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Institute of Medicine outlines research plan on US gun violence

NHS hospitals fear that GPs will invite tenders to avoid legal challenges

Adrian O'Dowd LONDON

NHS hospital trust managers are worried that GP commissioners may decide to open up some commissioned services to competitive tendering because they fear challenges from private providers, MPs have been told.

MPs on the parliamentary health select committee held an evidence session on 11 June as part of their inquiry into implementation of the changes to the NHS brought by the Health and Social Care Act 2012 and asked about the act's controversial section 75 regulations. These regulations govern competition when GPs are commissioning health services and were the cause of concern earlier this year that they would open up all NHS services to market competition and bring possible legal challenges to clinical commissioning groups from the private sector.¹

MPs asked about the regulations and whether the witnesses believed that there had been any major changes as a result of them.

Matt Tee, chief operating officer for the NHS Confederation, which represents NHS and private healthcare provider organisations, giving evidence, said, "Our private sector members are not generally of the view that the world has changed as a result of the section 75 regulations.

"They are loath to go to law over this. They would much rather that these things were resolved without going to law. To do that costs them a lot of money."

Views of the confederation's NHS members were different, however, as he said, "There are two things that concern our NHS members, and they are both about uncertainty.

"One is they are unsure how the regime will work going forward. Where that leads us to is examples, at least anecdotally, where . . . the commissioners are worried that they may get in trouble if they do not put services out to competition. The second place of uncertainty is people are uncertain about what the competition policy intent is of the government."

David Bennett, chairman and chief executive of the health regulator Monitor, also giving evidence, argued that the new regulations represented no change from those that had governed primary care trusts.

Cite this as: *BMJ* 2013;346:f3818



JUICE IMAGES/ALAMY

Outcome data on nine more types of surgery in England will be published from July

Surgeons' performance data to be available from next month

Krishna Chinthapalli BMJ

Data on performance of individual surgeons in nine specialties will be published in England from July, the Royal College of Surgeons announced on 10 June.

Norman Williams, the college's president and a colorectal surgeon, said at a press conference, "We really do see this as a watershed moment for the profession, and it is all about transparency. I think it is most appropriate, particularly after the Francis report [on failings at Mid Staffordshire NHS Foundation Trust] . . . and what we want to do is drive up standards to get everybody up to a really excellent standard."

The move comes after NHS England's commitment to publish outcomes for individual surgeons in December 2012.¹ For the first time, publication of data will cover all NHS operations of named consultant surgeons in bariatric surgery, colorectal surgery, head and neck surgery, orthopaedic surgery, thyroid and endocrine surgery, upper

gastrointestinal surgery, urological surgery, and vascular surgery. Cardiac surgeons have been reporting outcomes for named consultants since 2005.² One non-surgical specialty, interventional cardiology, will also publish individual performance data from July.

The data will be collected from existing national audits overseen by specialty societies, the Royal College of Surgeons, and the charity the Healthcare Quality Improvement Partnership. After adjustment for risk, the information will be published on the NHS Choices website.

The methodologist for many of the audits, David Cromwell, said, "You'll probably get a set of figures indicating the surgeon, the number of operations they've performed, and some measure of outcome. In most cases it will probably be the proportion who died after surgery."

If a surgeon were performing above the upper limit of random variation for complications, Cromwell said that the first step would be to allow the surgeon

to check the data for errors. He added, "Once they've done that we would reanalyse the data. Only then, if they fell outside the limit continually, there will probably be a question to ask and we'd have to go in and look at more processes."

Williams noted that standards had risen in cardiac surgery since publication of outcome data.

He acknowledged that there had been pressure to publish data on outcomes from organisations such as the *BMJ*.^{3,4} He said, "I remember reading an editorial saying why is it that cardiac surgeons are the only ones presenting [individual data]. We're actually answering [the *BMJ*'s] call. We're trying to widen it. We say to the rest of the profession, 'It's about time you did as well.' We're happy to lead, but I think GPs, diabetologists, geriatricians, psychiatrists should be stepping up to the plate as well."

