this week

FOLIC ACID page 170 • **BAWA-GARBA** page 172 • **MESH AUDIT** page 174

Doctors urged to self report to GMC

A prominent campaigner for transparency in medicine has asked the GMC to remove him from its register and for his clinical practice to be scrutinised, after admitting to clinical errors that are likely to have led to deaths of patients. He has called on other doctors who have made similar mistakes to also report themselves to the GMC.

Consultant cardiologist Peter Wilmshurst called for his practice to be investigated after trainee paediatrician Hadiza Bawa-Garba was struck off (see page 172).

In a rapid response to *The BMJ* Wilmshurst has asked the GMC to investigate whether he is "fit to practise."

Over four decades of practice, Wilmshurst said, he has made clinical mistakes, including delayed diagnosis and errors in treatment. He wrote, "Some sick patients died. I am sure that many would have died anyway, but in some cases my errors are likely to have contributed to poor outcomes and some patient deaths. Therefore I have asked the GMC to investigate my clinical practice over the last 40 years to see whether I am fit to practise. Other doctors who have made similar clinical errors may also feel obliged to report themselves to the GMC."

Wilmshurst pointed out that the High Court agreed with the GMC that honest errors should be career ending mistakes and that judges in the case thought that the three members of the Medical Practitioners Tribunal Service's fitness to practise panel had made a mistake. "Will the GMC be asking the MPTS to remove those three individuals from the list of panel members, so that they cannot make a mistake at a future tribunal?" he asked.

In another protest at the court's ruling, doctors have said that they will cut up their registration certificates outside the GMC headquarters in London on 3 February.

David Nicholl, a consultant neurologist at Sandwell and West Birmingham Hospitals NHS Trust, has written to the health select committee and the Professional Standards Authority to say there were now "sufficient concerns regarding the GMC" and its ability to function, "given that they have lost the confidence of the medical profession."

The GMC has said it would be meeting people and organisations to discuss the Bawa-Garba case. Terence Stephenson, GMC chair, said this would include "how gross negligence manslaughter is applied to medical practice, in situations where the risk of death is a constant and in the context of systemic pressure."

Deborah Cohen, London **Cite this as:** *BMJ* 2018;360:k481

Peter Wilmshurst has asked to be removed from the UK register as some of his sick patients have died, possibly owing to his errors

LATEST ONLINE

- Doctors can stop ventilating 11 month old boy brain damaged at birth
- Union vows to support NHS staff who refuse to act as "border guards"
- UK ranks in the middle of European healthcare survey

SEVEN DAYS IN

REX

"Add folic acid to flour to end birth defects"

The UK government has been urged to fortify flour with folic acid to prevent birth defects, after a reappraisal of existing evidence concluded that there was "no scientific basis" for setting an upper limit on folate intake.

Researchers at Queen Mary University of London and the School of Advanced Study at the University of London concluded there were "elementary" flaws in a previous analysis from the US Institute of Medicine that suggested that the daily dose of folic acid should not exceed 1 mg.

The authors of the reanalysis said it would be a "dereliction of public health duty" if the UK government failed to fortify flour. If the UK had adopted the same level of fortification as had the US in 1998, neural tube defects, such as anencephaly and spina bifida, in an estimated 3000 babies could have been avoided.

The lead author, Nicholas Wald of the Wolfson Institute of Preventive Medicine at Queen Mary, said, "It seems a tragedy that something that could be so easily and safely prevented leads to terminations and the births of affected individuals. Folic acid is not harmful. Failure to fortify is harmful."

Gareth Iacobucci, *The BMJ* Cite this as: *BMJ* 2018;360:k477

Therapeutics

Public health inquiry into prescribed drug addictions

The growing problem of dependence and addiction to prescription drugs will be the focus of an independent evidence review by Public Health England, reporting in early 2019. Covering benzodiazepines and z-drugs, pregabalin and gabapentin, opioid pain medicines, and antidepressants, it will ask why one in 11 patients (8.9%) has one of these drugs prescribed, why prescribing addictive medicines has risen 3% in five years, and why antidepressant prescriptions in England have more than doubled in 10 years. Steve Brine, public health minister, said, "We know this is a huge problem in other countries like the US—and we must absolutely make sure it doesn't become one here."

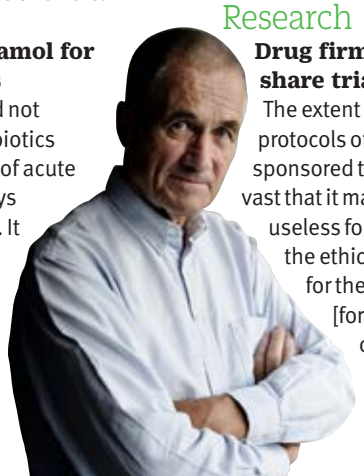
Use paracetamol for sore throats

Doctors should not prescribe antibiotics for most cases of acute sore throat, says NICE guidance. It cites research from 2014, which found that 60% of patients who attend general practice with a sore throat leave with a prescription for antibiotics. Patients should be encouraged instead to take paracetamol or ibuprofen, and be advised that local anaesthetic or antiseptic lozenges may help.

New cancer drugs fund stays on budget

The new Cancer Drugs Fund has treated 15 700 patients since July 2016, NHS England reported, and almost a third benefited from earlier access to treatment. The original fund treated 74 000 patients in its first four and a half years, so the annual treatment rate has not changed significantly; it cost £1.27bn in five years. The new fund operates within a £340m a year budget.

Research



Drug firms reluctant to share trial protocols

The extent of redactions in protocols of drug company sponsored trials was "so vast that it made them rather useless for assessing the ethical justification for the studies and [for identifying] discrepancies with subsequent publications," said Peter Gøtzsche (below), author of a study in the *Journal of the Royal Society of Medicine*. He reviewed 78 trial protocols approved in Denmark from October 2012 to March 2013. "We could not identify any legitimate rationale for the redactions," he wrote. "The mistrust in industry sponsored drug trials can only change if the industry offers unconditional access to its trial protocols and other data."

Sugary drinks

Morrisons bans energy drinks for under 16s

The supermarket chain Morrisons joined Asda, Aldi, and Waitrose in banning the sale of 84 high caffeine energy drinks to children under 16, starting on 5 March. The move followed a study in *BMJ Open*, which found that some energy drinks contain 78 g of sugar. The UK soft drinks levy begins in April and aims to generate £1bn a year in tax revenue for sports funding.

Team USA

Doctor jailed for abusing hundreds of gymnasts

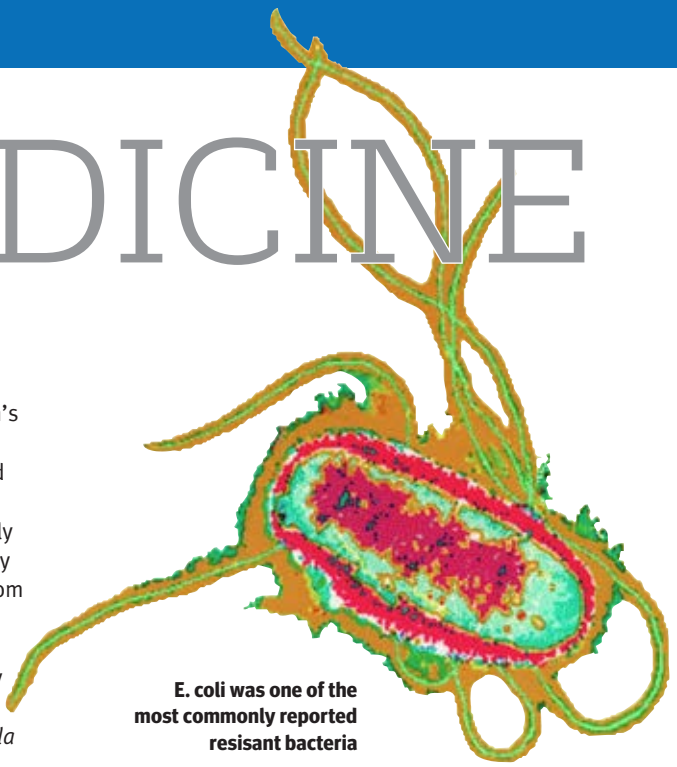
Larry Nassar (above right), a former doctor with USA Gymnastics and Michigan State University (MSU) who sexually abused hundreds of young athletes under his care, received a prison sentence of 40 to 175 years after a trial in which 156 young women gave impact statements. USA Gymnastics, MSU, and the US Olympic Committee were all repeatedly accused in court of having swept concerns about Nassar under the carpet. All three organisations face extensive litigation.

E-cigarettes

Short term benefit but uncertain longer forecast

E-cigarettes can help older smokers avoid cigarettes' worst health effects but can lead younger people to try the habit, a US report on more than 800 studies concluded. The National Academies of Sciences said the overall impact of e-cigarettes could be broadly positive, as millions of smokers shift to vaping; but these gains could be lost as more users are adolescent never-smokers.

