

this week

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SARAH TURTON / BMA

GPs vote to phase out “unsafe” PAs

The BMA’s General Practitioners Committee for the UK has voted to stop hiring physician associates in general practice and for existing roles to be phased out.

At a GPC UK meeting on 17 October an overwhelming majority of members voted in favour of a motion saying it believed that the role of PAs in general practice was “fundamentally unsafe.”

The vote came after the Royal College of General Practitioners recently changed position so that it now opposes PAs working in general practice. Last November the BMA’s GP Committee for England called for a pause in the recruitment of PAs in general practice. The latest motion goes further by asking for the role to be phased out across the whole of the UK.

The BMA has called for staff working in PA roles to be given opportunities to retrain into more suitable ancillary NHS roles.

Katie Bramall-Stainer, chair of GPC UK, said, “We are aware that this is a challenging and politically heightened issue. At the heart of it is patient safety, which needs to be prioritised, alongside acknowledging the responsibilities of employing practices and welfare of existing employees.

“It’s no secret that we desperately need more staff in general practice, but we need

to be sure that staff who see patients are suitably trained and competent to see them unsupervised. Workload is inextricably linked to the recruitment and retention of the workforce, so additional roles should not generate more work for already stretched GPs.”

Bramall-Stainer added, “We’d like to see PAs being given opportunities to retrain and take up other roles in the NHS, but the bottom line is getting more GPs into the workforce. We want to be able to give patients the care and services they need, when they need them, with the most appropriate clinician for their needs. To do that, the government must urgently invest in practice staff such as GPs and general practice nurses.”

Earlier this month the BMA said it was providing financial support to a legal case against the General Medical Council over how it distinguished between doctors and PAs. The case is being brought by the campaign group Anaesthetists United and Marion and Brendan Chesterton, the parents of Emily Chesterton, who died in 2022 aged 30 after two appointments with a PA, who she believed was a GP, her family said.

Gareth Iacobucci, *The BMJ*
Cite this as: *BMJ* 2024;387:q2301

Katie Bramall-Stainer, chair of the GPC UK, says practices need more investment in doctors and nurses, not physician associates

LATEST ONLINE

- EU tightens air quality standards as part of pledge to improve health
- Half of UK workers don’t have access to vital workplace healthcare, report finds
- AI could help diagnose fractures in urgent care, says NICE



SEVEN DAYS IN

ASSISTED DYING: Doctors allowed to voice personal opinions as bill is introduced



IAN DAVIDSON / ALAMY

NHS medical chiefs have cleared doctors to voice their personal opinions on the assisted dying bill, but they have also warned them not to directly engage patients in the debate, identify patients without their consent, or imply they speak for the medical profession.

The advice came in a letter from the UK chief medical officers and England's national medical director, Stephen Powis, published on 16 October, the day the Labour MP Kim Leadbeater (left) introduced an assisted dying bill that would give terminally ill people in England and Wales the right to end their lives. The letter added, "In our view it is entirely reasonable for any doctor to give their opinions, alone or in combination with others, and that the public would expect that."

Whatever parliament decides, the medical chiefs said they believe the profession will be unanimous on two things: "we must not undermine the provision of good end-of-life care" and "healthcare workers should be able to exercise freedom of conscience."

Leadbeater's bill is due to be debated in parliament in late November. A bill is also proceeding through the Scottish parliament.

● BIG PICTURE, p 92

Matthew Limb, London [Cite this as: BMJ 2024;387:q2288](#)

Public health

Food industry urged to turn to healthier products

Former food company executives, nutrition experts, and campaigners wrote an open letter to food business leaders calling on them to commit to five goals clamping down on the production of ultraprocessed and other unhealthy foods, for the sake of public health and the planet. The goals include meeting the World Health Organization's standards for responsible marketing and no longer targeting under 18s; increasing the proportion of sales that meet healthy food thresholds; and pricing healthier products equal to or lower than less healthy products. The letter also called for food producers to use sustainable production practices aligned with targets on deforestation and greenhouse gas emissions.

Nearly one in 10 secondary school pupils often vape

A quarter of 11-15 year olds have tried vaping, and nearly one in 10 (9%) vaped frequently in 2023, up from 6% in 2018, showed a survey published by NHS England. However, only



11% of young people reported having smoked tobacco at least once—the lowest level recorded by this survey—and the number taking drugs also fell. Only 13% reported having ever taken drugs, down from 18% in 2021.

Health officials issue vaccination reminder

Patients who are eligible for free vaccinations on the NHS have been urged to protect themselves against flu, covid-19, and respiratory syncytial virus (RSV) before winter sets in. Although covid activity remains low to moderate, flu and RSV have begun to increase slightly across most indicators but remain at low levels, showed surveillance data from the UK Health Security Agency. Conall Watson, consultant epidemiologist at the agency, said the RSV vaccine in pregnancy was an "important step in keeping babies well."

HRT

Prescriptions rise by 22%

Doctors prescribed 13 million more items of hormone replacement therapy in 2023-24 than in 2022-23, a 22% increase, said the annual report on HRT in England published by the NHS Business Services Authority. Over this

period the number of patients given a prescription for HRT grew by 12%, from 2.3 million to 2.6 million. In 2023-24 England's least deprived areas had over twice as many identified HRT users as the most deprived areas.

Frailty

NICE proposes more assessment to prevent falls



More comprehensive assessments of older people at risk of falls, including hazard assessments of their homes, are among draft recommendations from NICE in an update to its 2013 guideline on fall prevention. The recommendations include at-risk people over 50 and people in residential care settings. Assessments should include physical examinations, questions about possible dizziness, and balance and gait checks. Occupational therapists should carry out the assessments, said NICE, as modelling showed that this was cheaper and more effective. The consultation closes on 28 November.

Cancer

Record number of cases are diagnosed in NHS

A record 346 217 cases of cancer were diagnosed in England in 2022—an average of 948 a day. This was a 5% rise (more than 11 000 additional cancers) from the 329 664 cases diagnosed in 2021. Cancer registration statistics show that cancer diagnoses rose by 7% in men in 2022 and by 2% in women, and more cancers continue to be diagnosed in men—180 877 cases in 2022, which compares with 165 340 in women.

Inequalities

Deprivation and mortality link weaker in London

Age standardised mortality rates (ASMRs) for all cause mortality were lower in London on each decile of the Index of Multiple Deprivation than in other built-up areas from March 2021 to May 2023, showed figures from the Office for National Statistics. ASMRs in London and large built-up areas were generally highest in the white British ethnic group. Veena Raleigh, King's Fund senior fellow, said, "Deprivation seems to have a lower impact on health outcomes in London than in other major urban locations. This needs to be explored to see if there are lessons to be learnt."

MEDICINE

SIXTY SECONDS ON... **STANDING DESKS**

YOU MAY WANT TO SIT DOWN

If you've ever heard about or used a standing desk, you may be aware of their reputation as a healthier alternative to sitting all day at a desk. But new research has found their effects may not be as outstanding as previously suggested.

STAND AND DELIVER

Researchers from the University of Sydney used UK Biobank accelerometer data for over 83 000 adults to assess the dose-response relations of standing, sitting, and overall stationary behaviour time with cardiovascular disease (CVD) and orthostatic circulatory disease.

GET UP, STAND UP?