Cite this as: *BMJ* 2013;346:f3795

bmj.com Poll: Will access to individual surgeons' performance data improve patient care?

IN BRIEF

MMR uptake in Wales reaches record level:

Uptake of the first dose of measles, mumps, and rubella vaccine in Welsh children who reached their 2nd birthday in the first quarter of 2013 passed the 95% target for the first time, up from about 77% in 2003.¹ The proportion of 2 year olds who got the second dose of the vaccine was 90%. The number of cases of measles in Wales in the current outbreak, which is mainly affecting young people aged 10-18 years, has reached 1171.

Retailer is questioned about krill oil supplements:

The chairman of the House of Commons Science and Technology Committee, Andrew Miller, has written to Peter Aldis, chief executive of the health products retailer Holland and Barrett, to ask whether the krill oil supplements it sells in its shops come from sustainable sources and whether this information is clearly labelled on the products. The committee has recently taken evidence on the marine protected areas in the Southern Ocean.

BMA takes messages about NHS changes into GP surgeries:

The BMA has launched a poster campaign in GP surgeries in England to explain to patients how the NHS is changing and what this means for them. A new web portal (changingnhs.com) sets out the key changes, including competition and patient choice, NHS funding, the GP contract, and out of hours services. It also offers doctors' views and explains how patients can have their say.

Scotland spends more on private sector care:

NHS Scotland saw spending on independent care rise by 60% in the past year, Scotland's health secretary, Alex Neil, has said. The rise is partly a result of 20% undercapacity at the new Edinburgh Royal Infirmary because planners underestimated the rise in the population. Neil said that spending on independent sector care was only 0.5% of NHS Scotland's budget.

People taking HIV tests must use real names, Guangxi region says:

One of China's regions most affected by HIV has passed a regulation stipulating that people being tested for HIV must use their real names. The Guangxi authorities say that this will help with follow-up and making HIV policies, but AIDS activists say that it will deter people from getting tested. (See BMJ Group blog by Jane Parry at <http://bit.ly/11TrPag>.)

Cite this as: *BMJ* 2013;346:f3746

Proposal for GPs to take back responsibility for some out of hours care sparks debate

Ingrid Torjesen LONDON

A row has erupted over a suggestion by the Royal College of General Practitioners that GPs in England could potentially take back responsibility for providing out of hours primary care services for some of their patients.

The row stems from an article published in the *Guardian* newspaper on 4 June, in which the college's chairwoman, Clare Gerada, was reported as saying that GPs could take back responsibility for the out of hours care of patients who were heavy users of NHS services.¹ These would include frail, elderly people; people at the end of their lives; people with complex medical problems; and people with certain mental health problems. Together they would equate to about 5% of the total population or roughly three million people.

Instead of these patients seeking help through existing urgent care services or turning up at hospital emergency departments in difficulties, the proposal was that they would receive more personalised care tailored to their needs from new multidisciplinary teams led by GPs.

The article claimed that the college had met Department of Health officials to discuss the idea. But in a statement the college denied this. "The RCGP is not proposing that GPs take back responsibility for providing round the clock care and has not held any meetings with the Department of Health to discuss this," it said.

However, a spokeswoman for the Department of Health confirmed that a meeting had taken place between the college and the health sec-

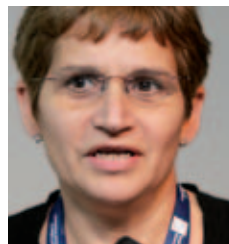
retary, at which the idea of GPs being involved with the out of hours care of some patients was raised, but she emphasised that the meeting was a wide ranging one and did not just dwell on out of hours care.

A college spokeswoman explained that the idea was one of a number of suggestions for improving the care of patients that appear in a college document, *The 2022 GP: A Vision for General Practice in the Future NHS*, that is due to be published shortly. "Every solution we have come up with is predicated on the basis that we get major investment and support for general practice," she said. "We are calling for at least 10 000 more GPs—we are asking for huge investment in money for general practice before any of this could be considered."

