NEWS

UK news Savile committed 50 criminal offences on 14 hospital sites, police say, p 2
World news Australian MPs demand more data on dabigatran, p 6
References on news stories are in the versions on bmj.com

bmj.com
People in the US have poorer health and die younger than those in other rich countries

Hackney GPs plan to take control of out of hours care from April

Zosia Kmietowicz BMJ

GPs in the London borough of Hackney are setting up a social enterprise to try to take back the running of urgent and out of hours care for their patients from the private company Harmoni.

Hackney Urgent Healthcare Social Enterprise is due to launch on 2 April, when GPs nationally take responsibility for commissioning most patients' services through clinical commissioning consortiums, as part of the changes introduced by last year's Health and Social Care Act.

In an announcement to patients about the planned changes for urgent and out of out of hours care in Hackney, the Lawson Practice, part of the consortium, said, "Local GPs are keen to take over responsibility ourselves. We know that our patients prefer seeing doctors they know."

Clare Highton, a GP and chairwoman of the City and Hackney Clinical Commissioning Group, told the *BMJ*, "We are keen to get a very high quality out of hours service, and we want to make sure it is integrated with accident and emergency so that we can reduce unnecessary visits. We are concerned that 111 [the new telephone service for urgent but non-emergency advice and care that is being rolled out across England] will increase demand for A&E [accident and emergency services], because we have a very large commuter population and it is not clear who will pay for 111 for these patients."

The out of hours service run by Harmoni across north London came in for criticism from doctors in December in a report in the *Guardian* newspaper.[1] They alleged that Harmoni's cost cutting led to staff retention problems, shortages of clinical staff, and unsafe working practices. Harmoni refuted the criticisms and categorically denied that the service has been unsafe.

Paddy Glackin, a GP in Islington, north London, and a member of the area's local medical committee, said that when local GPs ran the out of hours service Camidoc, which was run as a not for profit organisation, "there was a genuinely cooperative spirit," with GPs doing shifts and providing care directly to their patients. "When the out of hours service was run by a private company it ceased to be something that we did collectively. It changed the mindset of GPs," he said.

Cite this as: *BMJ* 2013;346:f309

Firms should release data from all licensed drug trials, say MPs

Nigel Hawkes LONDON

The drug industry should be obliged to release in a publicly accessible form all the information it possesses about trials of licensed drugs, the House of Commons Health Committee has said in a new report on the functioning of the National Institute for Health and Clinical Excellence (NICE).[1]

It should be "neither legal nor ethical" to withhold such data, said the committee. It was concerned that failure to observe this simple principle undermined the effectiveness of NICE, because the institute was forced to appraise drugs without having access to all relevant data.

"This situation cannot be allowed to continue," said Stephen Dorrell MP, the Conservative chairman of the Health Committee. At a press conference in London to launch the report he called for a "duty of candour" to apply to drug companies, citing remarks made to the committee by David Haslam, who in April will replace Michael Rawlins as chairman of NICE. Haslam told the committee that he found it "impossible to come up with any good argument that all data should not be released."[2]

To bring about the necessary changes, the committee recommended that the drug industry introduce a new code of practice and that the General Medical Council reiterate its guidance to doctors on the conduct of drug trials, to remind them that a failure to comply could lead to fitness to practise proceedings being brought against them.

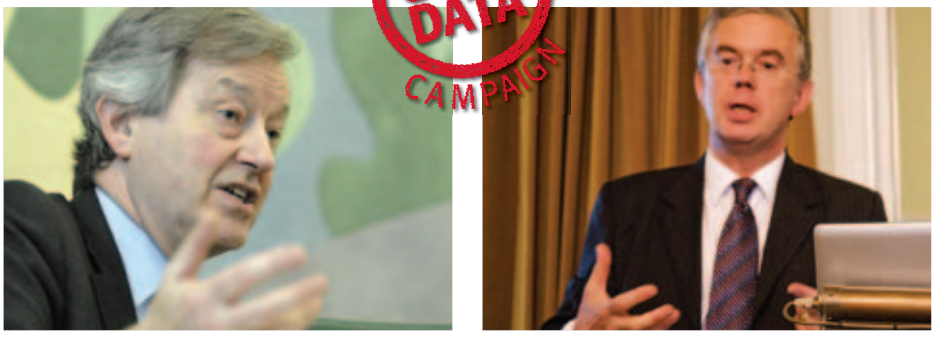
The committee was also exasperated by the failure of the government to make it clear how its value based pricing system for new drugs would actually work. Although the government had been in power for over two and a half years it had provided "very little detail" about value based pricing, a delay the committee described as unacceptable. "We are increasingly surprised that we haven't had more information," Dorrell said. "We're looking for greater clarity."

