**Foundation trust status makes little difference to performance**

Adrian O’Dowd  LONDON

Giving “foundation” status to a hospital trust makes no difference to clinical or financial performance, concludes a new study.

An analysis of trusts’ performance by York University showed that giving hospitals in England the greater independence promised with foundation trust status did not automatically lead to enhanced productivity and performance, as expected.

Researchers from the university’s Centre for Health Economics discovered that differences between trusts were of long standing and existed before foundation trusts were introduced in 2004, with the expectation that they would achieve high productivity, greater innovation, and better care.

The centre’s team compared the performance of hospitals that became foundation trusts with those that did not, using data covering a seven year period (2002-3 to 2008-9) before and after the introduction of foundation trusts.

The analysis focused on key measures of financial performance, clinical quality and performance (such as waiting times and rates of meticillin resistant *Staphylococcus aureus* (MRSA)), patients’ safety (indicated by NHS staff reports of “near misses” and errors), and staff satisfaction.

The report says: “Results confirm that the FT [foundation trust] policy per se has made no change in the financial performance of FTs relative to non-FTs, as measured in terms of surplus and RCI [reference cost index].”

On infections, the researchers found a similar picture, saying that their findings “suggest that the introduction of the FT policy has made no impact on the quality of patient care as measured by lower MRSA rates.

“The difference in MRSA rates between FTs and non-FTs pre-exists the introduction of FT status, and the general decline is probably due to greater pressure on all acute trusts to reduce their infection rates and closer monitoring.”

The centre’s director, Maria Goddard, said, “Our research basically shows that the policy of greater autonomy seems to have made no difference.”

**Do Hospitals Respond to Greater Autonomy? Evidence from the English NHS** is at www.york.ac.uk.

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**Ombudsman upholds eight in 10 complaints about the NHS**

Clare Dyer  BMJ

Croydon Health Services NHS Trust was asked by the parliamentary and health services ombudsman to pay £75 000 (£85 000; $120 000) to a woman whose leg was amputated because of failings in her care, the ombudsman’s latest annual report shows.

The award, unusually high for an ombudsman’s recommendation, is nearly 10% of the total £780 201.72 recommended to be paid out in 2010-11 by the current ombudsman, Ann Abraham, who oversees complaints against government bodies and the NHS in England.

In her last annual report before she retires, Ms Abraham highlights her report *Care and Compassion?*, published in February, which told the stories of 10 people aged over 65 for whom the NHS had failed to provide even the basic standards of care (BMJ 2011;342:d1064).

That report triggered a national debate about care for the over 65s, she says, although “sadly, access to justice came too late for nine of the 10 people featured in the report, who died either during the events that led to our investigation or shortly afterwards.” She is “optimistic that the stories in our report will be a catalyst for wide-reaching and profound change in the way older people are treated in the health service.”

Failures in care at the end of life feature in another case highlighted in her annual report: that of a man with stomach cancer who wanted to die at home. When his daughter came to collect him from Royal Bolton Hospital, “she found he had been left for several hours, was in pain, desperate to go to the toilet and unable to ask for help because he was so dehydrated he could not speak or swallow. The emergency button had been placed out of his reach and his drip had been removed, fallen and leaked all over the floor.”

At home the family discovered he had not been given the right pain relief and spent the weekend driving around trying to find the correct drugs before he died. The ombudsman recommended compensation of £2000.

Complainants come to the ombudsman if they are not satisfied with the way their complaints have been dealt with by their GP, local primary care trust, or hospital trust. Of 13 625 inquiries to the ombudsman in 2010-11, acute trusts accounted for 6924, primary care trusts 2714, and GPs 2581. Some 79% of complaints relating to healthcare were upheld.

The report does not name all the individual trusts provoking the most complaints; detailed figures for each trust will be given in a separate report in the autumn. However, it said that the number of complaints against Barts and the London, the trust that received the greatest number of complaints last year, at 146, fell to 112 this year.