Not so fast. The researchers found that standing more did not, over the long term, improve cardiovascular health and may increase the risk of varicose veins and deep vein thrombosis.

ANY OTHER STANDOUT FINDINGS?

The study, published in the *International Journal of Epidemiology*, reported that sitting for more than 10 hours a day was associated with higher orthostatic circulatory disease and major CVD risk—with a 15% increase in risk for every hour beyond 10 hours. Time spent standing was not associated with CVD risk but was associated with higher orthostatic circulatory disease risk, with every 30 minutes beyond two hours linked to an 11% increase in risk.

SIT DOWN NEXT TO ME?

The researchers emphasised that their findings did not mean people should stay sitting. Emmanuel Stamatakis, coauthor and director of the Mackenzie Wearables Research Hub, said, "Take regular breaks, walk around, go for a walking meeting, use the stairs, take regular breaks when driving long distances, or use that lunch hour to do some movement."

LET'S GET PHYSICAL

The NHS recommends all adults should do at least 150 minutes of moderate intensity activity a week or 75 minutes vigorous activity. We should also cut down on the time we spend sitting or lying down and make sure we regularly move, it adds.

Elisabeth Mahase, *The BMJ*

Cite this as: *BMJ* 2024;387:q2285

Clinical waste

NHS cracks down on single use medical devices

The Department of Health and Social Care has published a strategy aiming to substantially cut the amount of NHS medical waste by reducing single use devices and reliance on foreign imports. Disposable medical devices contribute substantially to the 156 000 tonnes of clinical waste produced by the NHS in England every year. The Design for Life strategy will change procurement rules to incentivise the use of reusable products and encourage innovation to enable more products to be reused, recycled, and remanufactured.



Disposable devices are a significant part of the 156 000 tonnes of NHS England's annual medical waste

International news

Italian law bans travel abroad for surrogacy



Italy's government has approved a law that prohibits citizens from seeking surrogacy abroad, whereby anyone returning to Italy after surrogacy will face three months to two years in prison and a fine of up to €1m (£830 000). The ban has been supported by Italy's far right government after a furious debate in the Senate and parliament. Promoters have claimed a rule of common sense against the "exploitation of the female body and children," while opponents, including civil and gay rights groups (above), have condemned the law as "useless," "unconstitutional," and "against children and rainbow families."

UK supports Marburg and mpox aid in central Africa

The UK announced a package of measures to tackle outbreaks of mpox and Marburg virus disease in

central Africa. It includes up to £9m to help strengthen surveillance systems, reinforce health services, and work with communities to raise awareness of risks and personal protective measures. Two experts from the UK Public Health Rapid Support Team—a field epidemiologist and an infection prevention and control specialist—have also been deployed to the Democratic Republic of the Congo to support the Africa Centres for Disease Control and Prevention, which is jointly leading the continental response with the World Health Organization.

WHO declares Egypt is malaria free

The World Health Organization has certified Egypt as free of malaria. It becomes the third country to be awarded a malaria-free certification in the WHO Eastern Mediterranean Region, following the United Arab Emirates and Morocco, and the first since 2010. Worldwide, 44 countries and one territory have reached this milestone. Certification of malaria elimination is granted when a state has proved, beyond reasonable doubt, that the chain of indigenous malaria transmission by *Anopheles* mosquitoes has been interrupted nationwide for at least the previous three years. A country must also show the capacity to prevent the re-establishment of transmission.

Cite this as: *BMJ* 2024;387:q2313

NHS ESTATE

The bill to repair the crumbling NHS estate rose to **£13.8bn** last year, up from **£4.5bn** in 2012-13

[*NHS England*]



Discrimination against ethnic minority and non-UK doctors “persists throughout career”

“Persistent and pernicious” inequality remains embedded in medicine despite some progress, with doctors from ethnic minorities and international medical graduates facing discrimination throughout their careers, the GMC has said.

Its latest annual progress report on tackling discrimination and inequality in medicine reports some positive trends, such as continuing reduction in the disparity in numbers of fitness to practise referrals in relation to a doctor’s ethnicity or place of qualification. But progress “remains stubbornly slow in some areas,” it added.

In a foreword to the report GMC chief executive Charlie Massey said, “For too many doctors, medicine is a story of discrimination and disadvantage. From the early days of education and training to the leadership positions of later years, issues of inequality are persistent and pernicious.

“Efforts to foster equality are not a nice-to-have—they lie at the heart of sustainable health services. When diversity is harnessed it can be transformational. There is huge potential in embracing many viewpoints

Efforts to foster equality are not a nice-to-have, they lie at the heart of sustainable services Charlie Massey

and experiences and the improved decision making this brings.”

Since the GMC set a range of targets three years ago, there has been a reduction of more than a third in the proportion of employers whose data indicate an excess of referrals of doctors from overseas or from ethnic minorities, from 5.6% to 3.2%.

There was a 0.13 percentage point difference between ethnic groups in overall rates of referrals to GMC in the five years from 2019 to 2023: 0.31% of doctors from ethnic minorities (of a total of 144 649 doctors) and 0.18% of white doctors (of 163 735) were referred. This was less than the 0.19 percentage point difference for 2018 to 2022.

New system enables anonymous reporting of sexual misconduct

NHS staff in England can anonymously report incidents of sexual misconduct at work after the launch of a new system to improve safety for staff. A new framework issued to hospitals outlines how NHS staff should recognise, report, and act on instances of sexual misconduct in the workplace. For the first time staff will be able to report sexual abuse through an anonymous form if they are uncomfortable with disclosing their name and personal details but want the incident to be properly investigated.

The policy follows sustained calls for action after an investigation by *The BMJ* and the *Guardian* in 2023 revealed a huge number of sexual safety incidents that were reported to NHS trusts in England and a lack of dedicated policies at many organisations for dealing with sexual assault and harassment.

Specially trained allies

The framework includes new guidance for people conducting investigations after a disclosure from a colleague, including advice on how to form a specialist review group with suitable expertise, as well as detailed steps to ensure that the right support has been offered. All cases will be treated confidentially, but line managers and HR teams will have direct access to experts in sexual misconduct throughout the investigation process.

Employees will have access to support from new specially trained allies, and “freedom to speak up” guardians will receive specialist training to improve the support they can provide. In addition, staff who have experienced sexual abuse may be offered pastoral support, including special leave if required.

Becky Cox, cofounder of the campaign group Surviving in Scrubs, welcomed the new policy. “These resources form the groundwork for any responsible healthcare organisation seeking to address the issue of sexual safety for their staff,” she said. “We hope these will increase awareness of sexual safety and empower staff with the tools to support survivors and hold perpetrators to account.”

Gareth Iacobucci, *The BMJ* Cite this as: *BMJ* 2024;387:q2268

Doctors are urged to offer ideas to inform NHS plan

For far too long, many patients have felt their voices weren’t fully heard in shaping health services. This is a crucial opportunity to change that

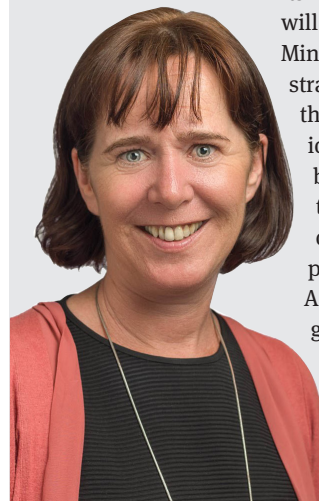
Rachel Power
(below)

The government has invited doctors, the public, and experts to help shape its 10 year health plan for England by taking part in what it describes as the “biggest ever national conversation” about the future of the health service.