The evidence it took indicated that the drug pricing changes might be more modest than first suggested. At present, manufacturers are entitled to set their own price, and NICE then makes cost effectiveness calculations on the basis of that price. NICE has no formal role in negotiating lower prices, but in practice, the report said, discussions do take place between the manufacturers and NICE about the price at which the drug would satisfy cost effectiveness criteria. "Against that background it is even less clear what substantive change is implied by the concept of value-based pricing," says the report.

The principal change is that the negotiations would be formalised and undertaken by (it seems) the Department of Health. But given that the system was supposed to be in place from April 2014 for newly approved drugs, and that the existing scheme needed to be extended for existing drugs, greater clarity was overdue, the committee said. It has urged the health department to end the uncertainty by March this year.

The committee also made recommendations on the £200m (€240m; $320m) cancer drugs fund.

Cite this as: *BMJ* 2013;346:f321



Stephen Dorrell MP (left) cited remarks made by Professor David Haslam, future chairman of NICE (right), that it was "impossible to come up with any good argument that all data should not be released"

IN BRIEF

NICE consults on guidelines for familial breast cancer: The UK National Institute for Health and Clinical Excellence has begun a consultation on a new draft version of its guideline on familial breast cancer. The updated guideline includes a number of potential new recommendations on issues such as when to offer genetic testing, what surveillance strategies should or should not be offered, and the use of tamoxifen or raloxifene as preventive treatments. See http://bit.ly/XarbUi.

SPL

Neuberger to chair inquiry into end of life pathway: The independent review looking at how the Liverpool care pathway is being used in practice for patients at the end of life is to be chaired by the crossbench peer Julia Neuberger, said Norman Lamb, the care and support minister, on Monday 14 January. Neuberger is senior rabbi at the West London Synagogue and former chief executive of the health think tank the King's Fund.

Breast care services at Solihull Hospital are to be reviewed: The lawyer Ian Kennedy is to chair an independent review of breast care services at Solihull Hospital to look at how the Heart of England NHS Foundation Trust responded to concerns raised by staff, patients, and the public relating to incomplete mastectomies. Police are investigating the surgeon Ian Paterson, who is alleged to have carried out botched or unnecessary surgery from 1994 to 2011.[1]

GPs are asked to comment on contract changes: The BMA has launched a survey (bma.org.uk/gpcontract) asking GPs in England for their views on the government's proposal to impose a series of non-negotiated changes to the GP contract. Responses will help inform the BMA's submission to the government's consultation on this issue, which closes on 26 February.

Cancer rate is rising in China: The incidence of cancer in China doubled from 1989 to 2009, to 3.1 million new cases, and the number of people who died from cancer rose to 2.7 million, show figures from the 2012 China Cancer Registry's annual report. Chen Wanqing, deputy director of the registry, told state media that the incidence was lower than in most developed countries but that the death rate was relatively high.[2]

Cite this as: *BMJ* 2013;346:f296

Police say Savile committed 50 criminal offences at 14 hospitals

Zosia Kmietowicz BMJ

Thirteen hospitals and a hospice have been named in a police report as playing host to the television presenter Jimmy Savile's abuse of children over more than 50 years.

Leeds General Infirmary and Stoke Mandeville Hospital were the main locations of Savile's alleged offending, with a total of 38 crimes reported to have taken place at the two sites between 1965 and 1995.

So far 214 criminal offences have been formally recorded against Savile, including 126 indecent acts and 34 offences of rape or penetration. Of these alleged offences, 50 were reported as taking place on hospital and hospice premises.

The report, *Giving Victims a Voice*, says that 450 people have come forward to allege incidents against Savile between 1955 and 2009. Most of his victims (73%) were children (under 18 years old), and 82% were female.[1] The peak of the offending that has been reported was from 1966 to 1976, when Savile was between 40 and 50 years old.