The report coincides with recommendations from the Law Commission, the official law reform body for England and Wales, for reforms to make it easier for citizens to complain to the five public services ombudsmen, including the health service ombudsman. The report is at www.ombudsman.org.uk/annualreport.

Cite this as: BMJ 2011;343:d4476
CMOs advise on exercise levels for adults and children

Matthew Billingsley BMJ

Children aged under 5 years should be physically active for at least three hours every day to stay healthy, while children aged 5–18 should have at least one hour of exercise a day, say new guidelines. Adults should aim for 150 minutes of physical activity a week.

Varenicline raises risk of heart problems, meta-analysis indicates

Nigel Hawkes LONDON

Smokers who use the smoking cessation drug varenicline (marketed in the United Kingdom as Champix) are at increased risk of heart problems, a new meta-analysis has concluded.

A team led by Sonal Singh of Johns Hopkins University School of Medicine in Baltimore and Yoon Loke of the University of East Anglia combined results from 14 trials to reach its conclusion, published in the journal of the Canadian Medical Association, CMAJ (doi:10.1503/cmaj.110218). Pfizer, which manufactures varenicline, questioned the conclusion, which it said was based on a very small number of events.

A single trial (Circulation 2010;121:221-9) accounted for more than half the total number of events; and in rapid responses to the CMAJ two correspondents questioned the quoted odds ratio. The meta-analysis reports 52 cardiovascular events (ischaemia, arrhythmia, congestive heart failure, sudden death, or cardiovascular related death) in 4908 users of varenicline and 27 in 3308 people in the placebo group. These figures give an odds ratio of 1.3. But the authors used the Peto method for calculating the odds ratio, which is appropriate when the effect size is small, the authors say, and the trials have roughly equal numbers of participants in each group, as in this case. They quote an odds ratio of 1.7 (95% confidence interval 1.1 to 2.7).

“Our new research shifts the risk-benefit profile of varenicline,” said Dr Singh. “People should be concerned. They do not need Champix to quit, and this is another reason to consider avoiding Champix altogether.” Dr Loke said that although the number of serious heart problems was low, at about 1%, these were occurring in healthy people. “These are life threatening diseases, and so any increased risk should be avoided, particularly as heavy smokers are already susceptible to cardiovascular disease,” he said.

In a rapid response posted to CMAJ two doctors from the Best Practice Advocacy Centre in New Zealand, David Woods and Mark Caswell, put a different spin on the results. They say that in absolute terms the increase in risk is only 0.24%, which equates to a number needed to harm of about 400.

“This is a very small increase in risk compared to the benefits of quitting smoking,” they say.

Primary care datasets will replace rumours about GP practices

Michael Cross LONDON

Government plans to publish the clinical performance and prescribing habits of GPs in England face a critical reception from professional bodies. Comparative clinical outcomes and data on general practices’ prescribing are among six datasets from the NHS to be made public from December 2011 under an initiative to make public services more transparent.

Bruce Keogh, the NHS’s medical director, said last week that publishing the data would allow patients to evaluate their local doctors objectively. “Rumour and word of mouth are no longer good enough,” he said.

Reaction was mixed. The BMA warned against creating “simplistic league tables,” while the Royal College of General Practitioners said that
GPs “have nothing to fear about demonstrating the high quality of care that they give to their patients.”

The NHS data will be released under what the prime minister, David Cameron, described as “the most ambitious open data agenda of any government in the world.” A key part of the plan is to make the data available for reuse by commercial firms offering online information and “apps” for mobile phones and computers. The datasets to be made available are:

- Comparative clinical outcomes of general practices in England, which are based on a set of 22 indicators
- Prescribing data, by general practice
- NHS hospital data on complaints
- Clinical audit data from all publicly funded clinical teams in treating key healthcare conditions (from April 2012)

**Laurence Buckman (left): the data promoted by Bruce Keogh (right) could be misleading**

- Staff satisfaction at each NHS provider of healthcare services, and
- Quality of postgraduate medical education (from April 2012).

