:c696).

During the two and half year case, the longest in GMC history, Dr Wakefield was found to have failed to show that he had received funding from the legal aid board through a solicitor who hoped to mount a legal action against the vaccine manufacturer and that he had filed a patent for a new vaccine when he submitted the paper to the *Lancet*.

The panel also ruled on two of Dr Wakefield's former colleagues—retired professor of paediatric gastroenterology John Walker-Smith and Simon Murch, now professor of paediatrics and child health at Warwick Medical School—who were coauthors of the *Lancet* paper, and who had carried out investigations that were not in the interests of children, without proper ethics approval. It determined that Professor Walker-Smith was guilty of professional misconduct and that "with regret" being struck off was the only appropriate sanction.

No sanctions were imposed on Professor Murch's practice.

See OBSERVATIONS, p 1169

Cite this as: *BMJ* 2010;340:c2803

New study to use "disease in a dish" to discover roots of MND

Zosia Kmietowicz LONDON

Scientists are to use stem cells created from people with an inherited form of motor neurone disease to try to understand the biochemical processes that destroy nerve cells in what one leading clinician has described as "a shocker of a disease."

Siddharthan Chandran, director of the Euan MacDonald Centre for Motor Neurone Disease Research at the University of Edinburgh and one of the project's lead investigators, said that recent advances in genetics and stem cell research have allowed scientists to "model human disease in a culture dish."

He said he hoped the work would ultimately lead to the discovery of drugs that would delay the progression of the disease, for which there is currently no treatment.

Professor Chandran was speaking at the launch of the three year, £800 000 international research programme, which is being funded by the Motor Neurone Disease Association.

For the research, scientists will grow stem cells from skin cells of a patient whose motor neurone disease is caused by a mutation on the TDP-43 gene. Although only about 1% of people with motor neurone disease have this mutation, the protein that the gene produces is present in 90% of cases and appears in clumps inside dying motor neurones.

During the next stage of the research the stem cells will be induced to turn into two cells involved in the disease—the motor neurones which are destroyed, and other "support cells" called astrocytes. These astrocytes are the "wind that fans the death of the neurones in the disease," and understanding how these two cell types interact may hold the key to developing treatments, said Professor Chandran.

Once the cells have been generated, researchers will "mix and match" them with cells from healthy controls to discover how healthy neurones and diseased support cells affect one another and how diseased neurones and healthy support cells interplay.

Samples from the experiments will be sent to Tom Maniatis at Columbia University in New York, who will examine which genes are being switched on and off as the disease evolves.

The materials generated as part of the project will be made available to other researchers through the UK Stem Cell bank, said Professor Chandran. "To conquer what is such a tough disease requires collaboration," he said.

Cite this as: *BMJ* 2010;340:c2761

Scientists report first self replicating bacteria with synthetic genome

Susan Mayor LONDON

A US research team has reported successfully constructing the first self replicating bacteria cells controlled entirely by DNA that had been chemically synthesised in the laboratory.

The research group first manufactured a modified genome for *Mycoplasma mycoides*, a single celled parasite bacterium that lacks a cell wall. They pieced together more than 1000 cassettes, or sequences of DNA, each 1080 base pairs long, to make the entire 1.08 million base pair chromosome—the largest synthetic molecule of a defined structure to be constructed.

The entirely synthetic genome was then transplanted into *Mycoplasma capricolum* recipient cells. After two days, viable cells containing only synthetic DNA were clearly visible, the research group reported online in the journal *Science* last week (doi:10.1126/science.1190719).

"For nearly 15 years, our team has been working towards this publication—the successful completion of our work to construct a bacterial cell that is fully controlled by a synthetic genome," said J Craig Venter, senior author and founder of the institute (named after him) where the work was conducted. He heads the not for profit genomic research organisation, which has centres in Rockville and La Jolla, California, dedicated to advancing the science of genomics.