The report, compiled by the Metropolitan Police and the children's charity the NSPCC, said that Savile's role as a fundraiser and volunteer porter gave him a high level of access at Leeds General Infirmary, Stoke Mandeville, and Broadmoor hospitals. It is the first report to come out of Operation Yewtree, the police investigation that started on 5 October 2012, the day after an ITV programme was broadcast featuring five women who recounted abuse by Savile in the 1970s.

Jimmy Savile's role as volunteer porter gave him a high level of access to hospitals, said police

Peter Spindler, head of specialist crime investigations at the Metropolitan Police, said that the report "paints a stark picture emphasising the tragic consequences of when vulnerability and power collide. Savile's offending footprint was vast, predatory, and opportunistic."

Peter Watt, director of child protection advice and awareness at the NSPCC and a coauthor of the report, said that the scale of Savile's abuse "simply beggared belief."

He added, "Since the Savile scandal broke we have seen a surge in contacts about child abuse, both past and present, with many victims speaking out for the first time. Almost 800 additional children have been protected from abuse because the publicity around this case prompted people to contact our helpline. We are optimistic that this signals a watershed moment for child protection in this country. We must seize the opportunity if we are to make a lasting change."

Currently a total of 14 inquiries or reviews are under way into the abuse by Savile and others, including three by the Department of Health at Stoke Mandeville, Leeds General Infirmary, and Broadmoor Hospital.

Buckinghamshire Healthcare NHS Trust, which oversees care at Stoke Mandeville Hospital, set up the Speaking Out investigation last year. Anne Eden, chief executive of the hospital, said, "The investigation is serious and complex and is currently reviewing files and records from the last 40 years before it moves on to meeting and hearing from witnesses." The report is expected by the end of 2013."

A spokesman for Leeds Teaching Hospitals NHS Trust, which runs Leeds General Infirmary, said that it expected to also publish its report towards the end of the year.

Cite this as: *BMJ* 2013;346:f261

Private providers complain of unfair playing field in NHS

Zosia Kmietowicz BMJ

Too few tendering opportunities, different tax rules for private providers, and prices that did not reflect the full costs of services were affecting the ability of different providers to bid to run NHS services, stakeholders have told Monitor, the economic regulator of the NHS.

Staff terms and conditions in the NHS, including pensions, and the inability of private companies to access schemes such as insurance and information technology services could also mean that some providers were not operating on a "fair playing field" compared with NHS providers.

These issues could form the basis of new policies that the government was expecting to outline at the end of March after it considered Monitor's report, which was due to be published in about six weeks. The government commissioned Monitor last June to conduct a review of what matters affected how providers operated.

Abstracts often do not accurately reflect trial results, study shows

Nigel Hawkes LONDON

Bias and "spin" are commonplace in the reporting of trials of breast cancer treatments, a team in Canada has found. When trials failed to meet their headline objectives, authors often found positive results among the small print, and the severity of adverse effects was often understated.

Authors and journals needed to do better and readers to be alert to such subtle manipulation, say Ian Tannock and colleagues from Princess Margaret Hospital in Toronto.

The team searched for phase III trials of treatments of breast cancer between 1995 and 2011, finding 164 that met their criteria. They focused on the abstract—the only part of study reports that most busy doctors ever read—and assessed whether it accurately reported the primary endpoint of the trial and the toxicity of the treatment.

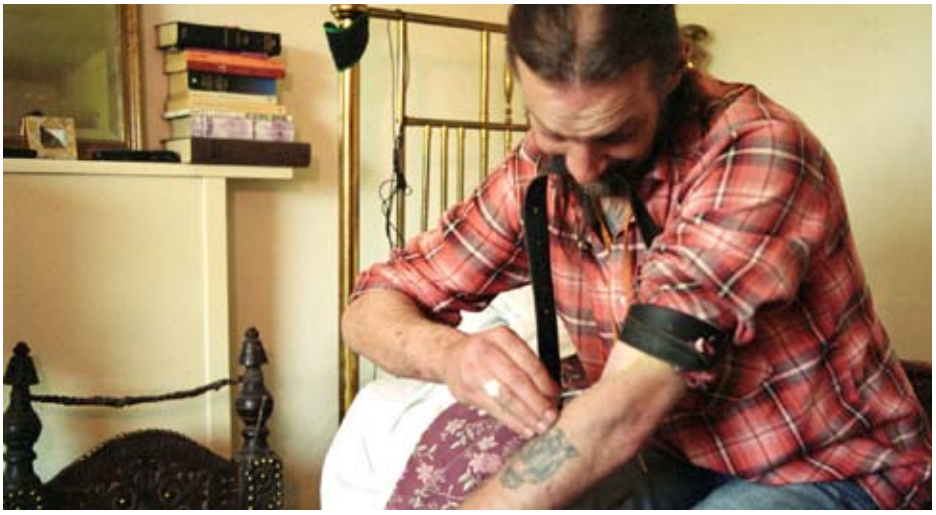
The primary endpoint, specified in advance, is the event chosen to show whether the treatment works: often it is overall survival. Trials may also have secondary endpoints, events that are of interest but that the trial has not been specifically designed to analyse.

