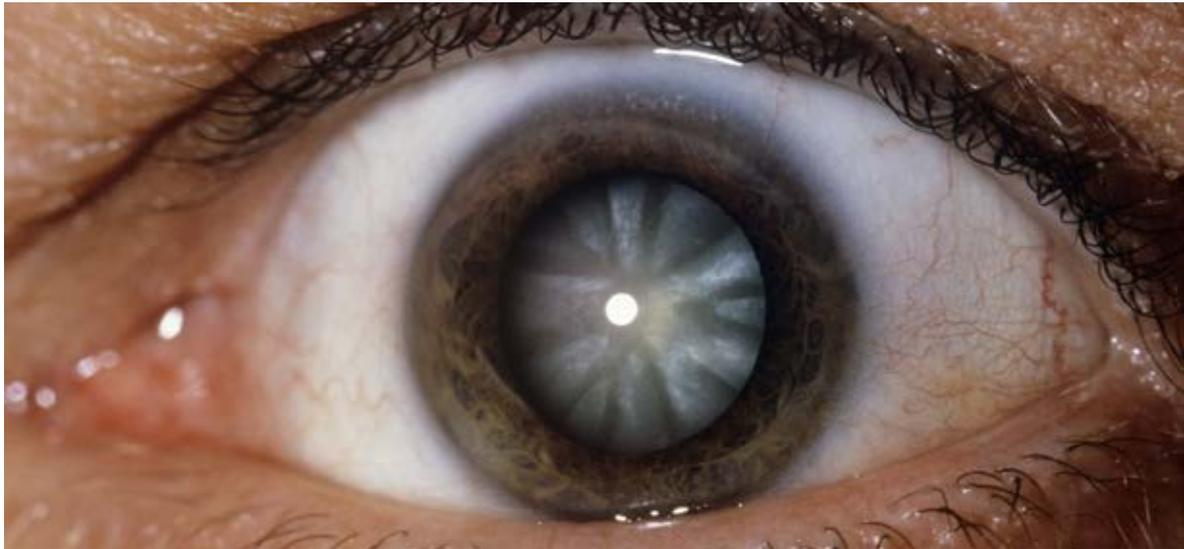


this week

MESH PATIENTS PROTEST page 172 • **ROLE FOR COMMUNITY HOSPITALS** page 175



Cataract guidance to halt rationing

New evidence that cataract surgery is cost effective will make it harder for service commissioners in England to ration treatment, experts have told *The BMJ*.

Draft guidelines from the National Institute for Health and Care Excellence for managing cataracts in adults contain new economic modelling showing that first or second eye cataract surgery is cost effective compared with no or delayed surgery.

The draft guidelines, which will be published in October 2017 after consultation, also make clear that visual acuity thresholds “should not be used to restrict access to cataract surgery.”

Experts said that the guidelines will make it tougher for clinical commissioning groups (CCGs) to justify controversial cost saving measures which have seen restrictions imposed in some areas on the basis of patients’ visual acuity or their ability to see clearly from one eye.

A recent investigation by *The BMJ* found that exceptional patient funding requests for cataract removal in England soared from 359 in 2013-14 to 1034 in 2016-17, showing the difficulties that some patients are having in getting referred for surgery.

The draft guidelines state that cataract surgery for a first or second eye is cost

effective because it can avoid costs in the future— from falls and broken hips, for example.

“Visual acuity thresholds, or limits on second eye surgery, were likely to incur avoidable quality adjusted life year losses in most cases, and could be shown to increase longer term costs by raising the demand for low vision services,” it said.

Janet Marsden, professor of ophthalmology and emergency care at Manchester Metropolitan University and a member of the guideline committee, said that she hoped the guidelines would end the “outrageous” restrictions imposed by some CCGs, such as limiting cataract surgery to one eye. “If CCGs take notice and take away that visual acuity bar, then it will get rid of the postcode lottery,” Marsden added.

Nick Wilson-Holt, consultant ophthalmologist at Royal Cornwall Hospitals NHS Trust and a member of the guideline committee, said the guidelines would “add some muscle to the view that patients should be offered cataract surgery if they’ve got a disabling cataract.” He added, “It will be less easy for CCGs to arbitrarily make up thresholds as they go along.”

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2017;358:j3588

Draft NICE guidelines say visual acuity thresholds should not be used to restrict access to cataract surgery

LATEST ONLINE

- Medical leaders call for Britain to take lead on nuclear disarmament
- More than 2000 more emergency medicine consultants needed in England, says royal college
- Large case series documents chronic brain damage in players of American football



MEDICINE

Finance

NHS balances its books but at a price

England's Department of Health ended the financial year in the black, its accounts showed, but some parts of the NHS were hit financially in the government's drive to balance the books, experts said. Anita Charlesworth, director of research and economics at the Health Foundation, said, "Despite primary care being a priority, last year spending on GP services fell as a share of the health budget, and the number of GPs working in the NHS declined."

Alcohol

Drinking will kill in next five years

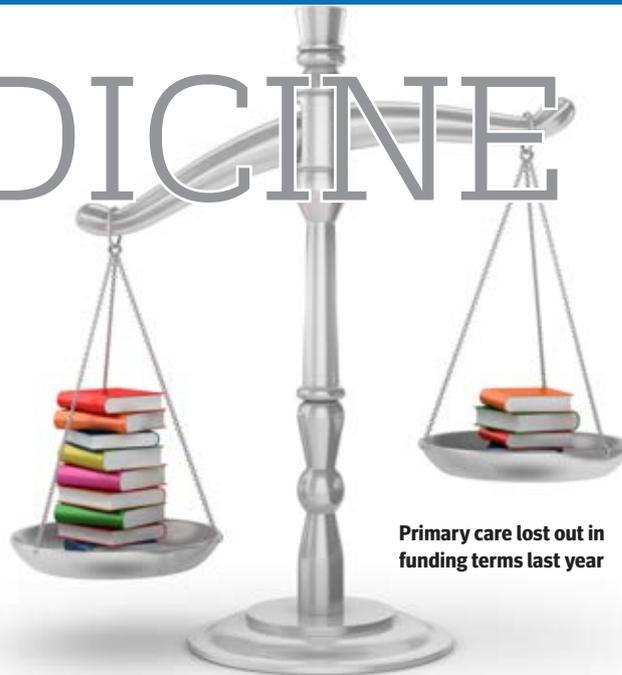
Alcohol misuse will be responsible for 10,000 deaths from 2017 to 2021. 1.5 million admissions, Sheffield University's Alcohol Research Group estimated. Some 10,000 of these will result from

liver cancer (above) and from alcoholic liver disease. The figures were calculated for the Foundation for Liver Research, which has published its *Financial Case for Action on Liver Disease* arguing for a minimum unit price on alcohol.