MEDICINE



E. coli was one of the most commonly reported resisant bacteria

Antimicrobials

WHO global data show high resistance levels

The World Health Organization's Global Antimicrobial Surveillance System, launched in 2015, has reported high rates of resistance to commonly used antibiotics. Data primarily showed pathogens isolated from blood, urine, stool, cervical, and urethral samples from 40 countries. The most commonly reported resistant bacteria were *Escherichia coli*, *Klebsiella pneumoniae*, *Staphylococcus aureus*, and *Streptococcus pneumoniae*, followed by *Salmonella* species, and the data showed huge variations in rates of antimicrobial resistance. For example, 100% of *E coli* isolates from urine samples were non-susceptible to ceftriaxone in Egypt, but the rate in Finland was less than 5%.

NHS

Winter pressure stabilises but remains intense

The proportion of patients seen within four hours of arriving in emergency departments in the third week of January was 80.5%, up from 79.5% the previous week and 1.02 percentage points up on last year, showed data collected by the Royal College of Emergency Medicine from 50 UK trusts and health boards. Bed occupancy in the week ending 21 January was 94.8%, and 2295 delayed transfers occurred, up from 2174 the previous week. GP consultations for flu-like illnesses rose only slightly, from 53.1 to 54.1 per 100 000 population.

England's first ACOs are postponed

The government will delay forming the first accountable care organisations in England until NHS England has conducted a national public consultation in the spring, said Jeremy Hunt, health and social care secretary, in a letter to Sarah Wollaston, chair of the Commons health committee.

ACOs began in the US, when groups of healthcare providers came together to provide care for a given population. Hunt wrote, "Following NHS England's consultation, we anticipate that a small number of sites could be in a position to sign an ACO contract later in 2018."

Brexit

Put patients first in talks, say health experts

Failure to reach a trade deal between the UK and the EU could delay or block the arrival of new drugs and technologies to and from the UK, the Brexit Health Alliance warned in a report that urged both sides to "put patients first."

It gave several examples of drugs that could be hit by supply disruption, including prostate cancer drugs made only in the UK and used in 80 countries, including all of Europe. The warning followed an admission from England's health secretary, Jeremy Hunt, that it will be "uniquely damaging" to the UK and EU if an agreement on access to new drugs is not reached.

Cite this as: *BMJ* 2018;360:k468

PIP

The government is to review 1.6 million disability benefit claims after dropping a legal challenge to a High Court ruling. Ministers had wanted to exclude people who cited mental health as a reason for claiming a higher rate of personal independence payment (PIP). The extra payments will cost an estimated £3.7 bn by 2022

SIXTY SECONDS ON . . . THE PRESIDENTS CLUB

A SEEDY DIVE FAVOURED BY TRUMP?

It's seedy, but has nothing to do with the US president. It is (was) an annual men only fundraising dinner, attended by City grandees and captains of industry. And attractive, scantily clad young hostesses are exposed to behaviour bordering on sexual assault, including groping and nudity. An undercover *Financial Times* reporter infiltrated this year's event to reveal the debauched antics to a shocked world.

SOUNDS AWFUL. BUT WHY IS THIS TALE OF WOE IN *THE BMJ*?

Two of the charities in line to profit from the attendees' drunken largesse were London's Evelina Children's and Great Ormond Street hospitals.

OH DEAR. HOW HAVE THEY REACTED?

With dismay. Evelina said, "This is not the kind of event we would wish to be associated with," and has declined the £400 000 pledged at the dinner by restaurant entrepreneur Richard Caring. According to media reports he was going to have a high dependency unit named after him. The hospital is also returning the £265 000 given in 1998, 2013, and 2017. Great Ormond Street Hospital will also refuse the money pledged at this year's shindig and is returning the total of £530 000 donated between 2009 and 2016 "because of the wholly unacceptable nature of the event."

BUT HOW CAN THESE CHARITIES AFFORD TO RETURN THIS MONEY?

They're not exactly cash strapped. Great Ormond Street Hospital raised £101.8m in 2016-17 so the £530 00 it is returning is about 0.5% of that. Evelina is part of Guy's and St Thomas' charity, whose income was about £27m in 2016-17.

WHAT HAPPENS TO THE CASH?

According to the Charity Commission, refusing to take money is straightforward but returning donations already accepted is more complicated. It may need to authorise such returns and charities should seek the commission's advice. The Presidents Club has since wound itself up—who would have thought a fun night out for drunk, entitled City boys could end so badly?

Anne Gulland, London

Cite this as: *BMJ* 2018;360:k431

NEWS ANALYSIS

Anxiety, anger, and bewilderment: the fallout from the Bawa-Garba case

The erasure of the trainee paediatrician from the UK register has left doctors fearful for their own careers and raised questions about what's next for the patient safety agenda, reports **Clare Dyer**

The case of Hadiza Bawa-Garba, who was struck off the UK medical register by the High Court on 25 January, could be a tipping point in the way the criminal justice and regulatory systems deal with doctors whose failings play a part in their patients' deaths.

Her case has sparked a realisation in the medical profession and government that a system that heaps the blame on an individual for wider hospital failures could stop the development of a no-blame culture in its tracks, further endangering patients' safety.

Within hours of the judgment, Jeremy Hunt, the secretary of state for health and social care for England, pronounced himself "totally perplexed" by the GMC's decision to appeal against a medical practitioners tribunal conclusion that Bawa-Garba should be suspended from the register but not struck off, despite her conviction for manslaughter by gross negligence.

By lunchtime on 29 January supporters had raised more than £200 000 to crowdfund advice on appeals against both the High Court ruling and her original conviction, and the needle was ticking up by the minute, with 27 more days to go (crowdjustice.com/case/help-dr-bawa-garba).

A donor who pledged £15 wrote, "Don't relent for your cause is just. Your colleagues across the world in Australia support you too!" Another, who gave £50, added, "My own experiences have shown a system at breaking point causing suboptimal care. Those responsible need to be held to account."

The High Court ruling has sparked fears in the medical profession that moves to develop a more open culture in the NHS could be scuppered, threatening patient safety. Thousands of doctors have signed a letter warning that the case could deter doctors from admitting their mistakes, leading to further tragedies in the future.

The Royal College of Paediatrics and Child Health said that it had initiated a "high-level dialogue" with the GMC and the Crown Prosecution Service to discuss the case, which had engendered "anxiety, anger, and bewilderment."

Hunt tweeted that he was "deeply concerned about possibly unintended implications here for learning and reflective practice in e-journals." Later he told the BBC, "For patients to be safe, we need doctors to be able to reflect completely openly and freely about what they have done, to learn from mistakes."

Evidence not heard

Among the evidence before the jury at Bawa-Garba's criminal trial was a reflective document from her e-portfolio, which she filled in seven days after 6 year old Jack Adcock (above) died from sepsis at Leicester Royal Infirmary. Yet the jury was not told of the many improvements the hospital had brought in after the serious untoward incident report, which highlighted the multiple system failures that contributed to Jack's death.

The medical practitioners tribunal heard about the context in which Bawa-Garba was working before it decided that erasure would be disproportionate. She had just returned from 13 months' maternity leave but had had no induction. She was asked to cover the children's assessment unit along with her own ward duties.

A foundation doctor and senior house officer were working under her, but both had only rotated to paediatrics that month. The consultant covering the children's assessment unit was teaching elsewhere. The hospital's IT facilities had broken down, and there were nursing staff shortages.

> **"These deeply concerning issues need to be addressed with some urgency"**
> AMRC

The tribunal took account of the system failures in deciding to suspend Bawa-Garba for 12 months. But the High Court ruled that the tribunal had impermissibly gone behind the verdict of the jury and that Bawa-Garba had to be struck off to maintain the public's confidence in the medical profession.

The Academy of Medical Royal Colleges said that the case "brings into sharp focus a number of deeply concerning issues which must be addressed with some urgency." The Royal College of Emergency Medicine agreed, adding, "We believe that unless clear action is now taken, the consequences of this case will have a damaging effect on the morale of junior and senior staff managing risks which are often much outside of their control."

"Truly humbled"

The crowdJustice campaign to fund advice on possible appeals was set up by the junior doctors Moosa Qureshi, James Haddock, and Chris Day. In a statement Bawa-Garba said that she was "overwhelmed with gratitude" and "truly humbled" by the response to the campaign. She added, "This tragic case raises some important questions. I share all of your concerns about the implications of this case and the GMC's actions on future patient safety.

"In the light of this huge outpouring of support, I plan to use your generous funds to change to a top independent legal team, to potentially challenge the GMC and to have an independent review of the original conviction."

Rob Hendry, medical director at the Medical Protection Society, which represents Bawa-Garba, said, "The strength of feeling on the outcome of this case and its implications have been clear to see. We are pleased Jeremy Hunt has acknowledged the concern. This is an important and timely gesture for the profession."

