this week

RAINBOW BADGES page 339 • **CANCER CARE** page 340 • **LMC CONFERENCE** page 342

CHRISTINA CHUNG/ICIJ

"Register all new medical devices"

THE IMPLANT FILES

The government must act urgently to reform medical device regulations, including a compulsory registry of all new implants, says the Royal College of Surgeons.

The call comes after a global investigation into the industry by journalists from 36 countries, including *The BMJ*, BBC *Panorama*, and the *Guardian*, which unearthed thousands of documents that reveal rising numbers of malfunctions and injuries.

The investigation also provides evidence of devices being implanted in humans after tests only in pigs or after small scale studies of tens of patients. The lack of transparency and available data means the true scale of problems remains hidden.

Derek Alderson, RCS president, said, "Government needs to address this urgently. There needs to be compulsory registration of every new device and implant that goes into a patient in the UK. Medical devices are manufactured and used to high standards in the UK. Nevertheless, there have been sufficient number of incidents to underline the need for drastic regulatory changes."

The legal firm Leigh Day, which acts for many people implanted with defective medical devices, said the situation should be a source of "shame" to the government. Boz Michalowska, its head of product safety and consumer law, said, "While these failing medical devices are wide ranging in nature and function, a common reason for their failure is inadequate premarket testing by the manufacturers, who race to get devices to market, leaving patients to become the unknowing guinea pigs."

She called for the creation of a "Nordic style" no fault compensation scheme, funded by manufacturers, for injured patients. "It should not be necessary for patients and lawyers to have to drag deep pocketed multinational device and pharma manufacturers through the courts."

A Department of Health for England spokesperson said patient safety was "our highest priority." "The MHRA [Medicines and Healthcare Products Regulatory Agency] has a robust process, and we expect it to follow up any safety concerns swiftly. We will work with the regulator to see what changes may be required."

MedTechEurope, the industry's largest trade association in Europe, said, "Millions of people have safely benefited from medical devices and can now live healthier, more productive lives."

Rebecca Coombes, head of news and views, *The BMJ*

Cite this as: *BMJ* 2018;363:k5010

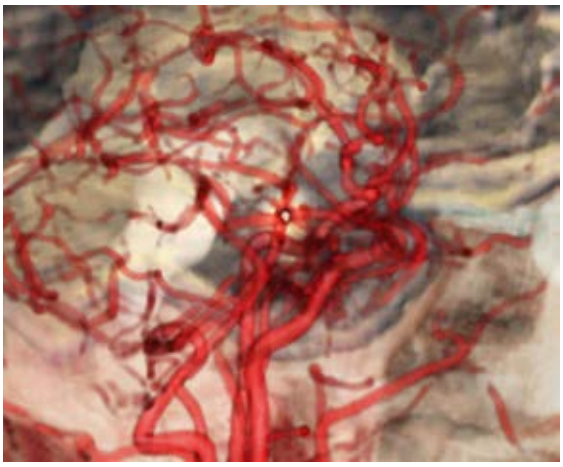
"Manufacturers race to get devices to market, leaving patients to become unknowing guinea pigs"
Boz Michalowska, lawyer

LATEST ONLINE

- Transition to immediate open access publishing under "Plan S" will be smooth, promise backers
- FDA recommends "modernising" how devices are reviewed in wake of global investigation
- Cuba begins to pull 8300 doctors out of Brazil after president elect Bolsonaro's comments

SEVEN DAYS IN

Thrombectomy can be considered up to 24 hours after onset of stroke, says NICE


SPL

Patients with acute ischaemic stroke should be considered for thrombectomy up to 24 hours after the onset of symptoms, a draft NICE guideline update recommends, as evidence shows that extending the eligibility period beyond the current 12 hour limit reduces disability and is cost effective.

The guideline committee recommended that thrombectomy should be offered to patients whose symptoms started in the previous 24 hours. Confirmed occlusion of the proximal posterior circulation should be demonstrated, with scans also showing the potential to salvage brain tissue.

The committee considered new evidence showing that thrombectomy improved functional outcome as measured by the modified Rankin score, when compared with usual care in patients who had no symptoms up to 24 hours previously. The guideline committee agreed that increased risk of procedural complications was outweighed by improvements in functional outcome. Further evidence showed that the procedure was cost effective when performed 6-24 hours after stroke onset.

The draft guideline is open for public consultation until 11 January 2019.

Susan Mayor, London Cite this as: *BMJ* 2018;363:k4995

Legal highs

Ban fails to curb children's psychoactive drug use

The UK government's ban on legal highs has failed to reduce their use by children and vulnerable adults and has driven their sale underground, a Home Office review reported. Assessing the impact of the 2016 Psychoactive Substances Act, which banned the production and sale of most psychoactive substances, the review showed a "considerable reduction" in the use of novel psychoactive substances ("legal highs") in the general adult population. But it showed no fall in their use by children, homeless people, or prisoners, or in the use of nitrous oxide by adults.

Mental health

Community mental health ratings fall

Only 30% of 12 700 people who completed a survey about their experiences of community mental health services this year rated their overall experience as nine out of 10 or above—down from 34% in 2017. This contrasts with people treated in hospital for a physical health problem, half of whom rated their care as nine or above. In the survey, carried out by the Care Quality Commission, 25% of respondents said that they had not seen workers from NHS mental health services enough for their needs in the past year.

Research news

Probiotics don't improve gastroenteritis in children

Commonly used probiotics did not improve diarrhoea or vomiting symptoms in young children presenting to hospital with gastroenteritis, show two randomised trials published in the *New England Journal of Medicine*. A US trial involving 971 children showed no difference in the duration of diarrhoea or vomiting or in the rate of household transmission with a five day course of *Lactobacillus rhamnosus* GG (dose of $1x10^{10}$ colony forming units twice daily) when compared with placebo in addition to standard treatment. A Canadian study showed a similar lack of benefit with a combination probiotic product containing *L rhamnosus* R001 and *L helveticus* R0052.

Obesity increases asthma risk in children

A US analysis of electronic data on more than 500 000 children aged 2 to 17 years published in *Pediatrics* found that the relative risk for incident asthma confirmed by spirometry was 29% higher in obese children than in matched healthy weight children (P<0.001). "There are few preventable risk factors to reduce the incidence of asthma, but our data show that reducing the onset of childhood obesity could significantly lower the public health burden of asthma," said Terri Finkel, study author, from Nemours Children's Hospital in Orlando, Florida.

Fractional doses are effective in yellow fever

A fifth of the standard dose of yellow fever vaccine protects against the disease for 10 years with no need for a booster, a study in *Annals of Internal Medicine* found. Ramping up production of the vaccine during yellow fever outbreaks is difficult, so using fractional dosing may be a useful strategy in mass vaccination campaigns, said the researchers. Some 97% of participants had protective levels of antibodies more than 10 years after receiving the fractional dose of 17D-YFV vaccine.

International news

Use of PrEP is advised for anyone at high risk of HIV

The US Preventive Services Task Force recommended that doctors offer preventive medicine to anyone at high risk of acquiring HIV. Only 78 360 US patients took the daily drug regimen in 2016, yet 1.2 million people are eligible, it said. About 40 000 people had HIV diagnosed that year. Routine discussion of pre-exposure prophylaxis, known as PrEP, has not yet permeated primary care, the panel said, although it can cut the risk of contracting HIV via sex by more than 90% and via injecting drug use by over 70%.

Scotland

Barrister investigates bullying in NHS Highland

An independent inquiry into alleged bullying in the NHS Highland region announced in September will be carried out by John Sturrock QC (below). Sturrock said, "My primary role is to provide a safe and confidential place for people. I hope that confidence and effective working relationships can be rebuilt."