Professor Keogh said that the open data programme would build on the success of publishing individual heart surgeons’ mortality rates. “Our heart surgery is now demonstrably better, with death rates half those of Germany. I want to bring this transparency to other areas of the NHS,” he said.

Francis Maude, the minister for the Cabinet Office, who is in charge of public service reform, said that he wanted “much more data on primary care to be published.”

Laurence Buckman, chairman of the BMA’s General Practitioners Committee, welcomed transparency in principle but warned that outcome measures are difficult to interpret.

“There are many factors which will affect one person’s health outcome: what other diseases they have, for example, or what healthcare support or social care is available to them. Any national audit would have to be sufficiently sophisticated to take this into account, otherwise we could end up with simplistic league tables which, without context, could mislead the public.”

Similarly, publishing GPs’ prescribing data without the context of the demographic characteristics of their populations will make it impossible for people to interpret the information appropriately, Dr Buckman said.

The Royal College of General Practitioners has also warned of the dangers of misleading patients and of identifying individual patients with very rare conditions.

Professor Keogh said that to avoid such risks it was essential that the initiative be led by GPs. But he warned that not all clinicians would be comfortable with the new regime.

See OBSERVATIONS, p 128.

Cite this as: BMJ 2011;343:d4415

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**Romantic novels “negate” sexual health advice**

**Polly Stoker** BMJ

Romantic fiction encourages the women of today to idealise sex and relationships, the consumer correspondent for the Journal of Family Planning and Reproductive Health Care said this month.

In the July issue of the journal, Susan Quilliam, relationship psychologist and agony aunt for Top Santé magazine, argued for the “huge relevance” of romantic fiction in relation to the women seen in doctors’ consulting rooms (J Fam Planning Reprod Health Care 2011;37:179-81).

Emphasising the number of hours women around the world spend reading romantic literature—in certain developed countries romantic literature is responsible for half of fiction sales, and some women spend as long as one day a week reading it—Ms Quilliam compared them to the very few sex education hours that women were exposed to. She wrote, “What we see in our consulting rooms is more likely to be informed by Mills and Boon than the Family Planning Association.”

In spite of the genre’s movement away from dated gender roles to “real life awareness” and the liberating depictions of female sexuality and desire, idealism and escapism remained prevalent within romantic novels, said Ms Quilliam.

Referencing Samuel Richardson’s Pamela as the first romantic novel, and tracking the progress of the Mills and Boon novel over the past 80 years, Ms Quilliam argued that the values championed by these texts were not only a negation of the health profession’s advice to its female public but were also unrealistic. Multiple orgasms, trouble free pregnancies, and near rape in the case of Pamela, were not the norm, explained Ms Quilliam. She added, “We aim to reassure our female clients that their first time may not be utterly joyful . . . but that they themselves are none the less existentially valid.”

Another major concern for the agony aunt and broadcaster is the absence of contraception within romantic fiction, particularly the use of condoms. She cited a study in 2000 that showed that almost 90% of all romantic novels did not even mention the possibility of condom use, and in the few that did “the heroine typically rejected the idea because she wanted ‘no barrier’ between her and the hero” (Psychol Woman Q 2000;24:179-88).

She continued, “Even more worryingly . . . there was a clear correlation between the frequency of romance reading and the level of negative attitudes towards condoms and the intention to use them in the future,” despite the fact that the survey readers fully understood the reading matter’s fictional element.

Thus, wrote Ms Quilliam, there is a “worrying” disparity between what romantic fiction is promoting in health terms and the behaviour sexual health professionals encourage in their clients.

The genre does have positive aspects, however, insisted Ms Quilliam. It “allow[s] women to feel good about their desires.”

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German doctor is fined €7000 for death of British patient

**Ned Stafford** HAMBURG

Daniel Ubani, the German doctor who while working as a locum GP in Britain unintentionally killed a patient with 10 times the recommended dose of diamorphine, was found by a German administrative court to be guilty of professional misconduct in the death and fined €7000 (£6200; $9750).