Commenting on the potential applications of the new

H1N1 review panel seeks access to confidential letters

John Zarocostas GENEVA

The chairman of the external expert review committee examining the World Health Organization's management of the H1N1 pandemic said the panel wants access to confidential documents between the agency and drug companies.

Harvey Fineberg, the head of the 29 member review committee, said, "We are aware we will want to have access to certain confidential documents that may be in place here at WHO, or elsewhere."

These documents include "contractual or letters of understanding with (the pharmaceutical) industry that have been considered private communications," he said.

MARTIAL TREZZINI/AP/PA

Harvey Fineberg is asking for "letters of understanding"

Dr Fineberg's remarks about more detailed probing came as ministers from around the world praised Margaret Chan, head of the WHO, for the agency's handling of the pandemic.

Dr Fineberg stressed that the review panel is well aware that concern has been expressed "about the potential influence of industry on decision making at the various advisory committees and in the WHO generally."

He said "We are very attentive to trying to understand and to identify the nature of any relations and the degree of influence that may have existed."

The panel has begun to explore this issue, he said, and will continue its investigation, "including discussions with representatives from the industry side."

Critics have suggested that WHO and expert advisory committees may have been unduly influenced by the drug industry, especially in upgrading the H1N1 outbreak from phase five to phase six, leading to the declaration of the pandemic on 11 June last year.

The declaration triggered advance purchase of the pandemic vaccine in procurement contracts concluded by some governments and vaccine manufacturers.

Dr Chan has dismissed the allegations as groundless. The chairmen of the key WHO advisory committees on the H1N1 pandemic have also been adamant that industry did not influence their actions.

Chen Zhu, China's minister of health, thanked the WHO chief for her "strong leadership," and for leading the secretariat over the past year in assisting countries in the fight against the H1N1 pandemic.

Similarly, Kathleen Sebelius, US secretary for health and human services, said "while some have questioned some of the actions taken by the international community, the outcomes speak for themselves. I believe we made the right decisions at the right times."

Dr Fineberg pointed out the WHO secretariat is being "extremely forthcoming" in making available all the documents requested.

Cite this as: *BMJ* 2010;340:c2792


JCVI

development, Hamilton Smith, also from the J Craig Venter Institute, said, "With this first synthetic bacterial cell and the new tools and technologies we developed to successfully complete this project, we now have the means to dissect the genetic instruction set of a bacterial cell to understand how it really works."

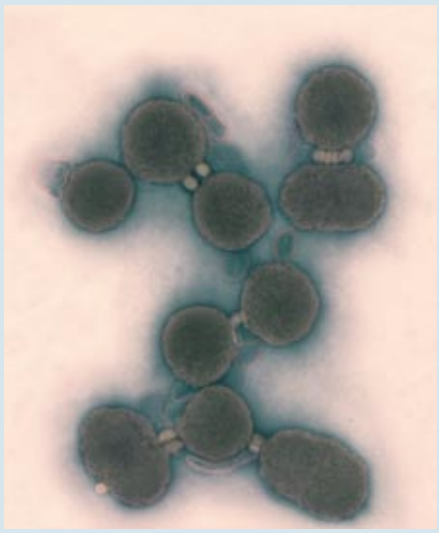
Accurate sequencing of genomes is not new, but one of the group's major achievements has been to create an error free genome that can then control cell replication. An error in just one base can create a completely inactive gene, which in turn can prevent growth, and the researchers said they struggled for many weeks with a deletion in a single base pair in one essential gene.

Dr Smith said that the group's next step would be to synthesise a cell containing only the genes necessary to sustain life in its simplest form—the minimal genome. "This will help us better understand how cells work," he explained.

The technical achievement has been widely applauded by the scientific community, but John Sulston, chair of the Institute for Science, Ethics and Innovation at the University of Manchester, and a member of the group that sequenced the human genome, warned that if Synthetic Genomics Inc, the company owned by Drs Venter and Smith that funded the new research, was granted patents on the synthetic cell, the company would have a monopoly on this type of genetic engineering.