MEDICINE

Big pharma

GSK tops drug index for poor countries

GSK, Novartis, Johnson and Johnson, and Merck KGaA retained their positions as the leading drug companies in terms of making their medicines available to patients in low and middle income countries. The independent Access to Medicines index, published every two years, ranks 20 of the world's largest drug companies on their work in this field. Of the lowest ranking companies only two, Bayer and Eli Lilly, had strategies in place for improving access to medicines.

Peers ask government to clarify its plans to ensure drug supply after Brexit

Junk food

London transport bans junk food advertising

Junk food advertisements will be banned on the Transport for London network from 25 February 2019 to help tackle child obesity, after a public consultation found support from 82% of Londoners. Food and drink brands, restaurants, takeaways, and delivery services will be allowed to advertise only their healthier products. Sadiq Khan, mayor of London, said he backed work to encourage healthy eating, including the Veg Power (vegpower.org.uk) campaign led by the Food Foundation. Public health experts have backed the advertising ban.

Brexit

Government must clarify drug supply plans

A House of Lords committee asked the government to clarify its contingency preparations to ensure that the UK still has access to drugs and medical products in a "no deal" Brexit. In a letter to England's health secretary, Matt Hancock, the House of Lords EU home affairs sub-committee warned it had heard expert evidence that a no deal Brexit may limit availability and delay supplies. It asked what work had been done to ensure that drug imports are treated as a priority at the border if the UK does not negotiate an exit deal, and it requested more details on plans to secure and prioritise airborne routes for medical products.

Royal College of GPs backs a people's vote

The governing council of the Royal College of General Practitioners voted to oppose the UK's exit from the European Union and to support a second referendum (a "people's vote") on any Brexit deal. The motions cited the potential damage to the UK from leaving the EU, such as making it harder to recruit and retain health and social care professionals, harming public health, and limiting access to medicines, devices, and radioisotopes. The college will now consider how to take the motions forward. The BMA passed a similar motion in June.

Cite this as: *BMJ* 2018;363:k5007

HUMIRA

Using biosimilar versions of adalimumab (Humira) is set to save the NHS

£300m

after deals with manufacturers—the largest such saving from a single drug contract in NHS history

SIXTY SECONDS ON . . . RAINBOW BADGES

ARE YOU COLOURING MY NAME BADGE?

Nope. We're talking about little pin badges that feature the NHS logo on a rainbow flag background, often associated with the LGBT+ pride movement.

A JAZZY VERSION OF JEREMY HUNT'S FAVOURITE LAPEL PIN?

Yes, exactly! But these badges are also a sign the wearer is a safe person to talk to about matters of gender identity and sexuality. They also show the wearer's workplace is a positive environment for LGBT+ people.

I REALLY WANT ONE

To get one you are expected to read through a range of articles and resources, including things like Stonewall's coming-out guidance, and sign up to three key principles. So wearers need to understand both the inclusion message and the responsibility that comes with wearing a badge.

DO PATIENTS UNDERSTAND?

They should. There are posters explaining what they are all about and encouraging people to ask wearers about them.

BUT WHO IS WEARING THEM?

The badges are technically only available to staff at the Evelina London Children's Hospital (although some have snuck out to royal college presidents and the health secretary). After launching in October, a fifth of staff are wearing them and staff in the rest of Guy's and St Thomas' trust should be able to get them from early next year.

BUT WHAT ABOUT ME?

Consultant paediatrician Michael Farquhar and communications manager Jessica Law, who lead the project, are to launch an implementation pack that will allow other trusts to give out badges. It will include the resources developed at the Evelina.

I DOUBT MY TRUST WILL PAY UP

The initial project was funded by a £5000 grant from the Guy's and St Thomas' Charity, and the idea is that other trusts' charities could do the same. Farquhar says that it should cost other trusts less to roll out.

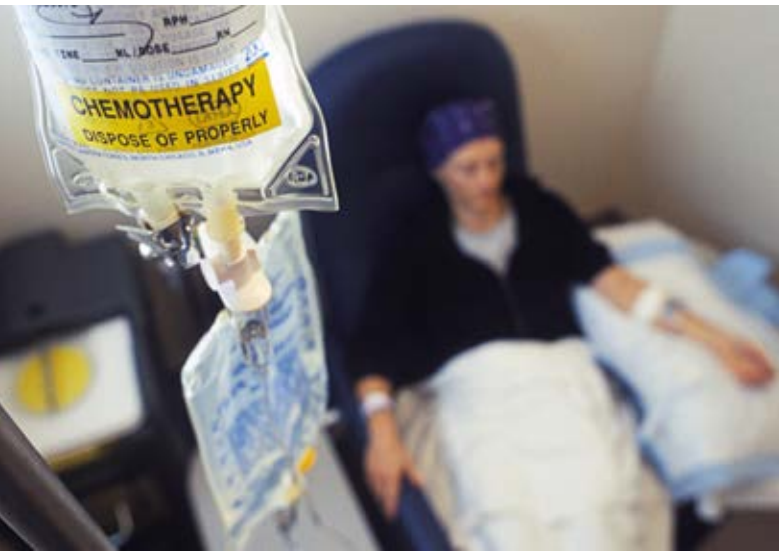
WHAT ABOUT GPs?

Watch this space. Farquhar and Law are working to get the badges into practices.

Follow @RainbowNHSBadge on Twitter

Abi Rimmer, *The BMJ* Cite this as: *BMJ* 2018;363:k4988

England has failed to close gap with similar countries in cancer outcomes



SAM OGDEN SPL

The gap in cancer outcomes between England and similar countries has not narrowed despite 20 years of well intended effort, says a new Health Foundation report.

Although England's outcomes have improved, other countries have improved as fast and have maintained their lead. "England is towards the bottom of the table, and not closing the gap," said Rebecca Fisher, a GP and coauthor of the report.

Mike Richards, former national cancer director and the report's lead author, said that thousands of deaths could be avoided every year if England matched the outcomes achieved by the best in Europe. "This is the equivalent of a jumbo jet of people falling from the sky every two weeks."

The comparisons are stark. A person given a diagnosis of colon cancer in Australia, for example, has a 71% chance of survival after five years, while a British patient with the same disease has only a 60% chance.

Nor is there any recent evidence of improvement. The disruption brought by the 2012 Health and Social Care Act caused a serious loss of momentum and the destruction of networks established under the 2000 NHS Cancer Plan, of which Richards was a principal architect. The years of tight budgets that followed the financial crisis of 2007-08 led to slippage of targets for rapid diagnosis and treatment.

The proportion of patients seen within two weeks of an urgent referral by a GP has fallen well below the target of 93%, while the numbers starting treatment within 62 days of an urgent referral are also well below the 85% target and fell sharply in the past two years.

Speaking at the report's launch, Richards said it was a 20 year view of cancer policy—"what has worked well, and what has worked less well"—against a context of rising cancer incidence as the population ages, and of vastly more complex treatments.

Two week urgent referrals

Early diagnosis remains a largely unsolved problem, with a fifth of cancer cases going undiagnosed until the patient presents as an emergency. Two week urgent referrals have worked, with a growing proportion being treated through this route. But hospitals reject some referrals by GPs as they do not meet the criteria.

The report identifies "a fraught relationship between primary and secondary care." It quotes Mick Peake, a professor of respiratory medicine, as saying, "The GP gets two letters. In the first the consultant says, 'You've been sitting on this patient for

Climate change is outpacing response, warn experts

The worldwide current slow progress in reducing global emissions of greenhouse gases threatens human lives and could disrupt and overwhelm health services, warns a major report from international experts.

The warning comes as the Met Office predicts that the UK will experience wetter winters and summers that could be up to 5.4°C hotter by 2070 as a result of climate change.

The *Lancet* Countdown on health and climate change report, a collaboration of 27 academic institutions, the UN, and government agencies, says that climate change is outpacing the urgency of the response. As a result more people are vulnerable to heat exposure, which could cause heat stress and increase the risk of cardiovascular and kidney disease, the report says.

