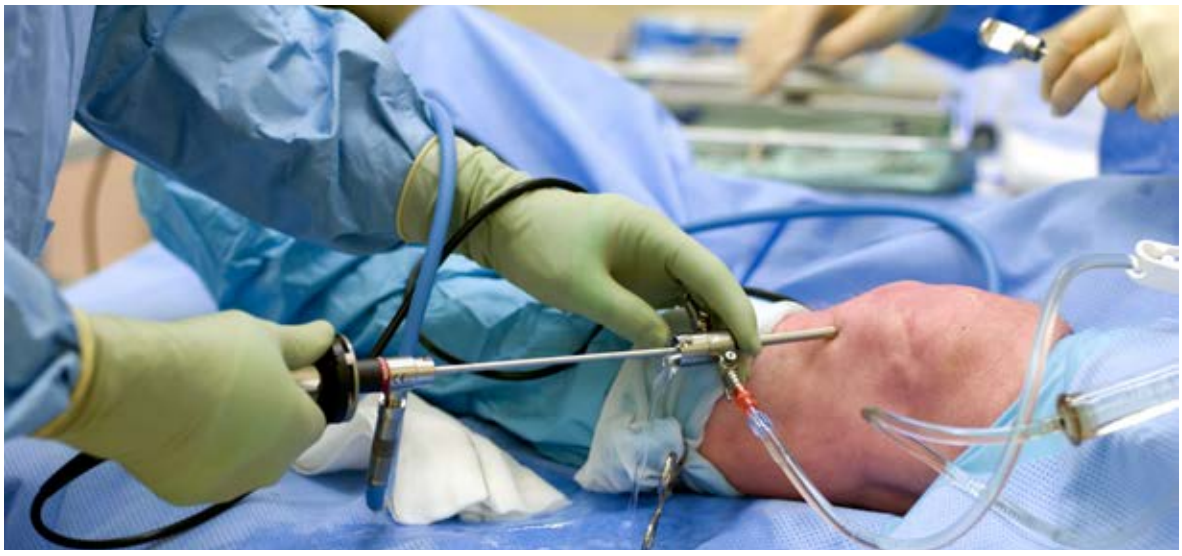
this week

TESTICULAR CANCER page 2 • **GP BOTS** page 3 • **STROKE PREVENTION** page 4



JIM VARNEY/SPL

Knee arthroscopy for patients with osteoarthritis is one of four procedures that NHS England wants to limit to exceptional circumstances

Seventeen procedures on NHS hit list

The NHS in England is proposing to cut funding for 17 procedures it considers unnecessary to save money and eliminate unwarranted clinical variation.

Under the plans four procedures will be funded only in exceptional circumstances, because of a lack of evidence for their effectiveness: injections for non-specific low back pain without sciatica; knee arthroscopy for patients with osteoarthritis; dilatation and curettage for heavy menstrual bleeding in women; and surgery for snoring.

A further 13 procedures, including breast reduction, varicose vein surgery, removal of benign skin lesions, and tonsillectomy, will be performed on the NHS only when specific clinical criteria are met.

The 17 routine procedures are carried out about 350 000 times a year in total and cost more than £400m a year. The NHS is aiming for what it termed a "moderate" reduction of around 170 000 procedures a year, which would save £200m. NHS England said the policy would also reduce avoidable harm and follow best clinical evidence, including NICE guidelines, recommendations of the Academy of Medical Royal Colleges' Choosing Wisely initiative, academic studies, and local clinical commissioning groups' work on procedures of limited clinical effectiveness, collated by NHS Clinical Commissioners.

Stephen Powis, NHS England's national medical director, told the *Times*, "We have to spend taxpayers' money wisely. If we are spending money on procedures that are not effective, that is money we could spend on new treatments that are clinically effective and would provide benefits to patients."

Although several CCGs across England already restrict access to these procedures, NHS England said it wanted to achieve consistency across the country as quickly as possible and have a "significant impact" by the end of 2019-20.

A 12 week consultation on the plans will close on 28 September.

The BMA's chair of council, Chaand Nagpaul, said, "Doctors welcomed news of a long term funding settlement for the NHS, but this latest development will seem a tough pill to swallow. While it's correct some surgical procedures are now shown to be clinically ineffective, the prime minister's investment should allow patients to get the care they expect from the NHS and allow doctors to provide the care they need, not ration it."

Gareth Iacobucci, *The BMJ*

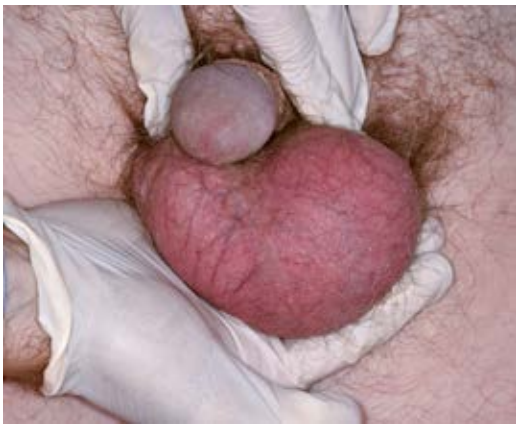
Cite this as: *BMJ* 2018;362:k2903

LATEST ONLINE

- Medical students need better mental health support from universities, says BMA
- NHS must make urgent plans for no-deal Brexit, MPs hear
- Non-invasive prenatal testing: public and doctors should be consulted, says BMA

SEVEN DAYS IN

Testicular cancer: study identi es extra symptoms for urgent referral



SPL

Contrary to traditional teaching, painful enlargement is a strong predictor of testicular cancer, a general practice study has shown. The research, published in the *British Journal of General Practice*, found that testicular enlargement—a lump or swelling—was the biggest risk factor.