The public engagement exercise is asking individuals and organisations to share their experiences, views, and ideas for fixing the NHS, through the online platform change.nhs.uk. It will be live until the start of 2025 and also available through the NHS App.

The government said the feedback it receives will inform its 10 year plan for the NHS that will be published next spring. Ministers have said the 10 year strategy will be underpinned by three big shifts in healthcare identified by the recent review by Ara Darzi: from hospital to community, analogue to digital, and treatment to prevention.

Among the areas the government suggests for feedback are how to develop neighbourhood





Attainment gap unchanged

The report noted that attainment gaps in postgraduate specialty exam pass rates remained much the same. In 2022 81.3% of white doctors and 70.6% of doctors from ethnic minorities passed (a difference of 10.7 percentage points) while in 2023 the respective figures were 82.2% and 71.6% (10.6 percentage points).

Medical schools, royal colleges, and medical faculties now have to report

their actions to tackle these issues to the GMC, and the report said that enhanced induction programmes for doctors new to the UK, tailored support for doctors ahead of assessments, and mentoring programmes were having a positive effect.

The GMC said it had taken various steps to mitigate bias and promote fairness, such as an updated set of decision making principles for teams responsible for making regulatory decisions. It also expects to meet its 2026

THERE was a **0.13** percentage point difference in the rate of referrals to the GMC in the five years from 2019 to 2023: 0.31% of doctors from ethnic minorities and 0.18% of white doctors

target for attracting more candidates from ethnic minorities to roles a year ahead of schedule but admitted that its targets on increasing representation among senior management had not yet been met.

Philip Banfield, BMA council chair, said, “While there may be signs of progress in some areas, we will not be satisfied until doctors of all backgrounds are afforded the same opportunities, free from discrimination, and treated with equal respect and fairness.”

Adrian O’Dowd, London

Cite this as: *BMJ* 2024;387:q2283

hubs, standardising NHS IT systems across England, and new opportunities for prevention.

NHS England’s chief executive, Amanda Pritchard, said the 10 year plan was a chance to spread best practices across the country. She said the NHS would be “leaving no stone unturned as we seek to harness frontline views, alongside those of patients and the public, to ensure this happens.”

Philip Banfield, the BMA’s chair of council, said, “We have always been open to discussions about how to mend our broken NHS and how to improve productivity and effectiveness of frontline services. Fundamentally this is about providing capacity across health and social care to free up administrative and structural logjams in an overly complex system—and this needs significant investment.”

Rachel Power, chief executive of the Patients Association, said, “For far too long, many patients have felt their voices weren’t fully heard in shaping health services. This national conversation, initiated by the government, is a crucial opportunity to change that.”

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2024;387:q2315

SAS doctors face tougher sanctions when unrepresented at tribunals, figures show

Specialist, associate specialist, and specialty (SAS) doctors and locally employed (LE) doctors in the NHS are much less likely than other doctors to have legal representation when facing misconduct charges at a medical practitioners tribunal, show figures from the GMC.

The statistics, obtained by the Medical Protection Society (MPS) through a freedom of information request, show that doctors without legal representation more often receive harsher sanctions, including erasure from the medical register.

SAS and LE doctors are the fastest growing part of the medical workforce, increasing by 40% over 2017-21. Many SAS doctors working in UK hospitals are from overseas.

The GMC’s figures were based on 1183 hearings at the Medical Practitioners Tribunal Service that concluded in 2019-23, including 408 that involved SAS and LE doctors. They show that 40% of SAS and LE doctors and 27% of other doctors were not legally represented when facing a fitness to practise hearing. Of the SAS and LE doctors without legal representation, 43% were erased from the register. But only 15% of SAS and LE doctors who were represented were struck off.

Among SAS and LE doctors, legal representation also increased the likelihood that their fitness to



practise would be found not to be impaired. Of those with a lawyer representing them, 25% were found to be not impaired, while only 5% of those without representation received a tribunal finding of no impairment.

Limited support

The MPS provides support for doctor members with legal and ethical problems, including GMC investigations and tribunal hearings. Karen Ellison, its lead medicolegal consultant, said there was likely to be a range of reasons for the findings. “It is possible that many SAS and LE doctors working solely in the NHS do not realise the limited support provided by state backed indemnity, which only provides protection in relation to clinical negligence claims. Many are also overseas graduates who may not be provided with enough information during their induction about the importance of protecting themselves against the types of risks doctors face in the UK.”

She added, “NHS trusts have a role to play here in providing information to all doctors—especially SAS and LE doctors—about the limitations of state backed indemnity and the importance of having legal representation should you receive a GMC referral.”

Clare Dyer, *The BMJ*

Cite this as: *BMJ* 2024;387:q2277

WEIGHT LOSS DRUGS FOR UNEMPLOYED PEOPLE

How will the government's trial work?

Ministers want to examine the impact of tirzepatide on people's health outcomes and employment status. **Elisabeth Mahase** looks at the practicalities of the study

? **What has been announced?**
A new partnership between the government and the pharmaceutical company Eli Lilly will trial “innovative approaches to treating obesity as part of a rounded package of care,” the government has said.

A key part of this collaboration will involve a five year, real world trial called Surmount-Real UK to evaluate the effectiveness of the weight loss drug tirzepatide (Mounjaro), a glucagon like peptide-1 receptor agonist (GLP-1 RA) that's similar to semaglutide (Wegovy, Ozempic). The study will look at its effects on weight loss, the prevention of obesity related complications, health related quality of life, changes in participants' employment status, and how many sick days participants take from work.

This trial will be carried out in partnership with Health Innovation Manchester and the University of Manchester. Principal investigator Martin Rutter, professor of cardiometabolic medicine, said the trial will focus on the “long term efficacy and safety profile of tirzepatide in a primary care setting compared with usual care.”

Illness caused by obesity causes people to take an extra four sick days a year on average
Wes Streeting

It's not yet clear how many people will be recruited to the trial, what the inclusion criteria will be, or when it will start.

? **Is tirzepatide available on the NHS?**
In June NICE published draft guidance recommending tirzepatide as an option for managing overweight and obesity, alongside a reduced calorie diet and increased physical activity, in adults with a BMI ≥ 35 and at least one weight related comorbidity.

NICE said lower BMI thresholds (usually reduced by 2.5) should be used for people from South Asian, Chinese, other Asian, Middle Eastern, Black African, or African-Caribbean ethnic backgrounds.

But unlike other GLP-1 RAs approved for NHS use, a two year prescribing time limit has not been set for tirzepatide. It is also expected to be available through primary care services, rather than through secondary care weight management services. NICE's final draft guidance is expected on 19 December.

? **How will the drug be rolled out?**
Earlier this month NHS England announced it had submitted a funding variation request to NICE, which, if approved, would allow it to roll out the drug over a 12 year period, instead of the usual three months.

NHSE has asked for a six month implementation period, after which 220 000 patients would become eligible to receive the drug—based on their health needs and clinical benefit—over a three year phased rollout. These patients would get the drug through a variety of community based and digital services, which would then be evaluated to determine which was the most effective.