In its statement the college said, "[The 2022 GP document] suggests ways of improving out of hours care by reshaping services to deliver better care and better coordination of care for patients. One of the ways of achieving this is by involving a range of professions—medical, nursing, pharmacy, and social care. Working together across federations of practices would also lead to better out of hours responsiveness and allow us to develop different models that are able to address the needs of different populations of patients, such as the frail elderly."

Richard Vautrey, deputy chairman of the BMA's General Practitioners Committee and RCGP member, said that practices working in federations to improve out of hours care was a viable option.

Cite this as: *BMJ* 2013;346:f3712



Clare Gerada: GPs should have responsibility for heavy users of NHS

Screening has not reduced deaths from breast cancer, study shows

Jacqui Wise LONDON

Mammographic screening has not had any effect, so far, on breast cancer mortality at the population level in England, a new analysis concludes.

Researchers from the Department of Public Health at Oxford University analysed mortality data before and after the breast cancer screening programme was introduced in 1988.¹ The research was based on data from the Oxford region between 1979 and 2009 because, unlike the rest of England, in this region all causes of

death and not just the underlying cause are included on death certificates. The researchers also looked at mortality data for the whole of England between 1971 and 2009.

The researchers found that breast cancer death rates peaked in 1985 and then started to fall before the screening programme was introduced. They found no evidence that declines in mortality were consistently greater in women in age groups that had been screened than in those that had been unscreened in the same time period.

Hospitals miss chances to cut alcohol related deaths

Susan Mayor LONDON

A third of people admitted to hospitals in England, Wales, and Northern Ireland with known alcohol related liver disease are not referred for support to stop drinking as part of their care, warns a new report from the National Confidential Enquiry into Patient Outcome and Death (NCEPOD).¹ It recommends that all patients with a history of potentially harmful drinking be referred to alcohol support services.

"Many people with alcohol related liver disease have multiple admissions with this condition," said Mark Juniper, consultant physician at the Great Western Hospitals NHS Foundation Trust, Swindon, and clinical coordinator for the report. "This gives clinicians an ideal opportunity

to offer appropriate treatment and advice to patients to help them stop drinking. Unfortunately, this isn't happening."

For the report a multidisciplinary group of clinical advisers reviewed case notes of 385 patients who died in hospital with a diagnosis of alcohol related liver disease in the six months from 1 January to 30 June 2011. These represented samples of three patients from each of the 218 hospitals taking part in the study. The advisers also analysed questionnaires on clinical and organisational information concerning 512 patients against criteria that they considered represented good care.

The NCEPOD advisers found that less than half of

patients (172/363 (47%)) received what they judged to be good care and identified 32 deaths that might have been avoided.

"This was a study of missed opportunities," they said.

Most of the patients had been to hospital at least once in the two years before the admission during which they had died. But many patients had not been screened adequately for harmful use of alcohol. Even when harmful drinking was identified, more than a third of these patients (47/138) were not referred for support to stop drinking.

Juniper said, "We know that abstinence works and that when simple advice is offered to patients one in eight will reduce their harmful drinking levels."

Cite this as: *BMJ* 2013;346:f3781



Most patients who died of alcohol related liver disease had been to hospital at least once in the preceding two years

LYNN HILTON/LAMY

Potential harms of type 2 diabetes drugs have been ignored, finds *BMJ* probe

Zosia Kmiotowicz BMJ

Drug regulators and manufacturers have been criticised for failing to take enough action in response to research highlighting the potential serious adverse effects of new forms of drugs used to treat type 2 diabetes, known as glucagon-like peptide-1 (GLP-1) based drugs.

A joint investigation by the *BMJ* and Channel 4's *Dispatches* current affairs programme has found that concerns about the drugs, also called

incretin therapies, started to emerge in 2007.¹ Since then many reports, regulatory documents, and adverse event databases have highlighted concerns about the safety of these drugs and linked them with an increased risk of pancreatitis, pancreatic cancer, and thyroid cancer.