University of Exeter Medical School researchers compared patient records of 1398 men who had testicular cancer with 4956 matched controls to determine which symptoms were associated with a higher risk. More than two thirds (67%) of the case group had consulted their GP in the year before diagnosis with at least one of nine features that were independently associated with the cancer. The three most common were testicular swelling, lump, and scrotal swelling. Others were hydrocele, orchitis/epididymitis, abdominal pain, raised inflammatory markers, and groin and testicular pain.

The authors say their findings suggest that recurrent testicular pain, unresolving epididymo-orchitis, or hydrocele should be added to the NICE guidance recommendation of urgent specialist referral.

Jacqui Wise, London Cite this as: *BMJ* 2018;362:k2900

Obstetrics

Anti-abortion bill is mooted in Poland

Poland is considering draft legislation to ban abortion in cases of severe fetal anomaly. The country already has one of Europe's most restrictive abortion laws, which is legal only to safeguard the life and health of women, in situations of severe fetal anomaly, or where the pregnancy results from sexual assault. If the bill is passed abortion care will not be available to women with a diagnosis of a severe fetal anomaly.

Plain packaging

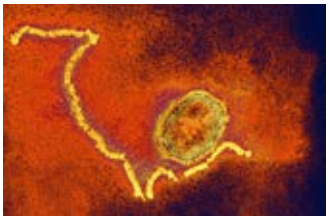
Latest legal challenge is rejected on evidence

The World Trade Organization rejected complaints by Cuba, the Dominican Republic, Honduras, and Indonesia that introducing plain packaging for tobacco products in Australia violated international trade. The organisation said the ruling was likely to accelerate plain packaging implementation around the world. Deborah Arnott, chief executive of the health charity Action on Smoking and Health, said, "The WTO said it was comforted by the strength of evidence, in particular from the UK, that plain packaging reduces the appeal of tobacco products."

Infectious disease

Huge spike in measles is seen in England

GPs in England were advised to be diligent against measles after a huge spike in cases this year. Public Health England reported 738 confirmed cases from 1 January to 2 July 2018, compared with 274 cases in the whole of 2017. It said that



the increase was linked to importations from Europe, which has had large outbreaks of the disease. Writing in the *British Journal of General Practice*, PHE experts emphasised the "vital role" of GPs in keeping measles under control.

Funding

Specific tax should fund social care, say MPs

People and employers should have to pay a specific contribution in the form of a new tax that would be used to fund adult social care, MPs on two influential committees concluded. A joint report published on 27 June by the parliamentary committees on health and social care and on housing, communities, and local government highlighted an estimated £2.5bn funding gap in the social care sector in the next financial year. Without significant change the recently announced extra resources for the NHS will be undermined, it warned.

Technology

Doctors "need training" in new technologies

Eric Topol, a digital medicine researcher reviewing how doctors should be prepared to work with new technologies, published an interim report saying that the profession would need training in areas such as "genomics or artificial intelligence algorithms and the ability to analyse and understand the implications of big datasets in the provision of future healthcare services, as well as a major increase in digital literacy." The government commissioned review calls for evidence from people with experience of introducing or developing technologies.

GP mobile app to be launched in England

Testing will begin in September of a new NHS mobile app for Apple and Android phones that will allow patients in England to book appointments, order repeat prescriptions, and see their medical notes. The app, which will be available from December, will also let patients sign up to be organ donors, decide how their health data are used, and use the NHS 111 service. The government responded to concerns from the Royal College of General Practitioners about security, saying that it would be at least on a par with banking.

Scientific misconduct

Seven researchers guilty in Macchiarini case

Seven researchers, including the now disgraced surgeon Paolo Macchiarini (below), are guilty of scientific misconduct, the president of the Karolinska Institute in Sweden ruled. Ole Petter Ottersen, who took office in 2017 with a mission to clean up the institute after a scandal over bioengineered implants damaged its reputation, asked for six articles to be retracted, including two published in the *Lancet*. Among the seven researchers was Karl-Henrik Grinnemo, who had alerted the institute to defects in the articles in 2014.

MEDICINE

New drugs

FDA approves cannabis based medicine

The US Food and Drug Administration approved its first prescription drug derived from marijuana, for treating two rare and severe forms of epilepsy. Epidiolex has been approved for treating seizures associated with Lennox-Gastaut syndrome or Dravet syndrome. These forms of epilepsy are frequently resistant to currently available treatments. The European Medicines Agency is also reviewing Epidiolex, and a decision is expected in 2019.

Sugar

Sales of sugary drinks on NHS premises fall

The proportion of drinks sold on NHS premises with added sugar has fallen from 15.6% to 8.7%, meeting a target set last year by Simon Stevens, NHS England chief executive, to reduce sales to below 10% of those bought in hospitals. Figures show that 10 million teaspoonfuls of sugar have been removed from canteens, shops, and vending machines—the equivalent of 1.1 million cans of drink, around 39 000 kg of sugar, and 160 million fewer calories.