The GMC's chief executive, Charlie Massey, said, "We have been speaking to the Royal College of Paediatrics and Child Health and a number of other organisations and individuals about some of the wider issues highlighted by this case. We will continue to work with royal colleges and others over the coming weeks to address the concerns that we are hearing clearly from doctors."

Clare Dyer, *The BMJ*

Cite this as: *BMJ* 2018;360:k456

Hadiza Bawa-Garba: challenge to the GMC's decision "possible"

The High Court over-ruled the tribunal's decision to suspend the trainee doctor

Lord Justice Gross, one of two High Court judges who ruled in favour of the GMC

Jack Adcock's parents: told *The Mirror* they felt they had "justice"

Paediatrician convicted of manslaughter must be struck off, rules High Court

A trainee paediatrician who was convicted of gross negligence manslaughter after the death of a 6 year old boy must be struck off the medical register to maintain public confidence in the profession, the High Court has ruled.

A medical practitioners tribunal last June suspended Hadiza Bawa-Garba for 12 months rather than erase her, after taking account of system failures that contributed to Jack Adcock's death. But two senior judges substituted the sanction of erasure, after the General Medical Council appealed against the tribunal's decision.

Mr Justice Ouseley, giving the leading judgment, said, "I have come firmly to the conclusion that the decision of the tribunal on sanction was wrong." Lord Justice Gross agreed, "with sadness but no real hesitation."

Jack died of sepsis at Leicester Royal Infirmary in February 2011. Bawa-Garba was given a two year suspended jail sentence in December 2015 after being convicted of manslaughter.

Ouseley said the tribunal's decision to suspend her contradicted the jury's findings that her failings were "truly exceptionally bad." He added, "The holes in the patient's safety net cannot reduce her personal culpability."

"Above-average doctor"

He went on, "There was no suggestion, unwelcome and stressful though the failings around her were, and with the workload she had, that this was something she had not been trained to cope with or was something wholly out of the ordinary for a year 6 trainee, to have to cope with, without making such serious errors."

He acknowledged that Bawa-Garba "before and after the tragic events was a competent, above-average doctor." But "this misconduct by manslaughter by gross negligence involved a particularly serious departure from the principles of [the GMC's] Good Medical Practice, and the behaviour was fundamentally incompatible with being a doctor," he added.

Rob Hendry, medical director of Bawa-Garba's defence organisation, the Medical Protection Society, suggested an appeal was possible, saying it was considering "all options in the interests of our members and the wider profession."

The GMC's chief executive, Charlie Massey, said, "The ruling clarifies that tribunals cannot go behind the jury's verdict when a doctor is convicted in a criminal court." But he added, "Doctors should never hesitate to act openly and honestly if something has gone wrong."

Clare Dyer, *The BMJ*

Cite this as: *BMJ* 2018;360:k417

BMJ OPINION Rachel Clarke

GMC has to be candid about conditions

Why has Bawa-Garba's treatment so convulsed the profession? We are angered, in part, by the absence from the GMC's narrative of the possibility that her negligence arose because of the working conditions into which she was thrust that day.

What, precisely, was Bawa-Garba meant to do? Down tools and say it was unsafe for her to work? Is that what we should all do now—walk out on our patients when rota gaps are dangerous? Or struggle on, sick with dread, knowing a patient may slip through the understaffed net, and that we too may face criminal conviction as a consequence?

When the BBC put this question to Charlie Massey, the GMC's chief executive, last week, he was evasive. Small wonder doctors are afraid. Many of us battle daily with understaffed bedlam. Yet the GMC's only advice to trainees, now terrified of both treating and not treating their patients, is platitudinous—essentially, tell someone senior you think conditions are suboptimal.

That is not helpful. What is the point of frontline doctors speaking out when those with clout—the GMC, the CQC, Jeremy Hunt, and the prime minister—know that in today's NHS, patients are jeopardised by rota gaps daily. The GMC could set a powerful precedent by speaking bluntly about the dangers of rota gaps. It could insist we report every one of them, and make it easy, and—crucially—safe for us to do so.

The GMC could set a powerful precedent by speaking bluntly about the dangers of rota gaps

It is time for the GMC to choose. Does it wants to be part of the problem or the solution? Because, now, every one of us could state the same refrain: #IAmHadiza.

Rachel Clarke, specialty doctor in palliative medicine

Surgeon faces GMC hearing following quashed conviction

David Sellu (below), the senior colorectal surgeon who was jailed for gross negligence manslaughter and who then had his conviction quashed by the Court of Appeal, is to face a six week fitness to practise hearing.

At the medical practitioners tribunal hearing in Manchester, Sellu faces charges of failing to provide good clinical care to James Hughes, who was at the centre of the criminal case against him.

The tribunal will investigate Sellu's actions during the days before Hughes died at the private Clementine Churchill Hospital in February 2010. Hughes was admitted to hospital under the care of an orthopaedic surgeon, who had performed a successful knee replacement, but Sellu was called in after Hughes developed abdominal pain.

Multiple organ failure

Sellu, now 70, performed an operation 25 hours after he first saw Hughes, but the patient died two days later of multiple organ failure, faecal peritonitis, and perforation of the diverticulum.

The jury at his November 2013 trial convicted Sellu, a respected surgeon of 40 years' standing, of gross negligence manslaughter by a 10-2 verdict, and he was given a two and a half year prison sentence. His imprisonment shocked doctors, and a campaign was launched to try to get the conviction overturned. By the time the case reached the Court of Appeal he had already served his sentence, half in prison and half on licence.

In November 2016 the appeal court quashed the guilty verdict, ruling that the trial judge's direction to the jury had been inadequate.

Two charges

Sellu faces two tribunal charges, both alleging he failed to provide good clinical care to Hughes. The first, relating to 11 February, alleges he did not "arrange for the requested CT scan to be carried out; perform surgery, despite being aware of the perforated viscus; or initiate resuscitative measures." The second allegation is that on 12 February he did not "review Patient A; make arrangements to perform urgent surgery; give clinical priority; or source an anaesthetist for surgery."

Clare Dyer, *The BMJ*

Cite this as: *BMJ* 2018;360:k419

Inquiry into damage caused by mesh implants launched

The government has said that it will conduct a national audit to investigate problems caused by vaginal mesh implants.

The safety of the implants has been brought into question by thousands of women around the world, many of whom are taking legal action against manufacturers, including in England, Wales, and Scotland.

The Department of Health and Social Care for England announced that it had accepted calls from the all party parliamentary group on surgical mesh implants and campaigners to conduct a retrospective audit into vaginal mesh implants. The audit aims to create a better understanding of the complications related to mesh implants for incontinence and prolapse. It will link data on patients' conditions and the type of surgery they underwent to subsequent hospital treatment and consultations in the NHS. The audit is expected to be completed by April.

Kath Sansom, founder of the Sling the Mesh campaign group, said that

Doctor is struck off for continuing abusive behaviour after suspension

A doctor who was suspended by a medical practitioners tribunal for writing derogatory emails about a colleague and a patient has been struck off the UK medical register after writing "a stream of abusive emails" about the GMC regulators handling his case.

Kamal Hameed Ubaid Al-Any, a former middle grade doctor who worked in the emergency department at the Whittington Hospital in north London, was initially suspended for four months in 2016.

"Insensitive, arrogant"

That case stemmed from a 2013 incident in which he had seen a young patient in hospital with her mother. A specialty trainee year 1 doctor saw the patient had become distressed and went to tell a consultant. Al-Any tried to stop him and told him not to involve anyone else.

After the mother made a complaint accusing Al-Any of being "insensitive, arrogant, and incompetent," he sent emails to the hospital calling her an "evil, abnormal, agitated woman," and that her behaviour differed little from that of a "prostitute." He wrote that his colleague was "a stupid child" and his "non-medical ethical behaviour might reflect his shallow limited medical experience and might reflect his personal, family, and social background."

In August 2016, a tribunal found Al-Any's fitness to practise to be impaired but considered his wrongdoing to be "easily remediable." It suspended him for four months. The first review hearing in March 2017 found no evidence of change, and extended Al-Any's suspension by a further nine months.

James Newton-Price, who chaired the latest tribunal, said, "While Dr Al-Any has engaged with the GMC, it has been in an unprofessional and aggressive way that brings the medical profession into disrepute." Four emails Al-Any sent to the GMC in autumn 2017 "accused various individuals of being liars, cheats, and criminals, without any foundation," said Newton-Price, reading from what he called "a stream of abusive emails which have made outrageous and extreme allegations."

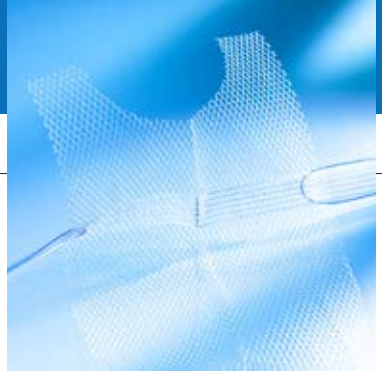
Al-Any, who qualified in Basra, Iraq, in 1978, was neither present nor represented at the Manchester hearing but provided written submissions.