Professor Sulston told the BBC, "I've read through some of these patents and the claims are very broad indeed. I hope very much these patents won't be accepted because they would bring genetic engineering under the control of the J Craig Venter Institute. They would have a monopoly on a whole range of techniques."

Cite this as: *BMJ* 2010;340:c2796


DEERINCK & ELLISMAN/NCMIR/UC, SAN DIEGO

An electron micrograph of aggregated *M mycoides* JCVI-syn1.0 developed by a team led by J Craig Venter (above left)

Former Roche employee questions marketing of oseltamivir to business continuity managers

Andrew Jack FINANCIAL TIMES

A former employee of Roche has questioned the drug company's sales practices for the antiviral drug oseltamivir (Tamiflu), as well as its efforts to maintain market share and tender for distributors for a broad range of products.

At Watford's employment tribunal, John Miller claimed the UK subsidiary of the Swiss group had put pressure on sales staff to promote the medicine osteltamivir to business continuity managers in companies keen to secure supplies of the scarce drug for private stockpiles, at a time of rising concerns about a flu pandemic.

His allegations came during his case to seek compensation for unfair dismissal, saying he was shifted internally and ultimately pushed out of the company because of his concerns over a series of regulatory and ethical breaches.

Roche denies the charges, arguing that it respected the law but that Mr Miller underperformed in his different jobs and was made redundant last year.

Mr Miller claimed that when he was asked to create a special business unit to sell oseltamivir to companies in 2006, he was given unrealistically high commercial targets to generate £15m-£20m (€17.6m-€23m; $21.8m-$29m) in the nine months until the end of that year, given the tight legal controls on the marketing of prescription drugs.

He also alleged that he discovered that there had been no effort to ensure sales staff only spoke to healthcare professionals, as the law requires for prescription medicines, and that the company also sold the drug to intermediary organisations employing medical staff, which in turn would sell the drug to clients.

He stated he was also concerned that discussions held with companies over the volumes of oseltamivir stock would breach competition rules designed to ensure fair allocation of the scarce drug. An additional concern, Mr Miller alleged, was whether non-medical customers had facilities to safely store and track the drug.

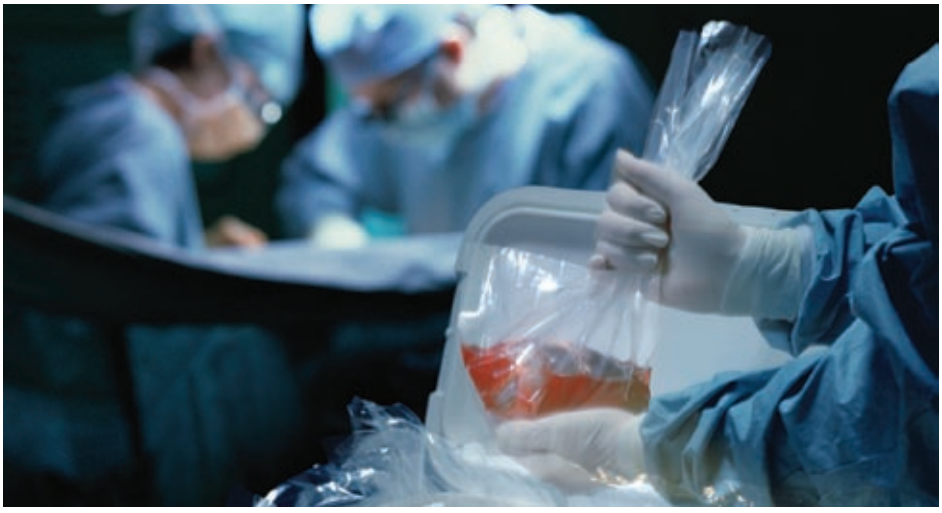
Martin Weatherhead, Mr Miller's manager, rejected his claims, telling the tribunal that Roche respected the law and had decided that it could "speak about business continuity" to non-medical customers, provided it did not mention the efficacy, dose or even the name of the drug itself.