Assisted dying

Campaigner vows to keep fighting

Noel Conway, 68, who has advanced motor neurone disease and wants a doctor to help him end his life, hopes to take his case to the UK Supreme Court after losing an appeal. He sought a court ruling that the ban on assisting suicide in England and Wales breached his right to respect for his private life under the European Convention on Human Rights. But the Court of Appeal agreed with a High Court ruling last October that the proposed scheme was inadequate to protect vulnerable people and could undermine trust between doctors and patients.

Pay

NHS pay should "link more closely to performance"

Pay structures in the NHS should be linked more closely to targets, said the Centre for Policy Studies, a right wing think tank. Its report said giving NHS trusts greater flexibility and linking pay more closely to performance could boost productivity and improve patient outcomes. It also recommended replacing clinical excellence awards for senior doctors with an annual bonus scheme available to all staff.

Research news

Multimorbidity package fails to improve life quality

The "3D approach" for managing patients with multiple chronic conditions does not improve health related quality of life, a randomised trial in the *Lancet* showed. The study compared disease focused reviews with a six monthly review focusing on health problems most bothering the patient, disease specific care, depression and dementia screening, and a drug review. Helen Stokes-Lampard, chair of the Royal College of General Practitioners, said she was surprised by the finding and called for more research.

Cite this as: *BMJ* 2018;362:k2908

CANNABIS

Legalisation in the UK could generate

£690m

a year in sales tax, plus £300m in income tax from employees in the sector and savings from the NHS and other public services

[Institute of Economic Affairs]

SIXTY SECONDS ON . . . GP CHATBOT

WHAT IS THIS?

Something that could solve the workforce crisis overnight, and allow GPs to retire pretty much immediately.

SORRY?

It's a smartphone symptoms checker—developed by Babylon, the company behind the virtual GP at Hand service—which uses artificial intelligence that is as good as, if not better than, GPs at identifying illnesses.

AND THAT IS BASED ON WHAT?

The ability to pass the Membership of the Royal College of GPs exam, apparently. A study found that the latest version of the app (not yet available) scores better than working doctors in diagnosing conditions featured in patient vignettes used in the exam.

THAT SOUNDS AMAZING, BUT WHICH JOURNAL WAS THAT PUBLISHED IN?

It doesn't appear to have been published in a peer reviewed journal—or any journal at all.

WHY NOT?

Because "the science is so poor, it's almost funny," says GP Helen Salisbury, from the University of Oxford. For a start, the study would not meet the conflict of interest policies of respected journals. Most of the researchers work for Babylon, and instead of using actors as patients the study used GPs—some of whom were also Babylon employees.

WHERE DID YOU READ IT THEN?

In a newspaper. A scientific paper was written up and distributed to journalists.

WHAT DOES THE RCGP SAY?

"An app might be able to pass an automated clinical knowledge test," but the answer to a clinical scenario "isn't always cut and dried."

SO, IS THE MRCGP EXAM NOT A GOOD TEST?

The app didn't actually take any part of the MRCGP exam. It was assessed on patient vignettes compiled for revision purposes, which, says Martin Marshall, vice chair of the RCGP, "are not necessarily representative of the full range of questions and standards used in the exam." As well as clinical knowledge, the MRCGP exam tests the ability to make evidence based decisions and to deliver person centred care through effective communication with patients and colleagues.

Ingrid Torjesen, London

Cite this as: *BMJ* 2018;362:k2897

Delegates vote to oppose Brexit "as a whole" and call for public final say

Doctors at the BMA's annual representative meeting have voted to oppose Brexit "as a whole" and called for the public to have a final say on the exit deal negotiated by the government.

The backing of all seven parts of the motion means a change in BMA policy on the European Union, as it has adopted a neutral stance until now. After a debate on 27 June some 76% of representatives voted to remain in the single market, and 91% supported free movement of healthcare workers and research staff.

William Sapwell, a junior doctor who proposed the motion, said that the NHS could not afford to lose any doctors from Europe "at a time when our workforce is stretched and rota gaps are prevalent."

Currently 7-10% of doctors working in the NHS are from the European Economic Area, and 40% of those have plans to leave "because of uncertainty about their immigration status and negative attitudes towards EU workers," he said.

Representatives also voted for the UK to remain a member of Euratom (the European Atomic Energy Community) to ensure the reliable supply of medical isotopes. Without a similar arrangement, said Sapwell, "radiotherapy and medical imaging services would be subject to the whim and chance of an unpredictable supply chain."

Major threat to health

The vote also supported early UK adoption of the European Clinical Trials Directive and called for the BMA to publicly announce its concern that Brexit poses a major threat to the NHS and the nation's health. BMA briefing documents show that the loss of reciprocal healthcare arrangements threaten to leave Britons abroad facing "crippling medical bills," said Sapwell.

He added, "The briefings also detail uncertainty in pandemic preparedness post-Brexit, uncertainty of the quality of the air we breathe, the food we eat, and the water we drink, and how our academic institutions are already suffering as a result of the vote. The government is woefully underprepared to ensure that the UK's health and wellbeing are secure in time for the self imposed deadline of 29 March 2019.

"The fundamentals are yet to be agreed on: what are the chances that these deals can be struck in the multitude of vital health matters documented in the briefing? Slim, zero, nada. Brexit is bad for Britain's health."

In supporting a public vote on the Brexit deal Sapwell said that many people were changing their minds on exiting the EU as the implications of the move became better known. "If a democracy can't change its mind then it ceases to be a democracy, and isn't it right that, as doctors, we inform the debate? After all, we believe in fully informed consent," he said.