NHS reforms

Most advanced STPs get most investment

The government allocated the first £1.5 billion of capital investment funding to spearhead integrated healthcare in England. The



Primary care lost out in funding terms last year

money will be targeted at areas of the country where emerging sustainability and transformation partnerships (STPs) have been assessed as the strongest and most advanced. Among the largest beneficiaries will be Greater Manchester (£100m to concentrate urgent and emergency care services in four hub sites around the city) and Cumbria (£100m to establish a new cancer centre at Cumberland Infirmary).

Planned A&E closures may have cost Tory votes

Proposed closures and reconfigurations of NHS hospitals may have cost the Conservatives a majority at the general election, research showed. Incisive Health, a health consultancy, reviewed election results from constituencies where the incumbent MP had a majority lower than 10% and where the swing was directly between Conservative and Labour. Constituencies where an STP contained an emergency department closure or downgrade saw double the swing from Conservative to Labour seen in seats with no planned changes (12% swing v 6%).

Cite this as: *BMJ* ; ;

SIXTY SECONDS ON... BLACK WEDNESDAY



ANOTHER DAY OF DISCOUNT SHOPPING? FANTASTIC!

No, you fool! This is Black Wednesday, not Black Friday. It's the first Wednesday in August, when a new cohort of junior doctors start working at NHS hospitals.

AH, LESS EXCITING. WHAT'S IT ABOUT?

Also known as the killing season, Black Wednesday is reported in the media every year as a kind of hospital-based apocalypse. In 2015, the *Daily Mail* described it as one of the most dangerous days of the year to go to an accident and emergency department.

IT ALL SOUNDS A BIT GAME OF THRONES. AM I GOING TO DIE?

Eventually, yes. In this context, research from 2015 found that patients admitted on the first Wednesday in August were 10% more likely to die than those admitted the previous Wednesday (odds ratio 1.10 (95% confidence interval 1.02 to 1.19); P=0.02).

SO WHAT SHOULD I DO IF GRANNY KEELS OVER NEXT WEDNESDAY?

Although that sounds worrying, the absolute difference was small: more deaths among patients admitted in August than in July (1.5 v 1.4) over nine years. Also, it's not known what the exact causes of death were or whether they were preventable. So, maybe still take granny to A&E.

CAN ANYTHING BE DONE?

Since 2012, medical graduates have shadowed the outgoing foundation year doctor for four days before starting work. The aim is to help new recruits become more familiar with working practices and hospital systems. The Academy of Medical Royal Colleges also recommends that consultants should be available during transition dates and that other doctors should not be on rotation at the same time.

YOU'VE JUST RUINED MY SUMMER HOLIDAY

Perhaps, but it's for the greater good, and that's what the NHS is all about, right?

SO ARE MORE PATIENTS LIKELY TO BE HARMED THIS WEDNESDAY?

Probably no more than they would in a scrum for a discounted telly at Asda.

Abi Rimmer, *BMJ* Careers

Cite this as: *BMJ* ; ;

Patients accuse mesh report of “whitewash”

“This was an opportunity for the NHS to take a lead and recommend a pause in the use of mesh”



Kath Sansom, a mesh recipient who set up a campaign involving more than 2000 affected patients

An NHS review of transvaginal mesh implants released this week has been branded a “whitewash” after failing to order a safety review of the devices, which patients say carry unacceptable risks of severe and life altering side effects.

The review, led by NHS England, looked at the use of implants to treat stress urinary incontinence and pelvic organ prolapse—surgery carried out in about 15 000 women every year in England.

An emotionally charged meeting in parliament last week heard testimonies from a dozen women on how mesh had left them disabled, in chronic and debilitating pain, needing bladders and bowels removed where the mesh had shrunk and sliced into them, unable to have sex, or with psychological problems.

The implants are subject to an ongoing inquiry in Scotland, where the use of mesh for pelvic organ prolapse is suspended and where around 420 patients are involved in civil litigation against manufacturers and health boards. In the United States hundreds of thousands of women are taking

action against manufacturers, and some £1.5bn has already been paid in compensation.

The report, involving NICE, the MHRA, and professional bodies, acknowledged that collection of data on complications from mesh implants had been “insufficient.” But it noted “significant progress” since an interim report in 2015, such as increased reporting of complications, better informed decision making, and improved care for the women affected. It concluded, however, that women should not be denied “effective surgical options because there is some degree of risk.”

Kath Sansom, a mesh recipient who set up a campaign involving more than 2000 affected patients, called the report a whitewash.

“No patients were invited to the review meetings for the last 18 months, and there is no acknowledgment here of how many lives have been catastrophically destroyed by these devices,” she said. “We need a suspension of mesh while we gather up non-biased studies, sort out problems

Teenage boys should not be given HPV vaccine, says joint committee

The human papillomavirus (HPV) vaccination programme should not be extended to boys, as it would not be cost effective, the UK Joint Committee on Vaccination and Immunisation has said in an interim ruling.

Pilot scheme

Since 2008, girls aged 12 and 13 in the UK have been offered HPV vaccination to protect against the development of cervical cancer in later life. HPV infects males and females, and in boys and men it can progress to cause anal, penile, and oropharyngeal and oral cavity cancers, and anogenital warts.

In 2013 Australia became the first country in the world to

fund a national HPV vaccination scheme for boys. A pilot scheme to evaluate a service providing HPV vaccination to men who have sex with men and who attend genitourinary medicine and HIV clinics is currently under way in England. Last year leading doctors, scientists, and academics urged the government to extend the HPV vaccination programme to teenage boys.

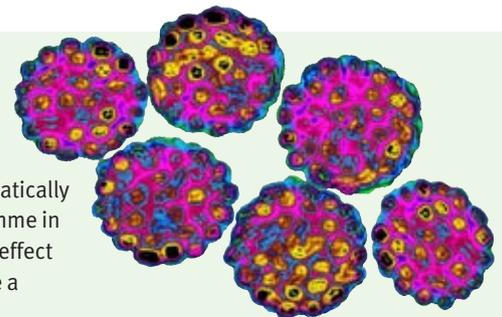
In its interim advice, now out for consultation, the committee said that data indicated that the HPV vaccine was safe to use in boys and generated similar immunogenicity to that seen in girls. However, it added that the risk of infection in males

had already been dramatically reduced by the programme in girls and that this herd effect would continue to have a substantial impact.

Benefits are insubstantial

It concluded that the additional benefits gained from extending the programme to adolescent boys would be small, relative to the effect of the girls’ programme.

However, Jonathan Ball, professor of molecular virology at the University of Nottingham and not a member of the committee, said that a reliance on herd immunity would not protect boys who went on to have sex with men when they were adults.



Ian Green, chief executive of the HIV and sexual health charity the Terrence Higgins Trust, called the decision “shortsighted.”

“A gender neutral policy on HPV vaccination is long overdue and would protect boys from cancers caused by untreated HPV, including penile, anal, and some types of head and neck cancer. It is shameful that this is still being denied to them,” he added.