The report, in *Annals of Oncology*,[1] found that a third of the trials were declared to be positive despite not finding a statistically significant benefit for the primary endpoint. "These trials were biased and used spin in an attempt to conceal that bias," the team said.

Studies without a positive primary endpoint were five times less likely to mention this in the abstract than those in which a benefit in the primary endpoint had been achieved. Some trials changed their primary endpoint between start and completion, and these were twice as likely to report a positive result for the new endpoint.

Studies funded by the drug industry were no more likely to be biased in their presentation than those funded by academic or government grants.

Cite this as: *BMJ* 2013;346:f179



JANINE WIEDEL PHOTOLIBRARY/ALAMY

"The BMA believes that drug users are patients first," said Averil Mansfield, head of the Board of Science

Drug users should be seen as having a medical condition like any other, says BMA

Gareth Iacobucci BMJ

Drug policy in the United Kingdom should focus more on health to help reduce the negative effects of illegal drug use, says the BMA.

The new report from the BMA's Board of Science says that the association was seeking to "open and refocus the debate on drug treatment and drug policy through the eyes of the medical profession," amid concerns that health could be sidelined in the current debate on drug use.

The report, *Drugs of Dependence: The Role of Medical Professionals*,[1] acknowledges that the UK's drug policies now show a greater sensitivity to social and economic factors than in the past but says that the focus on health remained "inadequate," warning that some users may be discouraged from seeking help because of a fear that they will be treated as criminals.

The report comes in the same week that a cross party group of peers called for a radical change in approach to tackling drug use, with all illegal drugs being decriminalised.[2]

The BMA's report, produced with the help of an expert reference group of specialists, examines the legal framework underpinning the current strategies and assesses the role that doctors and other medical professionals have in tackling drug misuse.

It says that people who are addicted to illegal drugs have a medical condition that should be treated like any other illness, and it adds that doctors should help to refocus the debate to ensure that it is based on public health principles and results in "better health outcomes for all illicit drug users."

Medical training should incorporate basic knowledge of the "social and personal factors increasing the risks of illicit drug use," its adverse health consequences, and the role of doctors in identifying drug related harm and initiating interventions, the report adds.

Doctors are also urged to maintain awareness of "the non-medical facets of drug use."

Averil Mansfield, chairwoman of the Board of Science, said, "The BMA believes that drug users are patients first. That's why we want health to be at the heart of the debate about drugs policy."

Cite this as: *BMJ* 2013;346:f306

However, Monitor said on 15 January that it would not be recommending that private sector providers be exempted from corporation tax.

In a discussion paper that Monitor published, drawing on 71 responses and more than 90 meetings with stakeholders, it said that the evidence "suggests strongly that there are a number of issues which are distorting the playing field."[1]

Most issues raised by stakeholders related to commissioning and tendering, with many providers complaining that there were simply too few opportunities to bid to run services.

Research by Monitor found that commissioners put out to tender just 3% of services that they could commission, "making it difficult for new providers to enter the market," says the paper.

Providers have also complained that the costs of services under the Payment by Results system did not reflect the true costs of delivering those services, giving some providers an unfair advantage.