The proposal has said people with a BMI of more than 40 and at least three of the specified weight related health problems—hypertension,

dyslipidaemia, obstructive sleep apnoea, and cardiovascular disease—would be first in line for the drug.

The next eligible groups would be people with a BMI of more than 40 plus two weight related health problems and then people with a BMI of more than 40 plus one weight related health problem.

After this three year period, all other suitable patients would become eligible over a maximum of nine years, NHSE has said. It argued that this plan is required so the roll out does not compromise other NHS services.

If rolled out to all eligible patients immediately, NHSE estimated the drug could cost the NHS £20m in just three years. It added that the required workforce, training, and infrastructure for a full roll out are not yet in place. NICE has not yet published its response to this proposal.

? **What have ministers said about the trial?**

Announcing the partnership with Eli Lilly, Wes Streeting, the health and social care secretary, said in the *Telegraph*, “Our widening waistbands are placing significant burden on our health service, costing the NHS £11bn a year—even more than smoking.

“And it's holding back our economy. Illness caused by obesity causes people to take an extra four sick days a year on average, while many others are forced out of work altogether.”

He added that “along with the rights to access these new drugs, there must remain a responsibility on us all to take healthy living more seriously. The NHS can't be expected to always pick up the tab for unhealthy lifestyles.”

? **How have clinicians responded?**
Speaking to *The BMJ*, Azeem Majeed, a GP and head of primary care and public health at Imperial



NHSE estimated the drug could cost the NHS **£20m** in just three years if rolled out to all eligible patients

College London, said the health secretary's focus on "getting obese people back into the workforce" risked "stigmatising individuals and missing the opportunity to address other critical health and socioeconomic issues."

He added that there were not many data on how many people were unable to work because of obesity and that the "main medical causes of inability to work are mental health problems, musculoskeletal conditions such as back pain and arthritis, and cardiometabolic diseases."

Majeed urged the government to tackle the "root causes" of obesity. "My own view is that the UK can't inject itself out of an obesity crisis and that medical treatments such as tirzepatide need to be supplemented with investment in public health and preventive approaches to obesity," he said.

Nicola Heslehurst, professor of maternal and child nutrition at Newcastle University and chair of the UK Association for the Study of Obesity, also told *The BMJ* she was disappointed in Streeting's "stigmatising comments."

"We have extensive evidence on the complex drivers of obesity, including health inequalities, and comments like this show how far we still have to go to educate policy makers and shift away from the blaming narrative that perpetuates stigma and causes harm to people living with obesity," she said. "Obesity care should be provided to those who need it most for their health, not using their ability to 'get back to work' to decide who is deserving, or undeserving, of care."

Heslehurst added that weight loss treatments such as tirzepatide did not work for all patients and must be provided as part of a "wider package of care that includes behavioural and surgical options, both of which are underfunded in the UK."

Last month *The BMJ* revealed that just half of England had access to comprehensive weight management services, with specialist teams for weight loss support and care, including medication or bariatric surgery, being unavailable to many people (*BMJ* 2024;386:q1950).

Elisabeth Mahase, *The BMJ*
Cite this as: *BMJ* 2024;387:q2281



The trial will focus on the long term efficacy and safety profile of tirzepatide

Martin Rutter



What's missing is the opportunity to tackle other critical health and socioeconomic issues

Azeem Majeed



This shows how far we have to go to shift from the blaming narrative that perpetuates stigma and causes harm

Nicola Heslehurst

Streeting orders overhaul of England's health regulators

The health and social care secretary, Wes Streeting (below), has ordered an overhaul of patient safety in England, with a review of six different oversight organisations, including the Care Quality Commission (CQC).

He said a fresh look was needed regarding the complex combination of bodies responsible for patient safety regulation and monitoring, as the CQC pledged further reform to tackle failings highlighted in two critical reports published this week.

Streeting added that recent inquiries such as that into the infected blood scandal had shown that having many organisations involved in related activities had possibly restricted, rather than supported, national system leadership on patient safety and may have created an "unquantified overhead on provider organisations."

The Safety Landscape Review will examine the roles and remit of the CQC, the National Guardian's Office, Healthwatch England, the Health Services Safety Investigations Body, the Patient Safety Commissioner, and NHS Resolution, to see whether a different approach or delivery model was needed. The review is expected to report in the new year, and Streeting said he would monitor the CQC's progress under its new chief executive, Julian Hartley.

"Patient safety is the bedrock of a healthy NHS and social care system," said Streeting. "That's why we are taking steps to reform the CQC—to root out poor performance and ensure patients can have confidence in its ratings once again."

THE CURRENT ASSESSMENT FRAMEWORK NEEDS TO BE RADICALLY SIMPLIFIED

Mike Richards

CQC reviews

Two separate reviews published on 15 October raised fresh concerns over the CQC's performance, inspections, and lack of capacity and capability to deliver improvements.

An analysis by Penny Dash, chair of the North West London Integrated Care Board, found that the CQC had substantially lost credibility within the health and social care sectors. She said, "Poor operational performance is impacting CQC's ability to ensure that services provide people with safe, effective, and compassionate care, negatively impacting the opportunity to improve services and, in some cases, for providers to deliver services at all."

Dash, who published an interim analysis in July of the CQC's operational effectiveness, said the latest full report confirmed those findings in greater depth. She said the regulator was doing fewer inspections—just 6700 in 2023, down from almost 15 800 in 2019—while producing poor quality and delayed reports and taking too long to reinspect providers after giving them a "requires improvement" or "inadequate" rating. "Providers do not understand how ratings are calculated and, as a result, believe it is a complicated algorithm or a 'magic box,'" she added.

Dash's full report recommends the CQC should clarify how ratings are calculated and make results more transparent. She said it should pause its inspections of regional integrated care systems and return to its original model of appointing permanent inspectors to focus on areas such as hospitals, GPs, and social care. Streeting has supported the recommendations.

In a complementary report commissioned by the CQC board, Mike Richards, a former CQC chief inspector of hospitals, also called for an organisational reset because of serious performance concerns. "In addition, the current assessment framework needs to be radically simplified and the major problems with the new IT system rectified," he said.

The CQC said it was taking rapid action in response to the reviews—for example, by appointing chief inspectors for regulation and improvement of hospitals, primary care, and adult social care services. It will also consider whether a fourth is needed for mental health services.

Matthew Limb, London Cite this as: *BMJ* 2024;387:q2272





THE BIG PICTURE

Call for assisted dying law

Members of the Dignity in Dying campaign group demonstrate outside parliament on 16 October, the day a private member's bill on assisted dying was introduced into the Commons.

MPs will have a free vote on Kim Leadbeater's Terminally Ill Adults (End of Life) Bill, allowing them to vote with their conscience and not face party discipline procedures.