Jacqui Wise, London

Cite this as: *BMJ* 2017;358:j3523

with hospital coding so we know the extent of this problem, and [have] a full safety review of mesh. We need a national database and mandatory reporting by surgeons.”

Sansom added, “There are black holes in data collection, little monitoring of patient outcomes, and a medical device regulatory system so weak that in the last five years we have witnessed the PIP breast implant scandal, the metal hip scandal, and now mesh—all under the nose of the MHRA [Medicines and Healthcare Products Regulatory Agency] that is supposed to be a watchdog for the NHS.”

John Wilkinson, director of devices at MHRA, said, “What we continue to see is that evidence supports the use of these devices for treatment of the distressing conditions of incontinence and organ prolapse in appropriate circumstances. We are not aware of a robust body of evidence which would lead to the conclusion these devices are unsafe if used as intended.”

Jonathan Duckett, vice chair of the British Society of Urogynaecology,

said, “We will continue to promote the [society’s] database to clinicians as a way of collecting more data that tells us about complications.”

Owen Smith, a shadow cabinet member and organiser of the parliamentary meeting, believes that the use of mesh implants in women is a scandal on the scale of the thalidomide disaster of the 1960s, saying that patients would be “deeply disappointed.”

“This was an opportunity for the NHS to take a lead and recommend a pause in the use of mesh until we know precisely how many women have been adversely affected by the product,” he told *The BMJ*. “The only people pleased with this report will be the medical device companies who marketed mesh so diligently and who now fear mass litigation.

“Many companies have already taken their mesh products off the market, and that alone should tell us that something is not right.”

Rebecca Coombes, *The BMJ*

Cite this as: *BMJ* 2017;358:j3603

USE OF MESH for pelvic organ prolapse is suspended in Scotland... around **420** patients are involved in civil litigation against manufacturers and health boards

Revalidation plan could reduce burden on doctors, says BMA

A plan by the General Medical Council to improve revalidation could make the process less burdensome for doctors, the BMA has said.

On 20 July the GMC published a plan to implement the recommendations made by Keith Pearson’s report, *Taking Revalidation Forward*, published earlier this year. In that report Pearson, chair of Health Education England and the GMC’s revalidation advisory board, said that more should be done to make clear what are and what are not mandatory parts of the revalidation process.

Chaand Nagpaul, the new chair of the BMA council, said that the plan was “an opportunity to reduce the burden that revalidation imposes on doctors... In particular, we want to see implementation of the recommendation

that local organisations should not use revalidation as a lever to achieve objectives beyond the GMC’s revalidation requirements.”

Pearson said in his report that he had heard concerns from doctors and royal colleges about employers adding requirements for appraisal or revalidation that went beyond GMC requirements. “I have been given examples of doctors being asked to carry out specific numbers or types of clinical audits; attend generic training courses; use specific templates or obtain fixed numbers of continuing professional development points before they can be revalidated. These are not requirements for revalidation,” he wrote.

Abi Rimmer, *BMJ* Careers

Cite this as: *BMJ* 2017;358:j3562

FIVE MINUTES WITH...

Paula Bolton-Maggs

The medical director of Serious Hazards of Transfusion discusses the latest findings on adverse events

“Earlier this month we published our latest annual report on adverse incidents related to transfusion. All NHS trusts in the UK now report to our scheme, and we receive 3500 to 4000 reports a year. In 2016, 87% of incidents were caused by human errors, quite a few of which highlight mistakes in the nine step, vein to vein transfusion process.

“We see certain common themes in the mistakes: one is not identifying the patient correctly; another is taking the blood sample and labelling it away from the patient. People are meant to carry out sampling for blood transfusion as one continuous process, but sometimes the person takes the blood sample, walks to the nursing station, gets interrupted, and labels the sample with the wrong patient details. The margin for error during that time is very wide.

“Transfusion mistakes are about miscommunication, failure to prepare or to hand over and document properly, and not following the proper procedures.

“I recently wrote to a hospital chief executive where two nurses had been dismissed after a transfusion to the wrong patient. Sacking staff isn’t a solution. If you don’t own up you can’t learn from your mistakes—but fear of dismissal may inhibit reporting.

“In 2016, three ABO incompatible blood transfusions occurred but also 264 near misses. We now recommend that people set up a transfusion using a checklist at the patient’s side to make sure that the right component is being given to the right person. This could save lives.

“An audit of adherence to a checklist in London found that it was less likely to be used when staff were experienced in transfusion; however, there’s no place for such complacency. Seniority and experience don’t prevent errors resulting from interruption or distraction.

“Our key message is to be safe and to follow all of the checks—just like a pilot.”

“Our key message is to be safe and to follow all of the checks—just like a pilot.”

Anne Gulland, London

Cite this as: *BMJ* 2017;358:j3555



SENIORITY AND EXPERIENCE DON’T PREVENT ERRORS RESULTING FROM INTERRUPTION OR DISTRACTION

International AIDS Society conference in Paris

LONG TERM ANTIRETROVIRAL INJECTION PROVES EFFECTIVE IN TRIAL

A long acting injection for HIV could transform antiretroviral therapy (ART) for patients who struggle to take a daily pill, a leading doctor has said, after the first study of a fully injectable antiretroviral regimen found it to be effective.

At the end of a two year trial of 286 people, 94% of patients who had received an ART injection of cabotegravir plus rilpivirine every eight weeks and 87% of those who had the injection every four weeks had the virus under control, defined as having fewer than 50 copies of the virus per millilitre of blood. This compared with 84% of patients who continued with oral treatment.

The monthly injection could be approved next year if further trials are successful.

Joseph Eron, professor of medicine at the University of North Carolina, USA, and lead author of the study, told *The BMJ*: “People with chaotic lives, people who have difficulty with adherence, and people with substance misuse or mental health illness may be able to take advantage of this long acting therapy,” adding that it could also be hugely beneficial for adolescents.

CHILD TREATED FOR HIV IN INFANCY HAS BEEN HEALTHY FOR NINE YEARS

A South African child who was infected with HIV at birth and treated for 40 weeks with antiretroviral therapy (ART) from nine weeks of age has remained healthy for the past nine years without further intervention. All scientists could detect was a reservoir of virus integrated into a tiny proportion of immune cells. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, which funded the study of babies born with HIV in 2007, said further investigation was needed to learn how to induce long term HIV remission in infected babies. “My conclusion is that if you treat people early enough in the course of the disease there will be varying degrees of delay before they rebound. Sometimes that delay can be measured in years so it’s conceivable that in a certain proportion of people you may have the capability of successfully withdrawing therapy safely from anywhere from many months to several years,” he said.

PREVENTION SUCCESS IN SWAZILAND



Swaziland, which has the highest HIV prevalence in the world, has reduced its rate of new HIV infections in adults aged 18-49, down from 2.5% in 2011 to 1.4% in 2016 (2.0% in women and 0.9% in men). Treatment coverage rose from 37% to 74%.

