this week

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SPL

Cosmetic treatment law is too lax

Surgeons who wish to offer cosmetic procedures should have to put their names on a compulsory register, a report on this growing industry has urged.

The report by the Nuffield Council on Bioethics calls on the government to do more to protect the public from the cosmetic treatments industry, estimated to have grown in value from £750m in 2005 to £3.16bn in 2015. It said that the Royal College of Surgeons' voluntary register for cosmetic surgeons should be compulsory and that training in cosmetic procedures should be easier to access.

The college launched the voluntary certification scheme in January, to which 125 have applied so far of 1150 surgeons it believes are eligible. The college has said that it was "not in a position to make the certification scheme compulsory," and it has urged the government to give the General Medical Council the power to highlight to the public which surgeons have been certified, to give the system "extra teeth." The college said, "The government urgently needs to change the law."

The Nuffield Council's report warned that "some of the most significant recommendations" of a 2013 report setting out how to make the industry safer have still not been implemented. Controls on the safety of some of the products used in procedures remain "completely inadequate," it said.

"It is unethical that there is nothing to stop completely unqualified people from providing risky procedures like dermal fillers . . . and children should not be able to walk off the street and have an invasive cosmetic procedure," said the council in a statement.

It called on the government, the royal colleges, medical authorities, and other institutions to work together to "close the gaps" in protection. The government should legislate to make dermal fillers available by prescription only, there should be statutory controls on cosmetic surgeons who practise invasive and non-invasive procedures, and the government must ensure that products and procedures cannot enter the market without robust evidence that they work and are safe, the report said.

Mark Henley, a plastic surgeon and one of the report's authors, said: "People make assumptions there are standards in place about safety, efficacy, and probity. People need to be much better informed."

Sophie Arie, London

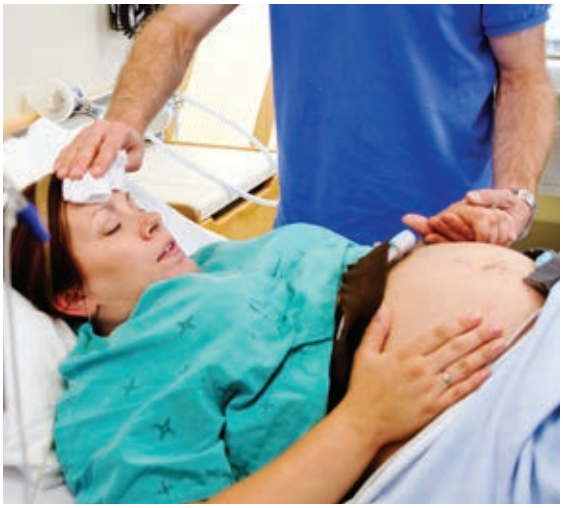
Cite this as: *BMJ* 2017;357:j2987

The Royal College of Surgeons' voluntary register for cosmetic surgeons should be compulsory, said the report from the Nuffield Council on Bioethics

LATEST ONLINE

- Drugs with FDA accelerated approval often have weak evidence
- Problem solving strategy can help prevent depression in low income mothers
- Patients in Wales to take control of medical records

SEVEN DAYS IN



Care at fault in 75% of birth injuries

Three quarters of deaths of babies or injuries to their brain during childbirth could be avoided with better fetal monitoring and neonatal care, a report from the Royal College of Obstetricians and Gynaecologists has concluded.

An investigative team conducted more than 2500 expert assessments of local reviews into the care of 1136 babies born in the UK in 2015, of whom 126 were stillborn, 156 died within the first seven days of birth, and 854 had severe brain injury. The *Each Baby Counts* report, the findings of which were based on 727 babies where reports provided enough information, concluded that in 76% of cases there might have been a different outcome with different care. *Each Baby Counts* is the college's initiative to halve by 2020 the babies who are injured during birth.

Zarko Alfirevic, a co-principal investigator and consultant obstetrician at Liverpool Women's Hospital, said, "Problems with accurate assessment of fetal wellbeing during labour and consistent issues with staff understanding and processing of complex situations, including interpreting fetal heart rate patterns, have been cited as factors in many of the cases we have investigated."

Jacqui Wise, London Cite this as: *BMJ* 2017;357:j2989

Brexit

New alliance will champion health in negotiations

The newly formed Brexit Health Alliance will highlight healthcare research, access to technologies, and patient treatment in Brexit negotiations. The group will argue that both Europe and the UK should maintain cooperation in research and in handling public health issues. It will also urge the UK government to commit to medical research and ensure that UK citizens keep the right to receive healthcare in EU countries. The alliance will complement the work of the Cavendish Coalition, which is concerned with health and social care workforce issues after Brexit.

Misconduct

Researcher is guilty of attempted murder

A jury found Hengjun Chao, 50, guilty of attempted murder for shooting Dennis Charney (below), dean of the Icahn Medical School at Mount Sinai, New York, who had sacked Chao for research misconduct in 2010. Chao lost his job after a faculty panel found that he had manipulated data in his research on gene therapy for haemophilia. He shot and seriously injured Charney last year. The jury found Chao guilty of second degree attempted murder, first degree assault, and first degree criminal use of a firearm.

Former registrar is jailed for two years

Anthony Madu, a former registrar in obstetrics and gynaecology who defrauded the NHS of £98 000 by moonlighting as a locum while on paid leave from his employment, has been jailed for two years. He received a two year suspended sentence when convicted in 2014 and was ordered to pay back most of the money. But on 13 June at Swansea Crown Court he was jailed for two years for failure to pay.

Research fraud

China vows to clamp down on academic fraud

China's ministry of science and technology said that it is investigating the case of 107 papers from China retracted by the journal *Tumor Biology* in April this year and that it has "zero tolerance" for academic fraud. The papers were retracted after the journal's publisher, Springer, found that the authors had submitted papers with fake email addresses of reviewers. The 524 authors under investigation, most of whom are clinical cancer specialists, have had their funding from the ministry suspended.

Blood donation

More black donors are needed to meet demands

NHS Blood and Transplant appealed for a further 40 000 black people to donate blood to meet demand among patients with sickle cell disease. The agency highlighted a 75% increase in the Ro blood subtype issued to hospitals from 2014 to 2016, amid expectations that demand will grow further. A high proportion of this blood will be used to treat sickle cell disease, which affects 15 000 people and 300 new babies each year.

HIV

Uganda plan omits highest risk groups

A plan to end HIV in Uganda by 2030, launched this week by President Yoweri Museveni, has been criticised by activists for not mentioning people at the highest risk, including gay men, sex workers, and drug users. The five point plan focuses on preventing new infections, particularly in teenage girls and young women, and eliminating mother-to-child transmission. It also aims to increase HIV testing in men to help achieve the UNAIDS target of ensuring that 90% of people with HIV have it diagnosed, that 90% undergo antiretroviral treatment, and that 90% have an undetectable viral load by 2020.

JAKE LYELL/ALAMY

Child depression

Antidepressant use rises

Prescriptions for antidepressants in people under 18 reached 166 510 in June 2016, up by 12% from April 2016, showed figures obtained by the *Guardian* newspaper under a freedom of information request. Among those treated with antidepressants were 10 595 children aged 7-12 and 537 aged 6 or younger.