Vulnerable people

Those most at risk include elderly people, city dwellers, and people with chronic diseases. Europe and the eastern Mediterranean are more vulnerable than Africa and South East Asia because of the larger numbers of elderly people living in cities.

The report says that 157 million more vulnerable people were exposed to heatwave events in 2017 than in 2000, with the average person experiencing an additional 1.4 days of heatwaves each year from 2000 to 2017.

The report tracks 41 indicators, including weather related disasters, clean fuel use, food security, meat consumption, air pollution, and scientific research articles about climate and health.

Small changes in rainfall and temperature can result in large changes in transmission of vectorborne and waterborne diseases, the report says. For example, climatic conditions are now at their most suitable for the transmission of dengue fever virus since 1950.

Heatwaves exposed 157 million more vulnerable people in 2017 than in 2000


RAYMOND ROIG/AFP/GETTY IMAGES

Between 1980 and the 2010s there was a 24% increase in the area of the Baltic region's coastline suited to epidemics of cholera.

But the report offers some cause for cautious optimism, such as the phasing out of coal burning and the increasing use of cleaner modes of transport such as electric vehicles.

Jacqui Wise, London

Cite this as: *BMJ* 2018;363:k5018

months now, and he's got advanced disease, he's going to die. What have you been doing?' Next day another letter arrives saying essentially, 'What are you doing sending me this patient? There's nothing wrong with him, what a waste of my time.' You can't win."

The report suggests that patients may need to find ways to bypass the "very strong" gatekeeper function of GPs but does not spell out how. "I don't know if there are other routes," Richards said. "I do not want to undermine GPs, who are under pressure not to refer people. Anything we did we would have to do very, very carefully."

Recommendations

Many of the recommendations in the report are familiar. Among the most prominent are improving access to diagnostic care, enlarging the diagnostic workforce, fully implementing NICE guidance on the threshold for urgent referrals (currently set at a risk of cancer of 3% or higher), and considering the introduction of rapid diagnostic centres outside hospitals.

At the launch, Richards welcomed the prime minister's promise to improve early detection of cancer, but added, "Setting targets and handing out money will not be enough.

"The NHS must change the way that care is currently organised to make it easier for people to be seen and diagnosed as quickly as possible, as we know this gives them the best chance of survival."

Emma Greenwood, director of policy at the charity Cancer Research UK, said, "Every part of the health system has its part to play, particularly encouraging more people to seek advice when they have symptoms, making sure more people are diagnosed early.

"But the significant shortages in staff qualified to diagnose cancer remain a major barrier to progress and we must, as a matter of urgency, see a clear plan to boost the cancer workforce—backed up by vital investment—as part of the NHS long term plan."

Nigel Hawkes, London

Cite this as: *BMJ* 2018;363:k5016

"I do not want to undermine GPs, who are under pressure not to refer"
Mike Richards, lead author

Abortion surgeon struck off

A surgeon, independently contracted to the British Pregnancy Advisory Service, who exposed patients to the risk of life threatening conditions during abortions has been struck off by a medical practitioners tribunal.

In one Merseyside case James Olobo-Lalobo failed to diagnose a molar pregnancy even though it had been suggested by the ultrasonographer in a preoperative assessment. He failed to initiate essential follow-up care.

In another case, he performed a dilatation and evacuation of pregnancy, followed by insertion of a Mirena contraceptive device. He did not use intraoperative ultrasound scanning, which is required by BPAS guidelines, telling GMC investigators that he preferred to scan on completion to verify complete evacuation. But the next day the patient presented at a hospital emergency department having just delivered a formed fetus.

The GMC's expert witness, who reviewed the case notes, found that the operating time, about five minutes, was insufficient to have performed both an evacuation and a contraceptive implant.

Rachel Wedderspoon, the tribunal chair, said there were no mitigating circumstances but several aggravating factors, including a lack of evidence of insight or remediation and a failure to collaborate with colleagues.

Olobo-Lalobo, who qualified in Uganda in 1973, did not attend the hearing. The erasure will take effect after 28 days unless he appeals.

Clare Dyer, *The BMJ*

Cite this as: *BMJ* 2018;363:k4991

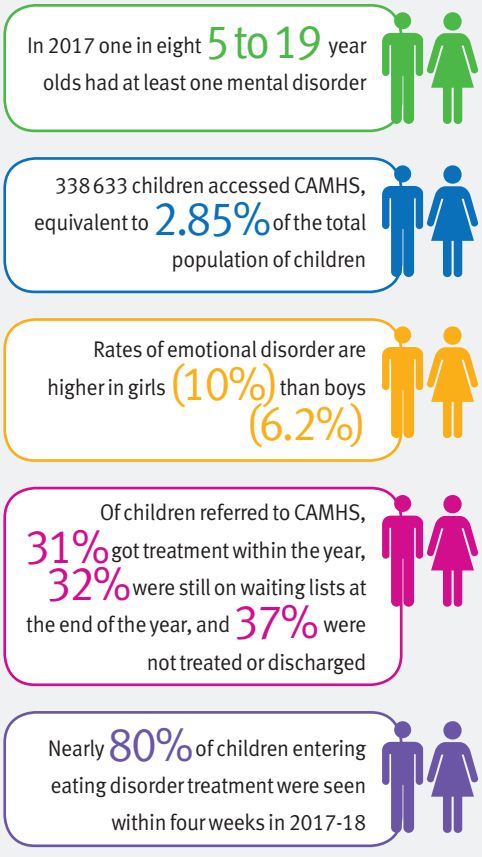
"Progress on child mental health services is too slow"

Children's mental health services show signs of improvement but the current rate of progress is still not good enough, a new report from the children's commissioner for England, Anne Longfield, has said.

The report came as NHS Digital published the results of a major 2017 survey on child mental health services, which collected information on 9117 children living in England combining reports from children, their parents, and teachers.

Longfield called for parity between child and adult mental health, which would require spending an additional £1.7bn a year, and for an expansion of specialist treatment so that no child who needs help is turned away—with a clear four week waiting time target.

She said, "I am pleased to see an increase in workforce and the numbers of children seen by CAHMS [child and adolescent mental health services]. There is still, however, a vast gap between what is provided for children and what is needed to treat them. The current rate of progress is still not good enough for the majority of children who need help."



Jacqui Wise, London

Cite this as: *BMJ* 2018;363:k4953

CONFERENCE ROUNDUP

DELEGATES REJECT CALL FOR PATIENT CHARGES

Representatives voted against bringing in charges for patients to see their GP. After a heated debate, a motion proposing the introduction of co-payments as a way to tackle the "dire state of general practice" was lost by 83 votes to 131.

Zishan Syed of Kent LMC, who proposed the motion, had argued that a radical new approach was needed to reduce the overwhelming pressures that were forcing surgeries to close. But opponents, including BMA deputy chair David Wrigley (above), argued that it was the government's responsibility to provide more funding and that patients should not be penalised.

BACKING FOR "LIMITED LIABILITY" GP PARTNERSHIPS TO REDUCE RISK

The conference urged the BMA's General Practitioners Committee to negotiate a form of limited liability in the GP partnership model to help reduce "the inherent risks" that put many GPs off partnerships and prompting others to retire early. The BMA should also push for a statutory cap on the financial liability that GPs can incur if they are the "last partner standing" and full reimbursement of the cost of providing NHS premises, the meeting said. Speaking in favour of the motion, Diana Hunter of Cambridgeshire LMC said that unlimited liabilities were "instrumental in the continuing demise of the partnership model."

"LOW VALUE" TREATMENT RESTRICTIONS MUST BE LED BY EVIDENCE

A motion was passed to stop requiring GPs to seek "prior approval" from clinical commissioning groups and acute care trusts to refer patients for procedures deemed of "limited clinical value." The motion said that many CCGs were inappropriately using the concept of limited clinical value procedures to save money. Delegates welcomed NHS England's consultation on the issue but said that the evidence base for limiting access to treatments must be approved by consultants, GPs, and the public. It called for "proper, evidence based evaluation" of all treatments that takes into account the potential cost of not providing treatment.

