this week

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SARAH TURTON/BMA

Katie Bramall-Stainer, chair of the General Practitioners Committee for England, says GPs have "no choice but to move ahead with collective action"

Huge vote for action over GP contract

GPs in England have voted in favour of taking collective action over their contractual terms and insufficient funding for general practice.

The action was announced by the BMA on 1 August after a ballot of GP partners asked about their willingness to take action in response to an imposed contract for 2024-25 that included a core funding uplift of 1.9%. GPs' leaders have warned that the deal has already forced some practices to close.

It will be the first time in 60 years that GPs have taken collective action.

Actions could begin immediately, such as GPs seeing no more than 25 patients a day, refusing to share patients' data "unless it's in the best interests of a patient," and switching off software that tries to cut prescribing costs. GP leaders said many of the actions would allow more time with patients and would highlight system failings in a bid to make the government take seriously general practices' requests for extra support.

Other NHS leaders said the vote was a "watershed moment" and warned that a cap on appointments could be "catastrophic."

Some 8518 GPs in England voted, out of 12 590 eligible voters (a turnout of 68%). An overwhelming 98.3% were in favour of taking part in one or more examples of collective action, from a menu of 10 options listed by the BMA, with just 1.7% voting against. The ballot was held between 17 June and 29 July.

Katie Bramall-Stainer, chair of the BMA's General Practitioners Committee for England (GPCE), said the clear verdict reflected "desperation" with the status quo. "GPs are at the end of their tether," she said. "For too long, we've been unable to provide the care we want to. The era of the family doctor has been wiped out by consecutive governments, and our patients are suffering as a result."

Bramall-Stainer said GPCE "understands the government has inherited a broken NHS," and it has had positive conversations with Wes Streeting, the health secretary. But she added, "Practices are still closing, so we have no choice but to move ahead with collective action to protect our practices and patients."

After the BMA's announcement, Streeting wrote to GPs to say he wanted to "reset the relationship" with government, referring to his commitment to allow GPs in England to hire 1000 more doctors this year through the additional roles reimbursement scheme and his acceptance of the pay review body's recommended 6% pay rise as "the first steps towards more sustainable general practice."

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Matthew Limb, London

Cite this as: *BMJ* 2024;386:q1717

LATEST ONLINE

- NHS staff will be offered covid vaccine this autumn, but JCVI recommends more limited rollout
- GMC clarifies handling of complaints related to doctors' activism
- Diabetes: One in 10 patients on NHS "soups and shakes" diet plan went into remission

SEVEN DAYS IN

BMA backs 22.3% pay rise over two years for junior doctors in England

The BMA is set to put a new pay offer worth 22.3% on average over two years to junior doctors in England, which if accepted will bring to an end the industrial action that began in March 2023.

The offer consists of an extra 4.05% for the pay year 2023-24 on top of the average 8.8% awarded last July, bringing last year's pay uplift to an average of 13.2%. This will be backdated to April 2023.

The Review Body on Doctors' and Dentists' Remuneration (DDRB) and the government also announced on 29 July an award for 2024-25 that would give junior doctors an average 8% rise.

Under the deal, a doctor starting foundation training in the NHS will see their base pay increase to £36 600, up from around £32 400, while a full time doctor entering specialty training will see their basic pay rise to over £49 900, from around £43 900.

The BMA's Junior Doctors Committee has recommended the deal to its members, recognising that the wider package was "a good step forward for our profession," while acknowledging "there is still more work to be done in the future."

The co-chairs of the committee, Robert Laurenson and Vivek Trivedi (far left), said the deal showed the "beginning of a government that is learning to treat doctors with more respect."

Zosia Kmietowicz, *The BMJ* **Cite this as: *BMJ* 2024;386:q1694**

Covid-19

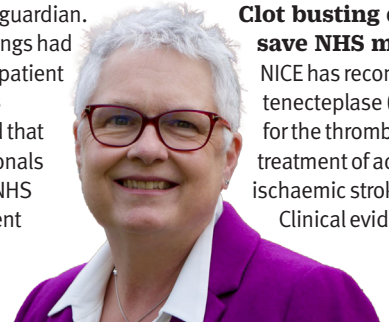
Psychiatric burden "lasts three years," finds study

A significant number of patients who were admitted to hospital with covid-19 still experience substantial cognitive and psychiatric effects as much as three years later, a longitudinal study has found. Almost half of the participants experienced moderate to severe depression, one in four reported moderate to severe anxiety, and four in 10 reported severe cognitive decline. One in nine had objective signs of severe cognitive deficit—equivalent to a loss of 10 IQ points—found the research, published in *Lancet Psychiatry*.

Clinical safety

Confidence to speak out falls to five year low

The proportion of NHS workers who feel secure in raising concerns about unsafe clinical practice is at a five year low, dropping from 75% in 2021 to 71.3% in 2023, warned Jayne Chidgey-Clark (right), the NHS national guardian. She said the findings had "implications for patient safety." The 2023 staff survey found that medical professionals were among the NHS staff least confident about reporting unsafe clinical practice. However, there was some improvement about whether people felt safe to "speak up about anything that concerns me in this organisation."



NICE decisions

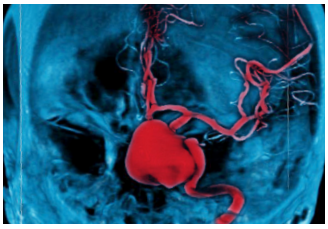
New option for treatment resistant glaucoma

An estimated 115 000 people with glaucoma or ocular hypertension could be eligible for the once daily eye drop treatment latanoprost-netarsudil (Roclanda, by Santen) after NICE recommended it for NHS use. Clinical trial evidence indicates that latanoprost-netarsudil is as effective as the combined treatment of bimatoprost-timolol, which is used if laser treatment is unsuitable and if a generic prostaglandin analogue monotherapy eye drop, such as bimatoprost or latanoprost, is not effective. Indirect comparisons also suggest that it has a similar effectiveness to other fixed dose combination treatments.

Clot busting drug could save NHS money

NICE has recommended tenecteplase (Metalyse) for the thrombolytic treatment of acute ischaemic stroke in adults.

Clinical evidence showed



it to be as effective as alteplase, which NICE also recommends but is more expensive, in breaking up blood clots or preventing new clots from forming after an acute ischaemic stroke. Tenecteplase is given during the early phase of a stroke. "The NHS could save millions by switching to it," said Helen Knight, NICE's director of medicine evaluation.

General practice

Private firm keeps contract after "serious breach"

A major private provider of NHS GP services will not have its practice contracts terminated despite a serious breach. A "change of control" took place at AT Medics last December, but the NHS was not informed until March, which was a "serious breach" of contracts. However, the North West London Integrated Care Board said that given the practices' performance and the importance of continuity of care it would not terminate but would continue to closely monitor performance.

Appointments rise by six million a year since covid

GPs delivered more than 28.7 million appointments in June, NHS England figures showed. Excluding vaccinations, this was a fifth more appointments than in June 2019, before the covid pandemic, when 22.8 million appointments were held. Around seven in 10 appointments happen within seven days of booking, mostly face to face. Amanda Doyle, national director for primary care at NHS England, praised hardworking GP teams but said, "We know there is more to do to make it easier for patients to access GP services."

Practices show marked rise in research participation

More than half of general practices in England (56%) took part in research supported by the National Institute for Health and Care Research Clinical Research Network in 2023-24, data showed. Some 3606 practices were involved, up 12% on the previous year. One in four people who participated in research supported by the network in England last year were recruited through primary care, a total of 270 538 participants. John Sitzia, executive director of the network, said health research was becoming "more embedded in communities."

MEDICINE

Alcohol

Europe tops WHO's consumption charts

"Little or no progress" has been made on reducing alcohol consumption and its harms in Europe, said the World Health Organization. In 2019 the average adult in WHO's European region drank 9.2 L of pure alcohol—the highest regional average in the world and equivalent to 102 bottles of wine or 31 bottles of spirits. Europe has some of the highest incidences of alcohol related cancers worldwide. Gauden Galea, a WHO special adviser, called for countries to implement policies effective in reducing alcohol consumption.