MEDICINE

Fewer people who did yoga for back pain needed painkillers

Research news

Yoga matches physical therapy for back pain

A weekly yoga class designed for patients with chronic low back pain over 12 weeks was as effective as 15 physical therapy sessions for reducing pain, improving function, and lowering the use of pain medicine, a trial found in the *Annals of Internal Medicine*. Yoga classes and physical therapy were both more likely to have clinically meaningful improvements in function than education classes. At 12 weeks just over half (55%) of patients doing yoga or physical therapy used pain medicine, compared with 75% of patients in the education group.

One in six elderly people is subjected to abuse

Some 141 million adults worldwide aged over 60 were subjected to psychological abuse (11.6%), financial abuse (6.8%), neglect (4.2%), physical abuse (2.6%), or sexual abuse (0.9%), a meta-analysis found. The review in *Lancet Global Health*, which looked at 52 studies up to June 2015, found a prevalence of elder abuse of 20% in Asia, compared with 15.4% in Europe and 11.7% in the Americas. "The health sector has an important role to prevent, raise awareness of, and provide evidence based guidance for healthcare practitioners to respond to elder abuse," the researchers wrote.

Smoking

Smoking falls among adults in England

The proportion of over 18s in England who smoke fell from 19.9% in 2010 to 15.5% in 2016, latest figures showed. Smoking decreased in all age groups, but the greatest reduction was among adults aged 18-24, down from 26% in 2010 to 19% in 2016. Smoking rates remained higher in men (19%) than in women (14%), and unemployed people were nearly twice as likely to smoke as those with jobs (30% *v* 16%).

Alcohol

Screening is lacking in emergency departments

Some 85% of 147 emergency departments surveyed do not routinely ask young people or over 65s about their alcohol consumption, a study found. NICE guidelines suggest that screening followed by feedback is the most effective way to reduce alcohol related harm. Robert Patton, from the University of Surrey and author of the study in the *Emergency Medical Journal*, said that problem drinking was "being swept under the carpet, which is dangerous . . . Alcohol can destroy lives and puts undue pressure on the NHS, so it is important that the support is in place to help those affected."

Cite this as: *BMJ* 2017;357:j2968

NHS FINANCES

Hospitals and other NHS providers ended 2016-17 **£791m** in the red, down from a **£2.4bn** deficit in 2015-16 but missing their target of **£580m**

SIXTY SECONDS ON . . .

THE CARLISLE METHOD

DO 2% OF RANDOMISED CONTROLLED TRIALS REALLY CONTAIN FALSE OR FRAUDULENT DATA?

So we're told. Personally, I'd have guessed far more. But RCTs are the gold standard, so it's no small matter if hundreds can be shown to be questionable by a straightforward method.

WHOSE METHOD?

John Carlisle, an anaesthetist at Torbay Hospital, has built himself a parallel career as fraudfinder general. He looks at the baseline demographic data—age, body weight, and so on—reported in trials and tests whether they really match what would be expected if it were the result of random selection.

SO IF PEOPLE ARE USING MADE-UP DATA, HE CAN SMELL IT?

It's surprisingly difficult to simulate randomness. The distribution of invented values tends to be wider, or narrower, than true randomness. If the divergence from randomness is extreme, such that the odds of it arising by chance are less than one in 10 000, he smells a rat. That's the case in 2% of the RCTs he looked at, including a dozen in *JAMA* and nine in the *New England Journal of Medicine*.

COULDN'T IT BE HONEST ERROR?

Yes, it could be. But it's striking how often he picks up papers by proved fraudsters. And even if it is honest error, authors are still reporting results that can't be trusted.

CAN IT BE USED IN PEER REVIEW?

Anaesthesia, where Carlisle reported the method, already does so. The problem is that if you set a high bar (as Carlisle does) you miss some papers retracted by known fraudsters. But if you lower it, you risk catching some that aren't fraudulent or wrong, and cast doubt on honest people.

COULDN'T FRAUDSTERS BACK-ENGINEER CARLISLE'S METHOD TO PRODUCE FALSE BUT PLAUSIBLE DATA?

In principle, yes. If dishonest researchers can fake randomness, they've got it made.

Nigel Hawkes, London

Cite this as: *BMJ* 2017;357:j2942

Children who miss appointments need better follow-up

Hospitals often fail to tell GPs when children miss appointments, and most practices have no protocol for dealing with such children when they become aware of them, a study has found.

Poor communication between primary and secondary care has important implications for child protection, as doctors may miss the opportunity to identify children at risk, said researchers from the University of Bristol.

To learn more about the characteristics of children who do not attend, the researchers accessed data on all new referrals to a children's

NON-ATTENDANCE

In most cases (59.9%) the patient's GP was not informed of the non-attendance

Doctor convicted of manslaughter is suspended for a year

A hospital doctor who was convicted of manslaughter by gross negligence in the treatment of a 6 year old boy who died from sepsis and myocardial infarction has been suspended for 12 months by a medical practitioners' tribunal.

Hadiza Bawa-Garba was a senior specialist registrar at Leicester Royal Infirmary in 2011 when Jack Adcock, who had Down's Syndrome, was admitted with diarrhoea, vomiting, and difficult breathing.

Bawa-Garba initially diagnosed gastroenteritis and ordered a fluid bolus, chest radiography, and blood tests. But she did not review the x rays or blood test results immediately and failed to appreciate the importance of the blood results when she did see them.

She failed to make a note that his routine drugs for high blood pressure should be discontinued, leading him to receive his normal dose, and failed to ask a consultant to review him. As the boy's condition deteriorated, a crash call went out, which she answered. On finding others trying to revive him she told them to stop, saying that he had a "do not resuscitate" order. In fact, she had confused him with another child. Her mistake was noticed within two minutes by a junior doctor and was not believed to have contributed to Jack's death, which was inevitable by that point.

An investigation by University Hospitals of Leicester NHS Trust found numerous errors by Bawa-Garba and nursing staff but also blamed systemic failures. She was interviewed by police in 2011 but was told in 2012 that no charges would be pressed. She then continued working at the trust with no further incidents until her conviction in 2015.

Both she and a nurse were convicted of manslaughter and received sentences of two years' imprisonment suspended for two years.

At her fitness to practise hearing in Manchester, lawyers for the General Medical Council argued that she should be struck off. The wholesale collapse in the standard of care she offered that day had come out of the blue, said Stuart Denney QC, and might therefore recur at any time. But he conceded that she had done everything possible since the incident to remediate her failings.

"The tribunal did not consider that your failings are irremediable"

In opting for suspension, the tribunal's chair, Miran Uddin, said that the tribunal took account of "multiple systemic failures" that the trust had identified, Bawa-Garba's unblemished record before and since, and evidence from colleagues. "Although your actions resulted in the early death of Patient A, you do not present a continuing risk to patients," said Uddin. "The tribunal did not consider that your failings are irremediable; indeed it has already found that you have remedied them."

Clare Dyer, *The BMJ*

Cite this as: *BMJ* 2017;357:j2928

hospital in southwest England from 1 September to 31 October 2012. Of the 2488 outpatient appointments booked, 142 (5.7%) were not attended. The specialties with the highest rates of non-attendance were endocrinology (11.4%), dermatology (11.2%), and neurology (11.1%).