David Strain, who declared that he was a recipient of research funding

"The government is woefully underprepared to ensure that the UK's health and wellbeing are secure"
William Sapwell

CURRENTLY 7-10% of doctors working in the NHS are from the European Economic Area, and 40% of those have plans to leave

Manslaughter cases should take into account system failures

"In medicine we are where the aviation industry was 30 years ago, still blaming the individual. This isn't good enough"
Philip Banfield

System pressures and failures should be taken into account by the law when considering individual responsibility in gross negligence manslaughter (GNM) cases following the Bawa-Garba case, the BMA has said.

Doctors unanimously passed a motion backing the move and also unanimously backed calls for an independent body to be given a remit to provide "confidential, professional, no-fault safety incident investigation" in medical cases, in line with how the aviation industry operates.

Philip Banfield of the BMA's Clwyd North division, who proposed the motion, said, "In medicine we are where the aviation industry was 30 years ago, still blaming the individual. This isn't good enough.

"The way GNM is being used in England and Wales threatens to block progress to improving patient safety."

Fair blame

Daniel Bunce of the BMA's southwest regional junior doctors committee spoke in favour of the motion. He said, "When an incident occurs in other high risk industries, such as the aviation or nuclear industries, serious event analysis takes place. This looks at system design, pressures on said system, and most crucially apportions fair blame.

"What it does not do is make an example of any individual. They ask, 'how can we stop this from happening again,' and then follow through on their recommendations."

from the European drug industry, said that 20% of NHS research and development funding came from European drug companies and a further 23% from European small enterprises. "If we lose our parity with the European Clinical Trials Directive that money may disappear," he said.

Effects already being felt

"It is already happening," he warned. "I have been clinical lead for global studies for many different studies. On 26 June [2016]—three days after the [Brexit referendum] vote—I got a phone call from one pharmaceutical company for a phase II study we were working on saying that, actually, we can no longer host this study within the UK because we are not sure, when this product develops, whether we will still be able to use the European market through studies done in the UK."

Opposing the motion, John Hyslop said that the BMA briefings were currently level headed and that "overegging" the consequences of Brexit risked the BMA's reputation in the eyes of the public.

Zosia Kmietowicz, *The BMJ*

Cite this as: *BMJ* 2018;361:k2821

David Bailey, chair of BMA Welsh council, also backed the motion. He said the current application of the law in England and Wales had created a "culture of fear which puts patient safety at risk by preventing open system analysis of mistakes and system evidence.

"It is increasing, not deterring, the chances of mistakes happening again," he said.

But while doctors backed a call for the BMA to "robustly participate" in any review of GNM, a separate part of the motion calling on the BMA to campaign for changes to the law on GNM, so that England and Wales are more aligned with the law in Scotland, was passed only as a reference.

Undo positive steps

This came after Jenny Vaughan, a consultant neurologist and member of of the BMA's Consultants Committee, had warned that such a law change may undo positive steps that were already being taken to protect doctors following the David Sellu and Bawa-Garba cases and the Williams review.

"If we change the law, we must almost start again from the beginning," she warned. "Let's focus on getting that just culture. It's the process that needs to change, not the law."

Gareth Iacobucci, *The BMJ*, Cite this as: *BMJ* 2018;361:k2870

More news from the ARM

CAP GP WORKLOAD

Delegates voted for the agreement of a sensible cap "on the workload of a GP which can be expected to be safely delivered in a day." Satish Narang (right), the GP who proposed the motion, said, "For the sake of quality and safety of patient care, and the sanity of GPs, we urge the BMA to take a fresh approach by defining and agreeing what is a safe workload. A sensible cap on the number of patients that a GP can be expected to see in a day must be introduced, taking into account that increasingly complex consultations can't safely be managed in 10 minutes."

Supporting the call for a cap, Sridhar Sampalli, an orthopaedic and trauma surgeon, argued that the increasing workload in general practice was putting patients at risk of misdiagnosis.

However, Gary Marlowe, a Hackney based GP, said that capping GP appointments would "divert attention from the [issue of] proper resourcing in general practice."

BACK DOCTORS WHO REFUSE TO TAKE PART IN PREVENT

Doctors passed a motion saying that the Prevent programme leads to racial profiling and backed a call for the BMA to support members who choose not to engage with the programme. Under the strategy NHS organisations—but not general practices—are legally obliged to report people who they think may be at risk of becoming terrorists.

Jackie Applebee (above), of Tower Hamlets Local Medical Committee, who proposed the motion, said the programme was not only ineffective but also responsible for building "a climate of fear and mistrust" that was contributing to racism.