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2018;363:k5009

GPs are "emotionally blackmailed" to cover specialist treatments

GPs are increasingly being put under pressure to prescribe beyond their clinical competency because of a lack of specialist service provision, local medical committees have warned.

The annual conference of England's LMCs heard on 23 November in London that there were particular problems accessing services for gender identity and eating disorders, meaning GPs were having to treat patients who ought to be first seen by specialists.

The conference unanimously backed calls for the BMA's General Practitioners Committee to negotiate for "safe and effective secondary care high risk medical monitoring" for patients with eating disorders to be available everywhere in England.

A separate section of the motion, calling on the GMC to amend its guidance on trans healthcare because current guidance was "in neither patients, nor doctors, best interests," was also passed.

Frances Palmer of Devon LMC was among several GPs to speak in favour of the motion. Palmer said she recently refused to prescribe hormone therapy to a patient because she did not think it was within her competency but added that she felt under pressure to prescribe because of long waiting times for specialised care.

Rock and a hard place

"I felt pulled between a rock and a hard place. I have read the GMC guidance, and I think I will have to prescribe to my patient for harm reduction," she said.

"The waiting time in Devon for my patient to be seen at a gender identity clinic is 18 months. My patient is not receiving the specialist care they need. [But] I do not think I am qualified to provide it . . . nor am I paid to."

Nasir Hannan of Bedfordshire LMC also spoke in favour of the motion. He raised particular concern about access to specialist eating disorder services, saying that death rates among patients with anorexia nervosa were "on a par" with those for myocardial infarction and cancer.

"GPs are being emotionally blackmailed into taking on the medical monitoring of these high risk, severely ill patients," he

"My patient is not receiving the specialist care they need. I do not think I am qualified to provide it . . . nor am I paid to" Frances Palmer, Devon LMC

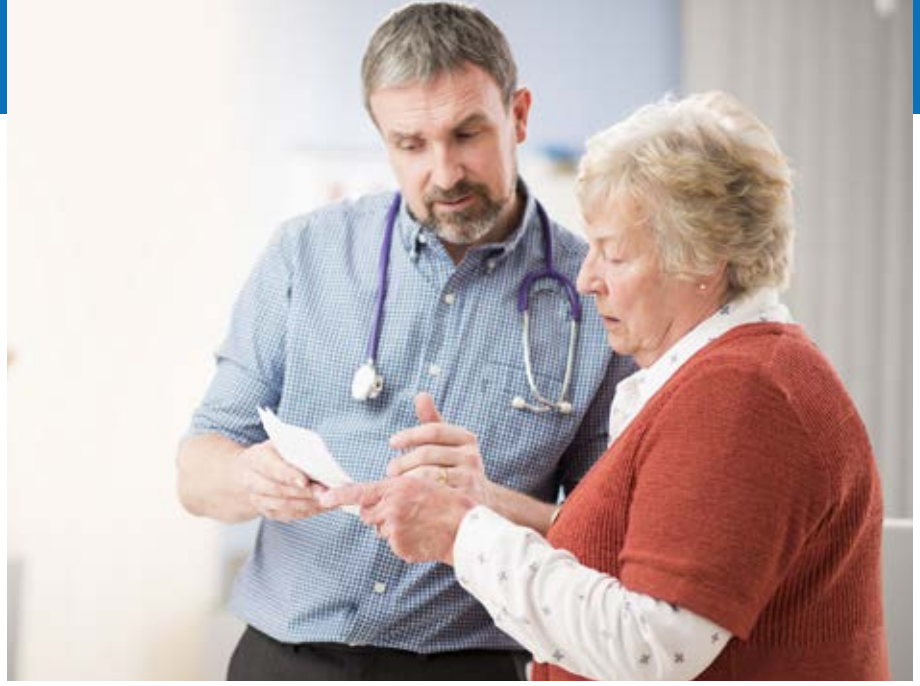
Leader calls for "long term cure" to relieve pressure on general practice

The government must follow through on its promise to invest in an "effective, long term cure" for the pressures facing general practice, the head of England's GPs has urged.

In a speech to the LMCs conference, Richard Vautrey (right), chair of the BMA GP Committee, said the government's pledge this week to invest an extra £3.5bn in primary and community care as part of the NHS's long term plan must be translated into "real, additional, and recurrent investment."

He said, "We already have meetings scheduled in the next few days to drill down to the detail as we cannot tolerate another five years like the last 12, and we must ensure that the crisis we face is properly addressed with real, additional, and recurrent investment."

He added, "We must see new funding used effectively, with practices



said. "We do not have the skills or specialist knowledge to deal with these patients, or the resources to follow the King's College guidance on the management of severe anorexia."

Annie Farrell of Liverpool LMC argued against the motion, saying, "Trans patients make up a tiny proportion of the population. It is not that difficult to follow guidance."

But Alex Freeman of Hampshire and Isle of Wight Clinical Commissioning Group, who proposed the motion, said, "I think our trans patients deserve better than they get from specialist services. But that doesn't mean to say that it's my job to do bridging hormones, when I'm not sure what effect that's going to have. It is highly specialised. I haven't done two years of specialist training.

"The GMC needs to get this right so we can give these patients the care they deserve."

Outwith competence

The conference unanimously called on the GP Committee to ensure that "no GP is pressurised by NHS England into prescribing medication outwith their competence due to failures of NHS England specialist commissioning."

It was also unanimous in calling for the committee to ensure that appropriate services for managing substance misuse were commissioned.

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2018;363:k4994

in control so that we can start to address workload pressures and deliver a safer service to our patients."

Vautrey paid tribute to the dedication and resilience of GPs and their teams in the face of huge workload pressures. But he said that widespread burnout must be tackled as a matter of urgency.

Workload pressures

Vautrey said, "The reality is an NHS that is in a year round crisis. The pressure is on 12 months of the year, day after day. We know and experience this daily pressure in our surgeries.

"We know and experience the pressures on our patients as they need more care from us, but we struggle with the capacity to be able to respond. And we know and experience the impact on our staff and colleagues, too many of whom are becoming ill as they struggle with unsafe workload.

"We know the illness, but our experience has shown that short term fixes will not solve this problem. More sticking plaster solutions will just make the patient sicker.

"Instead we need an effective, long term cure. We need nothing less than a properly funded NHS built on the solid bedrock of a thriving general practice."

Vautrey said it was positive that the health and social care secretary for England, Matt Hancock, had emphasised that general practice was what the rest of the NHS was built on, but added, "These words will count for nothing if they are not matched by action."

PLEDGE to invest an extra **£3.5bn** . . . must be translated into "real, additional, and recurrent investment"

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2018;363:k4989

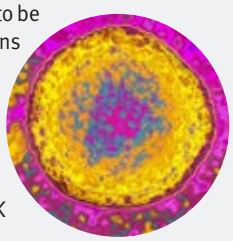
Hepatitis C: NHS seeks to identify 55 000 patients

NHS records will be used to identify 55 000 people who tested positive for hepatitis C between 1996 and 2017 to encourage them to seek treatment.

The patients identified by Public Health England (PHE) will be sent letters explaining that the infection is now curable. GPs will be told before the letters are sent so they can raise any concerns, such as a patient having a terminal diagnosis or having already been treated and cured.

Largest medical procurement

The proactive policy announced by PHE and NHS England marks a change of tack. When the direct acting antivirals for hepatitis C were launched NHS England rationed the numbers of people treated, but in February it launched the NHS's single largest medical procurement—believed to be worth hundreds of millions of pounds—aimed at setting an affordable price for the drugs in return for expanding the market among the 160 000 people in the UK believed to be infected.



So far, PHE says in a report, 24 500 people in England have had the new drugs in the past three years. A monitoring programme has found that 95% achieved a "sustained viral response," meaning that no hepatitis C virus was detectable in the blood 12 weeks after treatment completion.