Children who did not attend were more likely to live in an area of high deprivation (adjusted odds ratio 1.02 (95% confidence interval 1.00 to 1.02); P=0.04) and to have a child protection alert in their hospital notes (2.72 (1.26 to 5.88); P=0.01).

Repeat appointments

In most cases (59.9%) the patient's GP was not informed of the non-attendance. Repeat appointment letters were sent to 44.4% (63/142) of non-attenders, open referrals were given to 30.3% (43/142), and 25.4% (36/142) were discharged. Some 49.2% (31/63) of patients given repeat appointment letters were eventually seen by the specialty within 12 months of the missed appointment, compared with 14.0% (6/43) given open referrals and 16.7% (6/36) who had been discharged.

Nearly a third (40/142) of non-attenders were seen in A&E within 12 months. In addition, 23.9% (34/142) had contacted their GP about the same problem, and more than half (19/34) were re-referred.

Ten GPs were questioned about children not being brought to outpatient appointments. Only one of their 10 practices had a formal policy for managing the issue.

The researchers concluded, "Communication between primary and secondary care needs to be improved, and guidelines developed to encourage GPs to monitor children who DNA [do not attend]." They added that medical defence organisations advise practices to have a protocol to follow when informed of non-attendances.

Ingrid Torjesen, London

Cite this as: *BMJ* 2017;357:j2983

"Startling" distrust of drugs among public

Only a third of people trust the evidence from medical research, a survey for the Academy of Medical Sciences has found—half as many as trust what their friends and family tell them about medicines.

John Tooke (above), who chaired the committee that commissioned the survey, called the finding "startling." Speaking at a press conference in London on 19 June, he noted an urgent need to act now to give patients clearer, more useful information about medicines, saying that otherwise they would not reap the full benefits of new drugs coming to the market.

The academy's surveys of 2000 members of the public and 1000 GPs showed that more than four fifths of GPs and two thirds of British adults agreed with the statement that industry trials were often biased to produce a positive outcome.

It concluded that greater adherence to prescriptions will be achieved by greater public involvement in trials, reformulating patient information leaflets, re-educating journalists and press release writers, and increasing the role of NHS Choices, among other changes.

Patient information leaflets

Tooke specifically criticised patient information leaflets, which he said were hard to read and failed to strike a balance between the benefits and side effects of medicines. The report calls for a "clearer, more simplified and balanced appraisal of the benefits and potential harms of the medicine."

"Specialists, patients, and the National Institute for Health and Care Excellence will all have to be involved in rewriting the leaflets," said Tooke.

Nigel Hawkes, London

Cite this as: *BMJ* 2017;357:j2974

FIVE MINUTES WITH . . .

Debbie Robson

The King's College London researcher says smoking is not therapeutic for psychiatric inpatients

"During staff training to support the South London and Maudsley NHS Foundation Trust in implementing a comprehensive smoke free policy, one of the biggest barriers we encountered was staff fears that removing cigarettes may cause psychiatric inpatients to become agitated and increase physical violence.

"Mental health trusts went smoke free on wards in 2008. But patients could smoke in hospital grounds, with supervised cigarette breaks every one to two hours. When people who are dependent on tobacco are not given any replacement between smoking breaks, the effects of nicotine withdrawal, including irritability and restlessness, appear quite quickly. So the next cigarette appears to calm the patient as their nicotine levels are topped up.

WE FOUND A 39% REDUCTION IN VIOLENT INCIDENTS IN 12 MONTHS

"In the year leading up to the complete smoking ban [in September 2014], we provided new treatment pathways for smokers, ensuring nicotine replacement therapy was available as soon as patients were admitted to wards and allowing the use of e-cigarettes.

"We found a 39% reduction in violent incidents in the 12 months after introducing the smoke free policy compared with the 30 month period before.

"What we think is happening is that there's a change in culture and interactions on psychiatric wards. The day no longer revolves around smoking breaks, where patients are banging on the office door demanding to be let out. There are no longer flashpoints in ward gardens, where nicotine deprived patients are all suddenly in the same space. And there's less trading of tobacco between patients.

"It's time to draw a line under clinicians' long held belief that smoking is somehow therapeutic for mental health patients. We need to reinvest all the time and effort previously put into helping patients smoke into helping them stop smoking and living longer and healthier lives."

Susan Mayor, London

Cite this as: *BMJ* 2017;357:j2958

NHS pay cap is barrier to recruitment and retention, unions warn

The health secretary has said that he will investigate lifting the 1% cap on pay, as unions warn that it is bad for recruitment, **Tom Moberly** and **Abi Rimmer** report

The public sector pay cap is preventing the best people from being recruited and retained by the NHS, health unions have warned.

In a letter sent to the prime minister, Theresa May, on 19 June, 16 organisations representing NHS and public sector staff warned that the pay cap had forced professionals out of their jobs. "Those who stay are overstretched and under pressure to do ever more with less," the letter said.

The news comes after England's health secretary, Jeremy Hunt, expressed "sympathy" for calls to increase NHS pay and said he would put the case for lifting the cap on pay rises to the Treasury.

The cap, introduced in 2010, has limited NHS staff to 1% pay rises or below. NHS doctors' pay is determined by the recommendations of the Review Body on Doctors' and Dentists' Remuneration (DDRB). The DDRB has been told by the Treasury that overall pay awards should be within the 1% cap, and its recommendation for 2016-17 was for a 1% pay rise for doctors.

In their letter the organisations, which include the BMA and the Royal College of Nursing, warned that the "longstanding cap stands in the way of recruiting and retaining the best in healthcare."

"It is having a profound and detrimental effect on standards of care at a time when the NHS is short of staff across every discipline," the letter said. "This is alongside an uncertain future for EU nationals working in health and care."

The signatories called on the government to change its policy. "Government should remove the pay cap and tackle the real term loss of earnings so the NHS can retain and attract staff, resolve the workforce shortage, and ensure safe patient care," the letter said.

Commenting on the letter, BMA chair Mark Porter said that pay restraint had seen doctors' pay fall by up to 17%, leading to staff shortages and impacting patient care. "Doctors across the country will agree with the strong message we have sent, with nurses and allied health professionals, to this government, that the pay cap is unfair, unacceptable, and must be lifted," Porter said.

"The pay cap is unfair, unacceptable, and must be lifted"

"With the NHS at breaking point, politicians cannot continue to duck this issue. Investing in the workforce and providing fair terms and conditions must be a priority, otherwise the NHS simply won't be able to attract and keep the frontline staff needed to deliver safe, high quality patient care."

Speaking at the NHS Confederation's annual conference in Liverpool on 15 June, Jeremy Hunt was asked about calls to lift the current cap on public sector pay.

"I have a great deal of sympathy for the case that nurses, among others, have made on the issue of pay," he said. "They do an

HALF OF SALARIED AND LOCUM GPs ARE STRESSED

A BMA survey has found that sessional (salaried and locum) GPs face increasing stress related illness

1 Stress

The BMA emailed 13 800 of its members who it identified as working, or potentially working, as sessional GPs and received 2079 responses (a 15% response rate). Just over half reported having felt unwell because of work related stress in the previous 12 months.