Alison Shepherd, *The BMJ* Cite this as: *BMJ* 2024;387:q2314



STEPHEN CHUNG/ALAMY

COP29 must move from stalling to action

Real progress is needed on fossil fuels and supporting vulnerable countries

In November, the 2024 United Nations climate change conference (COP29) will take place in Azerbaijan, a country where fossil fuels account for two thirds of its economy.¹ Attendees will gather after a northern hemisphere summer that was the hottest ever recorded, with predictions that 2024 temperatures will reach 1.57°C above pre-industrial levels.² The 2016 Paris Agreement³ committed countries to keep “the increase in the global average temperature to well below 2°C” and pursue efforts “to limit the temperature increase to 1.5°C above pre-industrial levels.” However, a recent survey of authors of the reports of the Intergovernmental Panel on Climate Change found that most are sceptical that warming will be kept well below 2°C.⁴

The past year has seen the health and livelihoods of millions of people around the world severely affected by extreme weather. Heatwaves across South and Southeast Asia resulted in school closures and deaths from heatstroke. Rains and flooding in Brazil led to 100 deaths and hundreds reported missing or injured.⁵ Floods in Kenya displaced more than 200 000 people.⁶ Canadian wildfires drove towns to evacuate. A cyclone forced almost one million people in Bangladesh and India to evacuate.⁷ In the US, millions were ordered to evacuate as Hurricane Milton made landfall in Florida.⁸

Two issues will dominate and test COP29: hastening the transition from fossil fuels to renewable energy and high income countries increasing financial support to vulnerable countries. Lower income nations, which are most exposed but have contributed the least to climate change, are proposing four priorities: ambitious new climate finance goals, more ambitious climate action plans, accelerated adaptation efforts and finance, and a sufficient response



Every COP has been followed by a rise in greenhouse gas emissions

package for the loss and damage they have experienced.⁹

Fossil fuels account for around four fifths of global energy supply,¹⁰ are the main cause of global warming, and cause major damage to health, not least in contributing to seven million premature deaths a year from air pollution.¹¹ Yet fossil fuels did not feature in the calls for action that resulted from COP meetings until the Glasgow COP in 2021.¹² In 2020, countries responsible for 93% of all CO₂ emissions provided net direct fossil fuel subsidies of \$305bn,¹³ more than three times the \$80bn climate finance provided to developing countries.¹⁴ The 2021 Glasgow pact marked a minor breakthrough, with a call for countries to accelerate “efforts towards the phase down of unabated coal power and phase-out of inefficient fossil fuel subsidies.”¹² But it had little impact.

Judged on the detail

In the following year global fossil fuel investment increased by 10%, reaching more than \$1tn.¹³ COP27 saw no progress, but COP28 ended with a call for governments to “transition away from fossil fuels.”¹⁵ While this was a welcome step, it lacked detail. COP29 will be judged by the detail in commitments to phasing out fossil fuels. The UK foreign secretary, David Lammy, has said that “action on the climate and nature crisis will be central to all that the Foreign Office does.”¹⁶ His priority is to build a “global clean power alliance”

with the shared goal of “making net zero power a reality, everywhere.”

The second issue on which COP29 will be judged is financial assistance from high income countries to vulnerable countries. Again progress has been woefully slow. A loss and damage fund was established at COP27, but this falls way short of what is needed. At COP28 wealthy nations committed just over \$700m to the fund, which is less than 0.2% of the \$400bn a year that is needed.¹⁷

Nobody can escape the climate and nature crisis, and it is in the interest of high income countries to support vulnerable countries. Health editors around the world have twice called for high income countries to recognise the moral necessity as well as their self-interest to meet vulnerable countries’ needs.^{18,19} This will not be easy with the US absorbed in an election, hard right populists flourishing in Europe, and the UK about to experience a cost cutting budget.

Every COP has been followed by a rise in emissions of greenhouse gases, and in 2023 more than 300 health editors warned that we are facing a global public health emergency.²⁰ Yet health didn’t feature in the core agenda of the first 27 COPs. COP28 adopted a declaration that acknowledges “the benefits for health from deep, rapid, and sustained reductions in greenhouse gas emissions, and that good health is an outcome of successful adaptation across a range of sectors—including food and agriculture, water and sanitation, housing, urban planning, health care, transport and energy.”²¹

The biggest benefits to health will flow from drastic cuts in fossil fuels, rapid transition to renewable energy, and wealthy countries providing much greater support to vulnerable countries. The whole world is watching COP29 and needs to see it make real progress.

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Risk prediction in triple negative breast cancer

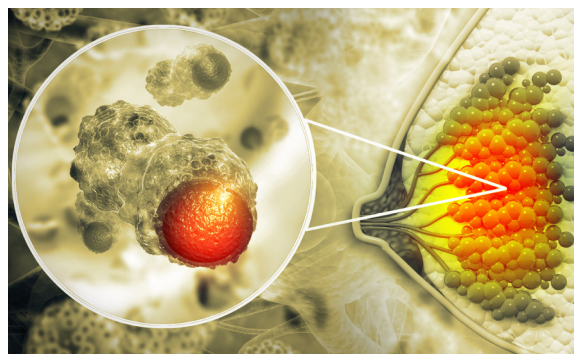
Multigene RNA signature signals benefit from intensified chemotherapy for a high risk group

Triple negative breast cancer is an aggressive subtype of breast cancer characterised by a lack of oestrogen, progesterone, and HER2 receptors which guide the use of targeted therapies. This disease lacks validated prospective biomarkers predicting response to treatment and outcomes beyond basic staging information. The traditional mainstay of systemic treatment for triple negative breast cancer has been chemotherapy.

We need to develop methods to guide treatment decisions in an increasingly complex therapeutic landscape in operable triple negative breast cancer. Enhanced understanding of risk of recurrence and sensitivity to treatment, as is the aim of the linked randomised trial by He and colleagues (BCTOP-T-A01) (page 101),¹ can inform decisions about who needs intensive treatment and who might be spared therapies with serious toxicities.

The BCTOP-T-A01 trial is the first to prospectively validate a multigene tumour RNA signature to guide choice of chemotherapy in patients with early triple negative breast cancer.¹ This gene expression signature is determined by quantitative real time polymerase chain reaction.²

He and colleagues' open label trial recruited 336 people with early triple negative breast cancer with a primary tumour size >10 mm, lymph node involvement, or both across seven cancer centres in China. The RNA signature was used to stratify tumours for risk. Participants at high risk were randomised to "standard care" with four cycles of postoperative epirubicin and cyclophosphamide followed by docetaxel or to the "intensive" regimen of four cycles of docetaxel, epirubicin, and cyclophosphamide then four cycles of gemcitabine and



A validated predictive test could enhance treatment decisions

cisplatin. Participants at low risk were not randomised and received standard treatment.

The disease-free survival rate was significantly better among participants at high risk who received the more intensive regimen than in those receiving standard care (90.9% v 80.6%; hazard ratio 0.51, 95% confidence interval 0.28 to 0.95). The three year overall survival rate was not significantly different (98.2% v 91.3%; 0.58, 0.22 to 1.54); with only 18 deaths across both groups, further follow-up is needed. As expected, the intensive chemotherapy carried a higher risk of haematological adverse events.

As validation of the prognostic value of this score, the patients at low risk had a more favourable disease-free and overall survival than did those at high risk who received the same chemotherapy. Whether the low risk group would have also benefitted from more intensive treatment remains unknown, so definitively classifying this test as predictive would be premature.

Implications for treatment

In patients with early hormone receptor positive breast cancer, multigene assays such as the Oncotype DX score have been used for many years to anticipate prognosis and, more importantly, to guide use of chemotherapy.³⁻⁵ Several groups have reported prognostic tumour signatures in triple negative breast cancer,⁶⁻¹⁰ but none has

been shown to predict response to treatment in a prospective study.