Advanced disease

The early focus of treatment was on patients with more advanced disease, but PHE now believes most of these have been treated. Of nearly 8000 patients identified but not yet treated, 41% show no liver fibrosis, compared with 32% in the 24 500 who have been treated; and only 0.6% of untreated patients have liver cancer, compared with 5.2% of those treated. From now on it will get harder to detect the people infected, partly because they may themselves be unaware or, if aware, they will often belong to hard-to-reach groups.

Graham Foster, NHS England's hepatitis C clinical chair, said, "This dramatic progress in treating hepatitis C is one of the biggest but least acknowledged NHS success stories. NHS England has helped transform the lives of thousands of people, and with fair pricing the NHS has a real prospect of eliminating hepatitis C altogether."

Nigel Hawkes, London

Cite this as: *BMJ* 2018;363:k4923

THE BMJ CHRISTMAS 2018 APPEAL

Help volunteer doctors, from Bangladesh to Bethnal Green

Doctors of the World brings healthcare to the most vulnerable people globally, including in the UK, as **Jane Feinmann** writes

The charity Doctors of the World works worldwide to empower the most vulnerable, and often forgotten, people to access healthcare. Twenty miles east of Beirut, for example, in Lebanon it supports five primary healthcare centres and one mobile clinic in the Beqaa valley, home to many of the 1.5 million Syrian refugees who now reside in Lebanon (pictured).

In Yemen, where war has left 22 million adults and children at risk of starvation, Doctors of the World's medical volunteers are helping in the three worst hit regions. And in Bangladesh, which hosts an estimated 700 000 Rohingya people who have fled from neighbouring Myanmar, it provides mental health support to the many refugees affected by violence.

As part of the global Médecins du Monde network, the charity delivers more than 350 projects in more than 80 countries through 3000 volunteers. It relies on individual donations to fund the long term care needed to help those caught up in the Gaza conflict, forced migration along Pakistan's border, or famine in Kenya.

"The exodus from Syria peaked two years ago but our volunteers are still providing much needed medical help throughout Europe," Peter Gough, an NHS GP in Bedfordshire and a trustee of Doctors of the World, tells *The BMJ*.

More UK clinics

And the charity's doctors are also in demand in the UK. Thousands of people, including undocumented migrants, asylum seekers, and survivors of human trafficking who are being wrongly denied NHS healthcare turn instead to Doctors of the World. Last year, volunteer doctors provided free medical care, advice, and advocacy for 1617 people in the UK, including patients with cancer, arrhythmia, and chest pain; those who needed drugs for chronic conditions; and pregnant women. "This is just the tip of the iceberg," Gough says.

This year *The BMJ*'s Christmas appeal will help support the charity's work worldwide as well as help it to extend its network of clinics in the UK. In 2019 it plans to move its only permanent clinic, in Bethnal Green, east London, to larger premises in nearby Stratford and to open a new clinic in Birmingham, such is the demand for its services.

"The people we see are long term members of our communities. Most are working and have been living in the UK for many years," says Gough.

Jane Feinmann, freelance journalist, London jane@janefeinmann.com

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EDITORIAL

Damping down noise pollution

Excessive clamour in hospitals is damaging for patients and staff

Excessive noise impairs communication, reducing the quality and safety of healthcare

Noise in hospitals is a common grievance among patients, families, and staff.[1] In the UK, 40% of hospital patients are bothered by noise at night, a consistent finding of the NHS Inpatient Survey.[1]

Hospital noise is a steadily worsening problem, with levels regularly exceeding international recommendations.[3 4] Noise levels over 100 dB have been measured in intensive care units,[4] the equivalent of loud music through headphones and the point beyond which damage to hair cells in the ear can occur.

Harms to health

Excessive noise impairs communication, causing annoyance, irritation, and fatigue[5] and reduces the quality and safety of healthcare. It has been implicated in the development of intensive care psychosis, hospital induced stress, increased pain sensitivity, high blood pressure, and poor mental health.[5-7]

Noise disrupts sleep; machines in particular have a greater negative effect on arousal than voices.[8] Post-discharge recovery is also compromised. In one study from Sweden, coronary care patients treated during noisy periods had a significantly higher incidence of re-admittance than those treated during quieter periods.[9] For staff, high noise levels can impact negatively on communication, performance, wellbeing, and caring behaviour, and can contribute to burnout.[5 6]

Patients report being ill equipped and ill prepared to deal with noise.[10] It can have a cumulative effect: when admitted for several nights, patients can feel trapped in a stress inducing soundscape, leading to premature discharge and heightened risk of poor recovery and readmission.

Three challenges hinder progress. First, noise is often incorrectly equated with high sound pressure levels. In physics, noise and sound are conceptually indistinguishable. With encultured perception, however, noise is defined as unwanted, uncontrollable, or unpredictable sound. Dripping taps may register low sound pressure levels yet still be considered noisy.

Second, noise is difficult to measure reliably. Materials used for hospital floors and walls, ward layout, acoustic properties of furnishings, and variables including bed occupancy all affect how sound is perceived. Published studies of noise measurements on wards usually report snapshot recordings over a 24 hour period, and rarely give detailed contextualisation of those readings. Validated measurement instruments are also lacking. One preliminary but promising approach uses a two dimensional plot of patients' subjective responses to sounds as a visual tool to evaluate noise reduction interventions.[11]

Third, there are many sources of noise. Alarms, trolleys, TVs, phones, and conversations are common disturbances.[12] Not all loud sounds are perceived as noise, however. Some patients find the sound of the tea trolley pleasing,[13] and some in the intensive care unit welcome ringing phones as a sign they are not alone.[14]

Interventions to date have included earplugs, noise warning systems, sound absorbing panels, educational initiatives, and noise reduction protocols.[15-18] Evidence suggests possible benefits, but the lack of randomisation, blinding, control groups, and long term follow-up, and the multi-component nature of many interventions make it difficult to isolate an initiative's effectiveness. Moreover, patients and relatives are rarely involved in research; they are seen as passive recipients of the soundscape rather than active participants in its creation. In the absence of firm evidence, future solutions should be based on a careful assessment of each hospital environment, and designed with input from all stakeholders, particularly patients and families.

Simple solutions

Patients and families need clear information about likely noise levels so they can consider simple solutions such as headphones with their choice of audio content. User friendly guides on the potential sources of noise can also help. Education for staff is also needed, to encourage a culture that considers noise reduction an integral part of safe, high quality healthcare.

Finally, early investigations of sound masking and noise cancellation technology suggest potential for use in healthcare.[19] Sound masking—the addition of background, broadband sound (such as white noise) —has been shown in a non-randomised trial to significantly improve sleep in hospitals, for example.[20]

For too long, noise in hospitals has been an intractable problem. Researchers must expand their focus from quantitative reductions in sound pressure levels to broader qualitative improvements in hospital soundscapes. Full patient partnership in this research will help accelerate progress in what has been an unacceptably slow moving field.