Erasure, the tribunal concluded, was a "proportionate and necessary sanction."

Clare Dyer, *The BMJ* **Cite this as:** *BMJ* 2018;360:k352

the announcement was a sign that the government was finally listening to the women affected. "After two decades of mesh use with poor audit, the government is finally hearing the voices of women whose lives have changed beyond repair," she said. "A survey of 570 women in Sling the Mesh shows a third have suffered mesh slice into their vagina or organs, and eight out of 10 have pain walking or sitting. Six out of 10 have lost partners because of the strain, while seven out of 10 have lost sex lives. A third have had to give up work because of pain. Not surprisingly, six out of 10 suffer depression and anxiety."

NHS England estimates that more than 100 000 women have had surgery involving mesh and that complications affect between 3% and 5%. But some recent studies indicated that a 10th of women experience serious complications, the all party parliamentary group said.



Mesh has caused serious complications in a 10th of women, studies report

It said that the audit would improve understanding in the NHS of the scale of the risk that mesh surgery poses to women. Owen Smith, the Labour MP who chairs the group, said, "I'm delighted that the government has listened to our concerns and has now agreed to undertake this audit to get a better understanding of complications related to mesh surgery.

"I hope the audit will provide crucial answers about the proportion of women adversely affected by mesh surgery."

On 30 January the all party parliamentary group was due to hold a meeting in parliament for MPs from all political parties to meet clinicians to discuss mesh.

"After two decades of mesh use with poor audit, the government is finally hearing the voices of women whose lives have changed beyond repair"
Kath Sansom, Sling the Mesh

Abi Rimmer, *The BMJ*

Cite this as: *BMJ* 2018;360:k472

Royal society calls for labels on alcohol bottles to include information on calories and healthy drinking guidelines

Calorie content and health warnings should appear on alcoholic drink labels, a report by public health doctors has urged.

The Royal Society of Public Health warns of an "alcohol health awareness vacuum" with just 16% of people aware of alcohol guidelines, one in 10 aware of the link between alcohol and cancer, and 80% of people unable to correctly estimate the calories in a glass of wine. It says action is needed to raise public understanding of the effects of alcohol on health.

Drinkers survey

The society commissioned a survey of nearly 1800 adults to look at the effects of different pieces of label information. Participants were shown three pictures of bottles of wine or beer whose labels contained different pieces of information and asked which one they would purchase: only alcohol by volume; only calorie content; or both calorie content and alcohol by volume. The results showed that including calorie content on labels led to a shift to choosing drinks with fewer calories, especially among women and younger drinkers.

The society had been in talks with the Portman Group, which represents the alcohol industry, about labelling guidelines. The group published its own last year calling for three minimum pieces of information: unit alcohol content per container; the pregnancy logo and message; and active signposting to Drinkaware. The society described them as "even less informative" than current labels.

Shirley Cramer, RSPH's chief executive, said the EU Commission's March deadline for manufacturers' proposals on calorie labelling gave the UK a chance to lead the way. "If Britain is to leave the EU, we ask that any additional regulatory freedom be used to strengthen that contribution—not degrade it. Sections of the alcohol industry have thus far acted to hinder, rather than help, this important agenda—they must take this opportunity to change tack and play their part—or be compelled by government to do so."

Ian Gilmore, chair of the Alcohol Health Alliance, said: "[The Portman Group] decision not to endorse the findings of this report is yet more evidence that producers cannot be relied upon to communicate the risks linked with alcohol. We know from our own research that 81% of the public want to see the guidelines on labels."

Anne Gulland, London

Cite this as: *BMJ* 2018;360:k415

THE PROPORTION of young people aged 18 to 24 choosing low calorie and low alcohol drinks rose from 50% to 66% when labels were more detailed

THE BIG PICTURE

Bright side of life with Parkinson's

Abstract artist John McLean was diagnosed with Parkinson's disease in 2013, but much to his surprise it not only did not herald the end of his career, it actually seemed to give it a boost.

"I do as much painting now in two days as I did in a week when I could work full-time, which amazes me," McLean told the *Times*. The artist suspects that the drug levodopa, which replaces depleted dopamine, could be fuelling this new level of creativity.

McLean, whose creative process is followed in a new film *Which Way Up,* to be shown at the Glasgow Film Festival next month, says he has refused to allow his diagnosis to limit his work: "Parkinson's is completely irrelevant to me in how, and why, I appreciate and make art."

Talking to Parkinson's Life, a community website for patients and families, McLean said: "I've noticed more hand-brush strokes coming in, as it seems my fine motor skills are not so badly affected by my Parkinson's.

"I never thought I'd find myself saying something as positive as this, but it looks as though having Parkinson's has exposed me to some techniques that I might have otherwise missed."

Alison Shepherd, *The BMJ*

Cite this as: *BMJ* 2018;360:k464

PROUDFOOT LTD

EDITORIAL

Criminalising doctors

What must we learn from Jack Adcock's death?

Fear is toxic to both safety and improvement, and health systems must abandon blame as a tool. So wrote Don Berwick in his report after the Mid Staffs care scandal.[1] He called for a commitment to learn from mistakes and to act on that learning.

Recent events have set those wise words at nought. Last week the tragic case of 6 year old Jack Adcock (right), who died from sepsis in 2011, reached what may be its final punitive phase, with the erasure of a trainee paediatrician from the medical register. Jake Adcock's mother has said she wanted justice for her son and to ensure that no one else would suffer in this way.[2] Sadly the opposite is more likely. This case, and a growing number of others,[3] risks driving doctors towards defensive medicine, discouraging them from discussing errors, and denying health systems the chance to improve.

Hadiza Bawa-Garba was convicted of gross negligence manslaughter in 2015[4] and later temporarily suspended from practising medicine by a medical practitioners tribunal. But the General Medical Council wanted her struck off and has now won its appeal against the tribunal's decision. Her criminal conviction and the GMC's actions have caused an outcry among doctors, distressed that one doctor has been made a scapegoat and understandably fearful that they too are now vulnerable to criminal charges if they make mistakes.

A criminal case?

Should this case ever have gone to court? Not if Berwick's report had been acted on. "Recourse to criminal sanctions should be extremely rare and should function primarily as a deterrent to wilful or reckless neglect or maltreatment," it said.[1] No one in possession of the facts and an open mind could call Bawa-Garba wilfully or recklessly neglectful.

> No one in possession of the facts and an open mind could call Bawa-Garba wilfully or recklessly neglectful

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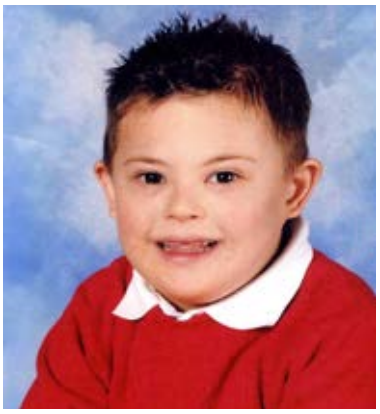

Delays in assessment, acting on test results, and administering antibiotics meant that the diagnosis of sepsis and recognition of the seriousness of Jack's condition came too late.

Also, when Jack arrested soon after he was given enalapril by others without her knowledge, Bawa-Garba mistakenly interrupted resuscitation efforts having confused him with another patient. But she was doing two doctors' jobs, managing acutely sick patients across four floors, with no breaks in her 12 hour shift, junior doctors who had both only just rotated onto the team, agency nurses, breakdowns in IT, and inadequate senior cover.

However, the jury weren't told about many of the corrective actions subsequently deemed necessary to make the hospital safe. The prosecution argued these weren't relevant to the circumstances in which Bawa-Garba was practising on the day.[5]

Many questions remain. Was it not the consultant's, medical director's and management's responsibility to ensure adequately supported medical and nursing provision? Given the hospital's inherent conflict of interest, why was there no independent review? Why did the GMC feel compelled to pursue an appeal? It says it could not allow its tribunal to go behind the decision of a jury in a criminal case and wanted to avoid a loss of trust in the profession.[6] But the medical practitioners tribunal was able to hear about important system factors that the jury in the criminal case was not,[7] and other doctors with criminal convictions have been allowed to continue to practise.[8]

Positive change

In an unprecedented show of support, crowd funding has raised more than £200 000 for Bawa-Garba's legal representation, so her criminal conviction may yet be overturned. And perhaps most importantly of all, people from across the health and regulatory system are now talking to each other about what needs to change.