He and colleagues should be commended for developing a new risk signature and validating its use for patients at high risk in a prospective clinical trial. However, the findings may not change management for many oncologists, because the control arm, which represented standard care in 2016 when recruitment began, does not reflect modern evidence and practices in much of the world.^{11 12} Modern treatment for early disease can now include immunotherapy for high risk cases and adjuvant poly (ADP-ribose) polymerase (PARP) inhibitor therapy for those with a BRCA mutation.^{13 14} Carboplatin is increasingly used.¹³ Additionally, systemic therapies are now recommended before surgery for most patients to help to gauge treatment response and minimise invasive surgical interventions. Reconciling the lessons of BCTOP-T-A01—to add adjuvant cisplatin and gemcitabine for people with high risk cancers—with modern pre-surgical protocols containing platinum and immunotherapy agents is difficult.

The true innovation of this trial lies in its confirmation of the use of a genomic signature to identify a high risk group of patients who benefit from more intensive chemotherapy. A validated predictive test could enhance treatment decisions for many patients, perhaps to guide selection of neoadjuvant chemotherapies alongside novel treatments. Hopefully this score, and others, will contribute to treatment that is more personalised, more targeted, and less reliant on conventional cytotoxic chemotherapy for people with this difficult subtype of breast cancer.

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RESEARCH, p 101

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FEATURE

Lucy Letby case: what happens now?

The former neonatal nurse was found guilty of seven murders and seven attempted murders in August 2023. But questions have been raised about the evidence used to convict her. With a new statutory inquiry now sitting, **Chris Stokel-Walker** recaps what has happened with the case and looks at the wider implications

It was the most heinous of crimes. Nurse Lucy Letby was found guilty of seven murders and seven attempted murders of babies under her care in a neonatal ward at the Countess of Chester Hospital, where she worked from January 2012 until July 2016.

Letby was removed from the unit after the death of triplets capped off a torrid year for the ward, during which several babies were harmed, many of them dying in unexplained circumstances. Police began investigating the deaths in May 2017 at the behest of hospital authorities, and Letby was arrested at her home in July 2018.

The nurse was charged with 22 offences in total and was convicted of many of them in August 2023 (see timeline). “You acted in a way that was completely contrary to the normal human instincts of nurturing and caring for babies and in gross breach of the trust that all citizens place in those who work in the medical and caring professions,” said High Court judge James Goss, when handing Letby 14 whole life sentences for her crimes.

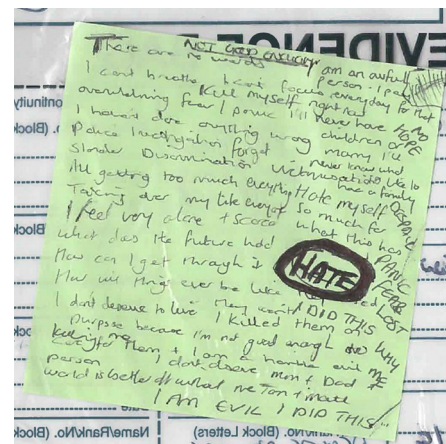
He added, “There was a deep malevolence bordering on sadism in your actions.” (Letby would later be convicted of a further, 15th crime, in July 2024 after a retrial.)

Unsettling set of crimes

The case shocked the nation—and the world. And it traumatised a hospital trust. “This case has had a profound impact on our patients and our local community and also our staff—who come to work every day determined to provide safe and high quality care for our patients,” said Nigel Scawn, medical director at the Countess of Chester Hospital trust on the day Letby was sentenced. He also apologised to the parents who lost children and said the trust had changed since she killed so many.

In October 2023 the government agreed the terms of an inquiry into the case. “Losing a child is the greatest sorrow any parent can experience, and I cannot begin to imagine the hurt and suffering experienced by the families affected by Lucy Letby’s horrific crimes,” said the then health secretary, Steve Barclay. “We have a duty to get them the answers they deserve, to hold people to account where they need to be, and to make sure lessons are learnt.” Kathryn Thirlwall, one of the UK’s most senior judges, was appointed to lead the inquiry.

Yet despite the court’s sentencing and the seemingly unequivocal evidence at the time, serious questions have been raised about



Page from a notebook written by Letby that was used in evidence in her initial trial in 2022


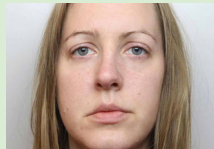
how the judgment was made, with high profile media publications raising doubts about the verdict.

Statistical anomalies

Prosecutors had relied on what they saw as damning evidence. One of the key pieces of evidence was a chart showing that Letby was on duty in every one of the cases where babies were harmed. But not everyone agreed that correlation was causation.

“Some of the evidence used in the trial was on the face of it statistical in nature,” Andrew Garrett and Sarah Cumbers, respectively president and chief executive of the Royal Statistical Society (RSS), wrote in a letter to Thirlwall as she prepared the terms of reference for her inquiry. “However, it is far from straightforward to draw conclusions from suspicious clusters of deaths in a hospital setting—it is a statistical challenge to distinguish event clusters that arise from criminal acts from those that arise coincidentally from other factors, even if the data in question was collected with rigour.”

That challenge in inferring proof from statistical evidence is something the RSS has long recognised. In 2022 it published a report on the sometimes shaky nature of

2012	2015	2016	2017	2018	2019
<p>January Letby joins Countess of Chester Hospital (below) after graduating</p> 	<p>8 June Letby murders Baby A, her first victim, by injecting air into his bloodstream. She murders three more babies in the same month</p> <p>June The hospital trust begins an internal review into the deaths</p>	<p>August to October Two more babies are murdered by Letby, and other murders are attempted</p> <p>October Consultants present senior management with concerns that Letby is responsible. They are not believed</p>	<p>February With six babies dead, and six more near misses, a second review is ordered</p> <p>April to June Letby murders two more babies and attempts to murder two others</p> <p>July Letby is removed from the neonatal unit where she worked</p>	<p>May The Countess of Chester Hospital NHS Foundation Trust invites police to investigate the deaths</p> <p>3 July Letby is arrested, suspected of eight murders and six attempted murders. She is released on bail later that month</p> 	<p>10 June Letby is arrested, suspected of eight murders and nine attempted murders. She is released on bail again</p>

What is a statutory inquiry?

Statutory inquiries operate in line with the provisions of the UK Inquiries Act 2005 and the Inquiry Rules 2006. Unlike non-statutory inquiries, they can compel witnesses to provide evidence and provide certain legal safeguards, and they also maintain clearer limits on the government’s involvement.

Some statutory inquiries, such as the Lampard inquiry into mental health services in Essex and the Post Office Horizon inquiry, have been converted from non-statutory inquiries to help ensure engagement of potential witnesses. Others are converted from inquests to enable proper consideration of otherwise confidential information.

such evidence. It’s also something that has exercised statisticians, who have shared their concerns about the extrapolation of certainty from what they believe to be uncertain statistics.