Roche said, "All of Mr Miller's claims are denied by the company and have been from the first time they were raised, over a year ago. Roche Products Limited has at all times acted with propriety, both in relation to Mr Miller and, more generally, in relation to its trading practices."

Cite this as: *BMJ* 2010;340:c2805


F. HOFFMANN-LA ROCHE LTD

Roche said it was allowed to speak to non-medical customers about business continuity during a pandemic, provided it did not mention the efficacy, dose, or name of its drug



BEN EDWARDS/STONE/GETTY IMAGES

More than 9000 people are waiting for a transplant in Europe but only 3000 are done each year

Pan-European organ transplant scheme promises to cut waiting times

Rory Watson BRUSSELS

The European Parliament overwhelmingly approved draft legislation on 19 May setting uniform quality and safety standards across the European Union that promises to reduce waiting times for organ transplants.

The measures, which cover all stages of the chain from donation to the transplantation, must now be approved by EU governments. Given that these have broad cross party support—over 640 MEPs approved them and just 16 voted against—this is now expected to be a formality.

John Dalli, the European health commissioner, described the parliamentary vote as a concrete example of how European legislation could help save lives.

"Common standards across Europe will ensure the highest level of quality and safety of organs while ensuring that all donations must be voluntary and unpaid. This is key to ensuring that European citizens that need an organ transplant can benefit from the best possible quality and safety conditions," he said.

While organ transplants are an established medical practice, queues are long and donation rates vary considerably across Europe. Some 60 000 people are on waiting lists and a dozen die every day before they can be operated on. Over 9000 people are waiting for a transplant in the UK, but only 3000 operations are carried out each year.

International cooperation already exists for the transfer of organs between countries.

The most extensive is Eurotransplant, which includes Austria, Belgium, Croatia, Germany, Luxembourg, the Netherlands, and Slovenia. Another, Scandiatransplant, covers the Nordic countries.

The new pan European system, which should be in place by mid 2012, will extend these exchanges. Each of the 27 member states will have one authority in charge of enforcing the quality and safety standards. They will be responsible for establishing procurement organisations and transplant centres, and putting in place traceability and management systems to monitor any adverse reactions.

The package will not affect existing rules in the UK, ensuring organs donated within the NHS will initially be earmarked for NHS patients.

Governments must ensure "the highest possible protection of living donors" and organ donations must be "voluntary and unpaid," although donors may receive compensation provided it is "strictly limited to making good the expense and loss of income related to the donation."

At the same time, MEPs adopted an action plan for organ donation and transplants, which is based largely on the system operating in Spain, where the donor rate of 34 per million citizens is almost double the EU average rate of 18 per million citizens.

The plan recommends appointing donor coordinators in every hospital and exchanging information and best practice to help countries with low organ availability improve donation rates. It also suggests countries should consider enabling citizens to join a donor register when applying for a passport or driving licence and to record this decision on official documents, such as identity cards.

Cite this as: *BMJ* 2010;340:c2785

Regulations on medical research need to be reinterpreted

Michael Rawlings said bureaucracy at trust level and excessive monitoring of trials and reporting of adverse drug reactions is stifling research

Zosia Kmietowicz LONDON

Removing the barriers that are currently "stifling" medical research in the United Kingdom will not require new rules on clinical trials to be written but for existing ones to be reinterpreted, the body charged with reviewing the regulation and governance of medical research has said.

The European Clinical Trial Directive, implemented in 2004, was intended to harmonise research across the continent and improve competitiveness in Europe. But it has been interpreted differently in different countries and in the UK has become "unbelievably complicated and burdensome, and, in many cases, it is not appropriate," said Michael Rawlins, chair of the working party of the Academy of Medical Sciences, which is conducting the review. He was speaking at a press briefing on 20 May, two days after the first meeting of the working party.

