this week

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SARAH TURTON/BMA

Demand for pay to return to 2007 levels

BMA ANNUAL REPRESENTATIVE MEETING

The BMA has been instructed by its members to pursue a large increase in pay, opening up the prospect that medical professionals will follow other workers in taking industrial action this year.

The association's annual representative meeting in Brighton passed a motion calling on the BMA "to achieve pay restoration to 2007 value for its members within the next five years" as doctors' pay has fallen against th retail price index by up to 30% since 2008.

Proposing the motion on 27 June, Emma Runswick of the BMA's North West Regional Council said, "In real terms, junior doctors are down around 25%, SAS doctors around 15%, GPs over a quarter, and consultants over 30%. This has been a deliberate choice by governments starting from the banking crash to make us pay for crisis after crisis we didn't create.

"And I'm not foolish. I know it's likely that industrial action will be required to move the government on this issue," she said, adding, "A union that could win a 30% pay award is a union that can win anything."

Opposing the motion, Anna Athow, of Enfield and Haringey in north London, said junior doctors had already demanded a 22% pay rise to restore their income to 2008 levels and would ballot on industrial action within six months. "We should be supporting them, not saying we'll go on begging the government for the next five years," she said.

"Please oppose this awful motion, which condones sitting on our hands and doing nothing for the next five years," Athow said.

Eleanor Draeger, a single parent who said she was struggling on her consultant's salary, warned it was "absolutely imperative" doctors did not reject the motion. "If you vote against this motion, the media will say doctors don't really want a 30% pay rise."

Runswick, who proposed the motion at the junior doctors' conference to ballot on industrial action in early 2023, said, "I absolutely want us to win this now. If your issue with this motion is that it's going to take too long, then you should have been with us two years ago, one year ago, when we were battling on this issue."

The DDRB submitted its recommendations to the government earlier this month. Its report will be published after the Department of Health and Social Care for England announces its pay decisions.

▶ ARM ROUNDUP, p 5

Ingrid Torjesen, *The BMJ*

Cite this as: *BMJ* 2022;377:o1590

Emma Runswick of the BMA's North West Regional Council proposed the motion to call on the government to achieve pay restoration within five years

LATEST ONLINE

- Doctor is struck off for dishonesty over child's death in 1995
- Founder of America's Frontline Doctors is sentenced to prison for role in Capitol riot
- FDA orders Juul to remove all its e-cigarettes from US market

SEVEN DAYS IN

GMC won't challenge Manjula Arora appeal and calls for sanctions to be dropped

The GMC has said it will not challenge GP Manjula Arora's tribunal appeal and has called for her one month suspension to be dropped by the High Court (left).

The case, which concluded that Arora's use of the word "promised" when requesting a work laptop amounted to dishonesty, sparked fury among doctors. They argued the action was "wildly disproportionate" and said the disciplinary process was biased against doctors who trained overseas. After the backlash the GMC said it would review the case to see whether any lessons could be learnt. Last week it named the consultant geriatrician and chair of the GMC's Black and Minority Ethnic Doctors Forum, Iqbal Singh, and Martin Forde QC to co-chair the review.

A GMC spokesperson said, "Having considered the tribunal's decisions and sought the views of external counsel, we believe the dishonesty test was applied incorrectly. That means the findings of dishonesty, impairment, and sanction should not stand. We have agreed with the doctor's representative to dispose of the appeal without need for a hearing. Should the court approve that agreement, the doctor will have full registration with a licence to practise and no fitness to practise finding recorded on her registration."

Elisabeth Mahase, *The BMJ* Cite this as: *BMJ* 2022;377:o1583

Covid-19

Valneva's covid vaccine is authorised in Europe

The European Medicines Agency recommended granting a marketing authorisation for Valneva's covid vaccine for use in primary vaccination of people aged 18-50. The vaccine, which contains inactivated whole particles of the original strain of SARS-CoV-2 that cannot cause disease, is the sixth covid vaccine recommended in the EU. It was given regulatory approval by the UK's MHRA in April.

Moderna will open UK vaccine research centre

The drug company Moderna is planning to build a new mRNA research and manufacturing centre in the UK that the government says will "future proof" the country against potential emerging health threats. The centre will develop mRNA vaccines for a wide range of respiratory diseases, including covid-19, flu, and respiratory syncytial virus. Moderna will also establish a global clinical trial base in the UK. Under the strategic partnership agreed in principle between the UK government and Moderna, patients will have guaranteed access to covid vaccines, including those against new variants.

Alcohol pricing

Policies could cut health harms, says WHO

European countries could significantly reduce health harms from alcohol consumption by introducing minimum pricing for alcoholic beverages, said the World Health Organization. The *No Place for Cheap Alcohol* report, published on 21 June, said introducing minimum prices alongside alcohol taxes would limit access to high strength, low price alcohol, which is associated with high levels of harm. It highlighted minimum unit pricing as one of the most effective policies.

Abortion

US Supreme Court ends right to abortion

Doctors condemned the US Supreme Court's 24 June ruling to overturn the 1973 Roe *v* Wade decision, thus ending women's nearly 50 year old constitutional right to abortion and leaving the issue for individual states to decide. Iffath Hoskins, president of the American College of Obstetricians and Gynecologists, said it would continue to support members, community partners, and all people "in the ongoing struggle against laws and regulations that violate and interfere with the patient-physician relationship and block access to essential, evidence based healthcare."

OPINION, p 24

Valproate

MHRA looks into possible transgenerational effects

The UK drug regulator is examining animal data showing that the epilepsy drug sodium valproate could trigger genetic changes that are passed on to future generations. The MHRA said its review of the safety of sodium valproate had taken independent advice from the Commission on Human Medicines about data showing changes to the testes in juvenile male animals and transgenerational effects in mice.

Monkeypox

High risk men offered smallpox vaccine

Gay and bisexual men at high risk of exposure to monkeypox will be offered the smallpox vaccine Imvanex (above right) to help control the ongoing monkeypox outbreak,

said the UK Health Security Agency. The updated strategy, endorsed by the Joint Committee on Vaccination and Immunisation and published on 22 June, said eligibility would depend on several factors but would be similar to the criteria for HIV pre-exposure prophylaxis. Clinicians will also be able to recommend vaccination for someone who has many partners, participates in group sex, or attends "sex on premises" venues.

Public inquiry

Litany of failings allowed consultant to misdiagnose

A series of failings by Belfast Health and Social Care Trust allowed a consultant neurologist, Michael Watt, to go on misdiagnosing and wrongly treating patients' illnesses for a decade, a public inquiry concluded. In 2018 Watt was at the centre of the largest patient recall in Northern Ireland, when more than 5000 patients were recalled. A review of his high risk patients found that nearly one in five had received a diagnosis described as "not secure."

MEDICINE

Fatigue

Poor hospital food fuels junior doctors' exhaustion

Lack of access to hot or healthy meals beyond 6 pm is fuelling fatigue among staff and affecting patient care, the BMA warned. In a survey of junior doctor representatives at UK hospital trusts and health boards, 73% said that hot food provision during the night was unsatisfactory. Just 10% of UK trusts or health boards offered freshly prepared meals or smaller hot snacks after 11 pm, while just under a third offered pre-prepared meals to heat up.

Relying on cold food throughout night shifts is affecting trainee doctors' wellbeing

Cancer

Doctors issue warning about skin cancer apps

Smartphone apps that use artificial intelligence to spot skin cancer are endangering the public, warned the British Association of Dermatologists. Rubeta Matin, chair of the association's AI working party group, said, "The public has an understandable belief that these AI based skin cancer detection apps are safe to use. The reality is that many don't meet the standards required by regulators to diagnose medical conditions." The organisation has produced a guide to help the public spot potential warning signs when using diagnostic skin cancer apps (bit.ly/skinhealthinfo).