The action, taken by a section of the Administrative Court of Münster that focuses on healthcare professions, was officially termed a “censure” and seems to be the final legal challenge—criminal, civil, or professional—stemming from the death, said Volker Heiliger, spokesman for the Westfalen-Lippe Medical Association in Münster. Mr Heiliger said that Dr Ubani is still registered to practise medicine but that he privately practise in Witten, North Rhine-Westphalia, seems to have been closed.

Dr Ubani, who was born in Nigeria but holds German citizenship, was on his first ever UK shift for an independent provider of out of hours GP services in 2008 when he made a call to the Cambridgeshire home of David Gray, who had died from colic. Dr Ubani was told that the patient usually received 100 mg of pethidine for pain control, but he instead administered 100 mg of diamorphine, resulting in Mr Gray’s death. Dr Ubani was also found to have failed to properly treat two other patients during the same shift.

In March 2009 Dr Ubani was found guilty by a local German court of causing death through negligence and was given a nine month suspended sentence and fined €5000. Cambridgeshire authorities failed to bring Dr Ubani to England to face charges because of his conviction in Germany.

In February 2010 a UK coroner’s inquest confirmed the cause of death as diamorphine poisoning, describing the death as “gross negligence manslaughter.” In June 2010 the General Medical Council struck Dr Ubani off the medical register because of his “serious and persistent failings” in the clinical care of three patients.

Last year the Westfalen-Lippe Medical Association had planned to conduct its own fitness to practise hearing concerning Dr Ubani (BMJ 2010;341:c4653). However, Dr Ubani won a

**EU needs “failsafe” system on unfit doctors**

**Adrian O’Dowd** LONDON

A “failsafe” system of alerts about doctors who have lost their licence to practise in their own country must be adopted throughout the European Union to ensure that these doctors don’t simply move elsewhere and start seeing patients again, peers have been told.

Officials from the European Commission have admitted that the current system allowing the free movement of healthcare professionals across the EU is imperfect and needs reform.

The officials were giving evidence to the House of Lords’ EU social policies and consumer protection subcommittee on 7 July as part of its inquiry into the European directive on the mutual recognition of professional qualifications.

The European Commission is reviewing the directive, one of whose aims is for all member states to recognise each other’s healthcare qualifications and simplify the movement of clinicians across countries.

Jonathan Faull, director general of the internal market and services at the European Commission, giving evidence, said that the current system offered various benefits, such as helping some member states to tackle staff shortages.

Mr Faull admitted that the present system had problems, saying, “We need a failsafe system for immediate alerts to be sent around countries when a doctor loses the licence to practise in his or her home country.” This would prevent such doctors simply moving to another EU country to carry on working.

Peers asked about fears raised by the UK medical regulator, the General Medical Council, in a previous session that doctors in different countries had different training and that privacy laws were sometimes used to stop the GMC and the public from knowing about a doctor’s fitness to practise being impaired (BMJ 2011;343:d4200, 1 Jul).

The peers asked, “Are you not putting free movement ahead of patient safety?”

Mr Faull said, “We are certainly not doing that. We want to combine the considerable benefits of free movement with full confidence in healthcare professionals.”
court decision that only the regional government of Arnsberg, in North Rhine-Westphalia, has the authority to officially determine a doctor’s fitness to continue practising medicine.

Markus Wenning, the association’s medical managing director, told the BMJ that the regional government held the hearing and that Dr Ubani passed it.

He said that the Ubani case “casts a shadow on health authorities and—at least in the view of the public—the reputation of medical doctors in general.” He added, “I would have preferred our medical association to hold the fitness to practise hearing, but we were prohibited by our state’s vocational court for administrative affairs.”

In the most recent ruling the Administrative Court of Münster found that Dr Ubani was professionally malfeasant in his treatment of Mr Gray, saying that he “repeatedly breached elementary medical principles,” causing the “negligent death” of Mr Gray. The court said that Dr Ubani also made “gross treatment failures” with the other two patients by not realising the severity of the illnesses and trying to treat them on site, rather than admitting them to a hospital.