Sophie Cousins, Paris

“Independent” starch trial was done by original authors

Academics who refused calls to share the data underlying their landmark trial that triggered the downfall of starches for fluid resuscitation have announced an “independent reanalysis,” which confirms their original findings.

However, they have not made their data available to the wider scientific community—a key element of transparent research practice and what other academics have been calling for.

The 7000 patient trial, CHEST (Crystalloid versus Hydroxyethyl Starch Trial), is one of the most important pieces of evidence concerning the effects of hydroxyethyl starch solutions for increasing intravascular volume in patients in intensive care.

Published in the *New England Journal of Medicine* in 2012, CHEST reported that the hydroxyethyl starch investigated,

Voluven, was no different from saline in terms of mortality but led to greater use of renal replacement therapy. The trial helped persuade drug regulators in Europe and the US to issue safety warnings in 2013.

The latest “independent analysis” is the first time the CHEST data have been re-examined.

The new report, published as a short research letter in *NEJM*, was conducted by the Duke Clinical Research Institute. But only two of the eight authors of the reanalysis are from the Duke institute. The other listed authors all come from the George Institute for Global Health, which administered the original study. *The BMJ* contacted all eight authors for comment, asking how they could describe the new report as “independent,” given

Gynaecologist at largest Polish speaking clinic is struck off



A gynaecologist who worked in private practice at the UK’s largest Polish speaking clinic has been struck off for recklessness and dishonesty.

Krystyna Tajchman (above), who qualified in Poznan in 1980, faced charges relating to the treatment of two patients at the Green Surgery in Greenwich, southeast London.

Tajchman was found to have performed two procedures on “patient A” that were not clinically indicated: a cervical cauterisation in 2011 and a colposcopy in 2013. In neither case did she perform a proper examination.

She hurried the patient on

both occasions, the tribunal found, by offering a £100 discount if she would undergo the procedure that same day.

When the patient showed reluctance to undergo the second procedure, Tajchman told her that she was at risk of cancer and that it was “too late” for any medication, the tribunal heard.

Tajchman had not shown remorse and “continues to pose a risk to patients”

Tajchman then used an uncoated metal speculum, causing vaginal burns. Patient A sought a second opinion, and a hospital consultant wrote to Tajchman requesting “details



Community hospitals: a viable option?

The “cottage hospital” model of care is a good fit for the needs of an ageing population, says a new report. **Gareth Iacobucci** investigates

their involvement, but they did not answer the question.

Michael Murray, who testified on starch solutions at the FDA, commented, “I am obviously disappointed that it doesn’t appear that the investigators are inclined to share their data.”

Vinay Prasad, assistant professor of medicine at Oregon Health and Science University and an adviser to *The BMJ*, said, “Independent re-analysis means you make the data available for someone else to analyze. Re-analyzing your own data is like standing in front of the mirror and concluding you look good whether your face is turned left or to the right.”

Peter Doshi, associate editor, *The BMJ*
Cite this as: *BMJ* 2017;358:j3552

of recent consultation and operation notes.”

In her reply Tajchman denied carrying out the procedure and suggested that patient A’s pain dated from a smear test carried out by her GP.

Tajchman was also found to have prescribed oral contraceptives to “patient B,” who suffered from migraines, a contraindication for the pill. The patient experienced severe side effects. She also underwent a colposcopy that was not clinically indicated.

Joy Hamilton, the tribunal’s chair, said, “Dr Tajchman abused her position of trust and put her own financial interests before the interests of her patients.”

Tajchman had not apologised or shown remorse, added Hamilton, and “continues to pose a risk to patients.”

Clare Dyer, *The BMJ*

Cite this as: *BMJ* 2017;358:j3563

A report from RAND Europe, a non-profit research institute based in Cambridge, commissioned by the government, argues that community hospitals have the potential to assume “a more strategic role in healthcare delivery locally, providing care closer to people’s homes.”

But, with 44 sustainability and transformation partnerships (STPs) developing models of integrated care around England that seemingly focus more on cutting beds than on enhancing community hospitals, will the report strike the right chord with commissioners?

An evolving model

The traditional image of community hospitals, or local “cottage” hospitals—staffed by GPs and nurses and serving mainly rural, often elderly, populations—has fallen out of favour over the past 15-20 years as the NHS has focused more on caring for people in their own home.

But Emma Pitchforth, lead author of the RAND report, believes that the evolution of the “cottage” model could align with the new models of care and breathe new life into community hospitals.

“It seems particularly timely given the focus on integrated care, the challenge of ageing populations, the focus on providing care closer to people’s home, and the new

care models,” Pitchforth says.

The RAND report says that these hospitals provide, to varying degrees, inpatient beds, post-acute care, diagnostics, outpatient work, and minor procedures.

In 2017, the Community Hospitals Association estimates that there are 327 community hospitals in England and 500 in the UK. But it has lamented that 75 community hospitals have reduced their numbers of beds or had them closed in recent years and are struggling to stay viable as a result.

Helen Tucker, the association’s vice president, hopes that the RAND report will encourage commissioners to “look again at the evidence” for community hospitals before they wither on the vine.

“COMMUNITY HOSPITALS ARE COST EFFECTIVE [AND] PATIENT SATISFACTION IS HIGH”

“The report says they are cost effective, patient satisfaction is typically high, and it’s an important alternative to acute care,” she says. “If RAND are saying they are integral to integrated care, that’s a pretty powerful statement. But I think we’ve got to be quick or else we’re going to lose quite a few.”

She told *The BMJ*, “I’ve been to public meetings where commissioners are saying, ‘The new model of care is that you are going to be treated in your own home—we don’t need community hospitals.’ And local people are



apoplectic and are protesting in the strongest terms.”

Lack of strategy

But Nigel Edwards, chief executive of the Nuffield Trust health think tank, argues that RAND’s recommendations have been “superseded” by STPs, which are developing integrated care strategies that often involve reducing the number of beds in community hospitals.

He says that the absence of a “coherent and consistent strategy” of what a community hospital is and how it operates has hindered their effectiveness, especially in being able to provide fast and dynamic “step-down” care to help the flow of patients being discharged from acute care.

“There is a definite role for various types of post-acute care [such as] a hub for diagnostic services and a location for doing outpatient work and minor procedures,” he says. “It’s just that we haven’t got a coherent and consistent strategy of what a community hospital is or how it would operate.”

Cite this as: *BMJ* 2017;358:j3581

IN 2017 the Community Hospitals Association estimates that there are **327** community hospitals in England and **500** in the UK overall



PETER NICHOLLS/REUTERS

THE BIG PICTURE

Charlie Gard's parents end legal fight to keep son alive

Supporters of the terminally ill baby Charlie Gard gathered outside the Royal Courts of Justice on 24 July as his parents announced their decision to end their legal fight over the treatment of their son.