Medical cannabis

Review calls for national trial for GPs to prescribe

GPs should be allowed to prescribe medical cannabis as part of a national trial, advised a policy review commissioned by the Centre for Medicinal Cannabis and the Association for the Cannabinoid Industry. The review by Christopher Hodges, emeritus professor of justice systems at the University of Oxford, called for a new regulatory framework to "turbocharge UK cannabinoid innovation." He said, "It is no longer wise or sustainable for the government to continue to take a distanced, disinterested or laissez faire attitude to the sector as a whole."

Austerity

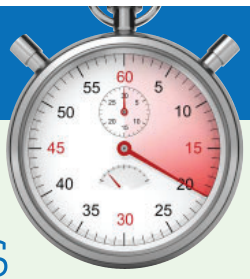
Local spending cuts link to poor health

Local government spending cuts are associated with worse multimorbidity and health related quality of life, concluded a longitudinal study of 147 English local authorities published in the *Lancet Regional Health—Europe*. After controlling for other spending, a 1% cut in public health expenditure was associated with a 0.15% increase in the prevalence of two or more chronic conditions. Although the researchers showed that total public health expenditure had increased slightly over the analysis period, like-for-like public health expenditure had actually fallen in real terms since 2014-15.

Cite this as: *BMJ* 2022;377:o1574

DENTISTS

One in three UK dentists are struggling to clear the patient backlog that grew during lockdown, and 74% said this had led to treatment delays and complaints *[Medical and Dental Defence Union of Scotland]*



SIXTY SECONDS ON . . . LIZZO

WHAT'S THE JUICE?

US singer, rapper, and songwriter Melissa Viviane Jefferson—known as Lizzo—is famous for songs that tackle matters of race, sexuality, and body positivity. But she found herself in hot water after releasing a single, "Grrrls", which included an ableist slur.

DO BETTER

Lizzo's use of the word "spaz"—a derogatory term that has its roots in a form of cerebral palsy known as spastic diplegia—was quickly criticised. UK charity Scope posted on social media, "Dear Lizzo, your songs spread the message of self-acceptance. Please don't leave disabled people out by using slurs in your lyrics. Self-love should be for everyone. We know you can do better."

A SYMPTOM OF A BIGGER PROBLEM

The use of such language in a song highlights a wider problem in society and in healthcare. Writing in *Evidence-Based Nursing*, Scottish nurse Cass Macdonald described what it's like to work as a disabled person in the NHS. She wrote, "Imagine being told you cannot possibly do your job. Imagine being berated or criticised for 'not keeping up.' For not 'getting better.'" She added that as more staff experience long covid, ableism is likely to become a bigger problem and one colleagues must challenge.

PATIENTS SUFFER

Ableism also affects the care of patients. Amy Robertson—a disabled and chronically ill researcher—wrote in *The BMJ*, "[During the pandemic] chronically ill, disabled, and immunosuppressed people were framed as disposable, or less inherently valuable. Within medicine, this rhetoric was reflected in forced or encouraged do-not-resuscitate orders and in the de-prioritisation of critical care for chronically ill and disabled people."

DID LIZZO LISTEN?

In less than 48 hours, the singer re-released "Girrls" with updated lyrics. In a statement she said, "I never want to promote derogatory language. As a fat black woman in America, I've had many hurtful words used against me so I understand the power words can have."

ABOUT DAMN TIME

As Lizzo herself once sang. But Scope was more diplomatic, "We're thrilled. This is a great example of someone listening, learning, and growing."

Marina Politis and Nick Phillips, *The BMJ*

Cite this as: *BMJ* 2022;377:o1573

TOM FALCON HARDING/SHUTTERSTOCK

What we know about the poliovirus found in London

Elisabeth Mahase outlines all the information so far about the vaccine derived virus detected in samples from an east London sewage works

What have they found?

Vaccine derived poliovirus was detected in sewage samples from the London Beckton Sewage Treatment Works between February and May 2022. The live attenuated (weakened) oral polio vaccine, which can cause the vaccinated person to shed traces of poliovirus in their faeces, has not been used in the UK since 2004. Therefore, the UK Health Security Agency has said the virus was probably imported by someone recently vaccinated abroad.

As of 27 June the HSA said that no associated cases of paralytic polio had been detected in the UK and the risk to the public was currently low. The UK was declared free of polio in 2003, with the last case of wild polio contracted in the country in 1984.

What do we know about polio?

Wild poliovirus has three types. Types 2 and 3 have been declared eradicated, but type 1 still circulates in some parts of the world. Polio is an acute illness that occurs after a person is infected by one of the polioviruses through the gastrointestinal tract. It replicates in the gut and can spread to the central nervous system.

How is polio transmitted?

The virus is transmitted through contact with an infected person's faeces or saliva. Although the incubation period ranges from three to 21 days, the virus can be excreted for three to six weeks in faeces and two weeks in saliva.

What are polio's symptoms?

Early symptoms are fever, fatigue, headache, vomiting, stiffness of the neck, and limb pain. However, one in 200 infections leads to irreversible paralysis, normally in the legs. Of those who become paralysed, 5-10% die as the muscles involved in breathing become immobilised.

How was it detected in London?

UK sewage is checked routinely, and around one to three vaccine-like polioviruses are generally detected every year, but these have previously been isolated cases. In recent months several genetically connected samples have been found, indicating that the virus is spreading.

Beate Kampmann, professor of paediatric infection and immunity and director of the London School of Hygiene and Tropical Medicine's vaccine centre, said, "The main worry is the genetic connectedness of the strains found in the sewage water, as it shows transmission in a group and not just a single 'excreter.'"

The government is now expanding wastewater surveillance.

What is vaccine derived poliovirus?

The weakened poliovirus contained in oral vaccine is able to replicate in the intestine but is around 10 000 times less able to enter the central nervous system than the wild virus. This means vaccinated people can mount an immune response, but the risk of paralysis is extremely low.

Compared with the inactivated vaccine, the live attenuated version provides better immunity in the gut and can also lead to shedding of the vaccine virus in faeces, which can further protect communities with low quality sanitation. However, in places where vaccine coverage is low, as the virus spreads from one unvaccinated child to another—often over a period of around 12 to 18 months—the vaccine virus can mutate into the form that can cause paralysis. The inactivated vaccine used in the UK does not result in poliovirus.

Does the UK routinely vaccinate against polio?

The UK switched from the live attenuated oral vaccine to an inactivated injectable version in 2004. It is part of the NHS routine childhood vaccination schedule and is given to children at eight, 12, and 16 weeks as part of the 6-in-1 course. It is then given at three years and four months as part of the 4-in-1 preschool booster, and later at 14 or 15 years as part of the 3-in-1 teenage booster. To be fully vaccinated against polio, a person must have had all of these vaccines.

How high is UK vaccine coverage?

In 2020-21, 95% of children under the age of 5 years in England had received the primary polio vaccine doses. London had the lowest uptake at 91%. Uptake of the preschool booster was at 85% across England and 73% in London. The teenage booster coverage was estimated to be 80.3%.

In Scotland uptake of the primary preschool, and teenage doses was 97.1%, 92.6%, and 80.3% respectively. In Wales uptakes were 95.6%, 92.9%, and 86.0%.

Kampmann said, "The mission now has to be that everyone gets their series completed, so we don't allow these strains to spread."

The main worry is the genetic connectedness of the strains found, as it shows transmission in a group and not just a single "excreter"
Beate Kampmann

Do fully vaccinated people need extra booster doses?

Not according to David Salisbury, chair of the WHO Global Commission for Certification of Polio Eradication. He said, "Fully vaccinated individuals do not require further boosters. Parents of children who have not completed their recommended polio vaccine doses should contact their primary care provider. This is especially important in London, where these viruses have been identified and vaccine coverage is lower than elsewhere."