Last year the union Unite said that the opening up of more NHS services to private providers could lead to private companies being paid more than the NHS would get for doing the same work because they had to pay corporation tax, had to access capital through private borrowing, and had higher costs in providing pension benefits.[2]

Stakeholders also said that they may face higher pension costs than NHS providers and higher costs for loans because they did not have access to government schemes. They also lacked access to the NHS insurance scheme, procurement schemes, and national information technology systems, they told Monitor

Cite this as: *BMJ* 2013;346:f289

Paying GPs to cut emergency admissions "would be unfair"

Gareth Iacobucci BMJ

A plan to tie a proportion of the funding for clinical commissioning groups (CCGs) to reductions in "avoidable" admissions to hospital of patients with long term conditions risks distorting priorities and creating a new "target culture," a senior doctors' leader has warned.

A quarter of the new "quality premium" incentive payment paid to new commissioning organisations in England from 2014-15 would depend on their achieving a reduction or no change in emergency admissions for specific conditions between 2013-14 and 2014-15, says draft guidance from the NHS Commissioning Board.[1]

The money allocated to the premium, proposed as part of the UK government's changes to healthcare,[2] will be determined after parliament sets regulations in the next few months. It will be paid on top of each commissioning group's main financial allocation for 2014-15 and the running costs allowance of £25 (€30; $40) per head of population.

But the BMA's lead GP negotiator on commissioning, Chaand Nagpaul, warned that the move could "distort priorities" for commissioning groups and place undue pressure on GPs, who are already paid incentives through the Quality and Outcomes Framework for helping to prevent emergency admissions.

To achieve full payment of the emergency admissions incentive, commissioning groups would have to ensure no increases in numbers of unplanned hospitalisations of adults with "chronic ambulatory care sensitive conditions," such as congestive heart failure, angina, and hypertension, and of children with asthma, diabetes, or epilepsy.

Nagpaul added that the onus being placed on commissioning groups and GPs to tackle admissions to hospital ignored the roles of other parts of the system. "There will be pressure on practices to contribute. But many of these admissions are outside the control of GPs: they relate to broader factors, such as increased morbidity in the population and increased life expectancy. Some relate to provider performance and some to social care."

Cite this as: *BMJ* 2013;346:f312

Spending in wealthy Richmond (left) will be similar to that in poorer Waltham Forest (right) next year

Two thirds of local authorities face shortfall in public health budgets

Caroline White LONDON

Around two thirds of local authorities in England will find themselves short of the money needed to meet their target spending per head on public health by the end of 2014-15, show figures on the two year settlements allocated to them by the Department of Health.[1]

This is despite real term increases of up to 10% on the budgets for both 2013-14 and 2014-15 proposed by the outgoing primary care trusts, which relinquish responsibility for public health this April.

The overall budget for public health services managed by England's 152 local authorities will be £2.7bn (€3.3bn; $4.4bn) in 2013-14 and just under £2.8bn in 2014-15. The health secretary, Jeremy Hunt, announced on 10 January that the money would be ringfenced.

Local authorities will not assume responsibility for immunisation and vaccination, health protection and surveillance, local infectious disease outbreaks, or emergency planning. But their remit will include five statutory services, including sexual health and the national child measurement programme.

The settlements for individual local authorities, however, show wide variation in spend per person. Altogether 99 authorities will fall short of their targets by 2014-15, by less than 1% in the London borough of Hillingdon, for example, to as much as 43% in its immediate neighbour to the west, Slough, in Berkshire.

The targets were worked out by the independent Advisory Committee on Resource Allocation, which used a new formula that was based on premature death rates among the under 75s and was weighted towards those areas with the poorest public health outcomes. But it has produced some apparent anomalies.

Wealthy boroughs, such as Richmond upon Thames, in London, which has a target of £33 to £34 per head over the next two years, has been allocated £40 per head for each year, while deprived boroughs, such as Waltham Forest in northeast London, with a targeted spend of £67-£68 per head, has been allocated £42 in the first year and £45 in the second.

"The figures are based on historical [primary care trust] spend, and it's about moving that to the formula developed by ACRA [the Advisory Committee on Resource Allocation]," Nicola Close, chief executive of the Association of Directors of Public Health, told the *BMJ*. "It will take several years before spending reaches the target based on the formula."

But the allocations were "good news, overall," she said. The legacy of high spending primary care trusts had to be passed on to the relevant local authorities to avoid services being cut overnight, she added.