Much credit for this must go to Jenny Vaughan, a consultant neurologist who clinically led the successful appeal of conviction of David Sellu.[9] She cofounded Doctors and Manslaughter (manslaughterandhealthcare.org.uk) and has worked with the Ministry of Justice, Department of Health, Crown Prosecution Service, and royal colleges to highlight the negative impact of criminalising healthcare.[3] A recent meeting at the Royal Society of Medicine discussed a range of measures to ensure that the right cases come to court in future—those involving persistent dishonest or malicious practice rather than unintended honest errors.[10]

It is tragic that a child has died. But no one is served when one doctor is blamed for the failings of an overstretched and understaffed system. We must channel the sadness at Jake Adcock's death, and the anger at Bawa-Garba's fate, into positive change for safer patient care.

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EDITORIAL

Homelessness and public health

The number of people sleeping on streets is soaring, with serious health implications for those affected

The number of people officially recorded as sleeping on the streets of England rose from 1768 in 2010 to 4751 in autumn 2017.[1] Charities estimate the true figure to be more than double this.[2] There has also been an increase in families housed by local authorities in temporary accommodation, rising from 50 000 in 2010 to 78 000 in 2017.[2] And in London alone there are an estimated 225 000 "hidden homeless" people aged 16-25—arranging their own temporary accommodation with friends or family.[3] This rise in homelessness is not confined to England but has affected most European countries.[4]

Health harms

The most common precursor of homelessness, falling into arrears with housing payments, has a negative association with self reported health comparable with that of unemployment.[5] People living in damp, cold, or overcrowded housing experience greater physical risks to health, and strains on mental health through insecurity and personal debt.[5] Associated health effects include respiratory conditions, depression, anxiety, unintentional injury, excess winter mortality, and skin irritation.[6] At the extreme end, when last calculated (for 2001-09) single homeless people had an average age at death of 47 years, compared with 77 years for the general population.[7]

Homelessness can result from the loss of employment, substance addiction, poor mental or physical health, domestic abuse, relationship breakdown, or childhood trauma and neglect. The risk is higher for those leaving an institutional environment such as the military, psychiatric hospitals, the care system, or prison.[8]

The rise in homelessness is almost entirely accounted for by an increase in families losing their privately rented housing. Between 2010 and 2016 the number of households accepted as homeless by English local councils rose from 42 390 to 59 260; the number becoming homeless because of losing a private tenancy rose from 6150 to 18 750 (figure).

Three likely causes are apparent. First, since the early 1980s, housing has been increasingly unevenly distributed,[9] causing upward pressure on housing prices and overcrowding. At the same time, reduced availability of social housing at truly affordable rent meant that, by 2016, as many poor families were living in private rented accommodation as in social rented housing.[10]

Second, the rise in visible street homelessness is partly the result of reduced funding for single homeless hostels and support services. Austerity has meant that, since 2010, the funding available for supporting vulnerable people with housing has been cut by 59% in real terms.[11]

Third, welfare reforms have reduced the value of housing benefit paid to subsidise housing costs. In 2011, housing benefit was restricted to the cheapest 30% rent in local areas. In 2013, a cap was introduced to limit the total benefits received by individual families, implemented by cutting the housing benefit paid. Rises in housing benefit were restricted to 1% a year from 2014 and frozen in cash terms from April 2016, whereas rents have been increasing at 2% a year. This has shifted the financial risk of rising rents from the state to individual families on low incomes.

The new working age benefit—universal credit—currently requires new claimants to wait for six weeks before receiving any support, though the government says that changes being implemented in February 2018 will reduce this waiting period.

The "housing first" model has had success in Finland, the only country in Europe where homelessness has fallen

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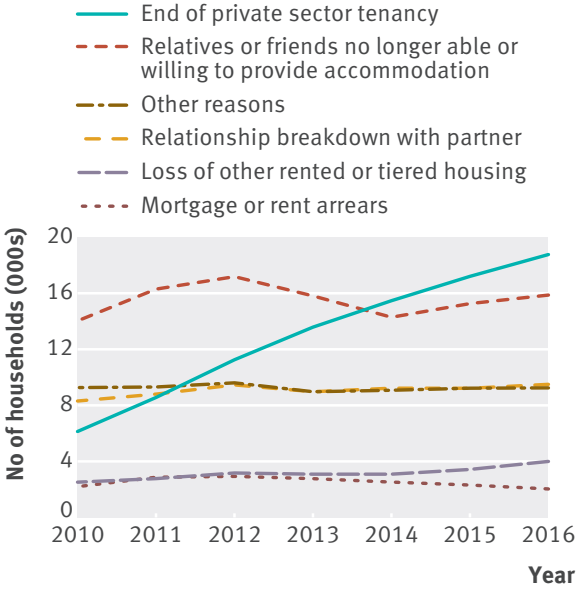

Reasons for losing last settled home among households English local authorities accepted as homeless and in priority need, 2010-16 (Department for Communities and Local Government)

Support services

Despite having more health needs, homeless people face barriers to accessing primary healthcare, leading to a higher rate of attendance at emergency departments.[8] This has prompted the development of some specialist primary healthcare services for homeless people, such as Oxford's Luther Street Medical Centre.

Support for rough sleepers has traditionally been based on a "treatment first" model. The "housing first" model turns this on its head, offering a secure tenancy first, in recognition that other problems may be difficult to deal with while people are on the streets.[12] It has been given some of the credit for the success of Finland's strategy, the only European country where homelessness has fallen recently.[4]

What is needed is a comprehensive strategy that improves support services for vulnerable people, an increased supply of affordable housing, more tenancy security, adequate cash benefits to cover the rising cost of housing, and more efficient use of our housing stock.

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ANALYSIS

Should we fear accountable care organisations?

The government and NHS England's plans for a major reorganisation of the health and adult social care system must come under greater scrutiny, argue **Allyson Pollock** and **Peter Roderick**

MALCOLM WILLETT

KEY MESSAGES

- Adoption of the accountable care organisation model raises several concerns, including uncertainties around further loss of public accountability, an unclear population base for care, and new funding arrangements for health and social care
- Private companies could be responsible for commissioning and providing all care
- The government and NHS England have not adequately explained the proposals
- Primary legislation is needed to uphold the fundamental principles of the NHS

The introduction of accountable care organisations (ACOs) into the English NHS signals a major reorganisation of the health and adult social care system. Plans for ACOs were proceeding without the usual public consultation followed by an act of parliament. However, after the launch of a judicial review (in which AMP is a claimant and PR is assisting the claimants), the government and NHS England have now announced there will be a public consultation in the spring.[1] Consultation and legislation are necessary safeguards to ensure the plans are consistent with the NHS's fundamental principles: a universal and comprehensive service that is publicly funded, accountable, and free at the point of delivery.

The term ACO emerged in the US in 2006,[2] and became a central feature of President Obama's health reforms.[3] In the US, ACOs consist of groups of doctors, hospitals, and other providers who are given incentives to improve quality of care and control costs. Providers within the ACO are entitled to a share of any "savings" to the public budget that are achieved.[4]

ACOs were designed to improve patient experience and control federal expenditure in a US system, which is dominated by private health and insurance companies. So far the evidence of ACOs' effect on quality is contested, and at best mixed.[5] The projected savings to federal budgets translated into a net loss in 2015, and spending may have actually increased.[6]

The US insurance based healthcare system is fundamentally different from the NHS, not least because it does not seek to provide universal care, giving rise to several questions and uncertainties about how the ACO model will apply in the NHS.

ACOs in the NHS

Sustainability and transformation partnerships seem to be the forerunner for ACOs in England,[7] but it is unclear how closely the introduction and expansion of ACOs will reflect what has evolved in the US.

Our analysis is based on NHS England's draft ACO contract published in August 2017 and its associated documents, although these might change after the consultation. According to NHS England, the "ACO model simplifies governance and decision making, brings together funding streams and allows a single provider organisation to make most decisions about how to allocate resources and design care for its local population."[8]

The draft contract is intended to facilitate the use of two new models of care—fully or partially integrated "multispecialty community

HOW IS "POPULATION" DEFINED?

Until the 2012 Health and Social Care Act, the government had a legal duty to provide key health services "throughout England," which was delegated to area based health authorities and latterly to primary care trusts (PCTs). Following the principle of universality, funding, planning, and accountability were based on the entire population of contiguous local authority and PCT geographical areas. The population denominator for needs assessment and resource allocation to PCTs was the number of residents, using population estimates derived from census returns, updated annually using birth and death registration and other data. Improvements to accuracy were occasionally made, but the principle of the denominator was derived from the duty to provide throughout the country—that is, universality.