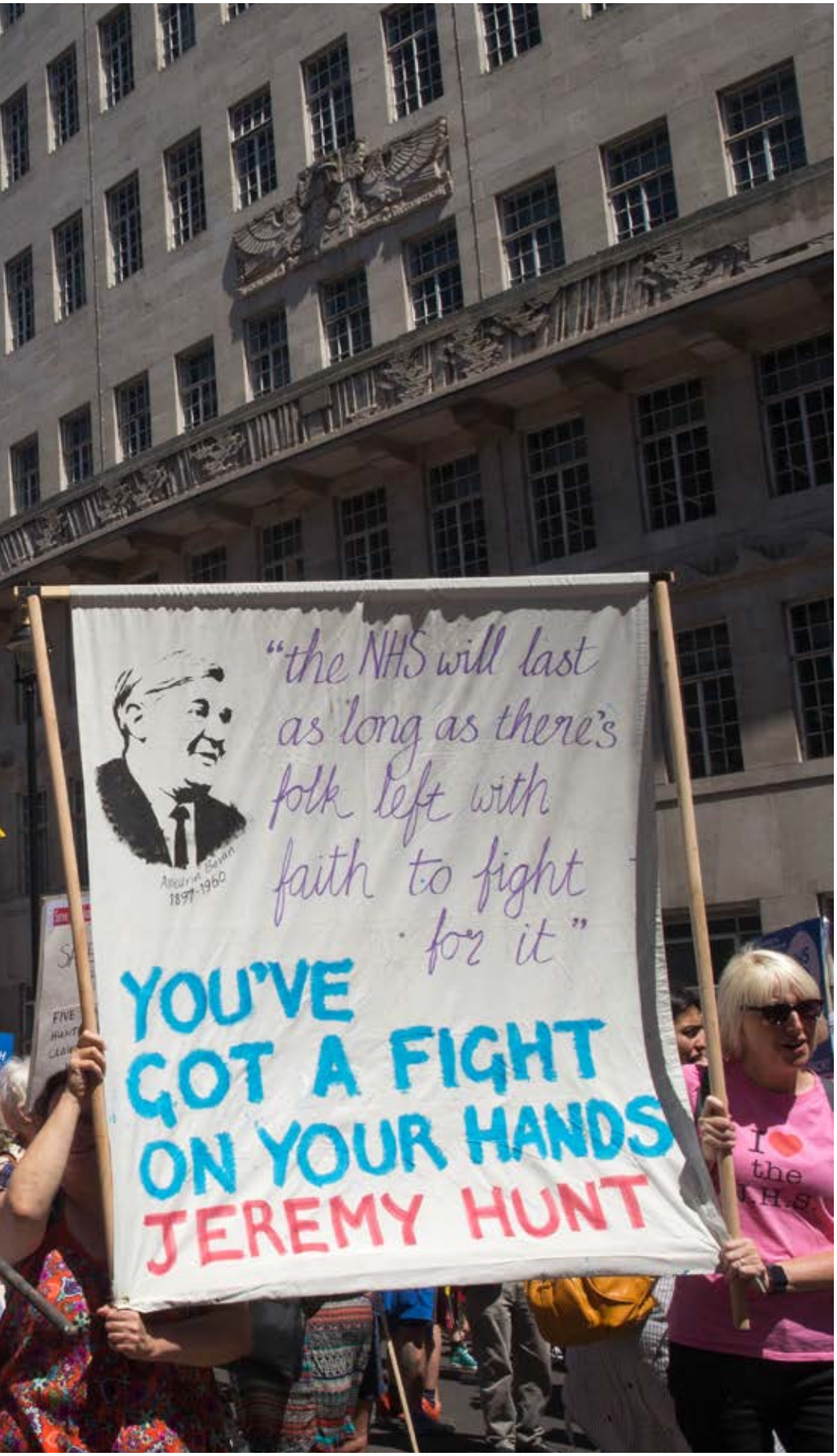
HOLD PUBLIC INQUIRY INTO GMC'S HANDLING OF BAWA-GARBA CASE

Doctors backed a motion declaring that they have no confidence in the GMC and for a public inquiry to be held into the regulator's conduct in the case of trainee paediatrician Hadiza Bawa-Garba.

Proposing the motion, Krishna Kasaraneni (right), the BMA's lead on workforce issues, said, "Whatever the reasons behind how the GMC dealt with this case were, it sent a profound message to the profession that medical regulation is heading in a very different direction. We can all relate to working in a system where there are simply not enough hours in the day to do justice to every single patient in our care. When faced with what seem like impossible situations, doctors—particularly junior doctors—need a helping hand and not a threat of criminal prosecution."

Speaking in support of a public inquiry, Moosa Qureshi argued that, although inquiries do not always uncover the truth, "it is the best chance we have got for creating change."

MARK THOMAS



THE BIG PICTURE

Warm birthday wishes for NHS

Thousands of people from across the UK marched through central London on one of the hottest days in years, to celebrate the NHS's 70th anniversary and to call for more funding from the government.

The demonstration on Saturday, 28 June ended with a festival-like rally in Westminster, in which speakers, including Labour leader Jeremy Corbyn, shared the stage with musicians.

Organised by The People's Assembly, the BMA, and other health unions and organisations, the demonstration followed an announcement by Theresa May that the NHS is to receive an annual average increase of 3.4% over the next five years. But chants of "shame on you" as the procession passed Downing Street suggested marchers have not been convinced.