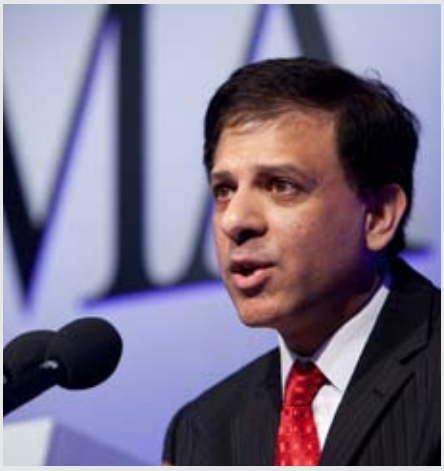
"The bottom line is that those boroughs [with a shortfall over both consecutive years] won't be able to meet their targets," Close acknowledged. "We would have liked everyone to have had the money they needed to meet the target straightaway, but that would have meant a significant increase in the quantum of around £1.2bn more."

Concerns have been voiced that cash strapped councils might interpret public health loosely so as to maintain other services. But a health department spokeswoman said that they would need to prove they had used the money to improve the health of the local population.

"The kind of services we would expect to see would include smoking cessation, drug and alcohol misuse services, and sexual health services," she said.

A spokesman for the Local Government Association, which represents local authority interests, told the *BMJ* that the two year settlement gave councils some stability and that the health department would revisit cases of shortfalls.

Cite this as: *BMJ* 2013;346:f234



Dr Chaand Nagpaul said that there was a risk of CCGs chasing targets to reclaim the money

CQC says 26 health providers are not employing enough staff

Nigel Hawkes LONDON

The Care Quality Commission has warned 17 NHS hospitals in England, eight mental health trusts, and the London Ambulance Service that they are failing to employ enough staff to operate safely.

The warnings were issued after CQC inspections, but the names of the organisations were not made public until Labour's shadow health secretary, Andy Burnham, asked the CQC for them.

In its *State of Healthcare* report, published last November, the CQC said that of 250 inspections it had made of hospital services 40 (16%) had shown a failure to meet a staffing level sufficient to provide a good service.[1] But this report covered the period up to March 2012, while the lower numbers released by Burnham included only those that were recorded as being non-compliant with staffing levels on 9 January 2013.

A spokesman for the CQC said that non-compliance with staffing standards did not necessarily mean that not enough staff members were employed, because "staffing" covered issues such as training as well as numbers. It had provided the information on request, as was its duty.

The health secretary, Jeremy Hunt, called for swift action. "There can be no excuse for not providing appropriate staff levels when across the NHS generally there are now more clinical staff working than there were in May 2010—including nearly 5000 more doctors and almost 900 extra midwives," he told the *Telegraph*.[2]

Some of the named hospitals have taken issue with the report.

Cite this as: *BMJ* 2013;346:f284

Decision to dissolve troubled London trust provokes anger

Adrian O'Dowd LONDON

Final proposals for a London NHS trust with large debts to be dissolved and its services allocated elsewhere have prompted strong opposition from local doctors and other healthcare staff from a neighbouring trust.

The final report on the South London Healthcare NHS Trust by the government appointed trust special administrator was published on 8 January,[1] setting out its proposals on how to deal with the trust, which has a deficit of more than £1m a week and a predicted accumulated deficit of £207m (€254m; $332m) by the end of the current financial year.

The controversial proposals for the trust, which encompasses Queen Mary's Hospital in Sidcup, Princess Royal University Hospital near Orpington, and Queen Elizabeth Hospital in Woolwich, say that the trust does not have a viable future and should be dissolved, with services being broken up.

The new report was drawn up by Matthew Kershaw, the trust special administrator, and a team of senior doctors, nurses, and health experts and advisers.

Kershaw was appointed last July by the then health secretary, Andrew Lansley, under the regime for unsustainable NHS providers, the first time this power has been used since its introduction in 2009. The new report confirms recommendations made in a draft report published in October last year.[2]

One key recommendation is that Queen Elizabeth Hospital in Woolwich form a joint trust with nearby Lewisham Healthcare NHS Trust. The new organisation would have a single emergency department in Woolwich rather than Lewisham, while Lewisham's recently refurbished emergency department would be turned into an urgent care centre.

Clinicians and patients of the Lewisham trust have reacted strongly to the proposal, saying that it was unfair and dangerous to close the emergency department as well as maternity services.

Jos Bell, a spokeswoman for the Save Lewisham Hospital campaign, told the *BMJ*, "Lewisham Hospital is one of the top 40 hospitals, and £12m has just been spent on a revamped A&E [accident and emergency] department there, which only opened last May, and now they want to close it."