The 2012 act abolished that duty along with strategic health authorities and PCTs, and replaced it with a duty on more than 200 CCGs to arrange provision (ie, make contracts) "for persons for whom it has responsibility." The original 2011 bill defined such persons only as those on GP lists,[13] but after a pause in the bill's progress, the definition was amended to include unregistered residents in a CCG area.[14]

However, according to NHS England "due to the absence of reliable data being available on the size of the unregistered population by area and their healthcare needs," the Advisory Committee on Resource Allocation in 2013 concluded that it is not currently possible to adjust the new formula to take into account an area's unregistered population.[15] This means that despite the legal definition of persons for whom CCGs are responsible, not everybody residing in a CCG area is covered by the funding formula as people not on GP lists are not counted. Conversely, it also means that people on a GP list who don't live in the CCG or ACO area are counted, and people who are registered on more than one GP list will be counted on each one (list inflation).[16]

providers" and "primary and acute care systems." In the fully integrated model, the ACO will have "full responsibility for provision and integration of care"[9] for up to 15 years.[10]

The funding

The government's intention is to move to a capitation system (lump sum per patient) with a linked outcomes and incentives payment scheme. The list based capitation payments will be derived from current commissioner expenditure.[11] The complexity in deriving risk adjusted capitation is enormous and well known.[12] Personal health budgets are also being proposed. We are concerned that these changes will further undermine risk pooling, social solidarity, and equity, which are required for universality, for reasons outlined in the box (above).[15]

It is unknown how ACOs can integrate health and social care services when their funding will be for a different population (GP lists versus local authority), and when ACOs will not have health service funding allocated for unregistered CCG residents who may be eligible under the ACO contract for local authority social services.

The contract

Under the draft contract, local CCGs, NHS England, and local authorities would pool their health, public health, and adult social care commissioning budgets and transfer them to the ACO in return for it providing, or subcontracting, defined "services" to "the population." However, social services are means tested and charged for, while health services are not[17]—how pooling would work in practice is unclear. The transfer of risk and responsibility for funding, commissioning, and providing health and social services to ACOs raises several concerns, the most serious of which we discuss below.

Who would be entitled to services?

Entitlement to services seems to depend on whether an individual falls within the definition of "the population." To meet this definition a person must either be registered on the ACO's list or be resident in the "contract area" and not on the list of a GP who's not part of the ACO (see box).

There is much uncertainty about what ACOs will provide and to which populations. The definition of "services" is complex and unclear and seems to involve finding a negotiated compromise between the services required by the commissioners and those proposed by the ACO.

This could lead to confusion if, for example, an individual lived in the contract area and required health and social services but was not on the ACO's list because their general practice was a member of a CCG which contracts with another ACO.

Public involvement and accountability

Transferring billions of pounds to non-statutory providers raises accountability issues, and there are several ways in which public involvement in and accountability for ACO decisions would be degraded, compared with the current position.

ACOs would not have statutory obligations, and public involvement would depend on the terms of the ACO contract. These terms are enforceable by parties to the contract, not by members of the public. Under the NHS standard contract, providers must involve "service users" and "the public" (among others) when developing and redesigning services. Under the ACO contract, ACOs would be required only to involve "the population." This raises the question of how the public would be consulted when service changes are planned through the contract, especially when neither ACOs nor CCGs have geographical populations, when GP and hence ACO lists may include people from anywhere, and when ACOs will not be funded to cover unregistered patients.

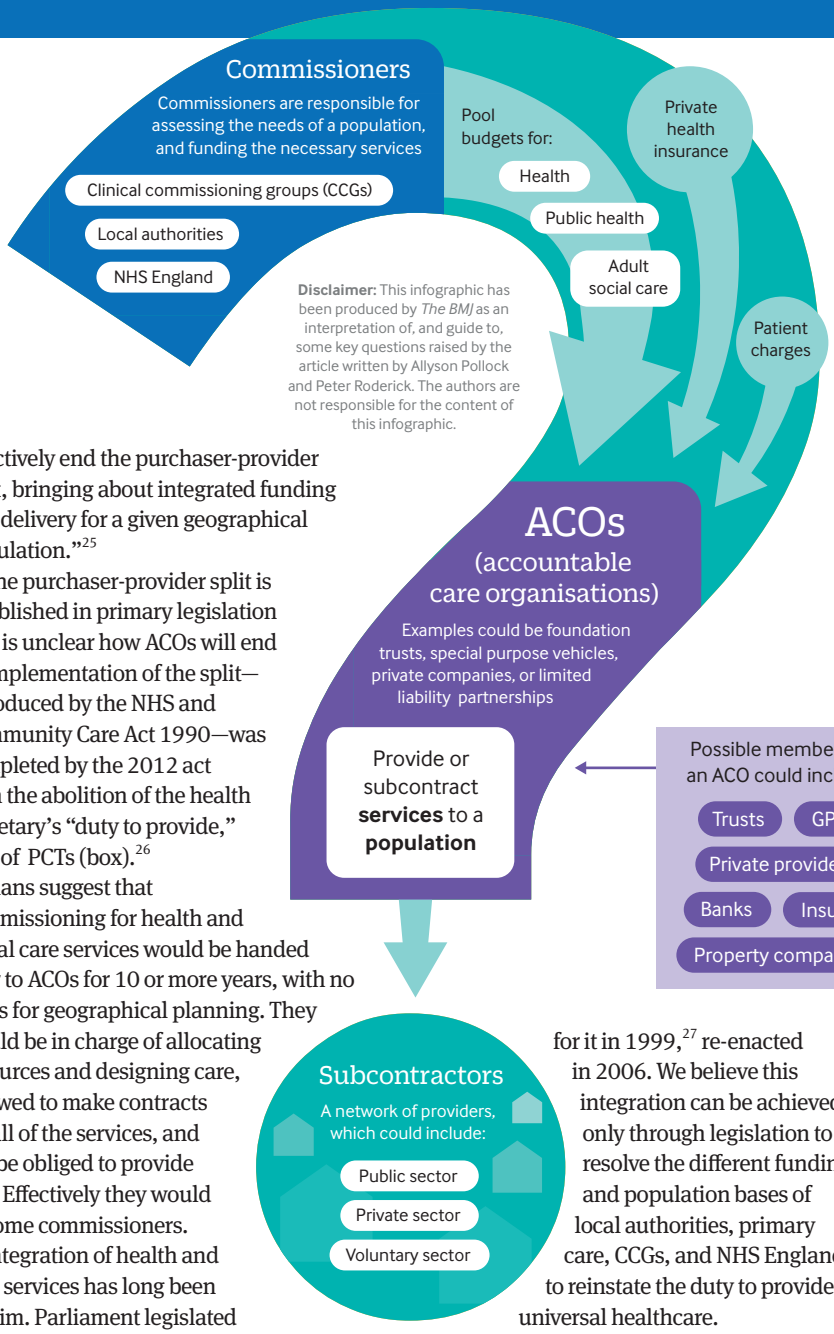
We do not know whether individual ACOs could be subject to judicial review, or to a human rights or freedom of information challenge—key mechanisms for holding public bodies to account. Outsourcing of public services to private and voluntary bodies has led to several cases where the courts have had to wrestle with where and how to draw the line between publicly accountable and private bodies.[18 19] In 2007, for example, the House of Lords held that private care homes funded through local authority contracts were not exercising functions of a public nature under the Human Rights Act 1998,[20] and this had to be reversed seven years later by the Care Act.

Assessment of needs

Assessing needs is the first stage of the commissioning function,[21] conferred on NHS England and CCGs under sections 3 and 3A of the Health and Social Care Act 2012. It is a core task of commissioners, with local people and communities supposed to be engaged throughout.[22 23] An ACO would be obliged to "develop and implement strategies to improve the health and wellbeing of the population" and to "maintain a documented, current and thorough assessment of the health [and social] care needs of the population."[24] This means that statutory duties would be transferred to the ACO, distancing democratically elected representatives and the public from the decision making.

Justification

In February 2017, NHS England's head, Simon Stevens, when giving evidence to the Public Accounts Committee, said that "accountable care organisations or systems…will for the first time since 1990



effectively end the purchaser-provider split, bringing about integrated funding and delivery for a given geographical population."[25]

The purchaser-provider split is established in primary legislation so it is unclear how ACOs will end it. Implementation of the split—introduced by the NHS and Community Care Act 1990—was completed by the 2012 act with the abolition of the health secretary's "duty to provide," and of PCTs (box).[26]

Plans suggest that commissioning for health and social care services would be handed over to ACOs for 10 or more years, with no basis for geographical planning. They would be in charge of allocating resources and designing care, allowed to make contracts for all of the services, and not be obliged to provide any. Effectively they would become commissioners.

Integration of health and care services has long been an aim. Parliament legislated for it in 1999,[27] re-enacted in 2006. We believe this integration can be achieved only through legislation to resolve the different funding and population bases of local authorities, primary care, CCGs, and NHS England, to reinstate the duty to provide universal healthcare.

However, the contracting associated with an ACO model is likely to lead to further fragmentation and loss of public control and public accountability. In the absence of the government's duty to provide throughout England, we believe this will leave wide open the possibility of groups of people and services being excluded, as providers seek to find ways to reduce their financial risks and maximise their gains. As well as loss of universal coverage, we expect that everyone will be required to produce proof of entitlement.