Semaglutide

FDA issues warning on weight loss drug overdoses

The US Food and Drug Administration has issued a warning after receiving reports

that patients were overdosing on semaglutide, with some requiring hospital admission, because of "dosing errors involving compounded semaglutide injectable products dispensed in multiple dose vials." In some instances patients had administered five to 20 times the intended dose of the glucagon-like peptide 1 receptor agonist. In the UK the National Pharmacy Association has urged people not to buy fake weight loss injections.

Anaesthesia

Consensus is reached on pipeline nitrous oxide

Pipeline nitrous oxide should be removed from anaesthetic practice in the UK and Ireland, says a new consensus statement by leading professional bodies led by the Royal College of Anaesthetists. While many anaesthetists have already moved away from routine use of nitrous oxide, the guidance will give trusts and health boards the clinical steer to decommission manifolds of cylinders, which will reduce greenhouse gas emissions.

CQC

Regulator has "significant failings," review finds

Health secretary Wes Streeting has said that the Care Quality Commission is "not fit for purpose," after an interim review found failings that included a lack of clinical expertise among inspectors and inconsistent assessments. Around a fifth of services had never been rated, despite some having registered with the CQC more than five years ago. The review outlined five key recommendations to start to fix it.

Marburg virus

Hope rises for vaccine against fatal disease

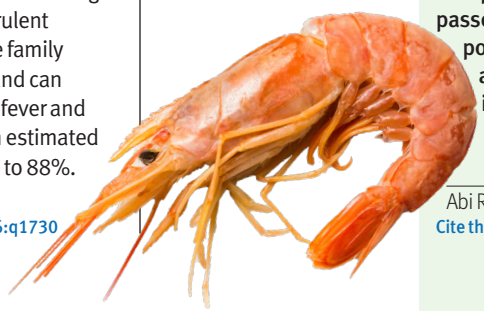
Oxford University has launched a first-in-humans vaccine trial to protect people against the deadly Marburg virus. Forty six people aged 18 to 55 will participate in the trial of the ChAdOx1 Marburg vaccine. The highly virulent disease is in the same family as Ebola (a filovirus) and can lead to haemorrhagic fever and encephalitis. It has an estimated case fatality rate of up to 88%.

Cite this as: *BMJ* 2024;386:q1730

SLAPPED CHEEK

England had **68** confirmed cases of parvovirus B19 ("slapped cheek syndrome") in June, up from the previous monthly peak of **46** cases in May 2018

[UK Health Security Agency]



SIXTY SECONDS ON . . . FOOD ALLERGIES

SHOULD I PUT MY PEANUTS AWAY?

We often hear announcements on aeroplanes asking us not to eat any nut products for the sake of a passenger with allergies. However, it turns out that this precaution may not be necessary.

THAT'S NUTS!

Apparently not. A systematic review commissioned by the UK Civil Aviation Authority has found that, in a typical passenger with a food allergy, the risk of having an allergic reaction on a commercial flight is lower than on the ground.

CRACKING FINDINGS

Indeed. Paul Turner, an expert in food allergy at Imperial College London, conducted the systematic review of relevant scientific articles published from 1 January 1980 to 31 December 2022. He found no evidence to support the idea that peanut and tree nut allergens were transmitted in the air during a flight.

SO, WE'RE FLYING FREE?

Not quite. While the review found no support for general "nut bans," it was in favour of buffer zones—where people seated next to a passenger with a food allergy are asked not to consume the relevant allergen.

DON'T BE SHELLFISH?

Some people might be annoyed that they have to forgo their lobster bisque, but the review found that buffer zones provide important reassurance to passengers with a food allergy.

HOW CAN PEOPLE WITH ALLERGIES HELP THEMSELVES?

One of the most effective things is to wipe down their seat area, including the tray and entertainment system. The review says, "The proteins which cause food allergy are often 'sticky' and can adhere to these surfaces, from where they are easily transferred to a person's hands and on to food." They should also carry two adrenaline autoinjector devices such as EpiPens.

IS THAT IT, IN A NUTSHELL?

Not quite. The review also found that passengers can struggle to find airlines' policies on food allergies or experience a lack of consistency in how cabin crew implemented these. Policies should be applied consistently to provide reassurance, it advises.

Abi Rimmer, *The BMJ*

Cite this as: *BMJ* 2024;386:q1724

NEWS ANALYSIS

GP COLLECTIVE ACTION: What happens next and what will the impact be?

Matthew Limb summarises the next steps for doctors angry at the imposition of their 2024-25 contract

SARAH TURTON/BMA

What is the BMA recommending? The association is encouraging practices to choose from a list of 10 actions (box, below), as few or as many as they think appropriate.

How will the actions affect patients?

Becks Fisher, director of research and policy at the health think tank the Nuffield Trust, said that, although the measures won't amount to a full walkout, "any reduction in the availability or efficiency of general practice will have a major impact," given pressure on the NHS. "This could mean longer waits to see a GP, more people going to A&E, and ultimately poorer care," Fisher said.

Fisher added, "GP partners voting for collective action is a watershed moment for the NHS. Unlike other recent strikes, this isn't primarily about the pay of individual GPs."

Gaurav Gupta, a GP in Faversham, chair of the Kent Local Medical Committee, and a BMA council member, who voted in favour of collective action to ensure safer conditions, said that general practice "was on its knees" amid high staff burnout rates and rising practice bankruptcies. He told *The BMJ*, "None of the things we are suggesting are going to have an immediate or acutely detrimental effect on patients. All we are asking for is a safe working environment.

"Patients might find the changes difficult to navigate, but it is for the long term benefits of patients and the NHS."

All we are asking for is a safe working environment Gaurav Gupta (above)

Kamila Hawthorne, chair of the Royal College of GPs, said, "Whatever actions practices take will have an impact. We urge the government to intervene and come to a resolution that is fit for purpose for patients and the GP teams working harder and harder to provide their care."

Are GPs who take action at risk of breaching their contract?

No, said the BMA in its guidance, and it advises GPs: "You can choose to start slowly and build incrementally or do all of them from day one as you wish. You do not need permission to do any of these actions. They are already permissible and will not result in contract breach."

What might lead to the action ending? The BMA hopes the

Collective action could become norm, warns head of England's GPs

The collective action being undertaken by general practices could be maintained in the long term to protect services and staff, the head of England's GPs has told *The BMJ*.

Katie Bramall-Stainer (right), chair of the BMA's General Practitioners Committee for England, emphasised that the collective action voted for by GP partners last week could be undertaken at any time and "doesn't need permission," because GPs are simply working to their contracts instead of going above and beyond.

"If practices find that, when they

THE 10 ACTIONS THE BMA IS ENCOURAGING GPs TO CHOOSE FROM

1. Limit daily patient contacts per clinician to the European Union of General Practitioners' recommended safe maximum of 25. Divert patients to urgent care settings once the maximum is reached. Doctors "strongly" advised to offer face to face consultations.
2. Stop engaging with the e-Referral Advice and Guidance pathway, unless GPs believe it to be a timely and clinically helpful process.
3. Serve notice on any voluntary services that plug local commissioning gaps and stop supporting the system "at the expense of your business and staff."
4. Stop rationing referrals, investigations, and admissions, including to refer, investigate, or admit patients to specialist care when it is clinically appropriate to do so; refer via eRS (electronic referral system) for two week wait appointments, but outside that write a professional referral letter instead of using any imposed pro formas, "where this is preferable."
5. Switch off GPConnect Update Record functionality that permits the entry of coding into the GP clinical record by third parties.
6. Withdraw permission for data sharing agreements that exclusively use data for secondary purposes (not direct care).
7. Freeze sign-up to any new data sharing agreements or local data sharing platforms.
8. Switch off medicines optimisation software embedded by integrated care boards for the purposes of financial savings or rationing (rather than the clinical benefit of patients).
9. Defer signing declarations of completion for "better digital telephony" and "simpler online requests" until more guidance is available. In the meantime: defer signing off "better digital telephony" until after October—do not agree to share call volume data metrics with NHS England; and defer signing off "simpler online requests" until spring 2025—do not agree to keep online triage tools on through core practice opening hours, even when maximum safe capacity is reached.
10. Defer making decisions to accept NHS pilot programmes while the BMA "explores opportunities" with the government.

action will help persuade the government to "fix" the problems with the 2024-25 national GMS contract, which GPs voted overwhelmingly to reject earlier this year.

The BMA has welcomed the government's commitment to accept in full the DDRB's recommendation for a 6% pay increase as a "step in the right direction."