John O'Donohue, a consultant physician at Lewisham Hospital, told the *BMJ*, "We are dismayed at the fact that the administrator has chosen to penalise a solvent and successful trust which is completely separate. We are in surplus and are meeting our targets and in the top 40 hospital rankings. We find this extraordinary."

Since 2010, four tests have had to be applied to NHS service changes, and in preparing the report the trust special administrator applied these tests, one of which is that the changes have support from GP commissioners.

GP commissioners in local clinical commissioning groups (CCGs) were involved in the development of the report's recommendations, and support from GP commissioners for the recommendations was sought through a consultation.

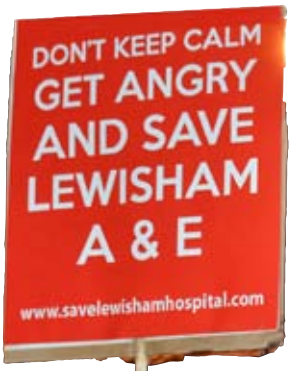
In response, Lewisham CCG raised a number of concerns, mainly about a possible detrimental effect on local residents of the proposed service changes at Lewisham Hospital. However, the other five CCGs in southeast London were more supportive of the proposals, arguing that they were the right solution for securing high quality services for their populations.

O'Donohue said that the tests had not been met, adding, "Unfortunately there is an element here of divide and rule. People know that if one A&E department is slated for closure, and it's not theirs, they will breathe a sigh of relief.

"As for the whole benefit of the Health and Social Care Act in terms of putting GPs in the forefront of the commissioning process, what does that mean if the government accepts a report that has a regional bureaucrat deciding what's best for the local health economy instead of the local economy itself?"

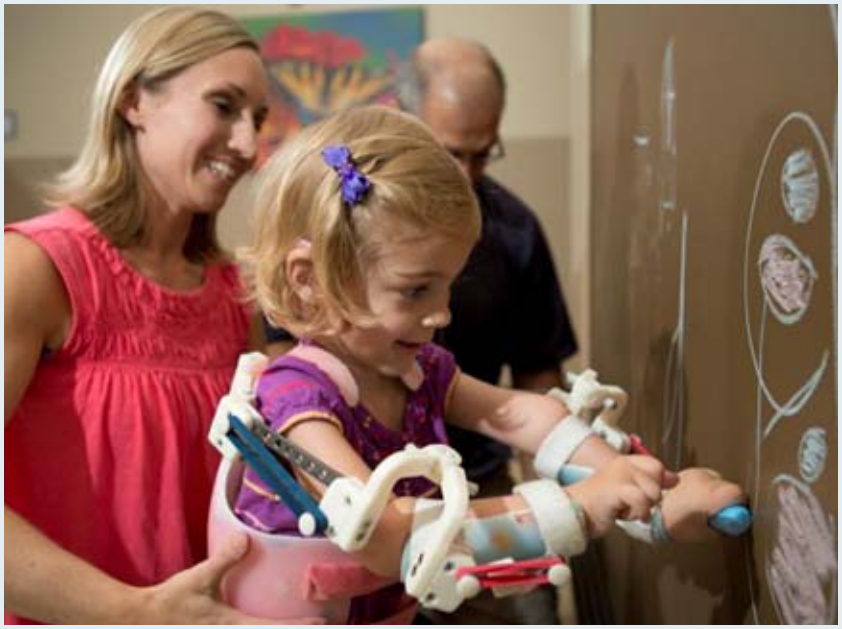
Publishing the report, Kershaw said that his final recommendations had taken on board many comments and opinions gathered during a six week consultation.

Cite this as: *BMJ* 2013;346:f189



A resident protests outside the BBC in January

SEE LI/DEMOTIX/CORBIS



CINDY BRODOWAY

"Magic arms" nominated for design prize for 2013

Annabel Ferriman BMJ

Emma Lavelle, aged 2, who has arthrogryposis multiplex congenita, has had her life transformed by a lightweight exoskeleton with tiny lightweight parts, designed by scientists and engineers at the Alfred I duPont Hospital for Children in Wilmington, Delaware.