Elisabeth Mahase, *The BMJ*
Cite this as: *BMJ* 2022;377:o1578

"Challenge GP contract with industrial action if necessary"

The BMA must organise the withdrawal of general practices from England's primary care networks by 2023 and lobby for that PCN funding to be moved into the core contract, doctors have said.

The motion, passed at the BMA's annual representative meeting 2022 in Brighton, also called for the association's General Practitioners Committee for England to organise opposition to the new contract, including through "industrial action if necessary."

The current five year GP contract was negotiated between the BMA and NHS England in 2019-20, with provision for negotiated changes every year. But negotiations came to a standstill in February when the BMA said it was clear that NHS England would not be offering sufficient measures to ease pressure on practices. NHS England then imposed changes to the 2022-23 contract, including that PCNs would be required to provide a full range of services from 9 am to 5 pm on Saturdays from 1 October.

PCNs SHOULD BE ABOLISHED, ALONG WITH ALL THE BOX TICKING
Jackie Applebee

Proposing the motion, GP Jackie Applebee, who also chairs the doctors' branch of the union Unite, said, "PCNs should be abolished, along with all the box ticking. Money should all be paid into core to allow us to determine how services are delivered. I understand that general practice needs every penny it can get and that the funding attached to PCNs can incentivise GPs to try to make them work, but the truth is that often PCN services struggle to break even."

Discussing the call for potential industrial action, Applebee continued, "The new contract has already effectively been imposed, but that doesn't mean that GPs are powerless. I know some of you will be worried about industrial action, but how much more can we take?

"We should take our lead from the National Union of Rail, Maritime and Transport Workers (RMT). They have quite rightly said enough is enough. No more pay erosion, no more service cuts. Despite the vitriol of the right wing press, public opinion seems to be on their side. The RMT's issues very much chime with those we face in the NHS. Solidarity to them. Let's channel our inner Mick Lynch [secretary general of the RMT]."

WE NEED A NEW DEAL FOR GENERAL PRACTICE. WE NEED TO GET GOING
Farah Jameel

The motion led to a long debate, although the discussion was overwhelmingly negative towards PCNs. Farah Jameel, chair of the England GP Committee, did not take a position on whether the motion should be passed. But she said, "We all want a new contract. We need a new deal for general practice. We need to get going. So what happens next in discussions with the government, [health] department, and NHS England is important, and how we as a profession come together as foot soldiers on the ground when we don't get the things we want is important. We need a plan and we need a strategy."

Jameel added that an indicative ballot on potential industrial action by GPs that ran in late 2021 was "not a formal ballot" and could not be acted on because the majority of the profession did not vote.

Elisabeth Mahase, *The BMJ*
Cite this as: *BMJ* 2022;377:o1599

News roundup of ARM 2022

GOVERNMENT HAS EXPLOITED DOCTORS' GOODWILL, SAYS BMA CHAIR

The government must guarantee that doctors will "never again be forced to risk their lives" because of failed pandemic planning, inadequate risk assessments, and substandard infection control measures, the BMA's council chair, Chaand Nagpaul (right), told the meeting in Brighton on 27 June. Nagpaul, who will step down this year at the end of his five year term, warned the government that it can no longer run the NHS by exploiting the goodwill of doctors, which has now run dry. "Doctors will and are walking away," he said. "The government needs to wake up."

GMC MUST FOCUS ON "SIGNIFICANT BREACHES"

The BMA must demand that the GMC focus only on investigating "significant breaches," representatives said. A motion, passed in full, also said the regulator must not impose sanctions on vulnerable doctors to send a message to the wider medical profession. Additionally, the GMC must conduct all investigations in a "more timely manner" and commit to trauma informed practice and direct fact finding with the subjects of their investigations rather than relying entirely on third party contributions. Proposing the motion, Scottish consultants committee member Tamasin Knight said, "The GMC must focus on serious allegations only; everything else they need to keep out of."

"STIFFER SENTENCES" NEEDED FOR PEOPLE WHO ATTACK DOCTORS

The meeting passed a motion calling for stiffer sentences to be imposed on people who attack doctors and other healthcare workers. Representatives also called for greater awareness of the prevalence of abuse of staff, for greater support to be offered to clinicians who are victims of abuse and malicious complaints, and for more support for those who are victims of "slanderous or malicious" complaints. But a call for the routine provision of self-defence training for all clinical staff was lost. The motion followed a recent investigation by *The BMJ* that found that the number of violent incidents at general practices recorded by police forces has almost doubled in the past five years.

NO EXCUSE FOR TRUSTS NOT TO OFFER PENSION RECYCLING, BMA SAYS

The BMA has committed itself to campaigning for pension recycling—which enables high earning doctors liable for punitive pension taxation to stop contributing to the NHS scheme but to still benefit from their employer contributions—to be available to doctors across the UK. Vishal Sharma, BMA pensions committee chair, made the commitment in response to a motion passed that said that the 6.3% centrally funded part of employers' contributions to NHS pensions was a part of the total employee reward. The motion demanded that it be included as a taxable payment to any doctor who withdraws from the NHS scheme to avoid pension tax liabilities as a result of breaching the lifetime or annual allowances.

Elisabeth Mahase, Ingrid Torjesen, *The BMJ* Cite this as: *BMJ* 2022;377:o1595

NEWS ANALYSIS

UK must focus on diagnostics needed to cut antimicrobial resistance, says review chair

A major review in 2016 concluded that, if left unchecked, antibiotic resistance could cause 10 million global deaths a year by 2050. **Jacqui Wise** reports from a parliamentary session on the issue

Politicians have failed to grasp the importance of new diagnostics to cut unnecessary use of antibiotics, the chair of a government commissioned review on antimicrobial resistance (AMR) has told MPs.

It is six years since economist Jim O'Neill published his review on AMR, which made 10 recommendations, including promoting rapid point-of-care diagnostics in primary and secondary care. Giving evidence to the House of Commons Science and Technology Committee on 22 June, O'Neill said he was pleased there had been progress on many of the recommendations, particularly reducing unnecessary use of antimicrobials in agriculture.

"Woeful" progress on diagnostics

But he said there was one area where the UK had been "woeful." He said, "It is alarming to me how we are not embedding state of the art diagnostic technology into our systems." He said doctors should be banned from "subjective" antibiotics prescribing based on "educated guesses" about infections.

Alison Holmes, professor of infectious diseases at Imperial College London, told the committee that diagnostics didn't necessarily have to be used at the first point of contact if, for example, there was a need to act quickly because of the threat of sepsis.

But she added, "If at 24 hours or 72 hours we know the patient has a specific infection then the antibiotic should be changed. Or if it's clear they don't have an infection then treatment should be stopped. There should be a focus on targeting therapy or stopping."

Holmes, who is also president of the International Society for Infectious Diseases, said diagnostics could also be used more widely. "It is becoming increasingly apparent that courses of antibiotics can be shorter," she told MPs. She added that there needs to be more research in this area so that recommendations on duration of antibiotic treatment could be revised safely.

The O'Neill review in 2016 stated that at least 700 000 people die each year because of drug resistance in illnesses such as bacterial infections, malaria, HIV and AIDs, and tuberculosis. It concluded that, if left unchecked, AMR could account for around 10 million deaths a year worldwide by 2050.

It is becoming apparent that courses of antibiotics can be shorter
Alison Holmes

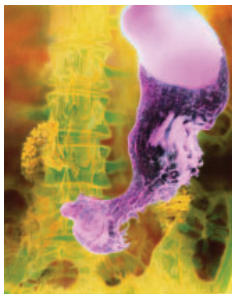
However, this is likely to be an underestimate. In February an analysis published in the *Lancet* estimated that the global burden of drug resistant infections in 2019 was 4.95 million, of which 1.27 million were directly attributable to drug resistance.