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EDITORIAL

Depression in older adults

It's a neglected chronic disease as important as dementia

Around the world we are witnessing a continued upward trend in life expectancy with the proportion of people aged over 80 years growing fastest. Depressive disorders are common across the life course and symptoms are present in up to a third of older adults. Depression in older people is associated with more functional and cognitive impairment than in younger adults[1] and carries significant costs for the person, the family, and the NHS. Comorbid physical illness, poor social support, and bereavement are known to increase risk of developing depression.[2 3]

Worse prognosis

With increasing age, the course of depression worsens: in a recent large cohort study of adults aged 18 to 88 years, people aged 70 and above experienced greater symptom severity compared with younger adults and a greater likelihood of still having a diagnosis after two years, even after adjusting for physical illness and antidepressant use.[4] Persistent severe depression is also known to be linked to the onset of dementia.[5]

In 2004, *The BMJ*[6] called for investment in new management approaches and research to improve outcomes in late life depression. But there remains a paucity of randomised controlled trials of pharmacological and psychological interventions in the acute treatment of depression. Although studies show efficacy similar to that in younger adults, participants are mainly the "younger old."[7]

There is very limited evidence for the effectiveness of treatment for depression in people aged over 75, older adults with chronic depression, or for long term treatments to prevent recurrence.[8] Despite this, antidepressants are prescribed for longer periods in older people than in younger people,[9] while observational data indicate that all classes of antidepressants are associated with increased risks of adverse events such as falls and seizures in older people.[10] Despite the Improving Access to Psychological Treatments programme offering non-pharmacological treatments geared to the needs of older people, uptake has been low.[11]

Collaborative Care interventions for depression include a structured management plan, symptom monitoring, simple psychological interventions, and enhanced communication between primary and secondary care. The 2004 *The BMJ*[6] proposed Collaborative Care to help older people with depression, especially those with chronic physical and social problems, and there have been recent positive findings from a large UK trial.[12]

Although it is understood that loneliness can play a role in late life depression, more work is needed to refine and evaluate psychosocial interventions that combat isolation. These include both befriending[13] and peer support schemes led by people who have experienced depression. Better understanding of the role of cerebrovascular disease and inflammatory mechanisms in late life depression might also pave the way for novel biological treatments.[14]

Family carers of older people with depression experience a level of burden akin to dementia carers.[15] Unlike intervention trials in dementia, however, studies into depression rarely measure carers' wellbeing. Carers have positive contributions to make: they are in a unique position to observe and recognise the evolving symptoms and so are pivotal to the recognition of the early symptoms of relapse. The carer is also a constant therapeutic ally when an older adult moves from home to hospital or residential care where depression may not be recognised.[16 17]

In 2006, Scott called for a "paradigm shift to recognise that depression is a life course disorder."[18] For older people this would mean a shift from the symptom focused management of acute depressive episodes to a chronic illness approach offering sustained support, a focus on physical and psychosocial functioning, and greater public involvement.

Too little attention

In recent years, public policy has helped to raise the profile of dementia and to promote research and education but, so far, late life depression has not received this attention. There have been some recent initiatives in patient and carer information, however, including a Royal College of Psychiatrists video and the MindEd online programme sponsored by Health Education England.

The evidence base for depression management does not meet the needs of an ageing population, many of whom will experience chronic or recurring depression. Research is needed to guide the use of long term person centred interventions, whether antidepressants, psychological therapies, or psychosocial. Such research must evaluate harms as robustly as benefits. Equally, depression in older adults needs a higher profile, akin to dementia, led by patients, carers, and clinicians, and following the established principles of chronic disease management.

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The evidence base for depression management does not meet the needs of an ageing population

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THE IMPLANT FILES

How lobbying blocked European safety checks for dangerous implants

Industry interests have wrecked plans to overhaul EU regulations for medical devices, report **Simon Bowers, Deborah Cohen, and International Consortium of Investigative Journalists colleagues**. Meanwhile, confidential reports of injury and malfunction have trebled in less than 10 years in many countries

For the past decade, European politicians have been at the centre of a lobbying storm. Bold plans to overhaul safety regulations for the millions of medical implants embedded in patients each year—including artificial hips, breast implants, stents, defibrillators, and pacemakers—have been wrecked by an army of lobbyists.

An investigation by the International Consortium of Investigative Journalists and its partner organisations, including *The BMJ*, has discovered how top EU politicians and officials were won over by misleading claims from implant industry lobby groups.

These claims had a pivotal role in shaping the course of EU policy and killing off any prospect of a fundamental strengthening of medical device regulation, first in the European Commission and later in the European parliament.

Public health campaigners say Europe is in urgent need of tougher rules. Even though millions of Europeans' lives have been lengthened or improved by medical devices, the EU has borne the brunt of many of the world's worst implant scandals, unnecessarily leaving many patients scarred, in pain, or even dead. Leading surgeons, regulators, lawyers, and campaigners have said Europe's approach to evaluating and approving new implants means that its citizens are treated "like guinea pigs."[1-3]

The Implant Files is a year long investigation into the behaviours of the medical device industry. The investigation was coordinated by ICIJ, involving more than 250 journalists from 36 countries, in the UK including *The BMJ*, BBC *Panorama*, and the *Guardian*. It traces rapid advances in device technology and reveals that safety regulations have struggled to keep up.

In their quest for rapid approvals many medical device firms travel first to Europe, which has some of the lightest regulations in the developed world. The industry's largest trade association in the region, MedTech Europe, said EU rules had influenced safety regimes[4] in Canada,[5] Japan, and Australia. More recently, industry lobbyists in the US have pressed regulators to adopt ideas from Europe.

KEY FINDINGS

- Secrecy remains across Europe about injury and malfunction data relating to medical devices. Freedom of information requests in 16 countries were denied or led to incomplete responses full of redactions
- Confidential injury and malfunction reports have trebled in less than 10 years in many European countries, including in Spain, Italy, and Ireland
- High risk medical devices have been certified as safe, often without any supporting trials in humans
- BBC *Panorama* and *The BMJ* found a device on the market that was tested on only pigs and cadavers, as well as one tested on just 33 patients for a short period
- The European Commission told ICIJ that injury and malfunction reports were likely to remain confidential as they were commercially sensitive. Publication would unnecessarily scare the public, the commission added

Suspect injuries, malfunctions, and deaths

Although the global implant industry is dominated by US manufacturers, and the US is by far the largest sales market, many firms choose Europe to try out their new—and sometimes harmful—products. This is done long before the devices have been tested to the satisfaction of the US Food and Drug Administration.

Examples of products certified as safe in Europe and later found to be flawed include PleuraSeal, a lung sealant that leaked[6]; RoboDoc, a robotic surgical device that caused tendon rupture and nerve damage[6]; and Brio, a deep brain stimulation implant to treat Parkinson's disease, which had to be removed from some patients after body fluids seeped into the device and it stopped working.[7]

In addition, European patients were the first to try Nanostim, a breakthrough pacemaker, some of which developed battery problems (see box overleaf); Trilucent, a breast implant filled with soybean oil, some of which went rancid, prompting regulators to recommend that thousands of women have them removed; and ASR resurfacing hip replacement. Each of these devices was eventually recalled, put on hold, or discontinued.

Official regulatory statistics often fail to capture the stories of European patients exposed to danger. Despite their limitations, incident reports offer the best available view of

ICIJ/CHRISTINA CHUNG

potentially dangerous medical products in use in Europe. Yet national health authorities refuse to make them public.

ICIJ reporting partners in 16 European countries have spent months seeking access to detailed injury and malfunction data held by national regulators. In each case, freedom of information requests were denied or led to incomplete responses, full of redactions.

In Belgium, regulators said it would take one person 5489 days to black out patient data or commercially sensitive information before requested documents could be released. In the UK, reporters tried asking only for injury reports relating to Essure, a sterilisation implant known to have harmed women, but were told this would violate the manufacturer's commercial secrecy.

Regulators in 19 countries—responsible for the safety of more than 85% of EU citizens—did respond, however, to an ICIJ request for the raw numbers of reported malfunctions, injuries, and deaths. The data they provided show a steep rise in incident reports over recent years.

In Germany, confidential reports have almost trebled in the past nine years. Regulation last year received 14 034 suspected device associated injury and malfunction reports. In France and the UK, incident reports have more than doubled in nine years, reaching 18 208 and 19 559, respectively. In Spain, they have quadrupled in seven years, while in Italy reports quadrupled in just four years.

Without more detailed data—such as the number of different devices on the market and how frequently they are used—it is impossible to know whether the rising number of injury and malfunction reports means products are getting more dangerous.

However, several countries, including the UK, Italy, and the Netherlands, said sharp increases in part reflected improved reporting practices.

Christian Gluud, head of the Copenhagen Trial Unit in Denmark, says keeping incident reports confidential is "totally medieval."