But GPC England chair Katie Bramall-Stainer said GPs still had hundreds of millions of pounds less in resources to run practices than even five years ago. "This will not be a 'big bang.' It will be a slow burn. It's likely that the impact may not be felt for some time. We hope this will give the new government time to consider our proposed solutions, including fixing our contract once and for all."

How have other health leaders reacted?

The NHS Confederation said it was "disappointing" that GPs were opting to take "drastic" steps in pursuit of a fair funding deal and urged GPs and the government to "work together to find solutions to avert this action in the interest of patients."

Its chief executive, Matthew Taylor, said, "Those actions that will have a direct impact on patient care, such as limiting the number of appointments, could also have a catastrophic effect on the entire healthcare system. General practice is now supporting more patients than before covid, so any reduction in their activity will put more pressure on, for example, A&E departments and waiting lists for treatment."

The Patients Association also urged both parties to settle the dispute as soon as possible. A spokesperson said, "Patients can't afford to be caught in the middle of this conflict, over which they have no say or any control. As practices begin taking action, it is crucial they clearly communicate any service changes to patients and provide clear and up-to-date information and guidance on accessing care."

What does NHS England say?

The NHS is asking the public to still come forward as usual for care and attend appointments during the collective action by GPs, as practices will remain open.

Amanda Doyle, the national director for primary care and community services, said that NHS teams had worked hard to plan for disruption and to mitigate the effects of the action to ensure services continued.

"We will continue to work with government to find a resolution and end collective action," Doyle said.

Matthew Limb, London
Cite this as: *BMJ* 2024;386:q1717

undertake various actions, that works out better for them and they're able to devote more time to their patients, then there's no reason for them to stop," she said.

The menu of actions (left), which includes limiting daily patient contacts per GP to the recommended safe maximum of 25 and stopping rationing referrals, investigations, and admissions, has been produced with the aid of the BMA's safe working guidance. It is designed not to harm patient care but to "remind practices of their autonomy and what was in their contract, and what is permissible for them to do to take their own steps to protect their own staff and their own workforce," Bramall-Stainer said.

She added, "What's really interesting, with some of the media headlines, has been how we could bring the NHS to a standstill by merely following what we're contracted to do—because that perhaps suggests we maybe deserve to be resourced for all that additional work we do, that we deliver to the NHS, that keeps it going."

Bramall-Stainer said the committee was hopeful for "meaningful negotiation and dialogue" with the new government and NHS England and acknowledged that the health and social care secretary, Wes Streeting, was promising greater trust between the profession and ministers.

But she added, "While we've still got practices closing, and we're still haemorrhaging GPs from the workforce, we have no choice but to take this action."

Gareth Iacobucci, *The BMJ*
Cite this as: *BMJ* 2024;386:q1742

England's primary and hospital doctors get 6% rise for 2024-25

GPs and hospital doctors working in the NHS in England will receive a pay rise of 6% for 2024-25, after the government accepted in full the recommendations of the Review Body on Doctors' and Dentists' Remuneration (DDRB).

The BMA said the award was an early sign the Labour government was beginning to recognise the value of doctors but that GPs would be disappointed by the uplift.

Mark Steggles (below), chair of the BMA's sessional GP committee, warned that employed GPs saw their pay eroded by up to 25% between 2008-09 and 2022-23 and that many felt "undervalued, overworked, and chronically underpaid."

He said, "Without addressing pay erosion, the NHS cannot hope to recruit or retain enough GPs, and it'll get even harder for patients to access the care they need.

"It's therefore imperative that the 6% uplift is fully funded, including on costs, by each nation's government to ensure that contractors are enabled to pass on the award in full and without delay."

Governments in Wales, Scotland, and Northern Ireland had not responded to the DDRB recommendation by the time of publication.

Zosia Kmietowicz, *The BMJ*
Cite this as: *BMJ* 2024;386:q1698

£82m allows English practices to hire 1000 more GPs this year

The government has set out plans to allow general practices in England to hire 1000 doctors this year through the additional roles reimbursement scheme.

Previously, practices were permitted to hire only non-medical support staff through the scheme, but ministers have removed the red tape and expanded the scheme to cover doctors by adding £82m to the ARRS fund.

The Department of Health and Social Care said the expansion had been "hard fought" by the BMA, Royal College of GPs, and a petition with more than 11 000 signatures. The department said it was taking the "emergency measure" for 2024-25 while it works with the profession to identify longer term solutions to GP unemployment and practice sustainability.

The health secretary, Wes Streeting, said, "It is absurd that patients can't book appointments while GPs can't find work. This is a first step, as we begin the long term work of shifting the focus of healthcare out of hospitals and into the community, to fix the front door to the NHS."

Gareth Iacobucci, *The BMJ*
Cite this as: *BMJ* 2024;386:q1714

PUBERTY BLOCKERS: **BMA calls for ban on prescribing to children to be lifted**

The BMA has called for a pause in the government's ban on the prescribing of puberty blockers to children and young people aged under 18 with gender dysphoria, which was upheld in the High Court on 29 July.

The association made the call on 31 July as it announced it was setting up its own "task and finish" inquiry to "publicly critique" the review on gender identity services for children and young people chaired by Hilary Cass, a former president of the Royal College of Paediatrics and Child Health.

The BMA council motion described the methods underpinning Cass's recommendations as "unsubstantiated" and "driven by unexplained study protocol deviations, ambiguous eligibility criteria, and exclusion of trans-affirming evidence." It commits the BMA to "lobby and work with other relevant organisations and stakeholders to oppose the implementation of the recommendations made by the Cass review."

But some BMA members are unhappy at the association's stance. BMA council member Jacky Davis told *The BMJ*, "I don't believe the BMA position on the Cass report represents the views of our membership, and certainly no effort has been made to establish its views."

She added, "The challenge now is for the BMA to convince its members and everyone else that it can produce an unbiased report on Cass when it has already attempted to seriously undermine her review."

Reacting to BMA's move, the Academy of Medical Royal Colleges issued a statement warning against "members of the medical profession questioning the validity of the evidence and consequently the findings" of the review. It said, "Further speculative work risks greater polarisation on this matter, which is not helpful."

The BMA is also now on a collision course with the government, which has maintained a ban on puberty blockers for under 18s that was imposed in April by the previous government after the publication of the Cass review.

The ban blocks healthcare access to a group of important, valued, and often victimised people
Philip Banfield

In a statement released after the BMA's announcement, the Department of Health and Social Care said the Cass review was a "robust report backed by clinicians and firmly grounded in evidence." A department spokesperson added, "We do not support a delay to vital improvements from the NHS to gender services." The department said NHS England would be implementing Cass's recommendations so that children and young people "get the safe, holistic care and support they need." It added, "NHS England has full confidence in the Cass report and we are committed to taking forward its recommendations."

At the heart of the dispute is a series of systematic reviews examining the robustness of practice and guidelines underpinning the care of young people with gender dysphoria,

Wegovy pilot scheme could be scrapped after failing to launch

EXCLUSIVE The pilot scheme for making the weight loss drug semaglutide (marketed as Wegovy) more widely available, announced last June by then prime minister Rishi Sunak, could be scrapped, as the new government reviews how to roll out obesity treatment across England.

The two year pilot scheme, backed with £40m in funding, aimed to improve access to semaglutide in the community, by expanding specialist weight management services outside hospitals, including through GPs.

However, despite promises that the pilots would launch in late 2023 or early 2024, *The BMJ* understands that they had not launched by the time of the general election, more than a year after Sunak's announcement. With a Labour government in place, the Department of Health and Social Care is now reconsidering how it will provide access to these drugs.

Labour previously criticised Sunak's decision to announce the pilot at a time when semaglutide was in short supply worldwide, saying it was "yet another example of Rishi Sunak overpromising and underdelivering."

Semaglutide, a glucagon-like peptide-1 receptor agonist (GLP-1 RA), is approved for use within multidisciplinary specialist weight management services. These are usually tier 3 services in hospital settings.

Access to GLP-1 RAs for weight loss has been extremely limited because of global shortages and the inability of tier 3 weight management services to keep up with the number of referrals.

Since the pilots were first announced NICE has issued draft guidance on another GLP-1 RA, tirzepatide (Mounjaro), recommending the drug could be prescribed by GPs as long as patients are also provided with support for diet and exercise. Final guidance is expected in October.