But a number of drug manufacturers failed to perform certain safety trials, delayed some studies, and did not publish their findings, the investigation found. It also criticises drug regu-

lators in Europe and the United States for their slow response to the concerns.

However, some scientists and manufacturers have defended their actions and the drugs' safety, arguing that the published evidence against the drugs was weak.

Others have called for all the study data to be made public for independent analysis.

● INVESTIGATION, pp 16-21; EDITORIALS, pp 7, 8

Cite this as: *BMJ* 2013;346:f3782



AP PHOTO/SPL

Other research shows that screening has reduced deaths, said Stephen Duffy of Cancer Research UK

The lead researcher, Toqir Mukhtar, concluded, "The findings do not rule out a benefit at the level of individual women, but the effects are not large enough to be detected at the population level."

The value of screening for breast cancer has been the subject of much debate in recent years. In 2012 a Swedish study found that mammography had little or no effect on breast cancer deaths.² And a recent Cochrane review found no effect of screening on total cancer mortality, including breast cancer, after 10 years.³

But in October 2012 an expert panel headed by Michael Marmot, professor of epidemiology and public health at University College London, concluded that there was a 20% relative reduction in mortality from breast cancer in women invited for screening.⁴ However, the panel also found that UK women invited to attend screening for breast cancer were three times as likely to be treated for a cancer that would never have harmed them as to have their lives saved.⁵

Stephen Duffy, professor of cancer screening for Cancer Research UK, said, "This study only looks at trends which overemphasise the peaks and troughs of death rates in a single year, rather than concentrating on the average death rate over several years. Other research shows that the average number of deaths from breast cancer since 1995 have dropped more in women who were screened [than in] those who weren't."

The authors of the new study commented that the clinical trials that informed the Marmot report were all conducted at least two decades ago and that the effect of screening on mortality needed to be considered in light of improvements in treatment and technological advances made in mammographic screening over the past 20 years.

Cite this as: *BMJ* 2013;346:f3780

GPs have been unfairly attacked over A&Es, says outgoing NHS chief

Adrian O'Dowd LONDON

GPs have been unfairly attacked by politicians and the media, the outgoing chief executive of the NHS in England has told managers.

David Nicholson, who recently announced that he would retire in March 2014,¹ told an audience of NHS managers that he had been “incensed” about recent attacks on GPs and accusations—including from the health secretary, Jeremy Hunt—that changes to their out of hours work in the 2004 GP contract had resulted in recent pressure on emergency departments.²

Nicholson spoke at the NHS Confederation's annual conference in Liverpool on 6 June, in which he openly criticised politicians of all parties and talked about the “tyranny of the electoral cycle,” which dictated how willing a government was to back change in the NHS. He argued that there were regular attacks on some parts of the health service and its staff, saying, “I was particularly incensed about some of the coverage in relation to general practice.”

General practice was in many ways the “distinctive characteristic” of the NHS, he said, adding, “In lots of ways the money has run out, there is no more growth in the system, and we are having one of the biggest reorganisations ever in the history of the NHS. The pressure is on, and yet hundreds of GPs said that we will take a leadership position in the NHS, [that] we are prepared to make that commitment to taking the NHS through some of its most difficult days.”

Nicholson said that the NHS had much to be proud of and that this had been reflected in the opening ceremony of last year's London Olympic Games. He said, “One of the things about the Olympics was the opening ceremony and the way in which the NHS played its role in there. There was a swell of feeling about the NHS. We all felt good about it.”

In his position as chief executive for almost eight years Nicholson had observed that in the run up to a general election political parties tended to avoid making or suggesting any



JASON ALDEN/BLOOMBERG/GETTY

changes to the NHS, such as closing or reconfiguring hospitals, but that there then followed a period of change, and then stability again before the next election.