"The estimate of how many people are dying from AMR related illnesses today from this really detailed analysis was twice as big as we thought," said O'Neill. "The health and economic threat from AMR could be even worse than from covid if we don't treat it much more seriously on a global basis."

Asked if anything else should have been included in his 2016 report, O'Neill said he wished he had made a recommendation that AMR could be cited on death certificates as a cause of death. This would have helped focus public attention on the problem, he said.

He added he also wished he had recommended that when the International Monetary Fund analyses member countries it includes spending on health systems, rather than just leaving it to WHO. "We have to find a way of investing in preventing diseases in terms of surveillance, diagnostics, and

GP suspended after retiring for failing to fast track woman


SPL

A GP who failed to refer a woman with symptoms of cancer and a known precancerous condition to the suspected cancer fast track pathway has been suspended from the medical register after his retirement.

Prakashchandra Jain posed little risk of repeating his misconduct even if he returned to practice, said Ian Comfort, chairing the medical practitioners tribunal. But he said that a three month suspension would send a necessary signal to other doctors.

Under the two week rule GPs who find suspected cancer symptoms in their patients must arrange urgent hospital appointments for them to see a specialist in 14 days.

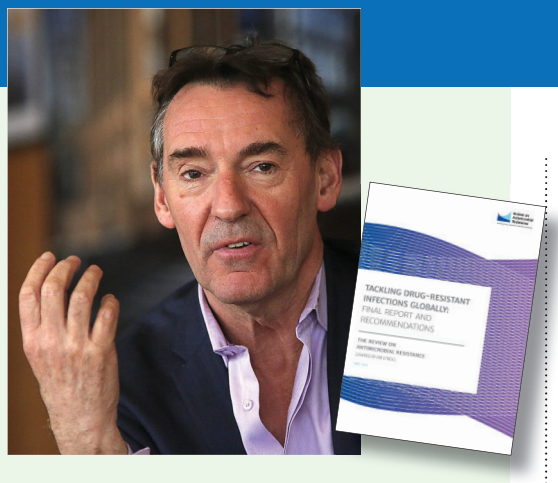
Jain's Patient A had Lynch syndrome, an inherited predisposition to many types of cancer, including stomach cancer. She was already in a screening programme, which in December 2019 discovered her carcinoma of the stomach. But she had seen Jain in January, June, and July that year with highly suggestive symptoms.

Ian Comfort, tribunal chair, said that a three month suspension would send a necessary signal to other doctors

In January she reported feeling generally unwell, and he had ordered blood tests that showed iron deficiency anaemia. Jain's failure to make a suspected cancer fast track referral then was the first allegation brought by the GMC.

Jain, principal GP at a practice in Cumbria, who qualified in 1975, was also accused of misconduct for again failing to refer Patient A to the fast track after a second consultation in June, when he noted she had lost weight. In July she reported dyspepsia, further weight loss, and recurrent diarrhoea, but he still did not make the referral.

Jain's counsel said the



O'NEILL stated in 2016 that at least 700 000 people a year die from drug resistance

having a stock of treatments, in the same way as we think about preparing for war."

Holmes emphasised the importance of preventing infection in healthcare. An estimated fifth of antibiotic prescriptions are to treat hospital acquired infections, she said. "We have to reduce infections that need antibiotics. Exposure drives resistance." She added, "Hospital acquired infections rose significantly during covid. These are a threat to us being able to deliver safe care."

Holmes told the committee it wasn't just about finding new antimicrobial agents but about optimising existing ones. "We can get much more bang for our buck in how we use existing agents, and we need to personalise treatments for different patient groups," she said. "It is not a one size fits all." She added, "AMR is a massive threat on both an individual and a societal level. The challenge is massive and real."

Jacqui Wise, Kent

Cite this as: *BMJ* 2022;377:o1551

GP had recognised the seriousness of the case and after the June consultation had tried to bring forward her scheduled screening instead of invoking the two week rule.

In the event, although Jain had specifically asked for the screening to be expedited, it came two months later than originally scheduled.

Patient A has since died. Her daughter referred the doctor to the GMC in 2020, the same year Jain retired. In 2021 he relinquished his licence to practise. He had an otherwise unblemished record.

Jain accepted he would be found guilty of misconduct and his fitness to practise would be deemed impaired. But the defence asked for a short suspension with no review hearing at the end of it, since Jain was not returning to practice and it was "a public interest case only."

The tribunal agreed.

Clare Dyer, *The BMJ*

Cite this as: *BMJ* 2022;377:o1534

Almost 19 000 GPs plan to quit in next five years, RCGP warns

General practice will lose around 18 950 GPs and trainees over the next five years unless the intense workload and workforce pressures are tackled, the Royal College of General Practitioners has warned.

The "mass exodus" is predicted by a recent survey of GPs' career intentions, and it occurs, says the RCGP, against a backdrop of a service at breaking point that risks compromising the safe care of patients.

In response to the findings the college has set out the actions it believes the government needs to take to tackle the workforce and workload crisis and to support practices.

The survey found that stress, working hours, and lack of job satisfaction were the reasons cited for quitting by 60% of those planning to leave for reasons other than retirement.

RCGP called for GP funding to be returned to 11% of total health spend

Overall, 68% of respondents said they did not have enough time to assess their patients properly, with 65% saying patient safety was being compromised because appointments were too short.

"Alarm bells"

Martin Marshall, chair of the RCGP, said the findings were "alarming."

"The intensity and complexity of our workload is escalating while numbers of fully qualified, full time GPs are falling. The college has been sounding alarm bells about the intense pressures GPs and our teams are working under, and the urgent need for support, since well before the pandemic, but covid has only exacerbated the situation. This is taking its toll on the health and wellbeing of GPs and other members of their teams—pushing many to consider leaving the profession earlier than planned," he said.

There are currently more GPs in training than ever before, with an intake of 4000 in 2021. But even this, if sustained over the next five years and with all trainees entering the profession, would not be enough to counter the numbers planning to leave and sufficiently increase GP numbers, the RCGP warned.

The college is calling for a new recruitment and retention strategy to go beyond the current target of 6000 more GPs and for an NHS-wide campaign to cut unnecessary workload and bureaucracy to free up GPs to spend more time with patients. It is also urging the government to invest in a new suite of IT products and support for practices to make it easier for patients to choose to see the same GP or the next available member of the team, and to returning funding for general practice to 11% of total health spend, including £1bn additional investment in GP premises.

Kieran Sharrock, deputy chair of the BMA's England GP committee, said, "This stark warning from the college is one that the government can ill afford to ignore."

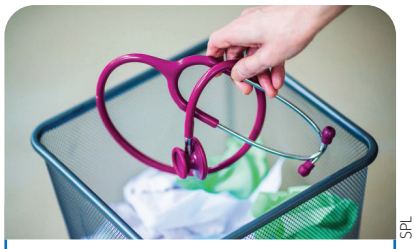
Many areas highlighted as needing urgent attention—including premises, IT, bureaucracy, and resourcing—were ones the BMA "has raised continuously" with the government, he said. "The government must also tackle punitive pension rules that are forcing doctors to retire or reduce their hours when the health service and patients need them most."

Wes Streeting, the shadow health and social care secretary, said the Conservatives were "breaking" their 2019 manifesto commitment to deliver 6000 extra GPs by 2024-5 and that 300 general practices had closed since the pledge was made. He added that a Labour party analysis of NHS data show there were 32 200 GPs in 2013, which compares with 27 700 today.

The Department of Health and Social Care was approached for comment but had not responded by the time of publication.