Connie Yates and Chris Gard had been fighting for the right to remove Charlie, who has infantile onset encephalomyopathic mitochondrial DNA depletion syndrome, from the care of Great Ormond Street Hospital for Children to take him to the United States for experimental treatment. But their barrister, Grant Armstrong, announced that they wished to withdraw from legal proceedings.

On 25 July, Armstrong told the court that Charlie's parents wanted him to die at home. However, in a statement Great Ormond Street Hospital said that this would not be in Charlie's best interests.

The hospital said that an end of life care plan had been drawn up for Charlie and specialists had discussed it with his parents. They proposed that he should be moved to a hospice. Discussions were ongoing as *The BMJ* went to press.

In June, Charlie's parents lost their appeal to the European Court of Human Rights to overturn a previous decision made by the High Court in April allowing Great Ormond Street Hospital to withdraw Charlie's life support. The case returned to the High Court earlier this month after the hospital applied for a fresh hearing in light of claims about new evidence of a potential treatment for his condition.

However, in his judgment, issued at the High Court on 24 July, Justice Francis said that Charlie's parents had to face the reality "that Charlie is beyond any help even from experimental treatment and that it is in his best interests for him to be allowed to die."

Abi Rimmer, *The BMJ*

Cite this as: *BMJ* 2017;358:j3589

“I’ve always told it as it is.” CQC chief moves on

Rebecca Coombes talks to Mike Richards about hospital inspections and standards ahead of his retirement

Mike Richards is something of a household name in medical circles. A consultant medical oncologist, then professor of palliative care, Richards was the first “health tsar” appointed by a buoyant Labour government in 1999.

Fourteen years later, came another first: England’s chief inspector of hospitals. He retires this week after four years in the media spotlight, never more so than when calling out poor quality standards in hospitals, including some of our most prestigious institutions. Richards has, he says, always been “prepared to tell it as it is, even when that is not always convenient.”

Speaking at the Care Quality Commission’s headquarters in London, Richards defends the record of hospital inspection on his watch.

A new inspection regime was launched in 2013 in the aftermath of the public inquiry into the Mid-Staffordshire hospital scandal and Richards, an urbane and shrewd operator, was the consummate safe pair of hands picked to run it.

In the initial wave, huge inspection teams of up to 50 people reported on all the core services at each acute trust in England. The process revealed huge variation between trusts, and in subsequent waves also took some high profile scalps—both Addenbrooke’s and the Barts Health Trust were put into special measures in 2015.

Richards bristles at the suggestion that the CQC has been guilty at times of showboating, and of having golden children such as Frimley Park, Salford Royal, and Manchester Royal Infirmary—institutions rated as outstanding that are serially trotted out as an example to all. “I can honestly say that my judgment has never been politically interfered with. If I’ve said something is inadequate, I’ve said it as it is. If we do repeat the outstandings, it’s because they are and they have

earned that. Would anyone have known Western Sussex was outstanding before we visited? It is not just the favoured few.”

Richards believes inspection is key in averting another Mid-Staffs disaster. “If it hadn’t been for the CQC we might have seen other things happen because people would have possibly cut staffing levels in a dangerous way and they would not have had the same focus on quality. The improvement in standards vastly exceeds the deterioration, which is quite remarkable at a time of austerity.”

But how far has inspection been a mechanism for improvement? Would change have happened anyway without the humiliation of some regions, such as Essex, which has seen most of its hospitals judged as needing improvement, although work is now paying off.

“I talked to Clare Panniker, chief executive of Basildon Hospital, which was the first trust to come out of special measures. After a press conference to celebrate she told me, ‘It’s almost entirely the same staff as when we went into special measures; it’s just that now we are getting the best out of them.’ That has stuck with me. Staff really want to do a good job. We are giving trusts an objective view of where the problems are, what needs to change: coming from outside to say it’s your maternity service that is letting you down, or your end of life care.”

Accountability

But what if trusts don’t agree with the CQC’s assessment? One criticism often made is that the inspection regime is not democratic. There is no appeal process, and findings could be seen to depend on the expertise and judgment of the individual inspectors.

“Consistency of judgment is always a challenge for any regulator, so we have built in processes. We have a clear, published framework of what we are looking for, the characteristics



of an outstanding or good; it is not done secretly behind closed doors. You need current clinicians on inspections who know what ‘good’ looks like—for example, the intensive care consultant whom I walked onto a unit with, said, ‘Mike, this place is as least as good as my unit, and my unit is good.’ The draft reports are all brought to a panel, and we go through all the judgments and ask does this make sense?”

Are inspections with no improvement methodology a waste of time?

“We’ve proved that sometimes holding a mirror up is sufficient,” he says. “Not always; that’s why we have NHS Improvement. It has had a special focus on hospitals in special measures and put a lot of resources into them.”

“You have to keep a strong firewall between the regulator and the improver, because we have got to be able to go back and say objectively, no, this hasn’t improved. If you’ve been the person helping with the improvement the temptation is to say, ‘We know they’ve tried hard; it must be better.’”

Funding challenges

Does he acknowledge that clinicians may feel many conditions are beyond their control? For example, although safe staffing levels are a recurring

PROFESSOR MIKE RICHARDS ATA GLANCE

Consultant medical oncologist 1986-95

Professor of palliative medicine at Guy’s and St Thomas’ Hospitals 1995-99

National cancer director at the Department of Health 1999-2013 (extended to end of life care in 2007)

Director for reducing premature mortality 2012-13

Chief inspector of hospitals 2013-17



LEGACY OF A CANCER “TSAR”

Mike Richards (inset) was one of the first of health tsars brought in by Labour in 1999, together with Roger Boyle for heart disease, Keith Willett for trauma, Tony Rudd for stroke, and others, including *The BMJ* columnist David Oliver. It was a golden age for clinicians in Whitehall, but that era is long gone. Doctors are no longer at the heart of government leading well funded programmes but instead operating arm’s length bodies.

Richards, the architect of the NHS cancer plan in 2000, says he had “a fair wind behind me.”

“I was fortunate that the politicians genuinely wanted to make a difference on cancer and heart disease, etc, and they knew they didn’t know how; they wanted someone to help them. I worked closely with civil servants and NHS managers. We built a movement on improving cancer.”

“Today we are in difficult times, but a lot of the legacy of that time has been preserved. Almost every cancer patient in the country is now treated by a recognisable specialist team. It may seem blindingly obvious now. Cancer by cancer we built up a network of specialist teams so that if you need surgery you will be treated by a surgeon who really knows about that cancer, not just doing one or two cases a year. You will have oncologists specialising in that field, and what’s more, they will be working together.”

Richards acknowledges that the NHS still has some of the worst cancer survival rates in Europe. “We absolutely do and that is, if you like, unfinished business. If someone wants me to help finish it after I’ve left here I might be very happy to help out. Nothing would give me greater pleasure.”

theme in CQC reports, the government has resisted setting standards and providing funds to meet them.