“The difference last time was that, during the 2010 general election period, political parties went around the country making promises of no change,” he said. “We said at the time it was not the right thing to do. What happened when we got a new government was we wasted those two

Advice to pregnant women is criticised as alarmist

Jacqui Wise LONDON

A report by the Royal College of Obstetrics and Gynaecology that advises pregnant women to avoid exposure to synthetic chemicals in a range of household products has been criticised for causing unnecessary stress and adding nothing to the debate.¹

The scientific impact paper, from the college's scientific advisory committee, said that pregnant women were exposed to hundreds of such chemicals at a low level and that this exposure could operate additively or interactively.

Although it concluded that on the present evidence it was impossible to assess the risk—if any—from this exposure, it said that women should adopt a “safety first” approach and assume that a risk was present even when it may be minimal or eventually shown to be unfounded.

It said that women should eat fresh rather than processed food whenever possible and to reduce consumption of food in cans and plastic containers, because they may contain chemicals such as bisphenol A and phthalates.

It also said that women should minimise the

use of personal care products such as moisturisers, cosmetics, shower gels, and fragrances. It recommended that women avoid buying newly produced household furniture, fabrics, non-stick frying pans, and cars while pregnant or breast feeding.

It also said that women should avoid paint fumes and the use of garden and household pesticides and should take drugs bought over the counter only when necessary. It also pointed out that labelling products as herbal or natural did not necessarily indicate that they were safe for use during pregnancy.

The report said that there was no official advice or guidelines on the potential risks of chemical exposure for pregnant or breast-feeding women and that women were often faced with scare stories about chemicals in the media that were inaccurate or exaggerated. The document's stated purpose was to raise awareness of the issue of exposure to chemicals and allow women to make an informed decision.

However, the report, which received much media publicity, has been widely criticised

for being unhelpful and alarmist. David Spiegelhalter, professor of the public understanding of risk at Cambridge University, said, “These precautionary ‘better safe than sorry’ recommendations are not necessarily cost free. They may feed anxiety and detract attention

from the known harms of bad diet, smoking, and excessive alcohol. And it is unclear how any benefits can ever be assessed.”

The report acknowledged that the epidemiological research linking exposure to chemicals to adverse health effects showed associations and did not imply causality. It also pointed out that levels of exposure to chemicals in animal studies were high, so extrapolation of their results to humans was inappropriate.

The Royal College of Midwives' professional policy adviser, Janet Fyle, said, “Pregnant women must take this [the new report's] advice with caution and use their common sense and judgment and not be unnecessarily alarmed about using personal care products, such as moisturisers, cosmetics, and shower gels.”

Cite this as: *BMJ* 2013;346:f3695



EDWARD BOCK/CORBIS

The report advises against the use of non-stick pans



The Olympics opening ceremony showed that people feel good about the NHS, said Nicholson

years where you can really make change happen. We spent our time talking about reorganisation and changes and the rest of it, and we didn't talk about the really important changes that are required for the NHS. We cannot allow the tyranny of the electoral cycle to stop us from making the real and fundamental changes that we need to make to the NHS."

Nicholson told the audience there was much to do over the coming months, adding, "Politicians will never run around saying to close hospitals, do this, do that—they will never do any of that. It is our job, our job as leaders in the NHS, to make the arguments with our patients."

Cite this as: *BMJ* 2013;346:f3739

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None of expected benefits of Labour's IT scheme have been achieved, report says

Michael Cross LONDON

The spectre of the last government's £10bn effort to computerise the NHS in England arose this week over the Department of Health's ambition to create a "paperless" service.

In a memorandum to parliament the National Audit Office (NAO) reported that virtually none of the expected benefits of the National Programme for IT, set up in 2002 and dismantled into component parts in 2011, had been achieved.¹

As at March 2012 its total costs "were significantly greater than total benefits," the memorandum says. "For a number of programmes, 98% of estimated benefits are yet to be realised."