Ingrid Torjesen, *The BMJ*

Cite this as: *BMJ* 2022;377:o1535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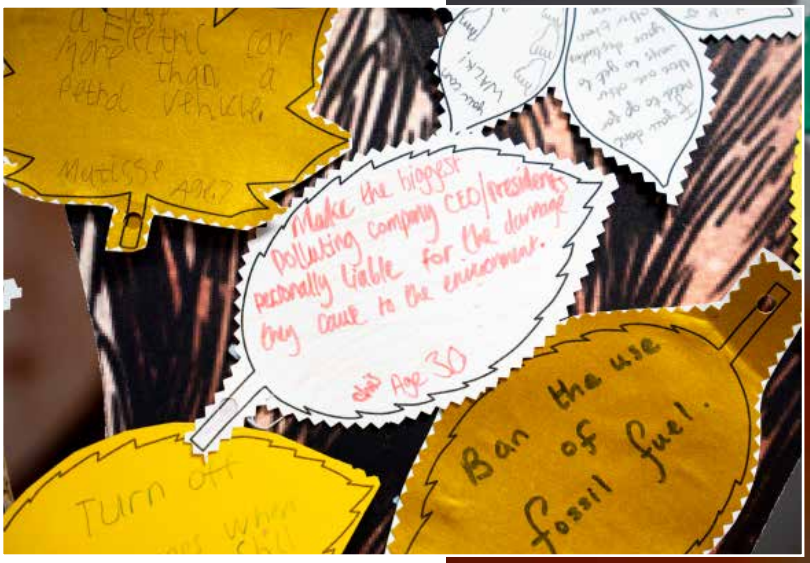
Of the 1262 GP and trainee respondents to the survey, 42% said they were likely to quit the profession in the next five years—with 10% doing so in the next year and 19% in the next two years



THE BIG PICTURE

Call for root and branch reform of air pollution

Children and teenagers at King's College Hospital in London marked this year's Clean Air Day by writing messages to help improve their air quality, on leaves that were displayed on a tree.

Other hospitals, schools, community groups, and councils across the country held their own events on 16 June to educate the public on the effects on health of air pollution. Children are disproportionately affected: in some areas of London children's lung capacity is reduced by as much as 10%.

Health professionals and patients were encouraged to demand that the government tighten air pollution limits, in line with the latest WHO recommendations. Anyone can check the levels of air pollution where they live or work at addresspollution.org. If levels are above WHO's recommended limits, you are urged to contact your council and MP to ask them to take action.

Alison Shepherd, *The BMJ*

Cite this as: *BMJ* 2022;377:o1576

People could cut down on using cars by sharing when going to shopping
James aged 6.
Just 40 min walking helps your lungs to get fresh air
Your lung function
Plus it's so beneficial to the environment!

EDITORIAL

The government's half baked food strategy

Human and planetary health will pay the price for this huge missed opportunity

The government's new food strategy for England[1] is its response to an independent review led by Henry Dimbleby, non-executive director of the Department for Environment, Farming and Rural Affairs.[2] His review provided a penetrating analysis of the seemingly intractable problems of the food system, showing it is possible to envision transformation in the interests of human and planetary health.

The review framed the challenges as arising from system failures and explored many domains including health, local and global environments, employment, education, and the economy. It showed the wide ranging external costs of the food system—including health effects mediated by unhealthy diets as well as pollution, climate change, low wages, inequalities, and food insecurity. Dimbleby concluded with 14 policy recommendations grounded in pragmatic and economic realities, encompassing fiscal and regulatory levers, subsidies, and industry incentives.

Disappointing response

The resulting government food strategy, published on 13 June, is disappointing, particularly from a public health perspective. While acknowledging the work of Dimbleby and his team, the strategy offers several alternative framings, positioning the proposals as about tackling the challenges of the coronavirus pandemic and Ukraine war, and seizing opportunities for post-Brexit trade deals while tackling the government's levelling-up agenda, rather than fixing system failures. The government also wants personal choices to drive demand for a healthier food system.

This framing is unhelpful for many reasons. The government argues that any measures that might increase food prices (such as more levies or marketing restrictions) would disadvantage poor people. However, such policies tend to be progressive, reducing inequalities in consumption of unhealthy foods and related outcomes,[3] and are supported by the public.[4]

WIKTOR SZYMANOWICZ/GETTY IMAGES

The strategy fails to get to grips with the nature of the challenge

Much is made of opportunities for economic growth in areas such as protein alternatives to meat. But growth in consumption of highly processed foods (including those that are vegetable based) is an important contributor to diet related ill health, which the strategy should address. Ultra-processed foods are associated in longitudinal studies with excess weight gain and increases in non-communicable diseases.[5]

The relentless pursuit of profit through value added processed foods is a big driver of what Dimbleby termed the "junk food cycle," which is at the core of current food system challenges. What we need is a system that values health and sustainability alongside profitability,[6] and this understanding is largely absent from the government's proposals.

The failure of the policy document to engage with Dimbleby's arguments for system change means that the proposed policies are not likely to shift the system in ways that will benefit population health. The most glaring omission is Dimbleby's proposed tax on salt and sugar as ingredients in manufactured foods, accompanied by associated subsidies for healthier foods—a combination that has a sound rationale.[7,8] The new tax was intended to build on the soft drinks industry levy, which emerging evidence shows is effective.[9]

Unmet recommendations

Overall, the food strategy falls a long way short of the ambition set out in Dimbleby's report. Of the 14 recommendations, only one is fully met (recommendation 5: funding school holiday activities and food programmes for the next three years), but this commitment was previously made.[12] Of the remaining 13, five are partly included, sometimes with considerable delays. For example, Dimbleby recommended a "community eatwell programme," but the food strategy commits only to a set of pilots to test place based interventions.

Dimbleby's well founded proposals to extend eligibility for free school meals and expand the healthy start scheme are nowhere to be seen; nor is the proposed "eat and learn" initiative for primary schools.

The government's food strategy fails to get to grips with the nature of the challenge, underestimates the severity and urgency of the problems, and is a missed opportunity to implement policies that could leverage change in the food system. The government has signalled that further policies may appear in the forthcoming health disparities white paper.[1] But, with the recent postponement of the 9 pm watershed ban on unhealthy food advertising and ban on price promotions[13]—already legislated in the Health and Social Care Bill—further regulation of the food system seems unlikely. With obesity rates continuing to rise, the food strategy is a huge missed opportunity for which human and planetary health will pay the price.

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Cite this as: *BMJ* 2022;377:o1520

Find the full version with references at http://dx.doi.org/10.1136/bmj.o1520

OPINION, p 24

EDITORIAL

Comorbidities and covid-19

Better understanding is essential for health system planning

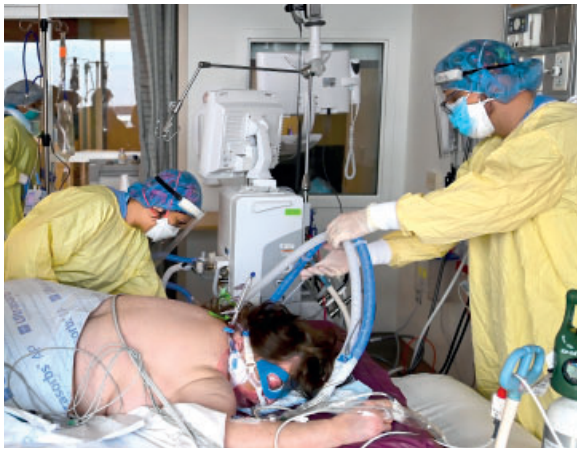
Over 530 million people worldwide are estimated to have had covid-19 by June 2022, resulting in more than 6.3 million deaths.[1] Although most people have few symptoms or mild to moderate illness, a substantial minority are at higher risk of more severe disease (requiring hospital admission) and adverse outcomes, including death and long covid. This is particularly true for people with comorbidities. Our understanding of which conditions increase risk, and their relative importance to adverse outcomes is still evolving.