The review was commissioned in March by the then secretary of state for health Andy Burnham, who said that red tape was affecting the UK's ability to attract industry funded research to the detriment to patients, academic science, and the economy (*BMJ* 2010;340:c1170, 17 May).

Professor Rawlins pointed out that in Belgium the authorities said that no changes were needed to regulations governing research studies after publication of the directive. But in the UK, lawyers interpreted the guidance

Medicalisation costs $77 billion a year in US, new study says

Bob Roehr WASHINGTON DC

The direct cost of medicalisation—the categorising of events or behaviours as requiring medical treatment—was $77.1bn (£53.6bn, €62.3bn) in the United States in 2005, or 3.9% of total domestic healthcare expenditure, according to what is believed to be the first ever study quantifying those costs (*Soc Sci Med* 2010;70:1943-7).

Investigators tried to be rigorous in what to include under medicalisation in the analysis, lead author Peter Conrad, a researcher at Brandeis University, near Boston, told the *BMJ*. They chose conditions for which there was broad agreement and where data were available.

They ended up with a dozen: anxiety disorders, behavioural disorders, body image, erectile dysfunction, infertility, male pattern baldness, menopause, normal pregnancy and delivery, normal sadness, obesity, sleep disorders, and substance related disorders.

Only direct medical costs were measured, not indirect costs such as transportation, lost productivity, or time off work.

"You could say, that's not very much because it is under 4%," said Dr Conrad. "On the other hand, it is more than we spend on public health or cancer. It is a substantial number but not one of the major drivers in health costs."

Almost half the costs were attributed to two conditions, uncomplicated pregnancy and body image services.

CHRISTOPHER BISSELL/STONE/GETTY IMAGES

Sleep disorders was one of twelve conditions covered by the study

He said it was possible to make international comparisons with some specific conditions. In the US, about 7% of all school age children are on medications for attention deficit hyperactivity disorder; "in England it is just over 1% and in France just under 1%. One can ask if we are over-treating or are they under-treating."

Dr Conrad views medicalisation as "a mixed bag. There are lots of things not in the medical realm that make people suffer"—such as poverty, which can cause stress and suffering—"but I'm not sure that the answer would be to medicalise those problems. On the other hand, we have medicalised a lot of emotional issues that make life more difficult."

One risk of medicalisation is that it tends to focus on the individual and ignores structural and societal aspects of the problem.

Cite this as: *BMJ* 2010;340:c2779

literally. For example, guidance that site monitoring "should" take place before, during, and after a study has been interpreted as "must" in the UK, which means numerous visits during the course of a trial.

Auditors charge around £20 000 each time they visit a trial site. These visits now make up a third of the cost of a typical study, or $150m (£105m; €122m) for a study that involves 20 000 patients.

"But there is no evidence that what they do is effective," said Professor Rawlins. The same degree of monitoring could be done by looking at study data off-site and would not incur the carbon footprint that visits do.

"A new interpretation could allow the same directive to be used," said Rory Collins, professor of medicine and epidemiology at the University of Oxford and a member of the working party. Similarly, "Clarification could quite quickly reduce costs," said Professor Rawlins.

The combined regulatory requirements of the directive and of other authorities—such as the European Medicines Agency, the UK Medicine and Healthcare products Regulatory Agency, NHS ethics committees, and individual trusts—have seen the proportion of the world's clinical trials conducted in the UK fall by two thirds, from 6% in 2000 to 2% in 2006. The number of patients involved in commercial trials in the UK between 2000 and 2006 fell from nearly 38 000 to almost 14 000.

The working party is collecting evidence on the regulation of medical research. Send by 1 June to regulatory@acmedsci.ac.uk.

bmj.com Editorial: Falling research in the NHS (*BMJ* 2010;340:c2375)

Cite this as: *BMJ* 2010;340:c2732

FDA panel to assess drug for low sexual desire in women

Ray Moynihan BYRON BAY, AUSTRALIA

Advisers to the US Food and Drug Administration will meet on 18 June to assess the drug flibanserin as a potential treatment for women said to have low sexual desire, or "hypoactive sexual desire disorder."