In explaining its reasons for limiting the sentence to a reprimand and fine of €7000, the court said that in almost 30 years of medical practice Dr Ubani had faced no professional legal action, that Dr Ubani had acknowledged his “deadly treatment failures” and had attempted to apologise to Mr Gray’s family.

Novel polymer could be used in coronary artery bypass

Geoff Watts LONDON

The synthetic windpipe used by the Swedish team who carried out last month’s pioneering implant surgery on a patient with advanced tracheal cancer was made of a novel polymer designed and tested at University College London. The work has shown that an artificial trachea can simulate the properties of a natural one and paves the way for further uses of the polymer.

The man who created the implant, Alex Seifalian, professor of nanotechnology and regenerative medicine at University College London, describes the material of which it is made as a “nanocomposite.” It comprises a polymer containing tiny, nanometre size crystalline particles. In the finished material these particles end up covering its surfaces.

The polymer implant acted as a scaffold on which stem cells taken from the patient’s own bone marrow were seeded to form a functional length of windpipe.

To ensure that the implant was a perfect replica of the Y shaped section of the trachea and bronchi it was designed to replace, the Swedish team supplied Professor Seifalian with computed tomography scans of the patient’s own organ. In his laboratories at London’s Royal Free Hospital he used these to make a glass mould on which to form the implant.

The finished item was sent to the Karolinska Hospital in Stockholm where the Swedish team placed it inside a specially built bioreactor. This incubated the stem cells while they colonised the polymer scaffold and penetrated its pores.

The colonisation, aided by various growth factors, took just two days.

Professor Seifalian foresees other uses for the new polymer, not least in coronary artery bypass surgery. This involves replacing patients’ own coronary arteries with lengths of vessel removed from elsewhere in their bodies. “Some patients don’t have any suitable veins, either because they’ve been used before or they’re not good enough,” said Professor Seifalian. This can be a problem in up to 30% of cases.

New European rules on food labelling will empower consumers

Rory Watson BRUSSELS

The European parliament overwhelmingly adopted legislation on 6 July to improve the clarity and degree of information provided on food packaging across the European Union. The new measures took three years to agree and are the result of a compromise between members of the parliament and EU governments. They will take effect in 2014.

The legislation details the mandatory information that a package must contain and aims to improve the legibility of labels by stipulating a minimum text size (an x height of 1.2 mm). John Dalli, the health and consumer commissioner, said that the new rules would empower consumers and “help them to make more informed decisions.” They would also contribute to efforts to tackle obesity and chronic diseases.

For the first time, a nutritional declaration concerning energy, protein, fat, saturated fat, carbohydrates, sugar, and salt levels will be compulsory. The information must be expressed per 100 g or 100 ml, making it possible to compare different products. Labels will also have to contain data on the item’s ingredients, “best by” or “use by” dates, any specific conditions on use of the product, and clear signalling of the presence of any substances with scientifically proved allergenic effects.

Information on country of origin, which has been compulsory for beef since 2000 after the bovine spongiform encephalopathy crisis, will be extended to other fresh meat (goat, sheep, poultry, and pork) and fish and possibly later to processed foods of which meat is an ingredient.

The European Commission will now have to examine whether mandatory origin rules should be applied to other items such as milk, dairy products, and unprocessed foods and whether the exemption from providing ingredients and nutritional information that alcoholic beverages will enjoy for the first five years of the legislation should be renewed or not.

It will also have to establish a definition for alcopops, which are not currently covered by the new legislation, although MEPs and governments agree that because of their alcoholic nature alcopops should have stricter labelling requirements and be clearly separated from soft drinks in shops.

BEUC, the pan-European consumer organisation, has generally welcomed the new legislation but criticised the failure to place mandatory nutrition information on the front of packaging (although this may be presented on a voluntary basis). Monique Goyens, the organisation’s director general, said, “Consumers will be able to make more informed choices on food products, but the regulation will not enable them to choose the healthiest products at a glance.”