Consultation and parliamentary process

We are deeply concerned that a national consultation on this major reorganisation of the health and adult social care system has been promised only after the launch of a judicial review, and that there is no plan for a new health act. Stevens has said that "we can do workarounds" of the legislation and "we will…push as hard as we can to get there without parliament itself having to legislate."[28] Previous changes of this magnitude have all been preceded by a process of public consultation and acts of parliament (table, see bmj.com). The consultation that has now been announced may help to allay concerns, but the absence of primary legislation remains worrying.

ACOs will be non-statutory, non-NHS bodies—even when formed by or including NHS trusts or foundation trusts. They will receive billions of pounds of public money but have no statutory accountability or governance obligations. Their form and ownership would be unrestricted[29] and could therefore include not only GPs and private companies but also insurers, banks, or property companies (infographic). They can be established as

COMMENTARY

The NHS faces bigger threats than ACOs


Nicholas Mays, left, professor of health policy
Nick Black, professor of health services research, London School of Hygiene and Tropical Medicine

Faced with the structural weaknesses and fragmentation produced by the Health and Social Care Act 2012, and struggling with a period of extraordinary financial constraint, ACOs can be seen as a commonsense workaround.

Other commentators see ACOs as a back door to the disastrous full scale privatisation of both the financing and supply of NHS services. This is based on the possibility that commissioners will be permitted to go out to tender to procure comprehensive, integrated services for a defined population from newly formed (based on previous NHS organisations, but not necessarily publicly owned), or entirely private, organisations. Given the restricted scope for making profit, private providers would have to raise more money from patients in user charges.

Other analysts, including the King's Fund and Nuffield Trust, argue the opposite—that ACOs are likely, if anything, to reduce the amount of outsourcing of NHS services to the private sector. The government states unequivocally it has no intention of using these developments as camouflage to require users to pay for services that were previously free at the point of use.

Both arguments seem to miss the point—the main threat to a universal service free at the point of use is more likely to come from long term austerity, which risks pushing more patients to pay for services, as academic Mark Hellowell argues.

Unable to meet demand

He points out that there has been a big increase in affluent patients choosing not to wait for NHS care. While this has always happened to some degree, if the service is increasingly unable to

offshore companies. The ACO would need a raft of contracts with trusts, general practices, private health companies, and voluntary organisations to provide services. This will lead to further fragmentation and bureaucracy, loss of public control, and unnecessary expenditure.

The Department of Health has consulted on technical changes to regulations to facilitate ACOs going live from April.[30] The changes, depending on the model type, would allow general practices to give one month's notice to NHS England of their wish to suspend their contracts and instead to operate under an ACO contract; patients must have been given notice of the practice's wish, and they will automatically be transferred to the ACO's list of registered patients, unless they register elsewhere. The secretary of state has refused to delay the regulations, despite being repeatedly asked by Sarah Wollaston, chair of the Health Select Committee, in an evidence session on 23 January.[31]

The lack of clarity surrounding ACOs hampers a full appreciation of the nature and scale of the changes. We have highlighted some of the most important problems. Legal action was begun on the grounds that without an act of parliament the plans are unlawful; there should be proper public consultation; and the principles which provide for decisions about our NHS to be clear and transparent have been breached.[32] The government and NHS England have conceded that there will be a national consultation, but that does not necessarily mean the policy will be reversed.

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meet demand for things like elective surgery and innovative cancer treatments, it could undermine the general population's support for a tax financed system.

The other challenge to the policy of large scale integrated systems is whether they can achieve the transformation that most people accept is needed. It may be that such change will be better achieved through multiple small scale initiatives, many of which have already demonstrated success despite contending with structures and policies that offer little encouragement, and, sometimes, obstructions.

As ACOs develop, it will be vital that they support and facilitate the creativity and entrepreneurship of the myriad health and social care staff and patients who can and want to change the face of services.

BRIEFING

Moving to accountable care

What do we know about efforts to integrate health and social care in England, asks **Tom Moberly**

How will UK ACOs differ from those in the US?

In the US, ACOs were formed under Barack Obama's health reforms. Groups of providers, serving a given population, are accountable, to patients and funders, for arranging care that meets set quality standards within a fixed budget.

In the English NHS, the plan is that ACOs will evolve from sustainability and transformation partnerships (STPs). They will integrate funding for, and be responsible for delivery of, all health and social care within a defined area. The King's Fund points out that it is "the idea of holding providers to account for improving [the totality of] health and outcomes for defined populations" that is the aspect of accountable care being adopted from the US to the UK. "Elements such as who pays for the care or who delivers it are not being adopted," it points out. "Put simply, accountable care is integrated care."

What legislation will form and govern ACOs?

This has yet to be determined, though NHS England announced on 25 January that it will launch a public consultation on the prototype ACO contract. NHS England has said they will not be a new type of legal entity and will not affect the commissioning structure of the NHS. "The consultation will set out how the contract fits within the NHS as a whole; look at the ways existing statutory duties of commissioners and providers would be performed under it; and will set out how public accountability and patient choice would be preserved," it says.

In late 2017, the government consulted on draft regulations to allow the piloting of a draft ACO contract. It says it intended to lay these regulations before parliament in February 2018 but that this might be delayed in light of a health select committee inquiry on, and two legal challenges to, the introduction of ACOs. The King's Fund says that because the UK now has a minority government "legislation on the NHS is off the agenda for the time being."

How ACOs will encourage collaboration without legislation is unclear. "The vestiges of market based reforms remain, but they have taken a back seat as the need for NHS organisations to work together to make decisions on the use of resources has been given higher priority," the King's Fund says.

Will legislation prevent private companies from taking ACO contracts?

None is planned. Jeremy Hunt has said that NHS commissioners are legally bound from discriminating against private companies when awarding contracts. In a letter on 22 January, he said that amending these regulations was outside the scope of the current proposals. But, he said, such an amendment "may be something a future parliament may wish to consider."

The King's Fund argues that, rather than opening up the NHS to more privatisation and competition, accountable care is likely to have the opposite effect. "The main participants involved in developing accountable care are NHS organisations and partners in the public sector and they are making progress by collaborating, not competing," it says. It says there is no evidence that private providers are taking a bigger role in areas that are furthest ahead in developing accountable care.

Why could ACOs be successful?

Simon Stevens, NHS England's chief executive, has argued that ACOs will drive integration across health and social care providers. "We are now embarked on the biggest national move to integrating care of any major Western country," he said last June. Stevens believes this improved integration will be achieved by dissolving the boundaries between commissioners and providers that have existed since the internal market was introduced in 1990. "For patients, this means better joined up services in place of what has often been a fragmented system that passes people from pillar to post," he argued.

NHS England has said ACOs are just one part of larger work to integrate patient care. "ACOs are only one tool for integrating primary care, mental health, social care, and hospital services, and not the only or main way to integrate services," it says.

Tom Moberly, UK editor, *The BMJ*
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Ethics and infertility research

As innovations in treatments for infertility and heritable disease come in quick succession, researchers say better public understanding of what is possible—and desirable—is crucial, reports **Sally Howard**

From human-animal hybrid "chimeras" to mitochondria donor "three parent babies" and gene edited "Frankentinie" embryos, the media often contribute to public fears about developments in assisted conception and medical genetics. Perhaps some bombast is understandable: after all, some of these innovations relate to the very nature of what constitutes a sperm, egg, or embryo.

Research in these areas could lead to new treatments for infertility and reproductive failure. Better understanding of how germ cells develop, for example, could improve understanding of reproduction and help prevent genetic diseases such as sickle cell and cystic fibrosis. But some researchers say overly conservative regulation is inhibiting this work.

"Why is the regulation of infertility treatment dominated by ethical considerations?"
Alison Murdoch, Newcastle University

Fifty years since in vitro fertilisation was first shown to be possible in humans, and 40 years since the birth of the world's first IVF baby, breakthroughs are coming thick and fast but regulation and public debate are struggling to keep pace. Where is the line between "a noble endeavour and an untrustworthy one," asked Sarah Norcross, director of Progress Educational Trust (PET), a UK charity that seeks debate on assisted conception, as she opened a conference organised by the charity in London in December.

Restrictive US rules

In America, a 1979 decree and 1995 bill amendment blocked public funding of research on embryos. From 2001, researchers have had to have a Food and Drug Administration (FDA) permit for privately funded in vitro fertilisation procedures that include the transfer of genetic material.

From 2015, a budget bill has prohibited the spending of tax dollars on research involving germline modification, including fees for processing permit applications.

Advances in assisted reproduction, including those to treat inherited genetic disease, have hit a dead end because of the US's regulatory landscape, Henry Malter, laboratory director at the US Fertility Center of the Carolinas, told the conference.

In 2001, Malter, as senior scientist at the Institute for Reproductive and Medical Science at the St Barnabas Medical Center in New Jersey, along with colleague Jacques Cohen, worked on an experimental treatment for in vitro fertilisation in which cytoplasm from a donor egg was injected into the mother's egg, along with sperm, at the time of fertilisation.