The components with the fewest benefits realised include the Electronic Prescription Service

and the Summary Care Record, which have yet to realise 98%. On the other hand, the national implementation of digital clinical imaging, the Picture Archive and Communications Service, has achieved 84% of its expected benefits.

The NAO said that the transfer of responsibility for projects from a central team to individual NHS trusts from April this year might put at risk the further realisation of benefits.

The reminder of the elusive nature of paybacks from information technology has not deterred the health department from its current digital ambitions.

On the day of the publication of the memorandum last week, Tim Kelsey, national director for patients and information at NHS England, told the NHS Confederation's annual

conference that a key element of computerisation, the 10 digit NHS patient identifying number, would become mandatory in April 2014 as a contractual obligation for service providers.

Although the number has featured in successive NHS IT strategies since 1992, many trusts still use local identifiers in parts of their work.

Compulsory use of the number was "one key step on the road to the full implementation of safe, digital record keeping in the NHS," Kelsey said.

Meanwhile, the health department has begun the process of picking suppliers of general practice computer systems for a national contract, expected to be worth between £325m (£380m; \$500m) and £1.2bn over two years.

Cite this as: *BMJ* 2013;346:f3759

Maps of premature deaths will help tackle variation, say public health chiefs

Ingrid Torjesen LONDON

Wide variation between local authority areas in England in numbers of avoidable premature deaths, independent of levels of social deprivation, has been shown by a new website launched by Public Health England this week.

The Longer Lives website (longerlives.phe.org.uk) uses data from the government's Public Health Outcomes Framework to map the overall rate of premature death in local authorities across England and also gives specific rates for the four major causes of premature death: cancer, heart disease and stroke, lung disease, and liver disease. These four conditions are responsible for 75% of the 153 000 premature deaths that occur each year in England.

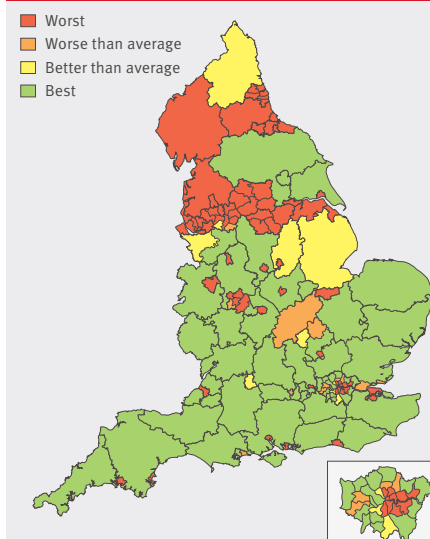
John Newton, chief knowledge officer at Public Health England, said that around 103 000 of these deaths were avoidable because the conditions could have been either better treated or prevented by reducing risk factors such as obesity and alcohol consumption, and poor housing.

He said that differences in how these factors were tackled contributed to a twofold difference between the best and worst performing local authorities in the rate of premature death from all causes and from cancer, a threefold difference in the rate of premature death from heart disease, and a fourfold difference in the rate from lung and liver diseases.

The website highlights which local authorities with similar levels of deprivation are performing better.

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Premature mortality in England, 2011



Source: Public Health England



TERRY HARRIS/REX

Without £44.1m from the Department of Health the trust would have failed to pay staff

PFI is blamed for financial collapse of Peterborough and Stamford trust

Matthew Limb

A hospital trust that went ahead with a private finance initiative deal despite warnings over its affordability has been declared “financially unstable in its current form” by the health sector regulator, Monitor.

Peterborough and Stamford Hospitals NHS Foundation Trust, which had already faced criticism from MPs over its “catastrophic” private finance initiative (PFI), would fail to pay staff if it did not receive a lifeline from the Department of Health for England, Monitor said.

The trust had built up a deficit of £37m by the end of 2012-13 and needed one-off support from the health department of £44.1m, said a report from a contingency planning team that Monitor sent into the trust to protect the interests of local patients. The report said that the PFI deal was costing £40m a year and had 31 years left to run.¹

However, the team said that the trust’s overall quality of clinical care was “appropriate” and that a decision was yet to be taken about how services could be delivered on a “sustainable” basis.