John Wilding, professor of medicine and honorary consultant physician at Aintree University Hospital, Liverpool, told *The BMJ*, "Given the NICE tirzepatide draft guidance, and the need to consider the best models of care, I expect there is a lot of discussion behind the scenes about how best to support people with severe obesity in the NHS.

"There are also limited skills and capacity to deliver this in primary care at the moment. I expect there will need to be some sort of phased introduction of these treatments, perhaps based on the Society of Endocrinology led guidance that prioritises those most in need."

Elisabeth Mahase, *The BMJ*

Cite this as: *BMJ* 2024;386:q1715

The two year **PILOT SCHEME**, backed with **£40m** in funding, aimed to improve access to semaglutide in the community

Jackie Davis and Nick Brown (centre) oppose the BMA's call, which is led by chair of council Philip Banfield

published in the *Archives of Disease in Childhood* in April. The papers found the evidence on the use of puberty blockers and hormones in young people was "wholly inadequate, making it impossible to gauge their effectiveness or their effects on mental and physical health."

Nick Brown, editor of the *Archives of Diseases in Childhood*, said, "A common thread in the review findings was the breathtaking dearth of quality evidence to guide care in this vulnerable group of young people."

Brown defended the research. "All of the systematic reviews underwent expert, independent peer review, and each was revised accordingly. We were, and remain, entirely confident as to their veracity. Counter to claims to the contrary, rigorous methods were adhered to at every step," Brown told *The BMJ*. "Criticisms of the methodology hold no water. The single search strategy used by the York group is far more yielding than the scattergun approach advocated by those still struggling to come to terms with the findings."

The Cass review has been backed by several academic bodies, including the Royal College of GPs and the Royal College of Psychiatrists.

Philip Banfield, the BMA's chair of council, said the ban was "unsubstantiated" and "discriminatory" and blocked healthcare access a "group of important, valued, and unfortunately often victimised people."

An NHS spokesperson said, "We will shortly be publishing our plan to implement the [Cass] report's recommendations and findings, which includes setting out scope for further research, so children and young people can receive the best possible care."

Jane Feinmann, London
Cite this as: *BMJ* 2024;386:q1722

Government's shelving of social care cap is a tragedy, says Dilnot

Chancellor Rachel Reeves has shelved plans to introduce a cap on social care costs and to build 40 hospitals to reduce pressure on public finances by £5.5bn this year and more than £8bn next year.

"In the previous parliament, the government made costly commitments to introduce adult social care charging reforms," Reeves told MPs. "They pushed them back repeatedly, including just two years ago, because they knew that local authorities were not ready and that their promises were not funded." She added: "It will not be possible to take these charging reforms forward. This will save over £1bn by the end of next year."

The reforms were first proposed by economist Andrew Dilnot who chaired the government backed Commission on Funding of Care and Support in 2011. Speaking to the BBC's *Today* on 30 July, Dilnot said, "It's a tragedy. To rip this up is unbelievably disappointing for hundreds of thousands of families. It's another example of social care being given too little attention, being ignored, and being tossed aside."

Reeves also said that under the 2020 commitment for 40 new hospitals by 2030 only six had started main construction and less than half had begun at all. "The previous government continued to maintain its commitment without anywhere close to the funding required to deliver them," she told MPs. "We will conduct a complete reset of the new hospitals programme, with a thorough, realistic, and costed timetable for delivery."

Adrian O'Dowd, London Cite this as: *BMJ* 2024;386:q1700

LECANEMAB: **Regulator rejects Alzheimer's drug amid debate over efficacy and safety**

The European Medicines Agency has rejected a marketing authorisation request for the Alzheimer's disease drug lecanemab, stating that the drug's small effect in delaying cognitive decline "does not counterbalance the risk of serious adverse events."

The EMA highlighted trial data showing that after 18 months of treatment the dementia rating score of patients taking lecanemab (which is marketed as Leqembi) increased by an average of 1.21, against a 1.66 increase in patients taking placebo—a difference it described as "small."

There were significant side effects, including swelling and brain bleeds
Tara Spire-Jones

The agency highlighted the "frequent occurrence" of amyloid related imaging abnormalities (ARIA), a side effect involving swelling and potential bleedings in the brain, in the treatment group. "The seriousness of this side effect should be considered in the context of the small effect seen with the medicine," it said.

The drug's manufacturer, Eisai, has appealed the decision, meaning the authorisation request will be re-examined within 15 days of receiving the opinion (25 July).

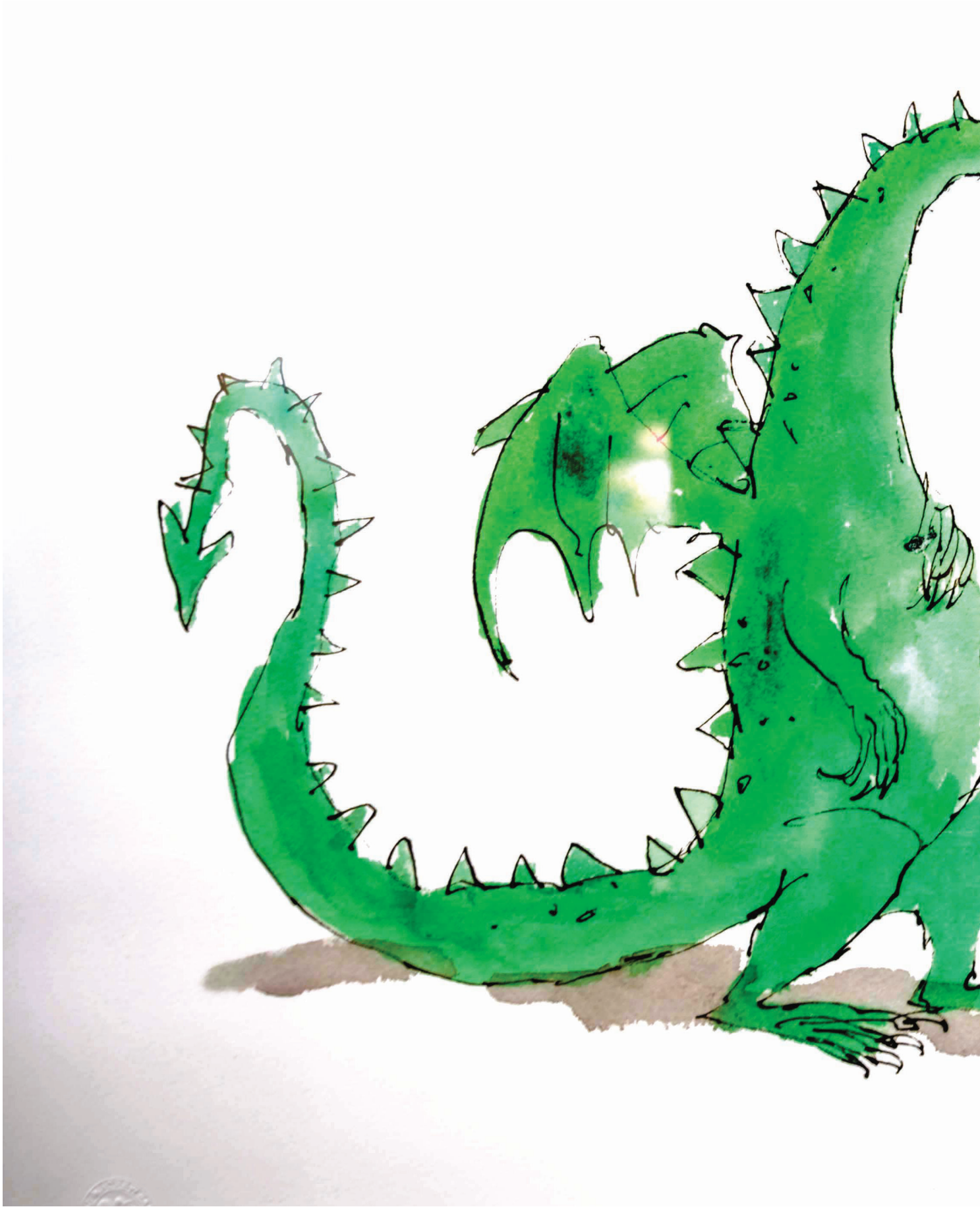
Lecanemab, priced at $26 500 (£20 690) per patient per year, binds to and eliminates amyloid β aggregates that are thought to contribute to neurodegenerative processes in Alzheimer's disease. It was approved in the US for mild cognitive dementia last year with a "black box" or "boxed" warning, because of the major safety risks associated with the drug, specifically brain swelling and bleeding. The UK the Medicines and Healthcare Products Regulatory Agency (MHRA) is currently reviewing the drug and is expected to make a decision later this year.