Beyond statistics, doubts have also been raised about the absence of forensic evidence (that is obtained through scientific methods, such as blood or DNA tests). And no one saw Letby directly harm babies. The Crown Prosecution Service also admitted in Letby’s most recent retrial, which ended in July, that some evidence used in her initial trial was incorrect. Door-swipe data that showed who had entered and exited the intensive care ward had been “mislabelled,” they said. “We have been transparent in clarifying this issue and rectified it for the retrial,” a CPS spokesperson told the media. “We are confident this issue did not have a meaningful impact on the prosecution, which included multiple strands of evidence.”

Media furore

Questions over the validity of the evidence have garnered the attention of the media, which initially reported largely uncritically on her guilt—at least in the UK. But in May this year the US magazine *New Yorker*

There are some who believe the deaths were not a consequence of a murderous nurse but of a malfunctioning healthcare system

published a story that disputed the guilty verdict. The article, which emphasised Letby’s side of the case, relied on experts who raised doubts about the statistical rigour of the evidence shown in court.

Restrictions on reporting Letby’s retrial in the 15th case, of which she was subsequently found guilty, meant readers in the UK could not access the story on the *New Yorker* website at the time it was published. Such restrictions, put in place so as not to prejudice a jury sitting on an active legal case, are commonplace in the UK. But the Conservative MP David Davis used his parliamentary privilege to suggest that blocking access to the story was “in defiance of open justice.”

Unbeknown to the UK public at the time, the *Guardian* was also investigating a story that suggested that the evidence used to convict Letby was not necessarily as definitive as presented. When Letby was sentenced to her 15th life sentence in July, the newspaper published its own investigation. Among its key conclusions: “There has been a growing chorus of voices raising questions about some of the key evidence presented in the trial. There was no forensic evidence to prove her guilt and no one saw Letby—who continues to maintain her innocence—causing harm.”

What happens now?

Despite the wall to wall press coverage and the repeated court cases, the current of which has Letby appealing her 15th whole life prison term at the Court of Appeal, the effects on the NHS and how it operates have been less well examined. It’s in this area

that the next few months, and the outcome of the Thirlwall inquiry, will have its biggest impact.

There are some, including within the healthcare service, who believe that the deaths were not a consequence of a murderous nurse but of a malfunctioning healthcare system. An open letter to the prime minister, Keir Starmer, signed by 19 nurses in August, suggests that some “are worried that this conviction is unsafe and as a result we and many of our colleagues are now terrified to continue working in the NHS as we believe that next time it could be one of us who is blamed for a failing system.”

The 19 unnamed nurses called on Starmer to establish a royal commission or independent review of the evidence used to convict Letby. “We believe this is crucial for nurses, and healthcare practitioners alike, so that we can feel confident and safe in our work,” they wrote. Letby and her legal team have taken heart from the response from some quarters, lodging repeated appeals, the most recent of which will take place this month.

Regardless of whether those nurses achieve their goals, or Letby successfully appeals her July 2024 conviction, the statutory inquiry (box) may help answer some of those questions. The 30 questions that frame the inquiry’s terms of reference will look not just at Letby and how the actions she has been convicted of occurred but also the extent to which the culture of the NHS, and the trust in which she operated, can keep babies safe and well looked after.

“These terms of reference have been agreed following engagement with the families, and I am confident Lady Justice Thirlwall will ensure their voices are heard as the inquiry gets under way,” said Barclay.

Chris Stokel-Walker, freelance journalist, Newcastle upon Tyne stokel@gmail.com

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2020

10 November
Letby is arrested and charged the next day with eight murders and 10 attempted murders. She is not granted bail

2022

10 October
The trial begins. Letby is tried on seven counts of murder and 15 attempted murders of 10 babies

2023

18 August
Letby is found guilty of 14 of the 22 charges

21 August
Letby is told she will remain in prison for the rest of her life as she is given 14 whole life sentences

30 August
The government makes its planned inquiry into the Letby case a statutory one

29 September
Royal Statistical Society writes to High Court judge Kathryn Thirlwall

(below), appointed to head the inquiry, expressing concern about the use of statistical evidence in the case

October
The government opens its inquiry



2024

May
New Yorker publishes its report into Letby. David Davis MP uses parliamentary privilege to question the convictions

9 July
Guardian publishes a lengthy investigative report into the statistical evidence used in the initial trial

5 July
Letby is given a 15th whole life sentence for attempted murder

24 October
Judges will consider an appeal by Letby over her 15th whole life sentence



INVESTIGATION

Pharma pours millions into the NHS for non-research work—but what is the money being spent on?

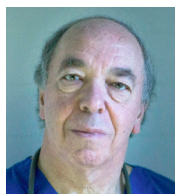
Many industry payments to the health service are unexplained and disclosure figures can't be trusted. This raises questions about unrecognised conflicts of interest, find **Hristio Boytchev**, **Piotr Ozieranski**, and **Mostafa Elsharkawy**

An analysis by *The BMJ* has found that pharmaceutical companies pay tens of millions of pounds to the NHS each year without the public being told what the payments are for.

The findings have led to calls for a shake-up of current transparency rules so that patients can see why these payments are being made.

Pharmaceutical companies paid £156m to NHS trusts in England between 2015 and 2022, according to new analysis of the Disclosure UK database. The Association of the British Pharmaceutical Industry (ABPI) database requires participating companies to disclose cash payments and other benefits in kind to healthcare professionals and organisations.

Even though the scheme has been lauded as one of the best among its industry run peers in Europe, *The BMJ* has uncovered widespread confusion about the intended purpose of the payments. For example, if any of these payments



Companies doling out £156m aren't doing it out of the goodness of their hearts
Joel Lexchin



Transparency is key to the trust between patients and clinicians
Julia Cumberlege

are for “educational” purposes that could be linked to the promotion of pharmaceutical products.

“There is a big difference between publishing some numbers and creating effective transparency,” says Margaret McCartney, a GP and transparency campaigner. She questions if it is “in the patient and public interest that such massive transfers of value are occurring between the pharmaceutical industry and the NHS.”

“When companies dole out over £156m, they aren't doing it out of the goodness of their hearts, they are doing it because they expect some kind of return on their investment. The unanswered question, so far, is what they want,” comments Joel Lexchin, professor emeritus at the school of health policy and management at York University, Toronto, Canada.

“Transparency is key to improving trust between patients and clinicians,” says Julia Cumberlege, a member of the House of Lords and chair of the Independent Medicines

and Medical Devices Safety Review published in 2020. The review focused on problematic drugs and medical devices—such as pelvic mesh that has harmed women—and called for more transparency and regulation of industry payments to doctors and the NHS.

“We all have a right to know about payments made by the pharmaceutical and medical devices industries,” says Cumberlege.

Lack of detail

Disclosure UK is not meant to name the recipients of payments related to companies' research and development, such as company sponsored clinical trials. And companies are not required to detail the exact nature of the remaining payments, including any possible association with promoted products. Instead, Disclosure UK lists broad categories such as donations and grants, events, services, joint working projects, or consultancy.

The BMJ approached trusts for more detail but few were able to explain the purpose behind these payments. Most payments went to large teaching hospitals, and many told *The BMJ* they didn't recognise or couldn't verify the figures. Guy's and St Thomas' NHS Foundation Trust in London, for example, did not “recognise these figures as accurate.” Some trusts said they found mistakes in the data, but would not provide more detail. Instead, they asked *The BMJ* to submit freedom of information requests for a detailed payment breakdown.