The plastic jacket and its parts are called the WREX (Wilmington robotic exoskeleton), but Emma, pictured with her mother Megan, calls them her "magic arms." The WREX gives children with musculoskeletal disabilities much better movement and the ability to lift objects.

It is one of the products that have been nominated for the Design Museum's Designs of the Year awards 2013, which will go on show at the museum in London from 20 March to 7 July. **For more information on the Designs of the Year see http://bit.ly/ZPBZbW.**

Cite this as: *BMJ* 2013;346:f291

Australian MPs demand more data on dabigatran

David Brill SYDNEY

Australia is standing firm on its refusal to fund the high profile new anticoagulant dabigatran (marketed as Pradaxa) for preventing strokes in people with atrial fibrillation.

A long anticipated report from the Department of Health and Ageing, published last month,[1] urged the federal government to again postpone a decision on whether taxpayers should fund the new generation anticoagulants until further data were available.

The government followed this recommendation, defying considerable pressure from the public and the drug's manufacturer, Boehringer Ingelheim, in a saga spanning almost two years.

The government has asked the company to gather more data, redo its economic analyses, and restate its case to a March meeting of the Pharmaceutical Benefits Advisory Committee, the expert group advising the health minister, Tanya Plibersek, on which drugs to subsidise.

Plibersek said that dabigatran had been used differently in the real world than in clinical trials and that its net benefit and cost effectiveness in clinical practice remained uncertain.

"We make no apology for thoroughly assessing the effectiveness and cost effectiveness of new drugs, balancing access to new medicines while also protecting public safety," she said.

The story of Dabigatran has taken several unusual twists since the Pharmaceutical Benefits Advisory Committee originally recommended it for public funding back in March 2011. A positive verdict on a drug by the committee usually ensures its smooth passage into the national Pharmaceutical Benefits Scheme, but dabigatran became politicised when the then health minister, Nicola Roxon, stalled its progress. Although the committee had found that the drug would prove cost effective, the initial outlay was huge: Roxon said that it was predicted to cost more than $A1bn (£0.7bn; €0.8bn; $1.1bn) over four years.

The drug was left in limbo for a time, until the government commissioned a comprehensive review of anticoagulation in atrial fibrillation. This took another 15 months.

Meanwhile, matters are complicated by the fact that 24 000 Australians are already receiving the drug free from Boehringer Ingelheim under a "product familiarisation" scheme, thought to be the country's largest ever.

The programme, which was launched shortly after the committee's positive verdict, is fully permitted under Medicines Australia's code of conduct but has divided the medical community.

Many of the anticoagulation review's 64 submissions called for dabigatran to be funded, including several from patients in the familiarisation programme.

Savithri Rao, a GP in Sydney, said that her four patients who were taking dabigatran had tolerated it well and found it easy to take, with minimal side effects. "Patients are very happy with it," she told the *BMJ*.

Others, however, have strongly criticised the programme. The Royal Australian College of General Practitioners, for example, has questioned whether companies should be allowed to roll out new drugs in general practice, where infrastructure is often lacking to systematically monitor patient safety.

There have been anecdotal reports of emergency departments being unsure how to handle bleeding in patients who are taking dabigatran. The Therapeutic Goods Administration issued two "safety advisories" in late 2011 urging caution over the risk of bleeding and advising close monitoring of renal function.

Controversy was further fuelled by a campaign launched by Boehringer Ingelheim urging Australians to sign an online petition to "demand 21st century stroke prevention." This drew over 1000 signatures but was later deemed to breach Medicines Australia's code on advertising drugs to the general public, landing the company a $A125 000 fine.

With so much attention on dabigatran, and with the rivals rivaroxaban (Xarelto) and apixaban (Eliquis) now making forays into Australia, the anticoagulation review surprised many by shifting the emphasis back on to the old, off-patent warfarin.

The 153 page final anticoagulation report made sweeping recommendations to improve warfarin use for the estimated 240 000 to 400 000 Australians with atrial fibrillation, including new national guidelines.

bmj.com Observations: From rags to riches: the atrial fibrillation story (*BMJ* 2012;344:e3871); Editorial: Cost of dabigatran for atrial fibrillation (*BMJ* 2011;343:d6980); Research: Dabigatran etexilate versus warfarin in management of non-valvular atrial fibrillation in UK context (*BMJ* 2011;343:d6333).

Cite this as: *BMJ* 2013;346:f303