Research continues

The president of the British Neuroscience Association, Tara Spires-Jones, who is director of the Centre for Brain Science Discovery at the University of Edinburgh, said that although the decision would be likely to "come as a disappointment to many," the size of the effect was "modest," with "significant side effects, including swelling and brain bleeds leading to death in a few people."

She added, "There are reasons to remain hopeful. Lecanemab has shown that it is possible to slow down disease progression, and research does work. Now we need to ramp up our efforts to discover new and safer treatments."

Elisabeth Mahase, *The BMJ*
Cite this as: *BMJ* 2024;386:q1692



Blake's art discharged—temporarily

For two decades hundreds of drawings by the acclaimed artist Quentin Blake have brought joy into the often sombre wards and clinics in hospitals across the country and beyond.

Because of the locations of the illustrations in healthcare sites from London to Sheffield and France, relatively few people—only patients, visitors, and hospital staff—get the chance to see them. To rectify this a Suffolk museum has joined forces with Blake to bring together under one roof many of his drawings of swimming babies, helpful dragons, treetop adventures, and poignant landscapes.

"Quentin Blake: the Illustrated Hospital" runs at Moyse's Hall Museum, in Bury St Edmunds, Suffolk, until 6 October.

Alison Shepherd, *The BMJ* Cite this as: *BMJ* 2024;386:q1741

EDITORIAL

Tackling research misconduct

Urgent steps must be taken to reduce misconduct, restore trust, and protect patients

Trust in academic research is essential if findings are to benefit citizens, society, and the environment. Trust must be earnt through transparency and having the right checks and balances in place.[1 2] One of the likely drivers of trust and distrust in research is the way research institutes, publishers, and funders respond to allegations of research misconduct. So the recent report by the UK Research Integrity Office (UKRIO) *Barriers to Investigating and Reporting Research Misconduct* is important.[3]

The report encourages early reporting of potential research misconduct in all academic disciplines and makes proposals to simplify the investigation process, improve collaboration between stakeholders, and increase the consistency of responses to allegations. The aim is to encourage further dialogue in the UK and internationally, with a view to reducing the prevalence of research misconduct and minimising its wider social impact.

The UK, like many other countries, has no laws or legally enforceable standards governing research integrity. It relies instead on employer led self-regulation based on a national code of conduct.[4] The code has been adopted by most funders and institutes in higher education but not by commercial organisations, which collectively were responsible for 59% of all expenditure on research and development in the UK in 2021.[5]

This system clearly has weaknesses, previously noted by the House of Commons Science and Technology Committee.[6 7] Key concerns include variation in definitions of research misconduct and procedures for dealing with it, slow or absent responsiveness to allegations, poor protection of whistleblowers, and an undue focus on controlling damage to institutional reputation. The UKRIO report echoes these concerns

The UK has no laws or legal standards governing research integrity

Lex Bouter, professor emeritus of methodology and integrity, Vrije Universiteit Amsterdam
lm.bouter@vu.nl

but, perhaps understandably, does not suggest more legalistic and centralistic oversight of research integrity, because that might divert attention from prevention. Indeed, self-regulation may be better than statutory regulation for encouraging all-important dialogue about research integrity in the workplace and fostering responsible research practices within organisations and research teams.[8]

Conduct on a continuum

One important recommendation in the UKRIO report is to improve understanding of research misconduct. Research conduct operates on a continuum ranging from responsible through questionable to unacceptable research practices such as fabrication, falsification, and plagiarism.[9] The choice of a cut-off on that continuum, to trigger investigation or sanction, is arbitrary. Intentionality is usually considered a defining feature of research misconduct, but intention is notoriously difficult to prove.

Many national codes of conduct also allow for the possibility of research misconduct through gross neglect, although this is also a subjective judgment. The Netherlands code of conduct for research integrity,[10] for instance, allows for shades of grey in the conclusion of an investigation (research misconduct, questionable research practices, or minor shortcomings) and lists criteria to help assess the severity of any research integrity breach. An independent evaluation suggests that this works quite well in practice,[8] and, as the UKRIO report points out, not reporting poor practices that fall short of research misconduct means that opportunities to respond are missed.

The report also notes that the true prevalence of research misconduct is unknown. Research from the Netherlands suggests, in line with systematic reviews of similar surveys,[11 12] that the prevalences of self-reported fabrication and falsification are over 4%, while most researchers admit to engaging in questionable research practices frequently.[13]

To facilitate timely action, retractions should be seen as neutral acts to correct the published record rather than a stigmatising sanction for research misconduct.[19 20] Once credible doubts are raised about an article, an immediate notice of concern should be issued. Cleaning up the published record is mainly the responsibility of editors, journals, and publishers, but they need robust support from research institutes and funders.

Besides providing adequate counselling and protection to both whistleblowers and researchers,[22] institutions and funders should empower researchers to conduct research responsibly by improving research culture and removing perverse incentives that encourage publication at the expense of research integrity.[23 24]

Fostering research integrity is the responsibility of all stakeholders in the research ecosystem. Getting it right is critically important, particularly in biomedical research, where fatally flawed or fraudulent research leads to bias in systematic reviews and clinical guidelines and causes substantial harm to patients.

Cite this as: *BMJ* 2024;386:q1595

Find the full version with references at http://dx.doi.org/10.1136/bmj.q1595

EDITORIAL

Four year medical degrees in the UK

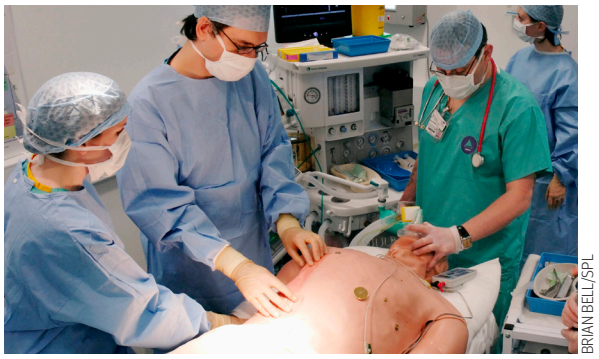
Shorter medical courses may be feasible, but at what cost?

NHS England's long term workforce plan supports the development of four year, rather than five year, undergraduate medical degrees. A "substantial proportion" of medical students will, apparently, take these shorter courses.[1] The four year degree is one of several initiatives aiming to increase the supply of doctors in the face of chronic medical workforce shortages.[2] Others include an expansion in medical student numbers (although to date, only 350 additional places have been awarded[3]) and an opaque, "medical apprenticeship" pilot.[4] However, as doctors face paradoxically rising unemployment, any increase in medical graduates must feed into a coherent workforce pipeline.[5]

NHS England argues that a shorter course will increase the domestic workforce more rapidly and reduce reliance on overseas staff. Proponents also argue that it will widen access to the profession by reducing student debt, which can deter people from less economically advantaged backgrounds.[6]

Most countries have medical degree courses lasting at least five years, although in the US and Canada medicine is a four year postgraduate degree, and even three year courses have been tried.[7] Some UK medical degrees are already conferred after shorter undergraduate training, such as most graduate entry courses for students with relevant knowledge. So compressing a medical degree to four years may be feasible, but is it advisable?

Mapping existing curriculums onto their original 1910 roots in the Flexner report[8] would be likely to reveal numerous "curriculum bulges" where content has been added but little has been removed. These could perhaps be trimmed and curriculums be more focused on the knowledge and skills essential for an increasingly digitised health system. There is also scope, at least during the preclinical years, to reduce the duration of holidays (currently 18- 20 weeks), although this would reduce opportunities for paid work.



BRIAN BELL/SPL

A wider consultation should be conducted to identify unintended harmful consequences

NHS England and the General Medical Council say four year courses will achieve the same educational standards as the traditional five years, and no robust evidence indicates that shortened medical training would be a risk to patient care or safety.