2 Time off

Just over a 10th of sessional GPs reported taking time off because of work related stress in the past year, with salaried GPs the most likely to report needing a break from work (14%). Morale was higher among locum than salaried GPs on average, although it was still only moderate.

3 Workload

Most respondents reported an increased workload, with three quarters of salaried GPs noting a rise. Over a third of locums said that control over their workload was their main reason for not becoming a GP partner, and they were more satisfied than salaried GPs with their work-life balance.

absolutely brilliant job. We need to factor in that there is an enormous amount of goodwill and an enormous amount of time given free of charge because people care about their jobs and they see it not as a job but as a vocation."

Hunt said that decisions on pay rises in the health service were outside his remit as health secretary. "We have a budget that we have to live within, and public sector pay is a matter for the chancellor," he said.

But he said that he would put the case for lifting the pay cap to the chancellor. "I have had a very constructive letter from Janet Davies, head of the Royal College of Nursing, since I came back into office," he said. "I will be meeting with her, and I will make sure that our conversation is reflected back to the chancellor before he makes that decision."

Niall Dickson, chief executive of the NHS Confederation, also said that the pay cap should be lifted. Speaking at the organisation's conference, he said that securing the workforce was one of the major challenges facing the NHS.

"The number of advertised vacancies in England, Wales, and Northern Ireland is growing year on year," he said. "Nurses and doctors are having to work rotas with gaps that cannot be filled, and we remain too dependent on agency staff."

He said that part of the solution lay in removing the pay cap. "There does now need to be movement in the pay cap for all staff as a contribution to retention, and of course, in our view, it should be funded by government," he said.

Dickson argued that the current political situation provided an opportunity for the NHS. "We cannot ignore the vulnerability of the new UK administration and how far its room for manoeuvre may be constrained," he said. "On the other hand, these constraints may present an opportunity. This government will have to work differently, finding areas of agreement on the issues that matter most to the electorate, and that clearly includes the NHS and social care."

A Department of Health spokesperson said, "The support and welfare of NHS staff is a top priority as they do a fantastic job—the government is committed to ensuring they can continue to deliver world class patient care."

Tom Moberly and Abi Rimmer, *The BMJ*

Cite this as: *BMJ* 2017;357:j2965

4 Roles

Female locum GPs were most likely to have chosen their current role to suit their preferred working pattern (20%), and 14% said that partnership working was too onerous or lacking in reward. A fifth of salaried GPs said that working in one setting and providing continuity of care was their main reason for staying in their current role.

5 Pay cap

Seven in 10 locum GPs indicated that they would consider leaving the profession if a cap on locums' pay was introduced in general practice, saying that they would quit the profession (28%), move overseas (25%), or retire early (17%). A further 8% said they would think about taking a career break.

Northern Ireland's GPs face £1m QOF reduction

The BMA has warned that general practices in Northern Ireland could lose out on as much as £20 000 because the Department of Health there has not adjusted funding for increases in practice lists.

Tom Black (below), chair of the BMA's Northern Ireland General Practitioners Committee, said that GPs in the country faced a £1m reduction to Quality and Outcomes Framework (QOF) funding.

He explained, "There are a lot of irregularities at the moment around QOF because big practices are closing and average list sizes are going up because of mergers. Essentially, when you calculate what you get in QOF [funding], it's your practice divided by the average practice list size, so if the average list size goes up then your income in terms of money decreases. What they normally do is recalibrate the QOF point value."

"The number of practices losing £20 000 could run into double figures"

Black said that many practices had collapsed in Northern Ireland, leaving other practices to take on the patients and increase their list size. "In Fermanagh we had five practice closures this year, and they have all had to merge with other practices. We're seeing it as well in big towns, where singlehanded practices see their future as not viable and they are merging," he said.

The value of QOF points in England was recalibrated in February this year because of increasing practice list sizes, but the Department of Health in Northern Ireland will not follow suit. "Essentially, the Department of Health is spending £1m less in Northern Ireland than it did last year," said Black. "From what we hear, the number of practices losing £20 000 could run into double figures, and then so many will be losing £15 000, £10 000, £5000 [that] 80% of practices will lose money."

He said that many practices in Northern Ireland were already facing underfunding, had workforce problems, and were unable to meet patients' demands.

The further cuts to funding are likely to mean that practices would be unable to afford to pay for locum GP cover for holidays, said Black. "What we intend to do is have a meeting to draw up a list for practices of what they can do in terms of cuts to services—so it could be a list closure, a half day closing, banning paperwork, reducing enhanced services, or reducing work done for hospitals," he said.

Earlier this year the BMA began to collect undated resignations from practices in Northern Ireland. "The undated resignations are still coming in, we get a handful every week, and I suspect after this that will escalate," said Black.

A spokesperson for the Department of Health commented, "GPs are being paid in line with the longstanding formula for calculating payments under the Quality and Outcomes Framework. The formula was agreed by BMA representatives as part of the Statement of Financial Entitlements for 2016-17."

Abi Rimmer, BMJ Careers

Cite this as: *BMJ* 2017;357:j2960

GRENFELL TOWER FIRE

The Grenfell Tower fire has tragically shown up the shortcomings of both central and local governments in its response to its poorer citizens. Here, we report on the immediate reaction to the fire by two local doctors, including one responding to his third major incident in 10 weeks. **Martin McKee** also asks how should public health doctors act now? And **Anna Minton** argues that tower blocks, if properly maintained, can support healthy lives

We cannot ignore the political determinants of public health

A public health response must confront the underlying causes

The questions began within hours of the tragedy. Could it have been foreseen? Was there a design fault? Why had the victims been concentrated among the poor and marginalised? More questions followed a few days later. How could politicians appear so insensitive in the face of such suffering? Why were so many warnings ignored? Who was responsible for the budget cuts that increasing numbers of people blamed for the disaster?

This was not London in 2017, in the aftermath of the fire in Grenfell Tower, a residential block that turned into an inferno trapping scores of people, with at least 79 people dead or missing. It was 2005, in New Orleans. The official line, repeated by President George W Bush, was that the flooding that followed Hurricane Katrina could not have been foreseen. Yet, it soon became clear that the Federal Emergency Management Agency had predicted that flood protection would be overwhelmed only four days before. Others noted how, while those with the means to escape did so, the poor and dispossessed were left behind.

Soon, people began asking how this could have happened in one of the world's richest countries. How could those in power fail to empathise with their fellow citizens, as when first lady Barbara Bush said that "so many of the people in the arena here, you know, were underprivileged anyway, so this is working very well for them"?

Some argued that what happened could only be understood by looking at the underlying political determinants of the tragedy, while others argued the opposite.

Many watching events unfold in June 2017 in west London felt that history was repeating itself. Even while the fire was still burning, local residents described how they had repeatedly attempted to draw the authorities' attention to the risk of fire. With tragic prescience, they predicted that "only a catastrophic event will expose the ineptitude and incompetence of our landlord." Soon afterwards, attention focused on earlier fires in similar blocks, amid allegations that ministers had failed to act on coroner recommendations.

Local council criticised

The response from the people of London was extraordinary, but the political response was not. The prime minister was accused of lacking humanity for not meeting relatives. The local council attracted particular criticism: Emma Dent Coad, Kensington and Chelsea's new MP, told newspapers that "there was no council presence" and "they weren't making sure that [those affected had] any kind of support." As evidence of local government failings accumulated, central government had to intervene with its own task force.