He says. "It should be urgently changed. We need much more transparency. Only if patients and doctors have full access to all the benefit and harm data can they make informed decisions."

Although the EU is currently reviewing how much information should be shared with the public on a newly expanded system called Eudamed, the European Commission told ICIJ that injury and malfunction reports were likely to remain confidential as they were commercially sensitive for manufacturers.

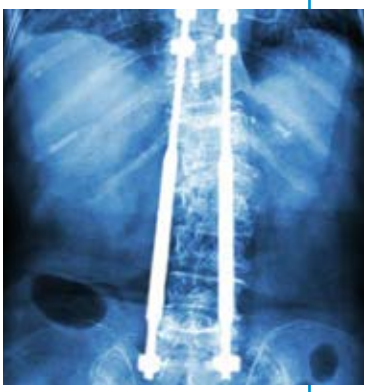
How much should doctors be told about devices?

Although Europe's new safety rules have been passed into law and will come into effect in 2020, some of the most controversial issues have been left hanging, to be resolved later.

One major concern remains: how much should doctors and the public be told about devices? At present doctors are left in the dark about the evidence behind medical devices. Even surgeons implanting devices do not always see the evidence.

BBC *Panorama* and *The BMJ* journalists looked at a treatment for children with early onset scoliosis called MAGEC rods (below). Instead of children having surgery every six months to extend conventional rods supporting the spine, surgeons use magnets to adjust the rods from outside the body. They are recommended by NICE as the preferred treatment. But despite being a wholly new technique, MAGEC rods were approved for use based on studies only in pigs and cadavers, the journalists found.

The MAGEC rod is just one of many implants conceived in the US but sold in Europe first.



Meetings are being held this month in Brussels to discuss what level of transparency should be applied to evidence collected about devices on the market. The stakeholders are principally industry representatives and notified bodies, with only one medical society and no patient groups.

Alan Fraser, a consultant cardiologist at University Hospital of Wales, is one of the few clinician stakeholders, and wants to see preclinical evaluations of high risk devices made publicly available, as well as accumulating postmarket surveillance data. "We think all that data should be available for clinical review by people who use these devices," he says.

Similarly, many public health experts see a clear advantage in being able to analyse the tens of thousands of injury and malfunction reports about implanted devices that are submitted to European regulators each year.

In the US, the Food and Drug Administration keeps a public register of such reports, available for doctors, patients, and academics to search. Under new EU rules, however, the regulators are expected to continue to hold similarly detailed information confidential.

Although a formal decision had not been announced, the commission told ICIJ that publishing details of patient harm possibly caused by medical devices would scare the public. A spokesperson said there was a need "to avoid unjustified mistrust and concerns."

A 2015 internal commission memo suggests there may be more to this policy decision than a desire to avoid unnecessary public concern. It reveals that EU officials met MedTech lobbyists, who warned them that Europe could lose out on investment if its new regulations insisted on greater transparency.

The memo records the lobbyists asking for more detail on "the relationship to be established between transparency needs and protection of commercially sensitive information." For MedTech Europe, the memo explained, "clarifying this adequately is crucial to make sure that [Europe] remains fit for attracting innovation and research investments."

Nanostim: tested on just 33 patients before approval for widespread use

European patients were the first to use Nanostim, a breakthrough pacemaker able to function without leads, some of which later developed battery problems.

The leadless pacemaker was developed to avoid some of the potential complications associated with traditional pacemakers, including infections and problems related to the leads.

But in 2016 St Jude Medical (now Abbott) halted further implantation of the pacemaker because of reports that premature battery failure was leading to low pacing output.

In 2013, the device was granted a CE mark by the British notified body BSI, one of about 50 private certification firms in Europe. But this investigation has discovered that only a few months earlier Nanostim was turned down by the German notified body TUV SUD because of lack of clinical data. It requested further studies from the manufacturers.

When we approached TUV SUD to find out what tests had been requested, a spokesperson referred us to BSI. We asked BSI on what evidence the device had been approved. We also asked the Medicines and Healthcare Products Regulatory Agency (MHRA). None of them would tell us.

"Thirty three patients with 90 day follow-up. That's tiny. A 90 day follow-up is not enough to learn much" Rita Redburg, University of California

Graeme Tunbridge, MHRA's manager for devices regulatory affairs, said: "There's very limited information we can share about specific devices because we're bound by confidentiality."

But ICIJ partner journalists working for Dutch daily newspaper *Trouw* and TV news programme *Avrotros* were able to get documents through freedom of information requests. These revealed that Nanostim was approved on the basis of a 90 day follow-up study in 33 patients.

Rita Redburg, professor of clinical medicine at the University of California in San Francisco, a cardiologist, and editor of *JAMA Internal Medicine*, is surprised that such a small study was sufficient to launch an implant in Europe: "Thirty three patients with 90 day follow-up. That's pretty tiny. And we're talking about a permanently implanted pacemaker. They're supposed to last 10, 20 years. A 90 day follow-up is not enough to learn much."

When criticisms about the lack of evidence were put to Abbott, a spokesperson said: "The Nanostim leadless pacing system was approved based on strong performance and safety data."

BSI said it couldn't answer our questions because of its duty of confidentiality to its clients. ICIJ news partners in other EU countries, including in the Netherlands and in Italy, obtained adverse event data for the Nanostim. But data for the UK—where a large postmarket observational study on Nanostim was conducted—were not available from MHRA, even though it oversees BSI.

Tunbridge said that MHRA wants to be world leader in information and transparency, but it it is hamstrung by how European law has been translated into UK law. "[Other EU countries] work differently, and we're bound by the laws under which we operate," he said.

The new European regulations, due to come into effect in 2020, cite that when applying to a notified body, manufacturers should declare if a previous application for the same product has been refused by another notified body.

Will this prevent the process of shopping around? Without transparency of the notified bodies' assessments it's impossible to say.

Patient experience: "I felt a bit like a guinea pig"

In 2014, Maureen McCleave became the first woman in the UK to have the Nanostim leadless pacemaker fitted.

The 82 year old was delighted to be offered the new device because it is delivered non-surgically. The device is inserted through the femoral vein with the help of a catheter directly into the right ventricle of the heart.

"I was over the moon, but I felt a bit like a guinea pig because I was going to be the first one; but I was grateful I'd been chosen because it sounded too good to be true," she told *The BMJ*/BBC *Panorama*.

Three years after her operation, the battery in her pacemaker stopped working. "I was a lot better after the operation until it all went wrong. Then I knew something was wrong because I was so tired," says McCleave.

The surgeons were unable to retrieve the device. McCleave now has a traditional pacemaker keeping her alive. But the Nanostim with the flat battery is still sitting inside her heart.

"I don't like the thought I've got a piece of metal in my heart that's doing nothing and it's just laying there. [I feel] disappointment. To have it done and then have to go through all that."

She says there has been no explanation why the Nanostim device stopped working.

"I don't like the thought I've got a piece of metal in my heart that's doing nothing"

"I'd like to know why it stopped working, and I'd like to know why I wasn't told in the beginning that there still was a lot of research being done on it because I was just assured that it would last me until I died."

Although the problems experienced by McCleave affected only a small number of the devices, they are a reminder of the unknowns surrounding these emerging technologies. Surgeons implanting these devices are unable to see the evidence on which implants are approved for use. The Nanostim documents came to light only after investigations by ICIJ journalists.

Because of the battery failures, the device is currently not being implanted.