Unintended consequences

However, "absence of evidence is not evidence of absence," and reducing the duration of undergraduate medical training by 20% will have unintended but predictable consequences. For example, in an increasingly technology driven health service, the humanity that doctors bring to their work will become ever more important for person centred care.[9]

Streamlined curriculums are likely to lose key elements such as longitudinal patient contact[12-14] and the arts and humanities[15 16] critical to developing professionals who can provide holistic care.[15 16] Pressure on clinical placements is increasing because of an expansion in training places for other practitioners, such as physician associates. This will lead to more simulation based learning, replacing all-important patient contact.

Importantly, the European Union recognises only primary medical qualifications awarded after "a minimum of 5500 hours of theoretical and practical training provided by, or under the supervision of, a university."[17] Thus, other countries may not recognise the UK's shortened medical degrees. Issues with international recognition would likely deter overseas students from studying medicine in Britain and encourage prospective UK medical students to seek a more widely recognised medical degree abroad.

A compressed, more intense course also risks increasing student attrition from the currently low dropout rates of around 2%. Students from less advantaged backgrounds who need paid work, those with caring responsibilities, or those living with disability or chronic illness may be particularly at risk of falling behind.

Four year medical degrees have been promoted as "widening access" to the profession.[6] Ironically, this was also the premise for longer, six year "gateway to medicine" schemes, introduced in 2001.[18] Gateway schemes have allowed some people from less advantaged backgrounds to study medicine but require considerable resourcing.[19] Academic outcomes are only modestly less favourable compared with students on standard entry courses, and narrow by the time of graduation.[20]

Roll-out of the four year courses should be paused pending the results of a pilot in a suitably representative setting and evaluated against clear outcomes, including widening access and educational performance. A wider consultation, including with prospective medical students, should be conducted to identify unintended harmful consequences.

Gabrielle M Finn, associate vice president for teaching and learning, University of Manchester
gabrielle.finn@manchester.ac.uk
Megan E L Brown, senior research associate in medical education, Newcastle University
Paul A Tiffin, professor of health services and workforce research, University of York

Cite this as: *BMJ* 2024;386:q1630
Find the full version with references at http://dx.doi.org/10.1136/bmj.q1630

WORKFORCE

“Things cannot remain as they are”: UK’s top obstetrician on staff morale

Ranee Thakar, president of the Royal College of Obstetricians and Gynaecologists, tells **Emma Wilkinson** about her concerns for a maternity workforce on the edge

RCOG

For years, maternity care in the UK has come under intense scrutiny. Inquiries into services at Morecambe Bay, Shrewsbury and Telford, and East Kent have all highlighted dysfunctional working relationships, defensiveness, and poor care.

Last year the Care Quality Commission (CQC) found that many people still weren’t receiving safe, good quality maternity services, and it highlighted issues around leadership, staffing, and communication. More recently, the first ever all party parliamentary group inquiry into birth trauma in the UK heard harrowing accounts of stillbirth, premature birth, and life changing injuries in babies and mothers.

Ranee Thakar, president of the Royal College of Obstetricians and Gynaecologists (RCOG) since 2022, says that maternity safety and improvement are absolute priorities but that she also has serious concerns about morale among people working in maternity services. She warns that staff burnout is putting the system under increased pressure and leaving it less able to provide good care and drive up standards.

This point is supported by the CQC’s *State of Care* report for 2022-23, which found an “overarching picture” of maternity departments under huge pressure with significant staffing problems at many trusts.

Depleted morale

The incredibly poor morale among staff “keeps me up at night,” says Thakar. It’s an issue she keeps returning to, pointing out that advocating for RCOG members who are working in frontline NHS care is one of the college’s key responsibilities.

She tells *The BMJ*, “We have to think about the effect that all these reports are having on the morale of the profession, which is something that really worries me. The college has a really vital role to play in amplifying maternity teams’ experiences and concerns and ensuring that the frontline voices inform government action.”

Although her visits to maternity units are largely designed to look at innovative practice, they also allow her to hear firsthand accounts of how stretched the services are and the impediments to making changes. Besides workforce shortages, the most common thing she hears about is how overburdened teams are by investigations, when what they want is to focus more on patient care.

“These inquiries are having a huge impact on the morale of maternity teams,” says Thakar. It’s right that there is scrutiny, she says, but clinicians go to work every day to deliver the best possible care in services that are stretched to their limits.

“We have to find a way to move forward—things cannot remain as they are,” she adds, emphasising that none of this is to discount women’s experiences of care. She expresses gratitude to all of those who have spoken to the inquiries and says that the RCOG has its own women’s network that informs its work and policies.

She explains, “The majority of pregnant women and birthing people give birth safely in the UK. And we do need to highlight that. In the latest CQC report there were many areas [that had shown] improvement, such as positive interactions with staff, women always having time to discuss their pregnancy during antenatal check-ups, and concerns during labour and birth being taken seriously.”

But questions remain as to why some trusts are doing much better than others. The RCOG is in the process of setting up a Maternity Safety Research Centre in partnership with the University of Birmingham that will identify best practice and “robust research approaches to improve safety and close gaps,” says Thakar.

The RCOG also points out that more than a decade of underinvestment has affected almost every aspect of NHS maternity care, from recruitment and training to having estates and equipment that are fit for purpose.

Teams

Thakar says that the royal college is "determined" to be a role model for better collaboration, as "we know that teams that train together, that work together, ultimately have the best outcomes."

She tells *The BMJ*, "We co-chair the Independent Maternity Working Group with the Royal College of Midwives, which was set up following the Ockendon review. We have been tasked to work with them on the response to the Kirkup report [on maternity and neonatal services at East Kent], and we have representatives from various professional groups—anaesthetists, neonatologists, sonographers—all of which are really important and sometimes get forgotten."

Through these groups the voices of frontline staff can inform government action, she explains, and can help to identify potential barriers to improvement. Disseminating best practice is key, she adds, and the college is in the process of developing a section of its website to share examples.

The RCOG has produced a wide range of tools, good practice papers, guidance to support safe staffing, guidance on raising concerns, and a workplace culture toolkit. There are also various quality improvement projects, including one on avoiding brain injury in childbirth. Despite this work and a decade of reports and inquiries, however, there's still a lack of clarity about how to effect longlasting change. And there are plenty of recent examples of poor care.

Thakar recognises this. "We have to keep an open mind; we cannot be defensive about it," she says. "It is really critical that the experiences of women and families are at the heart of driving change. We've seen this in the recent all party parliamentary group's report on birth trauma, and I commend the women who came forward to share their experiences.

"We need to listen more. There's a lot of work going on by Bill Kirkup and his group, around being able to identify problems before they actually happen."

CHRISTOPHER FURLONG/GETTYIMAGES

PETER BYRNE/PA/ALAMY

RICHARD MILNES/ALAMY

Recent maternity care inquiries have taken place at: (clockwise from top left) Royal Shrewsbury, Morecambe Bay, and QEQM Margate hospitals

Health inequalities

A particular focus for the RCOG is reducing health inequalities. In January it was reported that the number of women dying during pregnancy or soon afterwards had risen sharply to its highest level for 20 years.

Black women are three times as likely to die as white women, and the maternal death rate among women from Asian ethnic backgrounds is twice as high as in white women. Women living in the most deprived areas are also more than twice as likely to die during pregnancy or within six weeks of birth than women in the least deprived areas.

The fact that these figures aren't improving is "really worrying," says Thakar. It's a complex picture, as pre-existing conditions, comorbidities, and socioeconomic reasons play a part—but so do factors that affect the care that women receive, such as biases, microaggressions, and racism, she says.

In March the National Institute for Health and Care Research announced that it would invest £50m in research to tackle inequalities in maternity care. "It would be fair to say that there's a lack of research in this area, and if we don't know how to address it in an evidence based manner, if we don't measure it, it's really difficult to think about innovations to bring about change," says Thakar.