As with Hurricane Katrina, some of those affected quickly invoked the political determinants of the tragedy.

DAN KITWOOD/GETTY IMAGES

They highlighted an unwillingness to impose stronger safety regulations on landlords, the cuts imposed on the fire service, and the restrictions in legal aid that had prevented residents from advancing their case in the courts. As in New Orleans, views were divided. Those on the left highlighted the political dimension; those on the right condemned politicising the tragedy.

But if public health is concerned with the prevention of illness, injury, and premature death, it must work to avoid tragedies such as the Grenfell Tower fire by seeking to address the causes of the causes and, above all, by confronting those with power. It is the powerful who define the narrative in the media and in political discourse, decide who is to blame, what policies are acceptable, and even whose lives are important. They set the rules that relax standards on safety and employment rights. And they silence the weak, ignoring or discounting their views.

In response, public health professionals must make the invisible visible. They must emulate those who asked why 76% of third class passengers on the *Titanic* perished but only 39% of those in first class, those who showed that inequality

Public health professionals must make the invisible visible

is "killing people on a grand scale," and those who measured then exposed the human cost of austerity. They must also make visible the often hidden corporate determinants of health, such as the tactics used by tobacco, food, and alcohol industries in subverting healthy public policies.

In giving voice to the voiceless, health professionals can take inspiration from Rudolf Virchow, whose investigation of a typhus epidemic led him to conclude that the ultimate cause was the power of the aristocracy, propped up by the church. Speaking truth to power has become more difficult in England since the 2012, when large parts of the public health function were moved into local government, but it is impossible to achieve a comprehensive understanding of events such as Grenfell Tower without confronting the political determinants of health and challenging the forces that shape them.

Martin McKee, professor of European public health, London School of Hygiene and Tropical Medicine, London, UK

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BMJ OPINION Ahmed Kazmi

A local GP's experience of the Grenfell Tower fire

VCG/CONTRIBUTOR

Wednesday 14 June was a tragic day for so many and a very atypical day in our surgery. My clinic is less than 800 m from Grenfell Tower, and several of our patients were residents there. We spent the day trying to compile a list of our patients who had been dispossessed. We made comfort calls to those affected (especially the vulnerable ones), offered walk-in appointments to those who found themselves without their medication, and tried to offer some comfort. It is difficult, though. What do you say to someone who has just lost their home and everything they own? "I am so sorry for what has happened to you. Here is your insulin prescription."

I went down to help at the rescue centres. Walking past the tower was eerie. It looked like something from an apocalypse film. There were workers in white biohazard suits, police officers, and exhausted firefighters. The building was still smoking. I was fearful of what state the rescue centres would be in. I took a big breath and entered.

I struggle to describe what I saw without getting emotional. I didn't see or feel any despair or terror. The overwhelming feeling was of love, unity, and solidarity. Every corner of St Clement's Church and Rugby Portobello Trust, a youth charity, was taken over by agencies there to help: a makeshift housing office, a lost relatives bureau, the Red Cross, and a doctor and nurse station, to name a few. There were emergency service workers circulating around the floor. I have never seen so many priests in one place (which is saying something, considering I went to a church school)—even the bishop was there.

The most beautiful observation for me was the conduct of the local residents. People arrived one after the other with food, clothes, and toiletries. Volunteers quickly sorted the items and displayed them and helped the affected people pack what supplies they needed into bags. A group of young black Muslim boys, who were fasting for Ramadan, walked around with jumbo pizzas offering everyone a slice. A group of women arrived to offer face painting for the children.

What do you say to someone who has just lost their home and everything they own?

As a doctor, I felt slightly redundant. The centres were very well staffed as so many doctors and nurses had already volunteered their help. I sat down on the floor and played with some children. I may not have used my stethoscope those hours I was at the centre but I still felt I was acting as a doctor. I think that sometimes empathy and witnessing someone's grief are as important a part of our role as procedures or prescribing.

It was striking how all the usual prejudices and divisions that so often surface among us were suspended. People from all walks of life were empathetic and loving to one another. For a period at least people stopped being black, white, Muslim, and so on and were just "human." If this unity is possible in times of tragedy, I think it is realistic to aim for it all the time.

Ahmed Kazmi is a GP, west London

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BMJ OPINION Helgi Johannsson

I am a better doctor for allowing myself to stop, reflect, and grieve

I saw this tragedy unfold out of my window

At 3 am on the 14 June 2017 I was woken by the loud, grating ringtone that I use for the St Mary's Hospital major incident number. After the recent terror attacks in London my colleagues and I had become acutely aware that further major incidents could be on the horizon and I had saved the number into my favourites, allowing it to pierce through my "do not disturb" function.

After a few seconds I worked out what was happening and checked my phone. I had recently set up a WhatsApp group—which was only to be used during a major incident—for my consultant colleagues. I saw it had filled with messages about a fire where we expected mass casualties. I got up, looked out from our balcony and saw west London lit up with the flames from Grenfell Tower.

We had an enormous response from our staff, and I know that the other hospitals involved did too. We have a clear major incident protocol and, as this was the third time in 10 weeks that we activated it, everyone knew where they were supposed to be, how to communicate, and who to contact if they needed help. Our protocol is designed to avoid flooding the emergency department, but keep help close at hand. The flow must not be obstructed, and the right expertise needs to be in the right places.

Our response worked well, we provided good quality and compassionate care, and with help from our sister hospitals we cleared enough capacity so that we could have accepted many more patients than we received.

Effective communication is vital in major incident responses, as is being able to relay a message to multiple colleagues. One of our key learning points from the Westminster attack was not to overload the coordinating consultant with offers of help. When I set up the major incident WhatsApp group I was initially met by some puzzled looks, but after two further incidents it has proved invaluable. Fast mass communication, the ability to coordinate our response, and being able to plan the service for later on that day vastly improved the care we were able to provide.

WhatsApp has end-to-end encryption and is therefore confidential as long as you know whose phone is in the group, and it has a passcode. It is widely used in communication within NHS teams already, yet officially it is prohibited on information governance grounds. Perhaps it is time for the NHS to take the opportunities that this kind of technology offers and incorporate it into our everyday practice.

How does a major incident like this make you feel? I am immensely proud and honoured to be part of a service that is responsive, flexible, and provides high quality care in difficult circumstances, again and again. Despite this we still want to improve our pathways and make our care even better.

Being able to see the sheer scale of the fire when I woke up made the tragedy much more real, and I had a sick feeling in my stomach as I drove to the hospital. We treated a lot of children at St Mary's and I know that many of my colleagues are still upset about what they saw—trainees and consultants alike.

At the time of writing some of the bodies are being identified, their stories are being told, and the scale of the tragedy is becoming apparent. I am much more emotionally affected now than I was on the day. Some would say we must remain emotionally detached and equate that with professionalism, but I am human. I saw this tragedy unfold out of my window, and I feel I am a better doctor for giving myself permission to stop, reflect on what has happened, and to grieve.