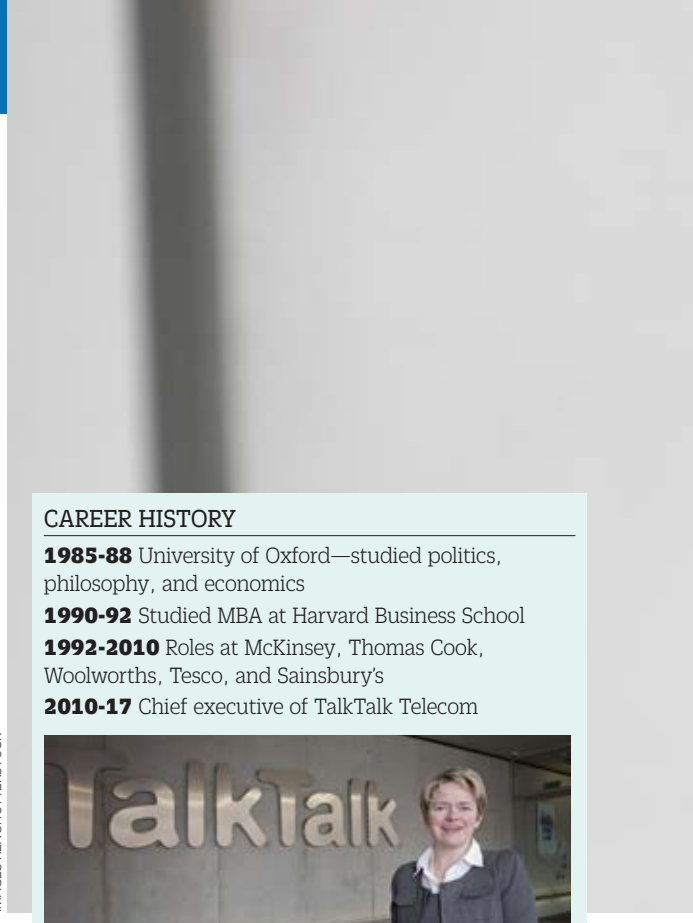
Alison Shepherd, *The BMJ*

Cite this as: *BMJ* 2018;362:k2918

PROFILE

Dido Harding: “I’m shocked at the lack of basic people management skills in the NHS”

Better—and constitent—leadership training would increase sta engagement and tackle workplace bullying, the chair of NHS Improvement tells **Tom Moberly**



IMAGES REX SHUTTERSTOCK

CAREER HISTORY

1985-88 University of Oxford—studied politics, philosophy, and economics

1990-92 Studied MBA at Harvard Business School

1992-2010 Roles at McKinsey, Thomas Cook, Woolworths, Tesco, and Sainsbury’s

2010-17 Chief executive of TalkTalk Telecom

2014 Appointed to the House of Lords (Baroness Harding of Winscombe)

2014-present: Non-executive director and chair of remuneration committee, Bank of England

2017 Chair of NHS Improvement

Since she joined watchdog NHS Improvement as chair in October 2017, Dido Harding has been struck by the ways in which the health service falls short in the treatment of its staff. “I am quite shocked at the lack of some of the basics of people management that I would expect to see,” she says.

“That’s not to say that there are not pockets of complete brilliance—of course there are. I’ve seen examples of some of the best people management and leadership I’ve ever seen. But it is unbelievably inconsistent.”

Harding joined NHS Improvement, which regulates NHS trusts in England, after a string of senior jobs in the private sector, most recently as chief executive of telecoms company Talk Talk. Speaking at the Health Foundation annual event in London on 22 May, she says that, coming into the NHS as an outsider, she can’t get her head around the prevalence of bullying among health service staff.

“It’s awful,” she says. “The percentage of staff saying that they have been a victim of or have witnessed bullying is three, four, fivefold more than you would see in other organisations.”

The high levels of bullying seen in the health service arise, she believes, from shortcomings in management skills across the NHS. “I suspect it’s a real indication of an immaturity in the whole system in what good management looks like,” she says. “Good management isn’t soft and fluffy—good management is about giving or having honest adult conversations. Bad management can often be interpreted as bullying.”

Low engagement

Data on bullying are collected as part of the NHS staff survey. But Harding points out that, even before you start looking in detail at people’s answers to these questions, the low overall response rates reveal a problem with staff engagement across the organisation.

“Best practice in the private sector for a staff survey is that at least 90% of your workforce fill it in,” she says. “There isn't a single organisation in the NHS that has 90% of its staff who have ever filled in a staff survey. People will say, when they’re at 65%, ‘This is amazing.’”

Employers need to see such poor response rates as a warning sign, she argues. “It’s the first indicator of how engaged your workforce is,” she says. “If they’re not even going to fill in a form telling you how they feel, they have already told you they’re not very engaged. We’re light years away from best practice on that.”

She believes that, to increase staff engagement, managers need to create an environment in which staff feel that their contribution is valued. “If you look at any study that has been done in the health sector—or in any other sector—about what determines whether you are engaged at work, it is how your line manager treats you,” she says. “It’s almost never how much you are paid, or how much money the organisation as a whole has got. It’s ‘Do I feel valued as a human being?’”

One way in which NHS Improvement believes it can drive up staff engagement is by using the influence it has on senior appointments in the health service. “The most powerful lever we use is people,” Harding says, “in the

BIG IDEA: A NATIONAL VOLUNTEERING SCHEME

Harding is trying to set up a volunteering scheme for all 1400 staff in NHS Improvement. "I want to find a way to get everyone in NHS Improvement to spend at least a couple of days helping on the front line in January," she says. "Helping could be making cups of tea or running errands, just being human and available.

"I'm trying to improve the culture of NHS Improvement," she explains. "I'm absolutely certain that seeing is believing and that the way we change the culture throughout the NHS, as leaders and managers, is by seeing it in the way that our patients see it."

"The harshest criticism I've heard of NHS Improvement is that we aren't much of a learning organisation ourselves, and I take that quite to heart"

leadership culture that we inspire and encourage, and the people decisions that we take either directly by appointing chairs or [less directly] by sitting on appointment panels for chief executives or medical directors. It is the most powerful lever that we can pull, and we don't pull it in anything like as structured and thought through [way] as we could, and we fully intend to."