The only payment type where contextual information may be available in Disclosure UK is for joint working, where the NHS and pharmaceutical companies pool resources on joint projects. These payments comprise only 14% of the overall value of payments to trusts between 2015 and 2022 and, even then, information can be hard to access.

Details of these joint projects should be provided on the websites of the pharmaceutical companies—but when *The BMJ* tried to inspect the nature of the biggest 10 such

Continued on p 100

NHS trusts' responses

The *BMJ* offered the 10 trusts that had received, according to its analysis, the most payments the opportunity to comment on the data.

Guy's and St Thomas' NHS Foundation Trust

"We do not recognise these figures as accurate for the trust. Guy's and St Thomas' is one of the largest, most research active trusts in the country and works with pharmaceutical companies to develop better treatments that improve the quality of care for our patients."



Oxford University Hospitals (OUH) NHS Foundation Trust

"OUH is one of the largest hospital trusts in England, and therefore it is also one of the largest recipients of industry funding."

Imperial College Healthcare NHS Trust

"Imperial College Healthcare is one of the most research active NHS trusts in the UK and so we would expect to have one of the highest research incomes from across all sources."

"What is included as 'non-research' funding in Disclosure UK data can, in fact, still be related to research in our hospitals. For example, as well as receiving payments from industry for delivering commercially sponsored clinical trials, the trust also receives funding from industry for some trials that are sponsored by the trust."

"The trust also supports the pharmaceutical industry in the development, evaluation, and assessment of drug safety, which also attracts funding that tends to fall outside the definitions of research funding used for Disclosure UK."

"Some of the payments reported in Disclosure UK as being made to Imperial College Healthcare NHS Trust were actually made to Imperial College London."



University College London Hospitals (UCLH) NHS Foundation Trust

The trust first asked *The BMJ* to submit a freedom of information request. It then did an analysis of the Disclosure UK website for the currently available years 2020-2022 and said that most of the payments concerned University College London and not the trust, "with less than £80 000 over three years relating to UCLH."



Manchester University NHS Foundation Trust

"We are one of the largest research and innovation trusts in the country, and as such we would expect to be among the highest level of recipients of such payments which support our research and innovation work programmes. All our activity takes place within the framework of NHS England, ABPI, and all other applicable guidance." The trust asked for a freedom of information request for details.

Barts Health NHS Trust

"We are one of the largest trusts in the country and occasional non-research income from pharmaceutical companies, used for staff education and development, accounts for 0.023% of our £2.4bn annual turnover. By comparison, on average we attract £10m each year through our commercial research portfolio, which accounts for 0.4% of our annual income."



University Hospitals Birmingham, University Hospitals of Leicester, King's College Hospital, and Royal Free London NHS trusts did not answer.

payments, only in five cases did it find links on company websites that led directly to specific projects, such as informatics for personalised healthcare and asthma treatments.

Millions for the trusts

The BMJ tracked all disclosed non-research payments to NHS trusts in England from 2015 to 2022 reported in Disclosure UK. The analysis involved developing an algorithm that corrected numerous mistakes and inaccuracies that drug companies made in identifying NHS trusts as payment recipients and considered payments reported under the names of both the trusts as well as their sub-units, such as hospitals and clinics.

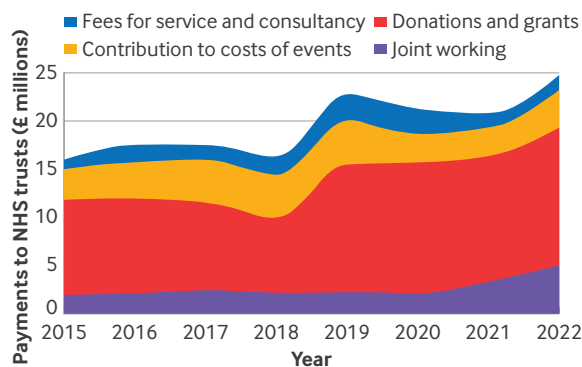
The analysis was complicated by missing unique identifiers for payment recipients, which are not mandated by ABPI. Because of these shortcomings, as well as the failure of many trusts to provide exact figures, the numbers can only serve as estimates.

In total there were 58 302 payments worth £156 882 790 made to 217 trusts. These payments make up a fifth of the value of all payments to healthcare organisations listed in Disclosure UK, such as general practices, commissioning bodies, professional societies, royal colleges, and medical schools.

The top 10 recipients accumulated £49 820 043, representing 32% of the total value of payments. They were Guy's and St Thomas', University College London Hospitals, Manchester University, Imperial College Healthcare, University Hospitals Birmingham, University Hospitals of Leicester, Oxford University Hospitals, King's College Hospital, Barts Health, and Royal Free London NHS foundation trusts.

The top 10 largest payments were worth £6 237 936. Most of the payments were relatively small, with 94% of payments below £10 000.

Of the 220 trusts operating in England between 2015 and 2022 only three received no payments, including two ambulance trusts.



Payments to NHS trusts by year and category



For true transparency data need to be accurate, be complete, and provide enough detail
Quinn Grundy

Calls for a stricter system

International experts slammed the quality of Disclosure UK data and the lack of transparency of the trusts.

Lexchin says, "We need to realise that when trusts are telling people to file freedom of information requests for information that should be public, voluntary disclosure is not the solution to transparency."

"Legislation like the Sunshine Act in the US that mandates disclosure by drug and device companies of transfers of value greater than \$10 to teaching hospitals is what is required."

In the US, research and non-research payments to teaching hospitals and several types of healthcare professions, such as physicians and nurses, are disclosed by law, even if they are of low value.

Quinn Grundy, assistant professor in nursing at Toronto University, adds, "For true transparency to exist, data on pharmaceutical company payments to publicly funded hospitals need to be not just available but easily accessible, accurate, complete, and provide enough detail that members of the public can understand why the company made the payment and what the hospital does with the money."

James Larkin, postdoctoral researcher at the Royal College of Surgeons in Ireland, who has used industry transparency databases for his research, is not surprised by the lack of quality data in Disclosure UK. He said such data generally allow for

big picture statements, but are not precise enough for detailed analysis.

That runs counter to one of the pillars of the transparency system, which is to safeguard against undue influence or corruption. Without detail, it's difficult to identify potentially suspicious payments. "If a journalist or a lawmaker wants to go through the data with the intention of finding individual cases of bribery, it would be difficult," Larkin says.

"This is an example of why it is so important to have legislated transparency reporting," says Barbara Mintzes, professor of evidence based pharmaceutical policy at Sydney University. "You should not be required to file a freedom of information request to obtain information on how much money a hospital has received from a pharmaceutical company," she says. "Hospitals are public institutions that operate within the NHS—this information should be publicly available and easy to access. The public has a right to know if a hospital receives industry funding, as well as what that funding is for."

"Disclosure UK is widely regarded as a European leader in transparency," said Amit Aggarwal, ABPI executive director of medical affairs and strategic partnerships. Since its launch, the database has evolved, he said. "However, we recognise there is always room for improvement, and we welcome constructive recommendations," he added. "Disclosure UK is only one, albeit crucial, element."

The Department of Health and Social Care has been working with healthcare providers on updated guidance regarding doctors' potential conflicts of interest and has sought views on proposed mandatory payment reporting following recommendations of the Cumberlege review, a spokesperson said.

Hristio Boytchev, investigations reporter, *The BMJ*

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