Helgi Johannsson is consultant anaesthetist and clinical director of anaesthesia and theatres

Cite this as: *BMJ* 2017;357:j2950

JANINE WIEDEL/ALAMY

High rise living after Grenfell

Housing is an important contributor to mental wellbeing. **Anna Minton** argues that well designed and well run high rise buildings still have a role in providing stability for people in social housing

"We need a piece on the housing apartheid in London, how London's poor end up living in death trap towers." This message from the *Evening Standard* landed in my inbox at 8 am last Wednesday while the Grenfell Tower fire was still burning. They wanted the piece by 9 30 am.

Alarm bells rang, and not only because it seemed unlikely that I could write anything informed in such a short space of time. It was also obvious that this appalling and preventable tragedy would feed directly into what I've come to describe as the "sink estate" narrative—the political rhetoric surrounding the demolition of hundreds of London's housing estates, which often include a mix of low and high rise housing. Advocates describe this process, which is replacing estates of affordable housing with luxury apartments alongside a small amount of affordable housing, as estate regeneration. Critics condemn it as social cleansing, breaking up lower income communities at a time of acute housing crisis.

The tower blocks themselves, if well maintained, are often liked by residents

The tower blocks themselves, if well maintained, are often liked by residents. At Grenfell a spate of dangerous power surges and numerous complaints about safety in the block—and across the borough—had been repeatedly ignored by Kensington and Chelsea Tenants Management Organisation (KCTMO), the arm's length management company that runs the 10 000 social homes in Kensington and Chelsea.

Over the past 20 years, most councils have given up the management and maintenance of social housing and in many areas, confusing partnerships such as the one between KCTMO and Kensington and Chelsea Council are in operation, blurring lines of democratic accountability. In a horrifyingly prescient blogpost entitled "Playing with Fire" the local residents action group wrote last year: "It is a truly terrifying thought but the Grenfell Action Group firmly believe that only a catastrophic event will expose the ineptitude and incompetence of our landlord." It later emerged that the KCTMO threatened legal action against residents who made complaints. It is this failure to make their voices heard that reveals how powerless and unrepresented the residents were and that serves as such a stark symbol of inequality in the midst of one of the richest parts of London, if not the world.

Regulatory failure has been another key feature, with the government failing to carry out a review of building regulations despite the repeated urging of the All Party Parliamentary Fire and Rescue Group.

The group had recommended that 4000 sprinkler systems be installed in similar towers.But rather than moving to do this immediately and reassuring thousands of fearful tower block residents, London mayor, Sadiq Khan, wrote in the *Observer* that: "It may well be the defining outcome of this tragedy that the worst mistakes of the 1960s and 1970s are systematically torn down."

Demolition is not the answer

So is Khan right to condemn the blocks themselves? Not according to many of their residents fighting to save their homes in London. Balfron Tower in east London, designed by Erno Goldfinger, is so popular that there has been a huge row locally over plans to turn it into luxury apartments in place of social housing. Research commissioned

IMAGEBROKER/ALAMY

by the government in the mid-2000s into high rise living across all tenures found that the majority of residents "loved" their tower blocks, in particular the views and sense of place. "Only mismanagement sullied their experiences, from broken lifts to lack of security," according to Loretta Lees, professor of human geography at Leicester University, who supervised the research. And of course, forests of luxury towers are mushrooming all over London and other British cities, and nobody is worried about multimillion pound penthouses catching fire.

This is an age old debate, which first took hold in the US during the 1970s when architect Oscar Newman researched the links between crime and the design of tower blocks in New York. His conclusion was that design influenced crime and that high rise living in particular encouraged opportunistic crime. This was hotly contested, with critics (who included UK prime minister Margaret Thatcher's advisers) claiming it was an environmentally deterministic view that ignored the root causes of social problems. But it is an approach that has heavily influenced UK policy makers ever since.

In the UK many estates are demonised

Housing insecurity

In other parts of Europe, large scale public housing estates, with and without tower blocks, continue to work as their architects intended, but in the UK many estates are demonised.

In London up to 100 estates have already been demolished or are in the process of being demolished, with many more demolitions in the pipeline. The problem for the communities who live in them is that while the number of houses for sale has increased it has also resulted in the net loss of 8000 social homes so far and the displacement of a great many households to other parts of the city or out of London altogether. Research shows that the stability of a person's housing situation and housing insecurity are highly correlated with mental health and wellbeing.

In their 2016 paper, "Housing the Mind," psychiatrists Ciaran Abbey and T B S Balamurali looked at studies that focused on high rise, multiple dwelling units versus low rise, which showed that high rise living could be detrimental to psychological wellbeing. But contrary to expectations, the research found that this was as a result of socioeconomic factors rather than because of the blocks themselves. "The belief was that social relations are more impersonal in high-rise dwellings," they wrote. However, when they examined the reasons further, they concluded that "it is social isolation, restricted play opportunities for children, no residential control and lack of feelings of ownership and loneliness which cause the difficulties, rather than the form of high-rise blocks themselves."

At a time of huge worry and uncertainty, threats to demolish people's homes cannot be helping.

Anna Minton is the author of *Big Capital: Who is London for?* published by Penguin.

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EDITORIAL

Trial transparency: A joint statement from funders

This new WHO statement from non-industry funders is a model of best practice

It costs nothing for an organisation to issue vague statements in favour of transparency and integrity. This time, a World Health Organization joint statement on clinical trials transparency, signed by 15 major non-industry research funders (see box), gives unusual grounds for optimism. Where previous documents have been shapeless, this one makes clear commitments to transparency, with timelines; it promises unambiguous outcomes where compliance can be easily assessed; it gives technical details around implementation; and crucially it includes a commitment for open self auditing, so progress can be monitored.

This matters, because definitive forward movement is long overdue. We have known that clinical trials are incompletely and selectively reported since the 1980s,[1 2] and much has been written on our collective poor progress since then.[3 4] A 2014 systematic review found 17 studies that followed up cohorts of trials approved by ethics committees,[5] of which only half were published. Twenty two cohort studies of trials on registries gave similar rates of unpublished results (54.2%, 95% CI 42.0% to 65.9%). Studies with statistically significant results were much more likely to be published, and this is consistent with previous reviews on the topic.[6]

Definitive forward movement is long overdue. We have known that clinical trials are incompletely and selectively reported since the 1980s

Finding the findings

The figure for non-reporting can vary, depending on how prevalence is assessed and where results are sought: a conventional academic journal publication, the grey literature (with variable levels of oversight), self published as a PDF on a company's own website, or posted in the results reporting section of a registry. A 2016 cohort study on 4347 clinical trials in US academic centres[7] found that 66.5% had reported results anywhere, ever; but only 35.9% had reported results within two years of trial completion; and only 28.6% had reported results in an academic journal within this time frame.

This is why, after decades of prevarication, the specificity of the WHO document is so important. It not only commits signatories to develop a transparency policy: it commits them to publish one within 12 months of signature. Signatories not only commit to share results: they commit to share results within 12 months of trial completion. There are no diffuse collective obligations: funders are in a position to secure compliance from grant recipients. Where the FDA Amendment Act 2007 and EU transparency legislation have limitations in their small print, the WHO statement uniquely and very simply covers all trials. It is also clear on where results should be reported. All trial results must be reported on the registry where the trial was registered. This ensures results are indexed and discoverable, and will make compliance easy to audit.