"Every woman deserves safe, personalised, compassionate care"

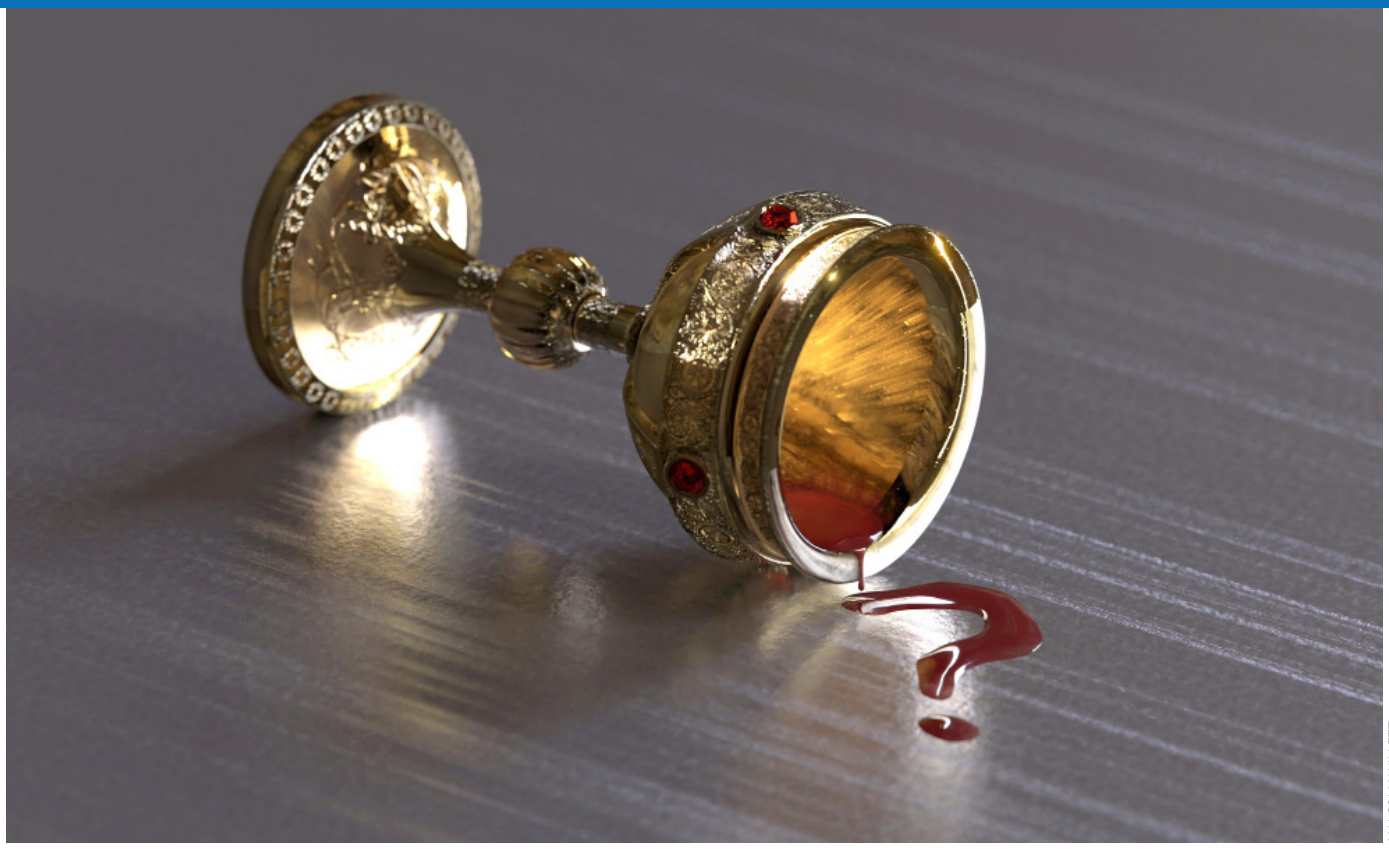
A recent survey of RCOG members has been done to identify what services are being offered to vulnerable pregnant women around the country, including questions on mental health and where there may be gaps.

"I think it's really important that the government commits to a time limited target to end the higher risk of maternal mortality in ethnic minority women and women living in more deprived areas—and there needs to be ringfenced funding for this," says Thakar. Service redesign has a role to play, she says, as maternity units are seeing increasingly complex patients, and patient expectations are changing.

"Every woman deserves safe, personalised, and compassionate care throughout their pregnancy," she concludes. "It is a journey, and it is going to take a while, but we've got to start somewhere."

Emma Wilkinson, Sheffield

Cite this as: *BMJ* 2024;386:q1708



MALCOLM WILLETT

BMJ INVESTIGATION

The holy grail of blood tests? New evidence casts doubt on a much hyped screening tool

A blood test being trialled in large numbers of people in England is facing mounting evidence against its implementation for early cancer testing. **Margaret McCartney** and **Deborah Cohen** investigate

Big promises have been made for the Galleri blood test, which its maker, the Californian biotechnology company Grail, says is capable of detecting more than 50 types of cancer. Harpal Kumar, president of Grail Europe, has hailed the test as a "groundbreaking and potentially life-saving advance that could have a tremendous human and economic benefit."

The NHS is currently running a £150m trial of the test, involving more than 100 000 participants in England. Depending on the results, the plan is to roll out a further pilot involving up to one million tests. If effective, the test would help the NHS meet its target to diagnose 75% of cancers at an early stage by 2028. Trial success would also hand Grail a lucrative deal; although contract details remain confidential, a single test in the US currently retails for $950 (£750).

Multicancer early detection tests such as Galleri are touted as a game changer. Instead of screening for one disease at a time, as the NHS does for breast, bowel, and cervical cancer, for example, technology now exists that has the potential to test for dozens of cancers from a single blood sample.

But experts believe that Galleri has been overhyped and that the current trial is unethical. Concern is mounting over why this particular new screening test has been selected, how it is being evaluated, and whether the bar to success has been set too low.

New evidence

Documents leaked to *The BMJ* indicate that the criteria being used, unpublished until now, are unsuitable to justify a new national screening programme aimed at saving lives.

They show that even Mike Richards, chair of the independent UK National Screening Committee, has privately voiced "serious concerns" to Amanda Pritchard, NHS England's chief executive, about the trial and its ability to provide sufficient evidence "on whether the benefits of testing outweigh any potential harms and at reasonable cost."

Other documents obtained by *The BMJ* detail the deal between the NHS and Grail, raising questions about whether it is too industry friendly. As well as agreeing to buy one million tests after satisfactory completion of the first stage of the trial, the NHS has committed itself to buying five million more tests by 2030 if the test fulfils certain criteria, show documents seen by *The BMJ*.

In return, Grail would build a "new state-of-the-art test processing and sequencing facility in the UK once the NHS commits to purchasing minimum annual volumes, keeping the UK at the global forefront of clinical application of genomics."

Richard Sullivan, director of the Institute of Cancer Policy at King's College London, says the Grail deal is a "clear cut case of public risk and private profit." He says, "It is following a pattern established in this country over the past decade where the regulatory or evidential bar is being set lower and lower in favour of the private sector, with the public sector (that is, our taxes) taking all the risk."

Added to these concerns, it emerged in June that Grail is facing a class action lawsuit in the US. Embittered investors, faced with steep losses, claim that the company exaggerated Galleri's effectiveness to increase its share price. The plaintiffs claim it was "false and misleading" that the rollout would "save tens of thousands of lives." A Grail spokesperson told *The BMJ* they "don't comment on ongoing litigation."

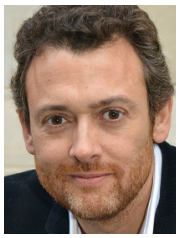
NHS trial: a mistake?

Experts also say it is unclear why an NHS trial is being done of a test that showed so little promise in earlier studies. The test is one of several multicancer detection blood tests, or "liquid biopsies," on the market and uses sequencing technology to analyse DNA fragments circulating in the blood, also known as cell free DNA (cfDNA). These cfDNA fragments from cancer cells have specific "methylation patterns." Grail says that Galleri checks over a million methylation sites in DNA, using machine learning and artificial intelligence to detect whether someone is harbouring a cancer.

NHS England claims the test can identify many cancers that "are difficult to diagnose early," such as head and neck, ovarian, and pancreatic cancers.

But some eight months before the NHS Galleri trial was announced in 2020, Grail published data showing that in patients already known to have cancer the test detected only 43.9% of stage I-III cancers.

The test could have tremendous human and economic benefit
Harpal Kumar



It's a clear cut case of public risk and private profit
Richard Sullivan

NHS decision making over Grail's test

As the NHS Galleri trial continues, there are concerns over the close relationship between key government figures and its manufacturer, Grail.

In 2021, as president of Grail Europe, Harpal Kumar issued a summary of the partnership between Grail and NHS England. This said that with "pivotal help from NHSE senior leadership, influential individuals/KOLs [key opinion leaders] and the AAC [accelerated access collaboration], we were able to persuade Grail leadership that the NHS is the best system globally in which to conduct such studies," with the promise of building a new facility and an "opportunity for UK plc."