"Good management isn't soft and fluffy—good management is about giving or having honest adult conversations"

Leadership overlooked

Since starting at NHS Improvement, Harding has seen that, although everyone knows the important purpose of the NHS as a whole, individual line managers often fail to show their teams why their part of the service has an important purpose in itself.

"If you are in a team with a manager who shows they care about you, who can describe your part in the enormous jigsaw puzzle that the NHS is, and that can help you really feel valued and included, you feel your part has a real purpose," she says. "All of those are the things that individual leaders can do."

NHS Improvement should have a big role in supporting the development of leadership and management skills across the health service, she argues. "We should be thinking about how we plan and develop talent at the most senior level," she says. "I'd like to see us develop a fully fledged approach to managing senior people in the NHS."

The importance of developing leadership and management skills has so far tended to be overlooked, she believes. In her view, the NHS too often underestimates not only the opportunities that improvements in leadership and management skills offer but also the work involved in honing those skills .

"It's much easier to teach doctors and nurses to be great managers and leaders than it is to teach me to be a doctor or a nurse," she says. "Nonetheless, it's a skill that needs to be taught and honed and practised—we are never too good at it to not practise."

Improving NHS Improvement

Although her organisation is seeking to raise standards across the NHS, Harding is open about the fact that NHS Improvement is "far from perfect" when it comes to its track record on improving itself.

"The harshest criticism I've heard of NHS Improvement is that we aren't much of a learning organisation ourselves, and I take that quite to heart," she says. "We have a huge amount of work to do to change the way we lead and manage our own teams, let alone how we then try to role model the right behaviour for the sector as a whole."

Poor alignment between NHS Improvement, which regulates trusts in England, and NHS England, which commissions health services, does not help the situation, she acknowledges.

"On a good day the NHS Improvement team and the NHS England team will ask a trust or an STP [sustainability and transformation partnership] roughly the same question in slightly different ways and ask them to fill in separate forms," she says. "On a bad day, they ask the same organisation to do directly contradictory things, and unfortunately there are quite a lot of bad days."

She says that the two organisations should be collaborating more closely to improve patient outcomes. "Together with NHS England we set, broadly, the rules of the game, the financial incentives and the non-financial incentives," she says. "We need to make sure, together with NHS England, that we're setting them to get the outcomes that we want."

Tom Moberly, UK editor, *The BMJ*
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Cite this as: *BMJ* 2018;361:k2657

EDITORIAL

New preventive treatments for migraine

High prices put promising monoclonal antibodies out of reach for many patients

What is a day without migraine worth? Drug companies, payers, and patients are wrestling with this question as new treatments for migraine are developed and brought to market. Monoclonal antibodies to calcitonin gene related peptide or its receptor (CGRP mAbs) are a novel class of preventive treatment aimed at reducing the frequency of episodic migraine, chronic migraine, or cluster headache.

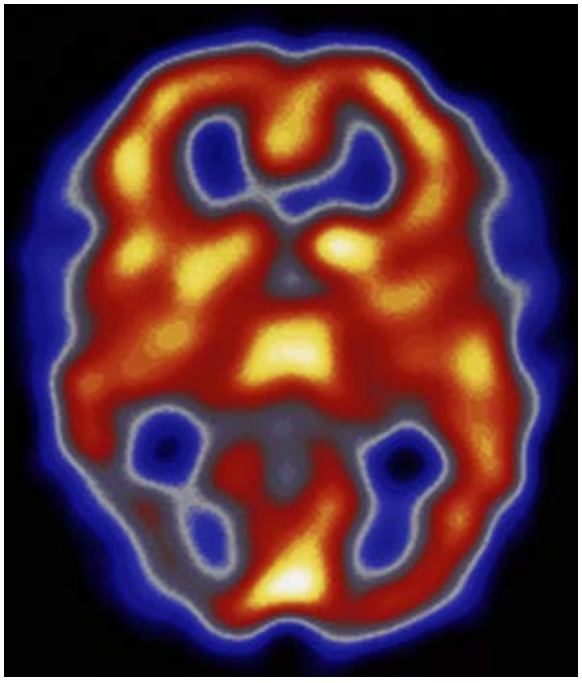
CGRP is a widely distributed vasodilatory neuropeptide that is involved in migraine pathophysiology. Four antibodies to CGRP or its receptor have been developed. Erenumab was approved by the US Food and Drug Administration on 17 May 2018, and has been recommended for marketing authorisation by the European Medicines Agency. Galcanezumab and fremanezumab are under FDA review; eptinezumab's licensing application has yet to be submitted to the FDA.

Modest benefit

This is a welcome development for the estimated one billion people worldwide who have migraine.[1] Existing preventive treatments are not effective for everyone with frequent episodes, and some are poorly tolerated. Trials of CGRP mAbs report a modest reduction in days with migraine per month compared with placebo, with few adverse effects.[2-5]

A network meta-analysis comparing erenumab and fremanezumab with existing preventive treatments (onabotulinum toxin A, topiramate, propranolol, and amitriptyline) reported similar efficacy for all treatments. The reduction in the number of days with migraine a month ranged from 1.3 to 2.4 in people with chronic migraine (headaches 15 or more days a month) and 0.9 to 2 days in those with episodic migraine.[6]

The US Institute for Clinical and Economic Review (ICER), which conducted the analysis, rated the net benefit of erenumab and fremanezumab as "comparable or better" than comparators for patients with chronic migraine who have not responded to one other preventive treatment. The evidence for episodic migraine was judged largely inconclusive because long term efficacy and safety data weren't available, with most trials lasting only 12 weeks. Since CGRP is a systemic vasodilator, rare but serious adverse events may become apparent only in post-marketing surveillance.