She also regretted the decision taken last year to reject the use of the “traffic light” scheme of red, amber, or green labelling.

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Antiparasite drug ivermectin cuts mosquito numbers by 80%  

Janice Hopkins Tanne  NEW YORK

Ivermectin, a drug commonly used to treat onchocerciasis (river blindness) in Africa, can kill mosquitoes that transmit malaria and may be another weapon in the fight against the disease, a new study indicates.

Researchers from Colorado State University in Fort Collins and Senegal’s Ministry of Health and Medical Prevention compared the effect of ivermectin on mosquitoes in three villages where residents had received an annual dose of the drug to control onchocerciasis with the effect in three nearby (less than 12 km away) control villages whose residents had not been given the drug.

Ivermectin “significantly reduced the proportion of Plasmodium falciparum infectious Anopheles gambiae sensu stricto (s.s.) [mosquitoes] relative to those caught from nearby control villages for up to two weeks post administration,” the researchers write in the American Journal of Tropical Medicine and Hygiene (2011;85:3-5).

Overall the researchers found a 79% reduction in the proportion of malaria carrying mosquitoes in the villages where residents had received ivermectin. Over the same period the proportion of malaria carrying mosquitoes rose. Previous laboratory studies have shown that ivermectin at concentrations present in human blood after laboratory studies have shown that ivermectin in the villages where residents had received ivermectin mosquitoes after ivermectin treatment and “were pleasantly surprised when the data came back so strongly significant.”

Joseph McCormick, formerly a leader on malaria with the US Centers for Disease Control and Prevention and currently dean at the University of Texas School of Public Health in Brownsville, told the BMJ, “This was the first time that we’ve seen this [killing effect] in the field.

“It is a breakthrough? I think it’s an addition, because it affects the mosquito directly [rather than preventing infection through use of insecticides and bed nets or treating it],” He said that it might be particularly useful in countries such as Senegal where malaria occurs mostly during the 3-5 month rainy season. “It’s not a very toxic drug. It could be given once a month or every six weeks,” he said.

David Sullivan, from the Center for Global Health at the Johns Hopkins Malaria Research Institute in Baltimore, called ivermectin “a nice small added tool.”

Cite this as: BMJ 2011;343:d4355

Malnutrition soars in Horn of Africa as crisis worsens by the day  

John Zarocostas  GENEVA

Rates of malnutrition and mortality among children are rising rapidly in drought stricken Ethiopia, Kenya, and Somalia, the United Nations and aid charities have warned. Unless aid is urgently dispatched and interventions scaled up, the crisis is expected to worsen, they say.

UN officials said that the rate of acute malnutrition is rising dramatically and that death rates have risen sixfold among children aged under 5 years in some of the worst affected areas.

The crisis, exacerbated by the severest drought in half a century, is getting worse by the day. The situation is most life threatening for the thousands of Somali refugees crossing over daily into Ethiopia and Kenya after having walked for days.

Adrian Edwards, a spokesman for the Office of the UN High Commissioner for Refugees (UNHCR), said in a telephone interview on 10 July from Nairobi that the child mortality rate had more than tripled in Ifo camp and had risen sixfold in Dagahaley in comparison with average death rates in the same period last year.

Both camps are part of the Dadaab complex in eastern Kenya near the border with Somalia, which houses nearly 400000 refugees. “These are pretty shocking figures,” said Mr Edwards, who is visiting the region with the UN high commissioner for refugees, António Guterres.

After visiting Dollo Ado refugee camp in eastern Ethiopia near the border with Somalia Mr Guterres said, “I saw with my own eyes the

Hospitalisation rates explain differences in Medicaid costs across US

Bob Roehr  WASHINGTON, DC

The rates and costs of hospitalisation explain much of the difference in states’ spending on beneficiaries of Medicaid, the US joint federal and state health insurance programmes for people on low incomes, a new study concludes.