Kumar is also a Grail shareholder and was knighted in 2016 while David Cameron was prime minister.

In 2018 Cameron was a paid adviser to Illumina, which spun off Grail in 2016 before finalising the reacquisition of it in 2020.

Freedom of information requests from *The BMJ* have shown that Cameron and Illumina staff met Nadhim Zahawi, then undersecretary of state for business and industry, in March 2021. Cameron is minuted as saying that in the NHS "our customers do not leave and join a new insurance business every couple of years. This means the data gained is invaluable, as you can look at a patient's data over their whole lifetime. This is a selling point of the UK which NZ [Nadhim Zahawi] may wish to emphasise." At the same meeting, it was planned that "Illumina will keep NZ involved in UK investment in R+D so they can be part of the UK life science success stories."

Disquiet

Usually, decisions on what constitutes cost effective NHS screening are made by the independent UK National Screening Committee. Freedom of information requests by *The BMJ* have revealed major disquiet expressed between UK NSC and NHS England regarding Grail.

In September 2023 UK NSC members wrote to NHS England saying that they would recommend evaluating how well the test worked outside a trial only when there was "a fair degree of confidence that the major screening questions (eg test accuracy, diagnosis, treatment, acceptability, ethics) are answered or there is strong reason to believe they would meet the criteria. The Grail test is well short of most of these, so the UK NSC would have been very unlikely to recommend large scale programmatic evaluation without more basic research."

In February 2024 Mike Richards, chair of UK NSC, wrote to Amanda Pritchard, chief executive of NHS England, with "serious concerns." He said that if the trial led to a rollout of a "million tests" the committee recommended the need for a control group, with research ethics approval, but "unfortunately, those responsible within NHSE for this phase of the programme have declined to take our advice on this."

As a result of all these failings, Richards said, the UK NSC might be unable to make a recommendation about the rollout of Galleri at the end of the project.

An NHS England spokesperson, however, says that they believed that Grail was "now being subjected to one of the largest and most rigorous investigations done in any healthcare system worldwide," that no decision had been made, and no further details were available.

By contrast, an NHS England source speaking to *The BMJ* under the condition of anonymity said, "The clinical or scientific data doesn't stack up, but that should have come first. This is not the way to do a trial—it should be done transparently. It's not been thought through at all."

Open door to industry

Concern over the decision making process around Grail serves as a timely reminder to the new health and social care secretary, Wes Streeting, who recently stated his aim is to make the UK a "life sciences and medical technology powerhouse." He said, "By ensuring the NHS works hand in hand with life sciences research institutions and medical technology companies, the government will drive the development of new treatments and help grow the industries."

But while an open door policy to industry might be one thing, it does not mean open standards, says Richard Sullivan, director of the Institute of Cancer Policy at King's College London. "The new government needs a more rigorous and transparent way of reviewing med tech clinical research, especially when it involves such widespread access to NHS resources," he says. "They also need to change their language. It's all promissory science and hype. This serves no public good whatsoever."

PETER MACDIARMID/PA/ALAMY

Harpal Kumar (left), president of Grail Europe, was granted a knighthood in 2016, when David Cameron (centre) was prime minister

In 2021 another Grail funded study in *Annals of Oncology* found that the test sensitivity for stage I cancers was only 16.8%. Many of the authors declared fees, patents, or stock holdings with the company.

These results are "strikingly low," says Clare Turnbull, professor of cancer genetics at the Institute of Cancer Research in London. "A good screening test would typically be anticipated to have high sensitivity for early stage cancers, as these are usually the cancers for which surgery would offer the patient a high likelihood of cure (or long term remission)," she adds.

Paul Pharoah, professor of cancer epidemiology at the Cedars-Sinai Medical Center, Los Angeles, agrees. "I do not think that the evidence was sufficiently strong to warrant the trial," he says. "With a sensitivity for stage I disease of less than 20% overall and only 44% for all stage I-III cancers diagnosed through other tests, I do not think a trial is ethical." He says it was unclear why "a trial of a test with such little promise" was done.

Some clues can be seen in emails obtained by *The BMJ* through freedom of information requests. On 15 October 2020 Illumina, the then parent company of Grail, emailed Nadhim Zahawi, a minister in the Department for Business, Energy and Industrial Strategy, requesting a meeting to discuss "this revolutionary technology" that could have "an incredibly positive impact on UK patients and for the UK economy."

The email referred to links that Grail and Illumina already had in the UK. Illumina's "world leading sequencing technology was invented in the UK," and Grail had a significant clinical trial programme with centres in London, it said.

It added, "We will continue to build on that foundation, and our other collaborations with the NHS, Genomics England, industry and academia to help realise the promise of the UK's recently published genomic strategy."

A government aide suggested that a meeting should be granted as "they are a big company that makes machines, it ticks the industry box." The deal, with a press release signalling the launch, occurred just six weeks later.

Sullivan says, "The oven ready alignment with the genomics community and the wider NHS England push in this area blinded [the government] to the wider considerations of whether this technology was in the public interest."

NHS England didn't respond to questions about why it didn't put a contract out to tender. Instead, a spokesperson said, "At the time of the agreement in 2020, Galleri was the only test for which a company was in a position to do a trial at sufficiently large scale."

Behind closed doors

The £150m NHS trial began screening participants in mid-2022, but its details have been marred by secrecy. It is generally considered good practice to have the trial protocol available for scrutiny before a trial starts and is publicly registered, with full details of how the trial is to be conducted and the outcome measures.

Clinicaltrials.gov records the start date of the trial as August 2021, but trial details were not uploaded until more than a year later, in October 2022. Funded by Grail, this prospective randomised controlled trial aimed to recruit 140 000 asymptomatic patients between 2021 and 2026. Participants make three visits to a mobile clinic over two years, with half having a Galleri test and half in the control group. The primary outcome measure was the absolute numbers of stage III and IV cancers diagnosed.

Interim results of the trial were published in an NHS England blog at the end of May, saying NHS England "did not find them compelling enough" to proceed directly to the planned large scale pilot programme in July 2024. Full details were not published. Instead, NHS England will wait for the final trial results, expected in 2026, before making any further rollout decision.

Documents obtained by *The BMJ* outline for the first time what the "success criteria" are that the trial needs to meet. The NHS has committed to buying a million tests if the Galleri test produces a positive predictive value (the proportion that gives true positives) of over 30%, a 30% reduction in stage IV cancers in the intervention arm, compared with the control arm, and a 75% higher number of cancers detected by Grail than in the control group.

Survival stage-for-stage is poorer for cancers detected by the Galleri-MCED than for those not detected
Clare Turnbull

I do not think a trial is ethical
Paul Pharoah

Would these criteria mean "success" for patients? Turnbull says that just demonstrating a shift in the distribution or proportion of cancers presenting at different stages does not tell us whether or not this multicancer early detection tool is improving survival in patients with those cancers. She cites a recent meta-analysis across screening studies for various cancers showing that stage distribution largely does not predict survival.

She adds, "Galleri's own data have shown that survival stage-for-stage is poorer for cancers detected by the Galleri-MCED [multicancer early detection] than for those not detected." This is crucial, she says, because it may be that the supposedly early stage cancers that are detected by Galleri are ones that have already metastasised—and that the technology is demonstrating that it is better than imaging at detecting early metastasis.

Pharoah agrees. "There is the whole question of what would be the appropriate endpoint. With a multicancer detection test (multi-harm opportunity from overtreatment) I cannot see that anything other than all cause mortality is sufficient." When such a large section of the population is exposed to screening, even a small proportion of false positive testing can have a large effect on demand for imaging and diagnostic investigations, costs, and waiting lists, he adds.

There are other warnings that the Galleri test might fail to deliver on its promises. A 2023 *Lancet* study suggests that the test's sensitivity is even lower in a screening population than in previous trial populations. In the Pathfinder study, conducted on asymptomatic patients in North America, 1.4% had a positive test, but 62% of these results turned out to be false positives.

Margaret McCartney, senior lecturer in general practice, University of St Andrews
mgtmmccartney@gmail.com

Deborah Cohen, investigative journalist, writer, and broadcaster, London

Cite this as: *BMJ* 2024;386:q1706