2008

European Commission says medical device regulation is too lax and moots plans to scrutinise high risk implants as rigorously as drugs. Industry responds with a barrage of objections

2010-2011

Two high profile scandals surface; breast implants and metal-on-metal hips

2012

The European Commission renews reform efforts following public outrage. This triggers another wave of lobbying. Even the UK regulator argues against tougher safety requirements for devices

2013

The medical device industry body in Europe launches a high profile media campaign ahead of the European Parliament vote. Fundamental reforms are defeated

2016

A *BMJ* paper finds that compared with the US, devices "approved in Europe were associated with a nearly threefold greater rate of safety alerts and recalls"

2018

A full suspension of the use of vaginal mesh is ordered in England to avoid further risk of life changing injuries. France orders an inquiry into textured breast implants following a rise in breast implant associated ALCL (large cell anaplastic lymphoma)

Light touch Europe

For nine years, lobbyists pressured politicians as they wrote and rewrote plans to reform Europe's safety rules before the Regulation on Medical Devices was finally signed into law last year, ready to come into effect from 2020.

Throughout, lobbyists fought to keep as much as possible of the EU's existing, light touch safety regime. This allowed private, for-profit certification firms, known as "notified bodies," to approve high risk products, as safe—often without any supporting evidence from human trials.[9]

The battle over how medical devices should be regulated shows how well connected lobbyists can overwhelm a process designed to protect the public. Lobbyists won over European politicians and bureaucrats with an array of tactics, including unsubstantiated claims about safety and dark warnings of lost jobs, increased taxes, and fewer healthcare choices.

At the moment, the only assurance of safety given to doctors and patients is the small "CE" logo on the implants packaging or instructions, which the patient may never see.

Disliked proposal

In 2008, the European Commission produced several reform options, including a proposal to transfer responsibility for assessing high risk devices, including implants, to a new department within the European Medicines Agency "on an equal footing" with the EMA's work regulating drugs.[10] In both Europe and the US, all new drugs must show an acceptable level of safety and effectiveness in clinical randomised trials.

These proposals for rigorous testing overseen by the EMA brought a barrage of 200 responses, including 117 submissions from manufacturers, industry trade associations, notified bodies, consultants, and experts, 27 from government regulators and just 33 from healthcare workers and academics. The majority of respondents were against involving the EMA, but there was a clear split, with industry and the notified bodies firmly rejecting the idea and doctors, academics, patients, and consumers largely in favour.[11]

Scandals and loopholes

This emphatic response might have been the end of the matter, but two high profile scandals surfaced, beginning in 2010.

French regulators discovered that tens of thousands of women had received breast implants that were susceptible to rupture. In France alone, more than 18 600 women had Poly Implant Prothèse (PIP) implants surgically removed.

Meanwhile, several makers of all-metal hip implants stopped production. In 2012, journalists from *The BMJ* and *The Telegraph* went undercover to expose lax device approval systems.

Changing course

Spurred by public outrage, the European parliament called on the commission to renew efforts to overhaul safety regulations.[13] But when new proposals finally emerged in 2012, they had been watered down.

An official "impact assessment" found there was no need to stop notified bodies from approving the safety of implants and other high risk devices, or to transfer that task to the EMA. The commission explained that it had held "targeted meetings at [a] senior level with representatives from industry associations and with notified bodies."

Several fact finding events had taken place, but records show they were dominated by industry lobby groups, with few independent medical specialists present and even fewer patient groups. Meanwhile, countries where lots of jobs depended on medical device firms, including Germany, the UK, and Ireland, began to line up in support of industry.

Even the UK regulator, the Medicines and Healthcare Products Regulatory Authority (MHRA), argued that it would be wrong to end the notified body system or to place additional requirements for clinical trials on devices before they are approved.

In documents obtained by ICIJ news partner *Le Monde*, MHRA said "pre-market authorisation would result in delays in the availability of new and innovative medical technology for European patients.

"Additional requirements for clinical trials will also place substantial costs on manufacturers and delays could mean that it is uneconomic to bring some devices to market," said the MHRA.

Parroting the lobbyists, the commission explained how current regulations allowed device makers to get cutting edge technologies into European hospitals for less than €10m. The cost for heavily regulated drug companies to develop a new product was about €1bn.[11]

Most importantly, it said, tougher safety regulations would bring no safety benefits for European citizens: "US studies . . . point to the faster pre-market assessment in Europe compared to FDA clearance of medical devices, while safety levels were considered equal."

Boston Consulting compared the number of products recalled because of serious risk to patients, and said: "[T]he number of recalls in Europe is identical to that in the US," but it used absolute numbers rather than relating

them to the total number of procedures. The research served as an evidential bedrock for the commission's rejection of fundamental reforms to device regulation. And it would be deployed by lobbyists, later on, to win round MEPs.

Emotional appeal

By time the commission's industry friendly proposal was in its first reading in the European parliament in 2013, German social democrat MEP Dagmar Roth-Behrendt made a last ditch attempt at more substantive reforms.

An experienced parliamentarian, Roth-Behrendt says she always saw device regulation as the "missing cornerstone" in European health law.

"I never tried to be radical; I always tried to compromise," she says. But her plans came under fierce attack from lobbyists.

In advance of a crucial 2013 vote on the Roth-Behrendt plan, MedTech Europe[16] launched an online lobbying campaign, once again relying heavily on Boston Consulting's claim that the latest cutting edge implants were approved three years faster in Europe without additional risk to patients. The campaign's catchphrase was: "Don't lose the 3."[16]

Roth-Behrendt's push for fundamental reforms was ultimately defeated in 2013.[17]

"I saw a huge amount of lobbying in the 25 years I was in the European Parliament," Roth-Behrendt tells ICIJ partners. "But the way this was done was the blackest I've ever seen.

Although the EU's new safety regulations were not signed into law for another four years, any hope of fundamental reform died with Roth-Behrendt's failed efforts.

When the text was finally agreed last year, Vytenis Andriukaitis, the EU commissioner for health and a retired cardiac surgeon, said he "happily welcome[d] the final compromise, which contains a series of crucial improvements to the current system."[18]

Glenis Willmott, who succeeded Roth-Behrendt as the European parliament's point person for tracking and reporting on medical devices law[19] says the legislation ultimately represented a compromise, including some valuable measures. There are new powers to appoint a panel of experts that will, in some instances, double check the work of notified bodies and a new requirement for all implants to be given an identification number to help keep track of them. These measures were "a big step forward," she says.

Not everyone agrees. Carl Heneghan, professor of evidence based medicine at Oxford University, says: "The new device regulations give the impression of creating safer devices, but more regulation does not necessarily mean better regulation." He says they amount to "a hundred pages of smoke screen."

Most angry of all is Roth-Behrendt. "Medical devices must be safe and reliable. That hasn't been achieved in the past, and it won't be in the future," she says. "With medical device scandals happening, those lawmakers and decision makers who have prevented better regulation or watered it down should explain themselves. Why did they not [do more] for more patient safety?"

Victory for trade bodies

At a conference in Berlin in October 2017, Dario Pirovano, a senior figure at MedTech Europe gave a presentation that listed industry successes, including some big ones.

He noted that proposals for an EU public authority to assess safety, similar to the FDA, had been scrapped and a proposal to require testing for efficacy—as is required in the US—had been rejected.

Other "major blockers to innovation" had been "deleted or balanced," Pirovano said.

For the MedTech Europe industry group and for its members, he declared, EU's new regime was a "positive result."

In 2016, *The BMJ* published an independent, peer reviewed study examining the safety record of medical devices approved for use in both the US and Europe. The study compared the safety profiles of 206 new devices approved in the two countries over six years. In contrast to the Boston Consulting study,[14] it found that devices "approved first in the EU were . . . associated with a nearly threefold greater rate of safety alerts and recalls."[21]

ICIJ asked Boston Consulting if it accepted the findings of *The BMJ* study, and for a response to criticisms of the company's methods. The consultancy firm declined to comment.

ICIJ asked the European Commission about the different conclusions reached by Boston Consulting and *The BMJ* study. In a statement, it said: "A comparison between the US and new EU legislative framework would require a more detailed discussion. Different analyses come to different conclusions and generally recognise that each of the two systems has specific benefits."

It added: "The Commission always acts in the European interest, not in the interest of any one group or stakeholder. In reforming the system of medical devices, commercial interests were never prioritised over patient health."

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