Initial case series, often unadjusted and with limited generalisability, provided preliminary insights.[2] Subsequently, increasing numbers of higher quality observational studies have attempted to unpick these associations. The US Centers for Disease Control and Prevention regularly reviews all such studies to update the list of conditions associated with greater risk of severe covid-19 and death.[3]

While risks generally increase with age and are higher among men, strong evidence now shows increased risks for people with various health conditions, including chronic kidney disease, diabetes, lung and liver diseases, cardiovascular disease, obesity, immunodeficiency, certain disabilities, and mental health conditions.

Relative risks

Risks are highest for people with complicated diabetes, obesity, and anxiety related disorders (relative risk about 1.3 compared with people without these conditions), and less for those with cardiovascular disease (relative risk roughly 1.1).[4] Evidence is more limited for other conditions such as overweight, sickle cell disease, and substance use disorders and inconsistent for asthma, hypertension, and viral hepatitis.



NATHAN DENETTE/PA

One in five people worldwide are estimated to be at higher risk of adverse covid outcomes

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Shamil Haroon, associate clinical professor in public health

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Although the exact mechanisms by which pre-existing conditions influence disease susceptibility and severity are not known, inflammatory and hormonal pathways are postulated,[5] as well as social factors such as living in crowded or institutionalised settings.[6]

One in five people worldwide are estimated to be at higher risk of adverse covid-19 outcomes based on the prevalence of chronic conditions.[7] Risk increases with age and with greater number of underlying conditions. Compared with someone younger than 40 years, the risk of death increases fourfold for people aged 50-64, and more than 10-fold for those aged over 85.[8] Similarly, compared with people with no underlying conditions, the risk of death is 1.5 and 3.8 times higher for those with one comorbidity and over 10 comorbidities, respectively.[4]

Although most people with covid-19 recover fully, some have longer term symptoms. A UK analysis of primary care records for 486 149 community patients with confirmed covid-19 showed that reporting persistent symptoms beyond 12 weeks was associated with many pre-existing conditions, including chronic obstructive pulmonary disease, fibromyalgia, anxiety, and coeliac disease, in addition to risk factors such as obesity, smoking, being female, and socioeconomic deprivation.[15]

Furthermore, evidence is growing that new chronic diseases can occur after acute covid-19. Data from a US administrative claims database showed that 14% of adults who had had covid-19 developed new clinical conditions within six months; a 1.65% higher incidence than that seen after other viral infections.[16] Clinical sequelae included interstitial lung disease, respiratory failure, congestive heart failure, arrythmia, and type 2 diabetes.[16] The cluster of symptoms and clinical outcomes differed by age, between men and women, and between those who were and were not admitted to hospital.

Mental health

Although pre-existing conditions and hospital admission were associated with higher risk overall, some outcomes, such as mental health diagnoses, were increased irrespective of age and comorbidities.[16]

Risk of SARS-CoV-2 infection, severe disease, and death have reduced in populations with high vaccine uptake.[18] Nevertheless, breakthrough infection still occurs, and there is some evidence that older people (>65 years) and those with underlying conditions remain at greatest risk, possibly because vaccine effectiveness wanes more quickly in these groups.[19 20]

We now have a better understanding of the conditions that increase risk of severe covid-19, but better quantification of the relation between comorbidities and different outcomes and the populations at risk is essential for future health system planning. Such information will also support policy decisions, allowing consideration of the differential economic, social, and health effects of protective interventions, including societal restriction.

Cite this as: *BMJ* 2022;377:o1431

Find the full version with references at http://dx.doi.org/10.1136/bmj.o1431

BMJ INVESTIGATION

Led astray? Industry's influence on drug and device watchdogs

Patients and doctors expect regulators to provide an unbiased, rigorous assessment of investigational medicines before they hit the market. But do they have enough independence from the companies they are meant to regulate? **Maryanne Demasi** investigates

Over the past decades, regulatory agencies have seen large proportions of their budgets funded by the industry they are sworn to regulate.

In 1992, the US Congress passed the Prescription Drug User Fee Act (PDUFA), allowing industry to fund the US Food and Drug Administration (FDA) directly through "user fees" intended to support the cost of swiftly reviewing drug applications. With the act, the FDA moved from a fully taxpayer funded entity to one supplemented by industry money. Net PDUFA fees collected have increased 30 fold—from around $29m in 1993 to $884m in 2016.

In Europe, industry fees funded 20% of the new EU-wide regulator, the European Medicines Agency (EMA), in 1995. By 2010 that had risen to 75%; today it is 89%.

In 2005 in the UK, the House of Commons' health committee evaluated the influence of the drug industry on health policy, including the Medicines and Healthcare Products Regulatory Agency (MHRA). The committee was concerned that industry funding could lead the agency to "lose sight of the need to protect and promote public health above all else as it seeks to win fee income from the companies." But nearly two decades on, little has changed, and industry funding of drug regulators has become the international norm.

The BMJ asked six leading regulators, in Australia, Canada, Europe, Japan, the UK, and US, a series of questions about their funding, transparency in their decision making (and of data), and the rate at which new drugs are approved. We found that industry money permeates the globe's leading regulators, raising questions about their independence, especially in the wake of a string of drug and device scandals.

Industry fees

Industry money saturates the globe's leading regulators. *The BMJ* found that the majority of regulators' budget—particularly the portion focused on drugs—is derived from industry fees (table).

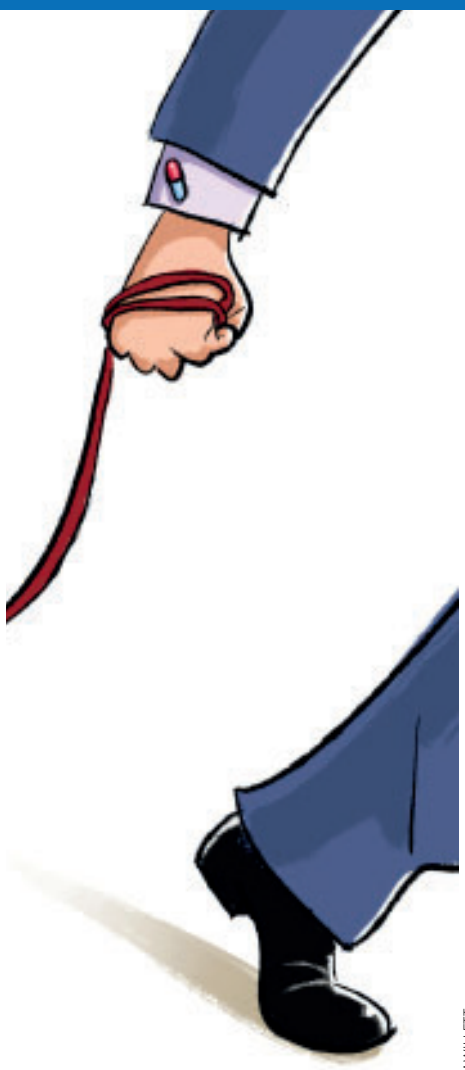
Of the six regulators, Australia had the highest proportion of budget from industry fees (96%) and in 2020-2021 approved more than nine of every 10 drug company applications. Australia's Therapeutic Goods Administration (TGA) firmly denies that its almost exclusive reliance on pharmaceutical industry funding is a conflict of interest (COI). In response to a query, the agency said, "All fees and charges are prescribed in our legislation. To provide transparency, the TGA fees and charges are published on the TGA website."

But for decades academics have raised questions about the influence funding has on regulatory decisions, especially in the wake of a string of drug and device scandals—including opioids, Alzheimer's drugs, influenza antivirals, pelvic mesh, joint prostheses, breast and contraceptive implants, cardiac stents, and pacemakers. An analysis of three decades of PDUFA in the US has shown how a reliance on industry fees is contributing to a decline in evidentiary standards, ultimately harming patients. In Australia, experts have called for a complete overhaul of the TGA's structure and function, arguing that the agency has become too close to industry.