Flibanserin was originally developed as an anti-depressant, but was not found to be effective and was never approved as one. Its German manufacturer Boehringer Ingelheim has recently released abstracts of unpublished randomised trials testing the drug's potential sexual benefits in women.

According to the abstracts, the company's trials of flibanserin in Europe failed to show any statistically significant benefit compared with placebo on the primary outcome measure: the number of "satisfying sexual events." A satisfying sexual event can be intercourse, oral sex, or masturbation, and does not necessarily have to involve an orgasm.

The company's North American trials, however, found the drug increased the number of satisfying sexual events for women by an extra 0.7 events per month compared with placebo, an increase deemed statistically significant.

Boehringer Ingelheim spokespersons told the *BMJ* that an extra 0.7 events per month was clinically meaningful. "That is not only our perspective but also reflects the patient perspective according to our data," they added. "The process for how these data were collected was agreed with the regulatory authorities."

In a recent press release, the company claimed that after six months of treatment "over 50% more women reported feeling 'very much improved,' 'much improved,' or 'minimally improved' with flibanserin compared with placebo." The total rates for these three categories combined were 48% for flibanserin and 30% for placebo.

When the category of women feeling "minimally improved" was removed from the calculations, the total proportion of women feeling "very much improved" and "much improved" fell to 21% for flibanserin and 10% for placebo, company spokespersons told the *BMJ*.

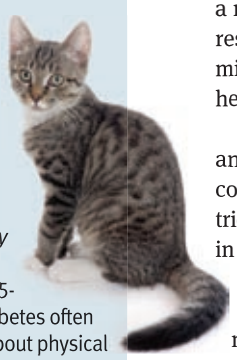
Common side effects included dizziness, nausea, fatigue, somnolence, and insomnia. Adverse events caused almost twice as many women on flibanserin as on placebo to discontinue treatment in the North American trials.

Ray Moynihan's book on female sexual dysfunction will be released in September 2010

Cite this as: *BMJ* 2010;340:c2786

IN BRIEF

Novartis fined for sex discrimination: A US federal court told Novartis to pay $3.36m (£2.33m, €2.70m) to 12 women sales representatives for discriminating against women in pay and promotions. It then fined the company $250m in punitive damages for discrimination from 2002 to 2007. About 5600 women employees can share in the larger award. They will also receive awards for lost pay. Novartis said it "strongly disputes the claims of past discrimination" and would appeal.



People with diabetes learn from treating their pets for the condition: People who treat their dog or cat for diabetes often use the knowledge they gain to improve their own health, suggests a Canadian study (*Anthozoos: A Multidisciplinary Journal of The Interactions of People and Animals* 2010;23:5-20). Similarly, people with diabetes often apply what they have learnt about physical activity, diet, and sugar levels when their dog or cat develops diabetes.

Haitian group wins 2010 Gates award: GHESKIO, a Haitian institution founded nearly three decades ago to fight a killer disease later identified as AIDS, has been awarded the 2010 Gates Award for Global Health for its years of clinical service, research, and training to treat effectively and prevent the spread of HIV/AIDS and related illnesses. The group also helped several thousand people made homeless by the earthquake on January 12 and opened a field hospital.

Record numbers of people are displaced by conflict: More people are currently displaced within their country by conflict and violence than at any point since the mid-1990s. In 2009, an "alarming" total of 27.1 million people were internally displaced, including a record 6.8 million newly recorded, according to *Internal Displacement: Global Overview of Trends and Developments* in 2009 (www.internal-displacement.org).

German doctors strike over pay: Some 15 000 doctors at 200 community hospitals in most German states went on strike on May 17, demanding a 5% wage increase and better compensation for all on call services. Talks on behalf of 55 000 doctors in more than 700 communities represented by the trade union Marburger Bund collapsed in April, when hospitals offered a 2.9% raise and bonuses only for night and standby duty.