This kind of audit, lastly, is vital, because compliance on celebrated transparency initiatives is quietly recognised as dire. In 2004, the International Committee of Medical Journal Editors (ICMJE) committed to publishing only registered trials[8]—extensive evidence shows that member journals routinely breach this guidance.[9] Around 500 journals have signed up to the CONSORT guidelines on trial reporting; a systematic review of 27 studies shows compliance is weak.[10] The FDA Amendment Act 2007 requires trials to report results within 12 months: compliance is estimated at only one trial in five.[11 12]

In the WHO document, by contrast, all funders have committed to conduct an open and publicly accessible audit of compliance, for both registration and results reporting, sharing data to allow external validation. This is vital and innovative: self audit with open data sharing is cheap and will help drive up standards.

What is next? After four decades of mediocre progress we have learnt from WHO and the signatories that precise, substantive public commitments on transparency are possible. No organisation should ever again be permitted to take credit for vague, superficial statements on transparency. No organisation should be allowed to make a promise without also committing to openly audit their compliance, sharing all their audit data as they go. But we can also revisit our existing commitments, to show that they are more than mere theatre. ICMJE, CONSORT, industry bodies, regulators, and every brand associated with a transparency initiative should revisit their wording, and require their adherents to openly audit their compliance; or, in a worst case scenario, they could publicly acknowledge that what others read as a firm commitment was, in reality, aspirational but unserious. When we give false reassurance that problems have been fixed, we hold back progress. That is not transparency. It is "transparency theatre."

Signatories on 18 May 2017

- Indian Council of Medical Research
- Inserm
- Research Council of Norway
- UK Department for International Development (DFID) (joined on 31 May 2017)
- UK Medical Research Council
- CEPI
- Drugs for Neglected Diseases Initiative (DNDi)
- Epicentre
- FIND (joined on 26 May 2017)
- Institut Pasteur
- Médecins Sans Frontières
- Medicines for Malaria Venture (MMV) (joined on 24 May 2017)
- PATH
- Bill and Melinda Gates Foundation
- Wellcome Trust

www.who.int/ictrp/results/jointstatement/en/

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SEE ANALYSIS, p 520

QUALITY OF CARE

Trusts earn better care ratings by engaging all staff

Reviewing their culture and working on relationships within hospitals has helped failing organisations improve. **Adrian O'Dowd** reports

Trusts that have managed to improve their bad ratings from the Care Quality Commission (CQC) have done so by better engagement with staff and ensuring that clinicians are more involved in organising and managing care, claims a new report.

The CQC report, published last week, details case studies from eight NHS trusts around England and looks at how they significantly improved quality of care and their CQC rating.

The report is based on interviews with staff, patients, and patient groups. All steps towards improvement by the trusts involved reviewing the organisation's culture and tackling any "disconnect" between clinicians and managers, between medical and nursing teams, or between different hospitals at the same trust.

"The first thing we did was get a sense of direction and support"
—Jackie Daniel

Three of the trusts had been put into special measures by the CQC after inspection visits, two had been rated "inadequate," and three had "required improvement."

The report's authors said that the priority for leaders had been to engage with staff and allow open conversations about what had to happen to improve. Trust chief executives and senior staff spent time on the "shop floor," meeting staff and setting up regular channels of communication. They worked with staff to produce shared values for positive cultural change, some of which involved recognising the need to tackle issues of equality and diversity among staff and patients.

The trusts took action through various initiatives, such as University Hospitals of Morecambe Bay NHS Foundation Trust creating "Listening into Action" projects, where frontline staff proposed projects to make a difference to patient care, as well as strengthening processes for reporting and learning from incidents.

A case study on Morecambe Bay explains what happened at the trust after it was placed in special measures at a June 2014 inspection. It came out of special measures in December 2015 and was then rated "good" after another inspection in February this year. The report quotes Andrew Higham, a consultant and clinical director for medicine at the trust, as saying, "We had gone too far down the road of management control and clinicians being disenfranchised with no say."

TRUST	FROM	TO
University Hospitals of Morecambe Bay NHS Foundation Trust	Special measures	Good
East Lancashire Hospitals NHS Trust	Special measures	Good
Cambridge University Hospitals NHS Foundation Trust	Inadequate	Good
Wexham Park Hospital	Inadequate	Good
University Hospitals Bristol NHS Foundation Trust	Requires improvement	Outstanding
Barking, Havering and Redbridge University Hospitals NHS Foundation Trust	Special Measures	Requires improvement
Leeds Teaching Hospital NHS Foundation Trust	Requires improvement	Good
Mid Essex Hospital Services NHS Trust	Requires improvement	Good

When Higham became clinical director he appointed 11 clinical leads in the specialties. "Suddenly, I had 11 deputies to share the burden," he said. "We appointed clinical managers to support the clinical leads. It was like a breath of fresh air. People feel engaged because they've been listened to, not just told what to do."

Mike Richards, CQC chief inspector of hospitals, commented, "Since introducing our comprehensive inspection programme in 2014, I have been encouraged by the number of NHS trusts that have made significant improvements in quality. We know from our inspections that strong leadership and a positive open culture are important drivers of change."

Amber Davenport, head of policy at NHS Providers, which represents NHS organisations, said, "This report reflects the fantastic work and the improvements made by trusts across the country, despite the mounting pressure that they face.

"While it is right that we celebrate the success stories, the report also highlights the funding, demand, and workforce challenges facing their improvement efforts."

Adrian O'Dowd is a journalist, Kent

Cite this as: *BMJ* 2017;357:j2921

"MANAGERS HAD GONE TOO FAR. CLINICIANS FELT DISENFRANCHISED"

Any trust that receives a bad rating after an inspection by NHS regulator the Care Quality Commission (CQC) could be forgiven for balking at the thought of trying to turn the situation around.

It can be done, however, as the University Hospitals of Morecambe Bay NHS Foundation Trust in Cumbria has demonstrated.

The trust serves a population of around 365 000, covering south Cumbria, north Lancashire, and the surrounding areas, and is made up of three hospitals.

In less than three years, the trust has moved from being put into special measures in June 2014 to being rated as "good" earlier this year.

Its reversal of fortunes provides useful lessons on how various trusts were able to make significant improvements in the quality of care and improve their CQC rating.

The scale of the problem in Morecambe was daunting, according to its chief executive, Jackie Daniel: "I walked into the organisation four years ago and it wasn't good, we were renowned for many bad things.

"We spectacularly fell over, in every sense, and I think when I arrived there were a lot of broken contracts with the public, with staff, with partners. It was not a great place to be. But it was a good way to start: it was a real watershed moment and an opportunity to recruit whole new teams and work in different ways."

In the CQC report, Daniel says: "Staff morale was low when we were so busy. With staff shortages, training needs were not being met, which led to staff being disengaged."

Daniel was wise enough to realise that staff relations with management were vital to tackling problems at the trust, which needed to create a culture where staff felt valued and encouraged to suggest improvements while also questioning poor practice.

"The first thing was to get some sense of direction and support," says Daniel. "We needed to start to tell the story of what had gone wrong and why, so that staff could make sense of it, and then tell them what we needed them to do, in what order, to put things right."

She spent time talking to staff and asked them, if they could, what they would change and why. Senior staff are now a lot more visible, regularly visit wards, and have made themselves known to staff.