Sociologist Donald Light of Rowan University in New Jersey, who has spent decades studying drug regulation, says, "Like the FDA, the TGA was founded to be an independent institute. However, being largely funded by fees from the companies whose products it is

They're not rigorous, they're not independent, they are selective, and they withhold data
Donald Light

Reliance on industry fees is contributing to a decline in evidentiary standards, ultimately harming patients



MALCOLM WILLETT

charged to evaluate is a fundamental conflict of interest and a prime example of institutional corruption."

Light says the problem with drug regulators is widespread. Even the FDA—the most well funded regulator—reports 65% of its funding for the evaluation of drugs comes from industry user fees, and over the years user fees have expanded to generic drugs, biosimilars, and medical devices.

"It's the opposite of having a trustworthy organisation independently and rigorously assessing medicines. They're not rigorous, they're not independent, they are selective, and they withhold data. Doctors and patients must appreciate how deeply and extensively drug regulators can't be trusted so long as they are captured by industry funding," says Light.

External advisers

Concern over COIs is not just directed at those who work for the regulators but extends to the advisory panels intended to provide regulators with independent expert advice. A *BMJ* investigation last year found several expert advisers for covid-19 vaccine advisory committees in the UK and US had financial ties with vaccine manufacturers—ties the regulators judged as acceptable.

Concern over conflict of interest extends to the regulators' advisory panels

A large study that investigated the impact of COIs among FDA advisory committee members over 15 years found that those with financial interests solely in the sponsoring firm were more likely to vote in favour of the sponsor's product, and that people who served on advisory boards solely for the sponsor were significantly more likely to vote in favour of the sponsor's product. Research exploring the matter from a cross-national comparative perspective is lacking, however.

In Australia, the membership of the TGA's Advisory Committee on Vaccines is published on the agency's website. The forms for recording past and current financial and non-financial interests are not, however, made public. A Freedom of Information (FOI) Act request for their financial disclosures in August 2020 had names and details of the disclosures redacted. After seeking additional details, the TGA indicated that this was "personal information" and therefore usually exempt under the FOI Act. Subsequently, panel members were approached directly by

HOW THE REGULATORS COMPARE

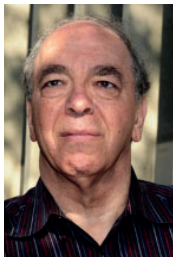
	Australia TGA	Europe EMA	UK MHRA	Japan PMDA	USA FDA	Canada HC
Budgets and fees						
Proportion of budget derived from industry[1]	96%	89%	86%	85%	65%	50.5%
Total annual budget[1]	AU$170m (£95m)	€386m (£331m)	£159m	¥29.1bn (£175m)	US$6.1bn (£5bn)	C$2.7bn (£1.7bn)
Transparency, COIs, and data						
Proportion of covid-19 vaccine committee members that declared financial COIs	50%	3%	32%	75%	<10%	0%
Declared COIs available as public information	No	Yes	Yes	Yes	Yes	No
Regulator routinely receives patient level datasets*	No	No	No	Yes	Yes	No
Drug approvals						
Proportion of decisions to approve new medicines (v not approve)	94%	88%	98.5%	Not disclosed	69%^ 29%#	83%
Proportion of new drugs approved through expedited pathways in 2020	20%	50%	36%[2]	26%	68%	16%

Note: Data sources and methods are detailed in the supplemental file
[1]Data refer to the year 2021 calendar year or 2020-2021 fiscal year
[2]Many agencies regulate beyond medical products (for example, food); where possible (US, Canada), we used the proportion of the human drugs budget
*Agencies still have the ability to request patient level datasets from sponsors
^FDA Center for Drug Evaluation and Research
#FDA Center for Biologics Evaluation and Research
FDA: US Food and Drug Administration; EMA: European Medicines Agency; TGA: Therapeutic Goods Administration; HC: Health Canada; MHRA: Medicines and Healthcare Products Regulatory Agency; PMDA: Pharmaceuticals and Medical Devices Agency

email and asked whether they would be willing to publish their declarations, but there was no response. Instead, they referred the enquiry back to the TGA which was willing to reveal that 5 of 10 committee members disclosed COIs—but did not say which members or provide any specifics, adding that "these interests usually do not give rise to a conflict." The agency's policy allows for excluding members from certain meetings because of a COI, but details of the COI and reasons for the exclusion are not published.

Joel Lexchin, a drug policy researcher at York University in Toronto, says, "People should know about any financial COIs that those giving advice have so that they can evaluate whether those COIs have influenced the advice they are hearing. People need to be able to trust what they hear from public health officials and a lack of transparency erodes trust."

Of the six major regulators approached by *The BMJ*, only Canada's drug regulators did not routinely seek advice from an independent committee and its evaluation team was the only one completely free of financial COIs. European, Japanese, and UK regulators publish a list of members with their full declarations online for public access, while the FDA judges COIs on a meeting-by-meeting basis and can grant waivers allowing participation of members (see table, page 13).



People need to be able to trust what they hear from public health officials
Joel Lexchin

All major regulators offer expedited pathways that are used in a significant proportion of approvals

MALCOLM WILLETT

Transparency, conflicts of interest, and data

Over the past decade, there have been improvements in the transparency and accessibility of trial data. Today the EMA and Health Canada (HC) both post to their website substantial amounts of clinical data received by the drug sponsor. In addition, Japan's Pharmaceuticals and Medical Devices Agency (PMDA) posts non-clinical data summaries.

Most regulatory agencies do not, however, undertake their own assessment of individual patient data, but rather rely on summaries prepared by the drug sponsor. The TGA, for example, says it conducts its covid-19 vaccine assessments based on "the information provided by the vaccine's sponsor." According to a FOI request from last May, the TGA said it had not seen the source data from the covid-19 vaccine trials. Rather, the agency evaluated the manufacturer's "aggregate or pooled data." The TGA does not have the individual participant level datasets pertaining to the covid-19 vaccine trials, which are held by the vaccine manufacturer.

"The TGA should not be relying on the analysis of that data produced by the drug companies. Rather the TGA should be reanalysing the source data," says Lexchin. "Further, the TGA should be holding public hearings before new drugs are approved so that it can hear from members of the public and outside scientists."

The TGA is hardly alone. Among global regulators, only two—the FDA and PMDA—routinely obtain patient level datasets. And neither proactively publish these data. Recently, a group of more than 80 professors and researchers called the Public Health and Medical Professionals for Transparency sued the FDA for access to all the data which the agency used to grant licensure for Pfizer's covid-19 vaccine. The FDA argued that the burden on the agency was too great and requested that it be allowed to release appropriately redacted documents at the rate of 500 pages a month, a speed that would take approximately 75 years to complete. In a win for transparency advocates, this was overturned by a US Federal Court Judge, ruling that the FDA would need to turn over all the appropriately redacted data within eight months. Pfizer sought to intervene to ensure "information that is exempt from disclosure under the FOI act is not disclosed inappropriately," but its request was denied.

Speedy approvals

Following the AIDS crisis of the 1980s and 1990s, PDUFA "user fees" were introduced in the US to fund additional staff to help speed the approval of new treatments. Since then, there has been concern over the way it moulded the regulatory review process—for example, by creating "PDUFA dates," deadlines for the FDA to review applications, and a host of "expedited pathways" for speeding drugs to market. The practice is now a global norm.

Today, all major regulators offer expedited pathways that are used in a significant proportion of new drug approvals. In 2020, 68% of drug approvals in the US were through expedited pathways, 50% in Europe, and 36% in the UK.

Accelerated approval processes have resulted in new drugs that were more likely to be withdrawn for safety reasons, more likely to carry a subsequent black box warning, and more likely to have one or more dosage forms voluntarily discontinued by the manufacturer.