Secondary factors were regional differences in the cost of living and of healthcare and the age and mix of patients, the study found (Health Affairs 2011;30:1316-24).

Average annual spending per Medicaid beneficiary across the US was $5163 (£3210; €3610) during the study period, 2001 to 2005. The 10 highest spending states averaged $1650 above that figure, while the 10 lowest spending averaged $1161 below it.

The mid-Atlantic region (New York, New Jersey, and Pennsylvania) was the most expensive in the Medicaid programme, said Tod Gilmer, the study’s lead author and a professor of health economics at the University of California at San Diego.

“They spend more in every area … There is more utilisation of hospital stays and higher costs per stay,” he said at the July

Access to primary care may explain why annual Medicaid costs per patient in California are less than half those in New York state
enormous suffering of the Somali people trying to reach safety and food. Refugee children are dying and their mothers reduced to walking skeletons.”

Allison Oman, UNHCR’s regional nutrition and food security officer in Nairobi, said that “between 45% and 55% of children arriving in Ethiopia and 30-40% in Kenya are malnourished.” The World Health Organization has set the emergency acute malnutrition threshold at 15%.

“Tragically when we see child deaths in our emergency feeding centre most are within 24 hours of admission despite our emergency care. They are just drained,” said Ms Oman.

Unicef said that mortality rates among children in some camps in Ethiopia and Kenya are above the emergency threshold of four deaths a day per 10,000 children.

Meanwhile, the aid group Médecins Sans Frontières said on 8 July that on the outskirts of one of Dadaab’s camp sites its teams found extremely high malnutrition rates among new arrivals. More than a third (37%) of children under 5 who were screened were found to be malnourished and 18% severely malnourished. In June the charity admitted 320 children to its inpatient therapeutic feeding centre, three times as many as in the same month last year. The charity found 43% of children aged 5-10 years to be malnourished.

Bob McCarthy, Unicef’s regional emergency adviser for eastern and southern Africa, said that timely reporting from health centres where nutritional rehabilitation activities are taking place is vital to prioritise the response.

Cite this as: BMJ 2011;343:d4454

Germany relaxes law on preimplantation genetic diagnosis

Annette Tuffs HEIDELBERG

The German parliament has passed a law that allows preimplantation genetic diagnosis (PGD) of embryos after in vitro fertilisation if there is a strong likelihood that the parents will pass on a defect or if the chances of a miscarriage or stillbirth are high for genetic reasons.

The law makes counselling before PGD obligatory and says that an interdisciplinary ethics committee has to agree each case.

MPs took a free vote on the law on 7 July after a long and emotional debate. A majority of 326 versus 260 voted for the law. In contrast to many other European countries, PGD was previously banned in Germany, and many couples went abroad for testing.

The new law became necessary after Germany’s Federal Supreme Court decided in 2010 to acquit a Berlin gynaecologist of illegal abortion after he carried out genetic diagnosis on human embryos and discarded those with genetic defects. The court ruled that because the goal of PGD was a healthy pregnancy and child, the screenings were lawful and the gynaecologist’s actions did not violate the country’s 1990 Embryo Protection Law, which recommends a three year jail term for anyone using an embryo in a way that fails to promote its survival (BMJ 2010;341:c374).

The strict proposal supported by Chancellor Angela Merkel had called for a total ban on PGD, arguing that it would lead to scenarios in which parents could choose a “designer baby.”

However, the Christian Democrat labour minister and doctor, Ursula von der Leyen, said that those worries were unfounded and that designer babies were a “fantasy.”

“It’s about severe illness in individual cases. I am firmly convinced that we should not close our eyes to how we can use modern medicine appropriately to support and help these long suffering families.”

Frank Ulrich Montgomery, president of the German Medical Association, who did not support PGD, said that doctors would have to take responsibility and provide a properly professional service under the conditions of the new law. “We do not want this [PGD] to become a routine examination in vitro fertilisation treatment,” he said.

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