Cite this as: *BMJ* 2010;340:c2745

WHO agrees new code to stop poaching of staff from poor countries

John Zarocostas GENEVA

The World Health Organization agreed on 21 May to a new voluntary global code of practice on the ethical recruitment of international health personnel, which discourages countries from actively recruiting from poor nations facing critical staff shortages.

Severe shortages in 57 poor nations pose a major threat to the performance of already resource strapped health systems and undermine the ability of these nations to achieve key health objectives, says the WHO.

The code, adopted by ministers during the annual World Health Assembly, also calls for countries that recruit staff from poorer countries to fund the training of health professionals in those countries.

It also recommends countries should "facilitate circular migration of health personnel [the freedom for medical personnel who have emigrated to go back and forth without restrictions]" so that skills and knowledge achieved can benefit both source and destination countries.

Richard Sezibera, Rwanda's minister of health, told the *BMJ*, "[The code is] a very good step in the right direction. It recognises the need for recipient countries, especially in the western world, to contribute to human resource development particularly in low income countries."

The new code, hammered out after intense negotiations on the sidelines of the assembly, included inputs from Norway, the UK, the European Union, Brazil, the Philippines, Zambia, Kenya, South Africa, and Botswana.

Margaret Chan, WHO director-general, lauded the outcome and told delegates, "You reached agreement on some important items that are a real gift to public health everywhere. Thanks to some all-night efforts, we now have a code of practice on the international recruitment of health personnel."

Earlier, Dr Chan had warned that the world faces a shortage of four million health personnel and she stressed that luring away health workers

Cancer drugs fund promised after NICE reject treatment

Zosia Kmietowicz LONDON

The new coalition government has reiterated its pre-election promise to give patients access to expensive treatments by emphasising the advisory nature of guidance from the National Institute for Health and Clinical Excellence (NICE) after the agency rejected a drug for the treatment of advanced liver cancer for use on the NHS because of its cost.

NICE guidance on sorafenib (Nexavar) for the treatment of advanced hepatocellular carcinoma says the drug should not be used in the NHS because its high cost cannot be justified by the small benefit it gives patients.

In response to the guidance the department of health said that primary care trusts should "consider carefully whether there are particular local or individual circumstances that would make it appropriate to fund sorafenib, or other drugs NICE has been unable to recommend for routine use."

The spokesperson said the department would be setting up a new cancer drugs fund to operate from April 2011. In the meantime it will be looking at joint payment schemes with drug companies "which will enhance access for patients to costly medicines."

Although it respected "the expert independence of NICE" the department said there would be significant reforms to the way that drugs are funded so that "patients can access the drugs most clinically effective for them."

It added, "We believe that it [NICE] must be allowed to continue to issue guidance free from political interference. However, we believe that there are fundamental failings within the wider system for drug pricing and access."

NICE considered sorafenib under its end of life drugs treatments framework and took account of an offer by manufacturers Bayer to pay for some of the cost. But even so it calculated that the lowest cost per quality adjusted life year (QALY) gained for the drug was £52 600 (€61 620; $76 560) with the higher end of the range costing substantially more.

NICE typically recommends the NHS to use treatments when they fall within a range from £20 000-30 000 per QALY. But for end of life drugs the QALY threshold can be extended to £40 000-50 000.

The guidance is at http://guidance.nice.org.uk/TA189.

Cite this as: *BMJ* 2010;340:c2832

from their own countries with better working conditions and pay wastes training.

Manuel M Dayrit, WHO director of human resources for health and a former minister of health of the Philippines, said that all health sector stakeholders, including private and non-governmental agencies, are expected to implement the code.

Although the term financial "compensation" is not included in the code, there is an expectation that donor countries and international institutions will support poor countries over the loss of health personnel both with technical expertise and financially, he said. The WHO is to track developments and in five years' time report on the implementation of the code.