Richards sighs and politely side steps this political minefield. “On safe staffing we always take a rounded view. We would never go on a 1:8 [nurse to patient ratio]. We look at planned levels against actual levels of staffing. We rated one hospital inadequate particularly because of its medical wards and had to close eight beds straight away because it hadn’t got the staff; we went back 48 hours later and the patients said, ‘this place is completely different.’”

In March, an emboldened Richards said the NHS was on “a burning platform” and that the current model of acute services was no longer fit to serve the public. As many as four out of five trusts needed to improve their safety record. But how many of problems flagged up by the CQC are the result of chronic underfunding?

“Well, I believe the NHS does need more funding largely because of rising demand. Look at the numbers of patients coming to emergency departments, the number of operations, and the difficulties in discharging patients back into the community.

“The acute care model is unsustainable. There needs to be more integration between primary care, hospitals, and community care homes. We need better medical care for care homes, to help people stay in care homes and to facilitate discharge. We need to adapt our model to take account of that.”

Sustainable transformation plans (STPs) are seeing these new models of care emerging. Will there be a corresponding integration of the CQC model, currently split between hospitals, general practice, and social care?

“There absolutely will be. When we’ve got an accountable care system, or an acute trust that also runs general practices and care homes, we need to have the right inspectors to inspect all different parts of this trust.

“That’s when our different sectors come together. It doesn’t mean we lose specialisation, but it’s not right to ask an inspector to inspect a care home one day, an intensive care unit the next, and a general practice on the third day. We need them working in teams to provide all we need for these complex providers. We can do that, and are working on that now.”

My judgment has never been politically interfered with

Lighter touch

Richards’ CQC tenure has seen an erosion of funding from the Department of Health. Its annual budget will have dropped by 13% in four years up to 2019-20 to £217m. It will survive through a “more focused and lighter touch,” says Richards. “In those most challenged trusts, we still need to do comprehensive inspections.”

He will be replaced by Ted Baker, the current deputy chief inspector of hospitals. Given that his successor is also male and white; is there enough ethnic and gender balance at this level?

“Out of three chief inspectors one is female, Andrea Sutcliffe. We now have a deputy chief inspector from a black and minority ethnic group. I do want to see more diversity, but it takes time.”

Richards is an expert mountain walker and bagged the Munros in Scotland a decade ago. As retirement beckons, and with a series of career peaks behind him, he now has the liberty to pull on his boots and take to the open road. But with a trusteeship lined up at Cancer Research UK, and vague hints of “unfinished business” in cancer care, his next step should be watched closely.

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More and more doctors are experiencing burnout—exhaustion and feelings of professional inefficacy. Not only is this damaging for doctors and patients but it has financial costs, say our editorialists (p 183). Bolstering individual resilience, they say, can only help so far; ultimately, professional culture and working environments must change.

On these pages, our experts revisit arguments around changing doctors' training hours. And our interviewee over the page, the BMA's medicolegal committee chair, dismisses "going the extra mile" as "the downfall of the NHS."

For more reflections on burnout, including from our weekly columnist David Oliver, see the Comment section, starting p 189.

HEAD TO HEAD

Should we bring back 24 hour shifts?

Longer working hours are not harmful to patients and encourage professionalism, argues **Steven Stain**. But **Michael Farquhar** highlights the dangerous effects of sleep deprivation



no

As doctors, we can be guilty of cultivating the illusion that we are extraordinary heroes routinely delivering outstanding care despite extreme pressures. The reality is that we are normal people

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When asked how many hours' sleep someone should have, Napoleon Bonaparte is said to have replied: "Six for a man, seven for a woman, eight for a fool."

Sleep is essential. We evolved to be awake by day and asleep at night. Our physical and mental health depends on sleep. Most adults need 7-8 hours of quality sleep each night to allow optimal daytime functioning.

Deprived of sleep, fatigue and its consequences soon appear: we become exhausted, achy, nauseous, less focused, more forgetful, more readily distracted. We

feel more irritable, find it harder to deal with pressure, become less productive, and less able to analyse risk or to perform tasks; it becomes increasingly difficult to think clearly, quickly, and effectively. Risk of harm to ourselves and those around us rises. Crucially, our sense of empathy fades.

For most adults awake for 16-18 hours, reaction times become impaired as if at the legal drink-drive limit. Effects of sleep deprivation rise rapidly. After 16 hours awake, every cell in your brain and body demands sleep. The longer sleep is denied, the more punishing that becomes.

Social folklore tells us "great people need less sleep." Winston Churchill was often awake at night but used long daytime naps to compensate. And Margaret Thatcher

yes

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The question of whether doctors should work 24 hour shifts has several aspects: are they harmful to patients, are they harmful to trainees, and are there benefits to trainees if they are going to have to care for patients for 24 hours after completion of training?

In the United States, the question of 24 hour shifts resurfaced with the recent decision of the Accreditation Council for Graduate Medical Education (ACGME) to revise the requirements for all residency and clinical fellowship programmes they accredit. Although many changes were to improve the clinical learning environment related to patient safety and physician wellbeing, the modest change of allowing first year residents to increase their maximum limit of hours on duty from 16 hours to 24 hours received the most attention.

Since 2003, the council's standards for residents' hours of duty have been based on an 80 hour weekly limit. They have allowed 24 hour shifts (with additional time to transfer patient responsibility) except for interns, who had a 16 hour limit applied in 2011. The council's comprehensive literature review on residents' work hours and learning environment found that evidence on the effect on patient safety was inconclusive and that resident learning and the shortened work periods under the 2011 standards resulted in workload compression and increased resident stress and potential risk of burnout.

Flexible duty hours

In response to these uncertainties, the American College of Surgeons (ACS), the ACGME, and the American Board of Surgery funded the Flexibility in Duty Hour Requirements for Surgical Trainees trial, a prospective "non-inferiority" study comparing the 16 hour limits for interns with flexible duty hour policies (up to 24 hour limits per shift).

The less restrictive duty hour policies (24 hour shifts) were not

It seems unreasonable to expect a surgeon to work a 12 hour shift and then to have another surgeon come in and take care of any complications or reoperations when necessary

associated with an increased rate of 30 day mortality or serious complications (9.1% v 9.0%) based on data from 138 691 patients obtained from the ACS national surgical quality improvement programme. This is the best evidence we have that 24 hour shifts do not adversely affect outcomes among surgical patients.

Effect on trainees

The effect of 24 hour shifts on trainees is uncertain. It is likely that they, especially in the most junior years, will be tired at some times during their shifts, but this may help prepare them for their responsibilities as attending physicians. Longer shifts with appropriate supervision (direct or indirect) allow for optimal patient care and the maturation of the trainees' clinical skills. The commitment to provide continuity of care when

necessary is an important part of professionalism.

Hypothetical discussions of working time limits often ignore the realities of physicians delivering patient care after they complete training. Optimal care immediately after operations may require care by the surgeon who operated on the patient—because he or she has a unique understanding of the relevant anatomy and what has been done.