SPL

A roughly 75% reduction in price of erenumab or fremanezumab would be needed to achieve full coverage

The manufacturer's listed price for erenumab is $6900 a year. Although this is below the predicted price, it is still around $150 000 per quality adjusted life year (QALY)—a threshold that strains the accepted upper limits of cost effectiveness in most countries.[6 8] The ICER estimates that each migraine-free day attributed to erenumab or fremanezumab costs between $130 and $340, relative to no treatment or treatment with onabotulinum toxin A.

At first glance, this may seem reasonable for a highly disabling disease, but the ICER estimates that only 20% of patients who do not respond to one preventive treatment could be treated with erenumab without exceeding the cost burden that society is willing to bear. A roughly 75% reduction in price of erenumab or fremanezumab, to $50 000 per QALY ($2200 a year), would be needed to achieve full coverage of the eligible population at acceptable societal costs.

If subsequent CGRP antibodies are priced similarly, this entire class of treatments may be out of reach for many patients. In the US, migraine disproportionately affects people of low socioeconomic status and those who are under-insured.[9] Such patients were also under-represented in CGRP mAB clinical trials. The highly disabled migraine patients who need these treatments most would be least likely to have access.

Priced out

Patients in the US are already struggling to afford essential headache treatments. Prices for previously inexpensive, well established migraine treatments have skyrocketed in recent years.[10 11]

If we unquestioningly accept high prices and the industry arguments to justify them, we are complicit in pricing patients out of treatment. Poorly treated migraine is associated with high costs to society, and limiting access may prove short sighted. The price of these agents must fall—both to reflect their modest efficacy, and to allow more equitable access to a treatment option that might succeed where others have failed. Otherwise, the price of progress may be simply too high.

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EDITORIAL

Adolescent mental health in crisis

We need to understand the causes to inform prevention

Universities UK recently reported a fivefold increase in the number of students disclosing mental health conditions since 2007 and growing pressures on student mental health services, despite only a modest rise in student numbers.[1] A growing number of UK and international studies show that affective disorders in young people are rising substantially, particularly among girls and young women.[2]

Causes of the escalation are uncertain. Some studies point to a rise in presentation and diagnosis rather than a true increase in incidence.[4] More people self reporting problems may partly reflect greater willingness to share feelings, such as suicidal thoughts, due to better mental health literacy. If the situation reflects a real deterioration in the mental health of young people, there are several possible explanations.

The young people affected are "generation Z," born in the mid 1990s and early 2000s. They grew up in the age of social media, the great recession (2008), increases in family breakdown, growth of international terrorism, and, in the UK, student debt and predicted gaps in prosperity between them and their parents.[5] Academic pressures at school cause stress, and the UK government has focused on testing in recent years. Many of these phenomena affect both boys and girls, although some factors, such as school performance pressures and lower family income, may be more likely to affect girls.[6 7]

We need to look beyond well recognised risk factors for poor mental health, such as abuse and trauma, to problems that have arisen in recent decades, that affect countries beyond the UK, and that affect girls more than boys.

One explanation is the rise in young people's use of social media after the launch of Facebook (2004), Snapchat (2011), and other platforms. Social media use may result in less face to face communication, overdependency on being "liked" for social validation,[8] and pressure to keep up with discussions 24 hours a day, leading to poor sleep.[9] Recent research provides some support for these concerns, with greater effects on girls than boys.[10 11]

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We need to look beyond well recognised risk factors for poor mental health to problems that have arisen in recent decades

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Funding boost

The UK government's recent green paper on children and young people's mental health confirmed its previous commitment of £1.4bn and an additional £300m to this area over five years.[13] It largely focused on improving funding for frontline mental health services and training non-health professionals such as teachers to recognise and help those experiencing problems, as well as incentivising schools to appoint a mental health lead.[13] Importantly, this shifts some of the responsibility for mental health from health services to schools, but as select committees' responses to the green paper have emphasised, it will place an additional, potentially unwelcome pressure on already stretched teachers.[14]

Although this attention on adolescent mental health is welcome, we urgently need research to better understand the underlying causes of recent trends to underpin the development of effective prevention strategies—an area given little emphasis in the green paper.[13] Half of all mental illnesses begin before age 14, and research into the mental health of young people is underfunded.[15]

Studies could include natural experiments to compare mental health between populations that are differentially exposed to possible risk factors; Longitudinal studies to clarify factors associated with risk and resilience; and qualitative research to illuminate differences in girls' and boys' exposure to possible risk factors. Intervention studies controlling exposure to one or more target risk factors are also possible.

This research is essential for developing a long term framework for children and young people's wellbeing, based on the principle that our mental health must be protected in the same way that we protect our physical health. A whole population approach is required, including schools, universities, workplaces, job centres and homes, so that emotional wellbeing and mental health becomes the foundation of our children's experiences throughout life's stages and transitions.

This would build a generation of young people with a deeper understanding of the importance of their own and others' mental health, the skills required to keep healthy, and an awareness of the signs of being unwell, so that they can seek help earlier for themselves and respond better to others in difficulty.

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