It led to 17 live births among 33 previously infertile couples. However, several children were born with mitochondrial DNA from both their mother and the donor.

The work was condemned by the profession at the time because data on safety and efficacy were lacking. "Press hysteria," as Malter described it to the conference, ensued, and when the FDA required that Malter and Cohen apply for an "investigational new drug application" costing several million dollars, they abandoned trials.

Media tropes that emerged during

UK REGULATION OF ASSISTED CONCEPTION

Human Fertilisation and Embryology Act 1990
Sought to clarify the legal parents of offspring born after new techniques and instituted the "14 day rule," making it illegal to conduct research on human embryos in vitro beyond 14 days

Human Reproductive Cloning Act 2001
Prohibited the implanting in a woman of a human embryo "created otherwise than by fertilisation"

Human Fertilisation and Embryology Act 2008
Reflected hybrid embryo debate and updated legal parenthood

Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015
Legalised mitochondrial replacement to prevent inheritance of mitochondrial disease

UK regulations largely "get the balance right," says César Palacios-González, research associate in medical law and ethics at King's College London, who studies the ethics of mitochondrial replacement, chimeras, and in vitro gametogenesis. He adds that the UK regulatory environment allows input from clinical professionals and frequent revision in light of new technologies.

John Zhang, medical director of the New Hope Fertility Center Clinic in New York City, enabled the birth of the first baby born with a two mother egg

MITOCHONDRIAL REPLACEMENT TECHNIQUES

In April 2016 John Zhang, medical director of the New Hope Fertility Center Clinic in New York City, enabled the birth of the first baby born with a two mother egg, injecting the chromosomes of one woman's egg through the cell membrane and into the cytoplasm of a donor egg.

This example of one mitochondrial replacement therapy (MRT) was reported to have resulted in the birth of a healthy baby, preventing Leigh syndrome, which is inherited through a mother's mitochondrial DNA. Zhang reconstructed and fertilised the egg in the US but, to avoid US rules, embryo transfer took place in New Hope's clinic in Mexico. Little evidence was published about the baby's health; the long term outcome is unknown.

In June 2017 further controversy surrounded Zhang's plans to commercialise the technique for treating infertility in older women, offering the full cycle in Mexico. Many critical researchers, including Robin Lovell-Badge, a developmental biologist at the Francis Crick Institute in London, have noted the absence of evidence that faulty mitochondria cause age related infertility.

In 2017, the UK was the first country to license the use of mitochondrial donation, but only when a couple is at high risk of having a child with a life threatening genetic disease.

the St Barnabas controversy—"three parent babies," "wild west" fertility clinics, and "cowboy scientists"—continue to dog assisted reproductive medicine, Malter says.

Genome editing

In 2015, Great Ormond Street Hospital successfully treated advanced leukaemia in two babies with immune cells genome edited to target cancer cells, a "world first." But this is unlikely to lead to an explosion of genome editing breakthroughs in fertility treatment and transmission of heritable disease. Under UK regulation, which is among the West's most permissive, it is only possible to edit the soma, the part of the human genome that is not inherited. The germline can be edited for research in the UK in pre-implantation embryos up to 14 days. This is not permitted for treatment.

Regulatory change in this area is unlikely without reasoned public debate, says PET's communications manager Sandy Starr. Last year, Starr co-authored *Basic Understanding of Genome Editing*, a report on public perceptions, with Genetic Alliance, a UK charity that advocates genomic research for health benefits.

The report says that policy makers should draw a greater distinction between genome editing for genetic enhancement, which provokes public anxiety and often dominates debate, and genome editing for genetic correction. Better public understanding might lead to more permissive regulation, and interventions for currently untreatable diseases "with a clear genetic cause," Starr thinks.

Alison Murdoch, professor of reproductive medicine at Newcastle University, warns against the tendency to allow ethical debates to dominate discussion. "Regulations are usually based on best practice as determined by clinicians, patients, providers, and the public," she told *The BMJ*. "Why is the regulation of infertility treatment dominated by ethical considerations?" she asks, adding that undue weight is given to those opposed to reproductive advances on ethical grounds.

Popular hyperbole

To counter "popular hyperbole," César Palacios-González, research associate in medical law and ethics at King's College London, told the conference, healthcare professionals have a duty to engage with ethical debates that accompany clinical advances. "Contrary to misconceptions among medical professionals, bioethicists have often already considered the ethics of up-and-coming technologies," he said, giving the example of MRT.

Controversy and regulatory attention around genome editing and MRT will "pale in comparison," adds Palacio-González, to the storm around coming technologies: in vitro gametogenesis—the creation of artificial sperm and gametes—and chimeras—the transplantation of human cells into animals that are in embryonic or early stages of fetal development.

In a breakthrough in 2017, Juan Carlos Izpisua Belmonte, a professor in the Gene Expression Laboratories at the Salk Institute for Biological Studies in California, successfully injected human cells into pig embryos and implanted them into surrogate sows, where they were allowed to gestate for three weeks. The successful production of these "chimera" embryos could be a key step towards producing laboratory grown human gametes, and organs for human transplant, although Palacio-González admits that both science and public opinion and regulation have "a long way to go" to reach this point. Human admixed embryos cannot currently be kept alive under UK or US law beyond 14 weeks.

Closing the conference, Norcross said that to chart a course through this new territory we need a thorough public discussion of what is possible—and desirable. This must include, she said, fundamental questions about how we define, scientifically and legally, such once basic concepts as sperm, eggs, and embryos.

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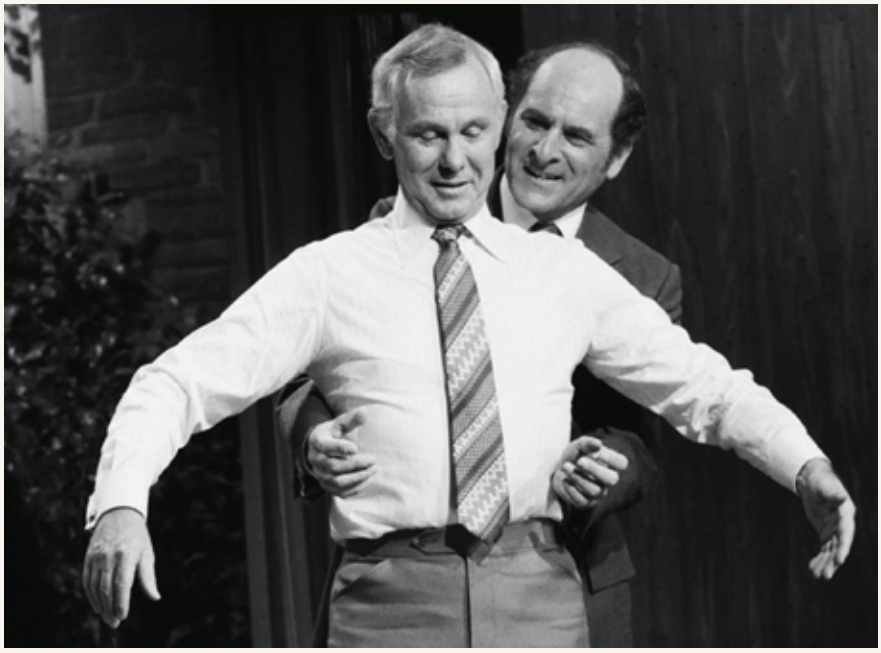

FROM THE ARCHIVE

Introducing the Heimlich manoeuvre

On this day in 1920 Henry Heimlich was born, the inventor of the eponymous manoeuvre to stop choking.

Heimlich first published his recommendation for choking as a personal commentary, "Pop Goes the Café Coronary," in the *Journal of Emergency Medicine* in 1974. Two years later, the Heimlich manoeuvre made its first appearance in the pages of *The BMJ* (*Br Med J* 1976;1:855).

The journal reported on a "dramatic article" of his in *JAMA* that opened by describing how "Each year, 3900 healthy individuals in the United States strangle because of food stuck in their throats."

The journal concluded that "In Britain, the problem does not seem large—possibly because the potentially lethal practice of drinking whisky with steak is less usual here. Nevertheless, there does seem to be a case for bringing the 'Heimlich manoeuver' to the attention of all who could save life by employing it, and in practice that means the general adult population. First aid teachers and health educators take note."

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WHAT YOU'RE TWEETING ABOUT

More plain language writing in journals

"Too often, academic journals are filled with complex language and turgid prose, which is intended not to inform the reader but to ennoble the writer, says @Richard56."

This quote from a BMJ Opinion article by Richard Smith was *The BMJ*'s most popular tweet in January and its sentiment seemed to be shared by many readers.

Heather Scarlett-Ferguson (@pharmGirl44) was one of those who replied in agreement: "Knowledge translation requires plain language writing. We need to continue to push for widespread acceptance of this or good research will remain read by some and used by few."

Read a shortened version of Smith's article on page 193.

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