The trust moved into a new site, the 616 bed

Peterborough City Hospital, in December 2010, which was funded through the PFI scheme. Since then the trust has consistently made losses and reported the “highest proportional deficit in the NHS in the financial year ended 31 March 2012.”

The House of Commons Public Accounts Committee said in January 2013 that the trust and health officials had not acted on repeated warnings about the PFI deal, which had proved “catastrophic” for the trust.

The committee said, “With inflation, the PFI is likely to represent a greater proportion of trust costs in future years. However, ending the arrangement would trigger a very substantial one-off payment.”

The hospital had been “underutilised,” said the contingency planning team’s report, and estates problems had contributed an estimated £22m to the trust’s deficit.

The trust’s forecasts for the next five years showed a continuing deficit of £38m or more each year and a cash shortfall of at least £40m a year.

Cite this as: *BMJ* 2013;346:f3735

German out of hours locum has conditions placed on his practice

Clare Dyer *BMJ*

A German GP who worked 13 hour shifts of up to 24 days in a row as an out of hours locum in southern England has had conditions imposed on his registration, after a finding that his fitness to practise was impaired because of misconduct and deficient professional performance.

Volker Bornmann attracted several complaints from patients who said that he wrongly diagnosed their illness or treated them dismissively during telephone triage or face to face consultations. The complaints led one of his employers, Hampshire Primary Care Trust, to open an investigation.

The Medical Practitioners Tribunal Service found Bornmann guilty of misconduct in two cases, holding that he “put patients at unwarranted risk of serious harm” through “deficiencies in consultation skills and serious gaps in medical knowledge.”

In a telephone triage in November 2010, he failed to consider the obvious diagnosis of pre-eclampsia in a pregnant woman with typical symptoms. The next day, in a face to face consultation with a 6 month old baby who had a two day history of vomiting and no bowel action, he failed to properly examine her, remove her from her car safety seat, or admit her to hospital. The panel also found that five other cases constituted a pattern of deficient professional performance.

Bornmann’s common practice of working double shifts of 13 hours did not constitute excessive hours under current guidance, the panel said, but his practice of working more than seven days without 24 hours off did.

The conditions mean that he must notify future employers of the finding against him and must agree to work under an appointed supervisor.

Cite this as: *BMJ* 2013;346:f3727

FDA officials disagree about the safety of ARBs

Mike McCarthy *SEATTLE*

Top officials at the US Food and Drug Administration and a senior safety reviewer have been quarreling over whether there is sufficient evidence to link angiotensin receptor blockers (ARBs) with an increased risk of lung cancer, the *Wall Street Journal* has reported.¹

Internal documents reviewed by the newspaper show that Thomas A Marciniak, medical team leader in cardiovascular and renal products at the FDA, has called on the agency to issue stronger warnings on the drugs, citing a review

he conducted that found a 24% increase in the risk of lung cancer in patients who take ARBs.

A meta-analysis of trials of ARBs published in *Lancet Oncology* in 2010 found a significant increase in new lung cancers in patients who received ARBs compared with patients in the control group (0.9% versus 0.7%; risk ratio 1.25 (95% confidence interval 1.05 to 1.49; $P=0.01$)) but no difference in cancer deaths (1.8% versus 1.6%; risk ratio 1.07 (0.97 to 1.18)).²

In response to concerns raised by the study, the FDA conducted a safety review of ARBs and

found that there was no raised risk of cancer.

But Marciniak reviewed the raw data and found that when compared with patients taking a placebo, patients taking an ARB had a 24% higher risk of lung cancer.

In a statement issued in response to the *Wall Street Journal* article the FDA said that it “respects and recognizes that scientific differences occur and we listen to all voices. The agency has procedures in place to manage internal disputes and we will follow those.”

Cite this as: *BMJ* 2013;346:f3730