It seems unreasonable to expect a surgeon to work a 12 hour shift and then to have another surgeon come in and take care of any complications or reoperations when necessary. Attending physicians, or at least surgeons, therefore may need to be available for a 24 hour shift to provide the best care to their patients. The best time to learn how to manage fatigue and recognise fitness for duty is under supervision.

No conclusive evidence indicates that working 24 hour shifts negatively affects patient care, and it is important for residents to train in a supervised environment to prepare them for independent practice.

claimed that four hours' sleep was all she needed—probably true during a crisis, but at other times she slept much closer to the typical amount. It suited her to be perceived as being strong, better than those around her, functioning at a superhuman level.

Their stories persist in common misperceptions: that extraordinary people function safely, effectively—even better—with less sleep than their peers. A few people may genuinely need much less sleep than typical, but probably less than 1% of us. Most adults have a physiological necessity for routines giving us at least six, and probably closer to 7-8, hours of sleep every 24 hours.

Superhuman myth

As doctors, we can be guilty of cultivating the illusion that we are extraordinary heroes routinely delivering outstanding care despite extreme pressures. The reality is that we are normal people—often asked to act in extraordinary ways to meet extraordinary

demands—with normal needs and physiology that cannot safely be ignored.

Healthcare systems must be designed accordingly. Our NHS must provide healthcare 24 hours a day, seven days a week, 365 days a year. Our systems must support us as functioning human beings; they must acknowledge, not ignore, the limitations of our physiology and the effect fatigue has on us and on patient care and safety. Healthcare systems must smoothly hand over patient care between well rested, optimally functioning teams, not rely on overtired, exhausted individuals to deliver the appearance, but not the substance, of continuity of quality care.

A policy of 24 hour shifts hits a double blow. It forces us to function sleepless for far longer than our brains and bodies expect to—functionally similar to working having drunk a few pints of beer. And it means we must work at night, a time of maximum physiological vulnerability, already lacking in sleep. Proud of being masters of physiology,

adeptly manipulating patients' rhythms from illness back to health, we must also recognise physiology's consequences on ourselves.

Accept ordinary

There is no shame in being ordinary, in acknowledging we have the same human needs as our patients for comfort, for rest, and for sleep. Without them we cannot function. The shame is in allowing systems to depend on us routinely being extraordinary because ultimately we—and they—will fail.

Should most doctors routinely work 24 hour shifts? No. Instead we must acknowledge sleep deprivation has profound effects on us and the care we deliver, and encourage better strategies to deal with them.

Napoleon declared those who prioritised sleep were fools; we must challenge the foolish thought that we can cheat our need for sleep without consequence.

Competing interests: See [bmj.com](#).
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“Going the extra mile” endangers staff, patients, and the NHS

The culture of doctors stretching themselves to work beyond their shifts and cover rota gaps has to end, Jan Wise, BMA medicolegal committee chair, tells **Tom Moberly**



Doctors who “go the extra mile” are exposing themselves to health problems and an increased risk of facing clinical negligence charges, Jan Wise, the head of the BMA’s medicolegal committee, says.

Speaking to *The BMJ*, Wise, pictured right, warns that doctors’ willingness to work beyond their contracted hours is affecting their own health. “People are burning out,” he says.

“You try to cover colleagues being away, and management don’t replace them, then people go off on long term sick,” he explains. “Doctors are putting their health at risk, and if a doctor’s health is at risk, patients’ health is at risk. They are not able to do what they are being paid to do, and they are not doing it as well as they could be doing it.”

Doctors who undertake work that is outside their contract of employment are also exposing themselves to medicolegal risks, he points out. “If the work is not resourced and it’s not rewarded, the safeguards that prevent things from going wrong are unlikely to be there effectively, and it means you’re more likely to end up in front of the GMC,” he says.

Papering over the cracks

But doctors’ willingness to take on extra work also causes wider problems for the health service, he believes. “I would say that it is the downfall of the NHS,” he says. “It means that people do not know how bad things are, and I regard it as unprofessional.”

If you do any piece of work for free, people don’t know the real cost of that work

By going the extra mile doctors are helping to obscure gaps in service provision from those responsible for managing workforce numbers, he argues. “If you do any piece of work for free, people don’t know what the real cost of that piece of work is,” he says. “If they don’t know the real cost, it gets a false value, and people don’t value you in the way you deserve, which makes it difficult for you to get what you deserve. More importantly, it sells your colleagues, your future colleagues, and your families short.

“You’re selling lots of people short, and that is just from an employee perspective. You’re also selling your patients short, because you’re making it difficult for managers to impress on the purseholders the cost of the service they are currently getting.”

Wise says that people staying on after the end of the shift is one of “the more obvious examples of short changing managers with information.” He hopes that the provision in the new junior doctors contract to “exception report”

when they have been required to work beyond their contracted hours will help ensure this information is passed on to managers. “It will definitely make it easier,” he says. “It’s easier for people to exception report than to go, ‘It’s the end of my shift, I’m going.’”

Culture shift

Wise also believes that there needs to a shift in the medical profession’s attitude to taking on unpaid additional work. “There needs to be a cultural change,” he says. Without a shift in attitudes, the failure to tackle staffing shortages could have a major impact “which may quite possibly precipitate a failure or a downsizing of the NHS,” he says.

“You’ll see a massive increase in part time working and a growth of alternative providers, who will be charging the public directly for service,” he argues. These providers will provide better terms and conditions for the doctors they employ than those available in the NHS, he believes. “It will probably be the conditions which are better and the terms don’t have to be much better,” he says. “If they’re only a little bit better, people will vote with their feet.”

Rather than capitulating to this as an inevitability, Wise believes that doctors need to reassert their rights to work the hours stated in their NHS contracts. “Nobody takes power away from you, you surrender it,” he says. “You have far more power than you think— just assert your rights.”

LACK OF RESOURCES IS NO DEFENCE AGAINST CLINICAL NEGLIGENCE CHARGES

In April, a barrister warned that judges considering prosecutions against doctors for gross negligence manslaughter would not view a lack of NHS resources as a defence against clinical negligence.

James Badenoch, QC, said, “We’ve often had discussions about whether financial constraints might be a defence against what otherwise might be called negligent failure to treat. And we have to conclude that, as yet, it would not.”

He added, “I don’t think that the limitations of finance, of staffing, of equipment, and the dreadful conditions that sometimes people in the NHS are working in has yet been considered a defence to negligent behaviour or treatment.”