Under other business, the assembly also endorsed moves to step up efforts to tackle the growing magnitude of non-communicable diseases—mainly cardiovascular diseases, cancers, chronic respiratory diseases, and diabetes, which kill nearly 35 million people per year.

The assembly also adopted a new strategy for reducing the harmful use of alcohol and resolutions to stem the marketing to children of junk food and drinks high in saturated fats, trans-fatty acids, free sugars or salt, to reduce the risk of non-communicable diseases.

"This is a world in which some 43 million pre-school children are obese or overweight. Think what this means in terms of life-long risks to their health," said Dr Chan.

It also passed a resolution calling for improvement in breastfeeding practices, which WHO estimates could save the lives of about 1 million children every year. Only 35% of children yonger than 6 months are exclusively breastfed, it says.

The assembly also adopted new guidelines on human organ and tissue transplantation.

Cite this as: *BMJ* 2010;340:c2784

MAURO FERMARIELLO/SPL

Western countries that recruit from poorer countries must fund training in such places, the code says

PHILIPPE WOJAZER/REUTERS

Carla Bruni-Sarkozy is overseeing the campaign to ensure no child is born with HIV by 2015

Campaign is launched to reduce number of babies born with HIV

Helen Mooney LONDON

The "political will" of governments worldwide must be harnessed to help eradicate the transmission of HIV from mothers to their newborn babies, experts said last week.

Diana Gibb, professor of epidemiology and consultant paediatrician at the Medical Research Council Clinical Trials Unit, University College London, told the *BMJ* that the political might of governments around the world, as well as the introduction of routine normalised testing, is needed to reduce the numbers of children who are born with HIV.

Commenting on a new campaign by the Global Fund to Fight AIDS, Tuberculosis and Malaria to mobilise the public on the issue of HIV in babies, Professor Gibb, who was instrumental in introducing routine HIV testing in pregnant women in the United Kingdom, said: "When we introduced universal testing in the UK, we carried out an economic analysis which showed that even in a low prevalence area like the UK it is very cost effective. Although testing in pregnant women rose to 45% globally in 2008, there are still nearly 500 000 babies being born each year with HIV."

The Global Fund hopes the new "Born HIV Free" campaign will rally public support for its work and achieve a world where no child is born with HIV by 2015. The campaign has been overseen by Carla Bruni-Sarkozy, wife of the French president Nicolas Sarkozy and Global Fund ambassador for Protecting Women and Children against AIDS.

The fund, which uses contributions from governments and charitable foundations, is seeking donations of up to $20bn (£14bn; €16bn) over the next three years.

"It is heartbreaking that over 400 000 babies are born with HIV every year even though we have the medical means and the expertise to prevent this," said Ms Bruni-Sarkozy. "I hope the campaign will inspire millions of people to support the Global Fund so we can finally put an end to this terrible injustice."

Last year executive director of the Joint United Nations Programme on HIV/AIDS Michel Sidibé called on governments to virtually eliminate mother to child transmission by 2015. HIV positive mothers can pass on HIV to their babies during pregnancy, labour, or delivery, or by breast feeding. However, the risk of transmission can be significantly reduced if the mothers get access to prevention and treatment services.

Mother to child transmission has been virtually wiped out in countries such as the UK because pregnant women who test positive for the virus that causes AIDS can be treated with anti-HIV drugs, generally three drug therapy. Other measures, such as delivering the baby by caesarean section, also help stop HIV being transmitted to the child.

Michel Kazatchkine, executive director of the Global Fund, said: "We can win this battle against AIDS if we get the funding we require. This campaign is intended to encourage people to sign up in support of the Global Fund and to show their leaders that there is strong public support to continue and increase funding for its mission."

The US is the biggest donor to the Global Fund. France is the largest European contributor. The UK has pledged or contributed $1.1bn since the fund began in 2002.

Cite this as: *BMJ* 2010;340:c2780