The trust created a Listening into Action (LiA) scheme, which asks frontline staff to propose projects and identify improvements that would make a difference to patient care. Consequently, various clinicians are now leading numerous projects. One example is specific education and training for staff to spot signs of acute kidney infection, which was proposed by an associate specialist doctor at the trust and is now in place.

Central to improvement was the appointment of consultant Andrew Higham as clinical director for medicine.

People feel engaged because they've been listened to, not just told what to do."

Doctors have been empowered at the trust, which as part of the changes has created five clinical divisions, each led by a clinician. Reporting and learning from incidents and alerts is handled better now and the executive team has weekly review meetings.

Working with the local population has also helped and the trust held a listening event with a local GP practice, during which trust staff heard about the good care that patients had received, as well as the bad.

Daniel explains: "The temptation is to pull down the shutters, but actually the thing to do is keep up a dialogue.

"The thing that I've noticed in the last year is how on their toes the staff are. My job is to create an environment in which they'll flourish, and where patients will get great healthcare."

Still ambitious for improvement, the trust is now aiming for a rating of "outstanding" and Daniel says she will use the trust's staff survey as her main indicator over the next 12 months.

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Morecambe's patients have also benefited

Do the new drugs live up to their hype?

A recent review questioning the effectiveness of direct acting antivirals has been challenged by clinicians who see the drugs as a life changing advance for patients. **Nigel Hawkes** reports

Hepatitis C antiviral drugs are effective

We are clinicians and scientists who have studied and treated patients with chronic hepatitis C virus infection over many years and patient groups that represent those affected by hepatitis C. The Cochrane review that you highlight (Hepatitis 'wonder drug' may be clinically ineffective, say experts, 9 June) analysed clinical trials, which are by nature short term, where the sole purpose was to evaluate the virological efficacy of new antiviral drugs. The trials were not designed to assess mortality, so it is hardly surprising the Cochrane review was unable to identify any impact on mortality.

Regulatory authorities and clinicians all recognise that clearing hepatitis C virus reduces mortality. Indeed, UK-based research shows that oral antiviral

for patients without viral hepatitis. These data are supported by similar analyses worldwide. The Cochrane analysis is fundamentally flawed, does not reflect international experience of the benefits of antiviral therapy, and has the potential to deter patients with hepatitis C from seeking life-saving antiviral therapy.

The real story is one of remarkable success over just a decade, transforming an unpleasant and sometimes fatal disease into one that is readily cured.

Prof Graham R Foster *Queen Mary University of London,* **Prof William Irving** *University of Nottingham,* **Prof John McLauchlan** *University of Glasgow,* **Charles Gore** *CEO, The Hepatitis C Trust,* **Graeme JA Alexander** *President, British Association for the Study of The Liver*

It can take decades for a person to realise they are infected with hepatitis C, by which time their liver may be significantly damaged. The objective of clinical trials is to

the hepatitis virus on progression early cirrhosis of the liver through end-stage liver failure and liver tra or liver cancer. This is why the mar that measure how much virus a pa carrying, and whether the virus ha eradicated, are of crucial importan

All of this is taken into account as part of its strict assessment proc

Our concern is that the Cochran Collaboration research has been re in a way that only tells half of this which is unhelpful for patients wh living through the pain of progress liver disease or end-stage liver fail

Dr Paul Catchpole *Association of the British Pharmac Industry (ABPI)*

Having contracted hepatitis C fr blood transfusions in 1978 and th I was permanently depressed, I w shocked to read a lengthy, negativ report in the Guardian. Having qu

The lead author of a Cochrane review casting doubt on drugs hailed as a cure for hepatitis C shows no sign of wavering in the face of a strong rejoinder from some of the UK's leading liver specialists.

Janus Christian Jakobsen, chief physician at the Copenhagen trial unit, told *The BMJ* that evidence from 138 trials reviewed by the Cochrane Hepato-Biliary Group showed no evidence that direct acting antivirals had any effect on hepatitis C morbidity or all cause mortality. "The most important conclusion of our review is that there is no evidence of the clinical effects of the drugs," he said. "No evidence at all."

The drugs have been approved as cost effective by the National Institute for Health and Care Excellence (NICE), but such is their cost that NHS England has won the right to introduce them slowly. For example, sofosbuvir-velpatasvir—a combination taken as a tablet once daily and approved by NICE last September—costs £38 980 for a 12 week course. The new treatment was also included in the latest edition of the World Health Organization's essential medicines list.

Janus Christian Jakobsen says all the trials were at serious risk of bias

Graham Foster hails the drugs as a "startling success"

Non-validated surrogate outcome

The drugs were approved after trials showed that they could produce a sustained reduction in the level of hepatitis C virus in the body. The Cochrane review does not contest this but says that its clinical relevance is questionable as it is a non-validated surrogate outcome. "We should look back in history and see how many times we have been fooled by surrogate outcomes," Jakobsen said. "The drug companies may benefit from it, but patients often do not."

Only 11 of the 138 trials included in the review looked at mortality. There were 15 deaths in 2377 patients taking the drugs, against one death in 617 patients on placebo, but the result, an odds ratio of 3.72 in favour of placebo, was not significant. Serious adverse events were less common in those taking the drugs, but again the difference was not significant. Only one drug, simeprevir, showed a significant benefit in reducing serious adverse events, such as admission to hospital, but a sequential analysis showed there was not enough information to confirm this result.

All the trials were by drug companies and are at serious risk of bias, Jakobsen said. "We know trials with a high risk of bias tend to overestimate benefits and underestimate harms. So the reality is probably worse than our conclusions suggest."

The message went down badly with UK specialists. Graham Foster, professor of hepatology at Queen Mary University of London, hailed the drugs in a blog post last year as "a remarkable, life changing advance in care." He saluted the "startling success" of the approach by citing figures from Public Health England (PHE) showing a reduction of more than 10% in mortality of the sickest patients in a single year.

Foster was among signatories of a letter published in the *Guardian* on 14 June making the same claim. Neil Cowan, policy and public affairs adviser at the Hepatitis C Trust, which organised the letter, told *The BMJ*: "The trials the Cochrane group used were not designed to assess mortality, so it's not surprising that they didn't identify any improvements."

> "There is no evidence of the clinical effects of the drugs. No evidence at all"

Genuine hope

The data show that in 2015 deaths attributed to hepatitis C fell to 357, from 387 in 2014, and first registrations for transplants from 144 to 83. "There is genuine hope that we are seeing an impact on the number of deaths from hepatitis related end stage liver disease and liver cancer," said Helen Harris, a research associate at PHE.

Jakobsen said, "This is the reaction we have had from two drug companies, who refer to 'real life' evidence. This is what they cling to. But there are many reasons why the mortality rate might go down. You need a randomised trial, carried out independently and focused on clinical outcomes, to find out.

"People argue that it's practically impossible to do trials to measure mortality because of the necessity of very long follow-up periods. The same people also argue that they can see a reduction in deaths in data from PHE when the drugs have only been on the market for a few years." Jakobsen said. "It doesn't make sense."

Should hard pressed health systems stop spending so much on the drugs? "It's not my job to say. Politicians and decision makers have to make that judgment, based on all the evidence, including ours."

Nigel Hawkes is a freelance journalist, London

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