Tom Moberly, UK editor, *The BMJ*

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Burnout damages more than just individuals

A system level problem requires a system level response to protect doctors and their patients

Although doctors have a professional responsibility to be at their best,¹ the wider profession and healthcare organisations urgently need to assume a greater responsibility for burnout. Burnout is a work related hazard that is prevalent among those working in people oriented professions such as healthcare.^{2,3} Care providers commonly develop intense interpersonal relationships with those they care for, often prioritising others' needs over their own. While helping and caring for others can be extremely fulfilling, it can also drain your emotional reserves. Over time, this may result in burnout, which is indicated by feelings of overwhelming exhaustion, depersonalisation or cynicism towards people and work, and a sense of professional inefficacy.^{2,3}

Burnout is generally high among doctors globally, although the exact rates vary by country, specialty, setting, gender, and career stage.³⁻⁷ Evidence suggests that many doctors will experience burnout in their careers, that rates are rising and have reached an "epidemic level,"^{5,7} and that burnout can have devastating consequences for affected doctors, their colleagues, their patients, and the healthcare system.³⁻¹¹

The source of burnout can lie within individuals (eg, perfectionism or relying on denial and avoidance as coping strategies), the medical profession (eg, the conspiracy of silence, the blame culture, the tendency to ignore distress), and healthcare organisations (eg, the burden of electronic medical records, changing work environments, poor leadership).²⁻¹³ Solutions, however, have traditionally focused on individuals and their resilience.⁷

Attitudes and evidence are now changing to recognise the importance of professional culture

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and the working environment.¹⁻¹⁷ For example, burnout is one consequence of the "hidden curriculum" in medical education, where learners witness and adopt their teachers' maladaptive behaviours, which are often reinforced throughout their careers.¹⁴ Chaotic clinic settings with bottlenecks to patient flow and lost charts are associated with doctor burnout as well as medical errors.¹⁵

Effective interventions

It is increasingly clear that effective interventions must be directed at the profession and healthcare organisations as well as at individuals. A recent meta-analysis showed that, although individual targeted interventions such as mindfulness, stress reduction techniques, and education around communication skills, exercise, and self confidence resulted in small reductions in burnout, they worked better in combination with organisational interventions such as rescheduling shifts, reducing workload, and enhancing teamwork and leadership.⁹

Medicine must change its culture to tackle the toxic aspects of medicine



A systems level approach is imperative, and the following changes can help drive this transformation. Firstly, medicine must change its culture to tackle the toxic aspects of medicine that cause and sustain burnout.¹¹⁻¹⁸ The profession must foster clinical leadership and a supportive organisational culture that encourages doctors to advocate for important reforms such as eliminating harassment and perfectionist expectations and minimising excessive demands.¹⁻¹⁷

Secondly, the medical profession and healthcare organisations must view doctors' wellbeing as integral to professionalism¹ and as central to patient care: burnout has been clearly linked to patient safety concerns and suboptimal patient care.^{10,18}

Thirdly, doctors' wellbeing must be recognised as a missing quality indicator for all healthcare systems.¹⁰ Improving the working lives of clinicians should be viewed as key to optimising system performance alongside other established aims such as enhancing patient experience, improving population health, and reducing costs.¹⁸

Against a backdrop of rising healthcare costs, governments and healthcare organisations should be persuaded by the potential savings from system level changes to reduce burnout. A Canadian study estimates that early retirement and reduced clinical hours from burnout will cost the health system \$C213m (£130m) in lost future service.⁸

Human resources are the most important asset of any organisation. As doctors continue to grapple with staying well, it is imperative that they have the support of their profession and their healthcare organisations to maximise their ability to care for themselves and their patients safely and effectively.

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The making of an opioid crisis

Other countries, including the UK, must learn from the public health devastation in the US

Human susceptibility to faulty reasoning and cognitive bias has undoubtedly contributed to the US opioid crisis. The *New England Journal of Medicine (NEJM)* recently published an analysis by Leung and colleagues documenting the blunder that resulted from a brief *NEJM* letter published in 1980.¹ The letter reported a low rate of “addiction” among hospital inpatients prescribed “narcotics.” This flawed letter of just five sentences has been cited 608 times since publication. Most citations use the letter as evidence that addiction is rare in patients prescribed opioids. In an unprecedented move *NEJM* issued an editor’s note on the original correspondence indicating that it has been “heavily and uncritically” cited.

Although it is unlikely that the letter, in isolation, had a profound effect on clinical care, its use is emblematic of the ways in which drug companies and others influenced educational and oversight infrastructures and exploited the human predilection to cognitive bias and reasoning by analogy.

After the humane and appropriate rise in the use of opioids for the palliative care of patients with terminal cancer and HIV in the 1980s to 1990s, several companies and clinicians extrapolated this experience to patients with chronic pain, despite limited evidence of efficacy or safety in such patients.

Commercial influence

Company representatives, experts (some paid), and funded organisations highlighted an “epidemic” of untreated chronic pain.² They posited diagnoses, subsequently held to be fallacious, such as “pseudoaddiction” to justify greater opioid prescribing.^{3,4}

Accreditation and oversight organisations such as the US



The millions of lives affected by opioid addiction should serve as sentinel events in a global early warning system

Joint Commission and the Federation of State Medical Boards supported efforts to measure pain as a “vital sign” and to allay concerns about opioids.^{5,6}

Companies funded shadow advocacy groups to promote their agenda.⁷ Paid experts cited inadequate but authoritative research such as the *NEJM* letter.⁸ Company executives pleaded guilty to criminal and civil charges that they and their employees misrepresented the risk of addiction with their products.⁹ In this way, “evidence” such as the *NEJM* letter played into a manufactured narrative that contributed to recent opioid prescribing practices in the US.

The public health devastation from opioids in the US has provided an opportunity to document their limited efficacy for chronic pain,¹⁰ for authoritative figures to re-examine and retract their support for opioids for chronic pain,¹¹ and for a prestigious journal to publish a warning on a nearly 40 year old letter.

We have been here before. For some time, modern clinicians have engaged in practices that seemed to

make sense until they were proved wrong. We prescribed lidocaine to prevent arrhythmias after acute myocardial infarction. We routinely prescribed hormone replacement therapy. We placed inferior vena cava filters after provoked deep venous thromboses. But, in contrast to those well publicised missteps, the role of pharmaceutical companies, experts, and authoritative bodies in enabling indication creep and shaping cognitive bias in long term opioid therapy for chronic pain seems especially pernicious.

We must now consider whether similar opioid crises could emerge outside the US¹⁴; whether the US Food and Drug Administration failed in its duty to ensure that marketing is consistent with science; and whether efforts are already under way to promote overuse of expensive newly formulated opioids, benzodiazepines, and stimulants.¹⁵

Dubious science

Finally, are educational efforts and systems in place to prevent such events in the future? High impact journals may now have review systems in place to limit the publication of dubious science; however, the proliferation of ghost writers, lower impact publications, and predatory journals create further challenges.^{16,17}

Oversight and accrediting bodies should be less susceptible to direct and indirect influence, although this, too, deserves closer scrutiny. Facing shrinking prescribing and lawsuits in the US, opioid manufacturers are now looking to international markets.¹⁸

The tens of thousands of deaths from opioid overdose in the US each year and the millions of lives and families affected by opioid addiction should serve as sentinel events in a global early warning system to prevent us from being fooled again.

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