"One reason why drugs approved by the FDA so close to the deadline may have had more safety problems is that the FDA reviewers were afraid of going over the deadline for making a decision and thereby jeopardising the revenue that the FDA gets from drug companies," says Lexchin.

Aaron Kesselheim, professor of medicine at Brigham and Women's Hospital and Harvard Medical School, adds that accelerated approvals generally have a lower burden of proof for efficacy.

"The accelerated approval pathway explicitly changes the underlying efficacy 'standard' in

THE REGULATOR-INDUSTRY REVOLVING DOOR

Critics argue that regulatory capture is not only being baked in by the way in which agencies are funded, but also staffed. A "revolving door" has seen many agency officials end up working or consulting for the same companies they regulated.

At the FDA, generally regarded as the world's premier regulator, nine out of 10 of its past commissioners between 2006 and 2019 went on to secure roles linked with pharmaceutical companies, and its 11th and most recent, Stephen Hahn (top), is working for Flagship Pioneering, a company that acts as an incubator for new biopharmaceutical companies.

In February, the US Senate narrowly confirmed Robert Califf (middle), a cardiologist, to lead the FDA, a position he previously held under the Obama administration. Califf's rehiring led some senators to argue that his ties to the pharmaceutical industry made him unfit for the role. Financial disclosure forms show Califf was paid $2.7m by Verily Life Sciences and in 2021 held a position on the boards of two pharmaceutical companies, AmyriAD and Centessa Pharmaceuticals.

After resigning from a senior position in the FDA's vaccine division, Philip Krause secured a role in the biotech sector. One study found more than a quarter of the FDA employees who approved cancer and haematology drugs between 2001 and 2010 left the agency and now work or consult for pharmaceutical companies.

Beyond the FDA, Ian Hudson (bottom), chief executive of the UK's MHRA between 2013 and 2019, now serves on the board of biotech company Sensyne Health and is a senior adviser for the Bill and Melinda Gates Foundation. Before joining the MHRA, Hudson held various senior roles at pharmaceutical giant SmithKline Beecham.

that it allows approval based on changes to a surrogate measure that is not well validated, and is only reasonably likely to predict clinical benefit," says Kesselheim who resigned from an FDA advisory committee last year in protest over the agency's approval of a controversial Alzheimer's drug. Following the committee's vote against approval, the FDA shifted the goal posts, approving aducanumab through an accelerated approval based on the disputed surrogate measure of lowered visible β-amyloid protein levels.

Courtney Davis, a medical and political sociologist at Kings College London, says that a general taxation or a drug company levy would be better options to fund regulators. "PDUFA is the worst kind of arrangement since it allows industry to shape FDA policies and priorities in a very direct way. Each time PDUFA was reauthorised, industry had a seat at the table to renegotiate the terms of its funding and determine which performance metrics and goals the agency should be evaluated by. Hence the FDA's focus on making quicker and quicker approval decisions—even for drugs not judged to be therapeutically important for patients."

User fees is the worst kind of arrangement since it allows industry to shape policies and priorities in a direct way
Courtney Davis

Reform

Critics argue that both small and large structural changes are necessary to help restore regulators' ability to carry out independent decision making, free of industry influence.

Lexchin outlines several reforms for advisory committees, including that all financial COIs, including the dollar amount of payment, be disclosed along with an explanation about why these people cannot be replaced with someone without COIs. Lexchin's suggestions align with longstanding recommendations from the US Institute of Medicine.

Kesselheim says one crucial step is for the FDA to re-examine its approach to expedited approvals. "There needs to be more clarity about the endpoints and what the scientific basis is for choosing an endpoint." Kesselheim says greater assurances are needed that the endpoints selected truly are "reasonably likely" to predict clinical benefit, as the FDA's accelerated approval standard requires. For expedited drugs, "you also need to make sure that a confirmatory trial is underway at the time of approval, so that it can be completed in a timely fashion. And if it isn't completed or the trial is negative, then you need to think about how you might pull back on the product," he says.

Light says it is no longer possible for doctors and patients to receive unbiased, rigorous evaluations from drug regulators. He suggests setting up non-profit organisations like Germany's Institute for Quality and Efficiency in Health Care, which was established to carry out evaluations of approved drugs that are independent of industry, rigorous, unbiased, and transparent. "The question is why weren't drug regulators doing this trustworthy, transparent, rigorous, unbiased job in the first place?" says Light.

While historical drug disasters like sulfanilamide and thalidomide raised the stature of regulatory agencies, Light argues regulators now need their own watchdog and is calling for a drug and vaccine safety board, independent of the drug regulator, with the authority, staffing, and funds to investigate incidents of patient harm. "Countries have independent safety boards for airlines and their passengers. Why not for drugs and patients too?" says Light.

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Cite this as: *BMJ* 2022;377:o1538

MEDICAL TRAINING

Why medicine must catch up on interprofessional education for a safer NHS

Different professions training together is often cited as a possible solution in health service safety reports. Yet much remains to be done to implement it—and to ensure medicine doesn't get left behind, finds **Emma Wilkinson**

We give students learning outcomes that mean they need each other
Liz Anderson

A long line of reports into safety in the NHS, including most recently Donna Ockenden's review of maternity services in Shrewsbury, have raised concerns about a lack of communication and "conflicting agendas" between healthcare staff. Although the challenges of team working are not specific to healthcare, this is a setting where the "effect of poor relationships and collaboration can have catastrophic long-term consequences," Ockenden noted.

One oft cited solution is making better use of interprofessional education at the undergraduate level and beyond. As early as the 1970s the World Health Organization made the case that health professionals learning together would build a stronger workforce that could respond better to the needs of the population. Yet current medical students paint a varied picture of their experience: from a few tickbox exercises through to some noting that learning from and with other groups was the most useful thing they had done. And experts say that even more is needed to improve interprofessional education after graduation.

Lack of understanding and progress

The UK based Centre for the Advancement of Interprofessional Education (CAIPE) defines interprofessional education as "occasions when members or students of two or more professions learn with, from, and about each other to improve collaboration and the quality of care and services."

CAIPE's joint chair Liz Anderson, who also leads on patient safety and interprofessional education at Leicester Medical School, says there is often a lack of understanding about what interprofessional education really is. It is not simply multidisciplinary training where different healthcare professionals come together to train on a topic of common value, she explains. "[At Leicester] we put a group of students together, give them learning outcomes that mean they need each other, and send them into the clinical context, going and talking to people and working out their problems."

At its core should be the patient experience and patient safety, says Sandra Nicholson, founding dean at Three Counties Medical School in Worcester. "It isn't necessarily, 'Oh yes, let's learn to work in teams'—as important as that is—but it's to learn to work in teams to the benefit of a patient."

In its 2010 framework for interprofessional education WHO said, "After almost 50 years of inquiry, there is now sufficient evidence to indicate that interprofessional education enables effective collaborative practice which in turn optimises health services, strengthens health systems and improves health outcomes."

Yet developments have been slow, says Andreas Xyrichis, senior lecturer in nursing at King's College London. "We have known this for a while, and we should be making faster progress.

"One of the challenges is that we're trying to change something that is so traditional and ingrained, and introducing that level of change is not easy, for many reasons."

Starting from scratch

A new medical school is an opportunity to start from scratch, says Nicholson, whose first cohort at Three Counties begins in September. "With very established schools, if you're trying to introduce a different way of thinking about how to deliver education it's difficult to disrupt the timetable. And if you're trying to put timetables from different professions together, it's even worse."

At Three Counties there will be weekly examples of interprofessional learning, which could be something in a lecture, a talk, or a session from another health professional—but that is only the beginning, Nicholson says. As a graduate course, some of the students may already have experience working as a healthcare assistant or nurse, she explains. "They're going to come in with their own preconceived ideas of what it is to work in a team, but we want to give them opportunities to see it from the perspective of other healthcare professions." This will involve periods of shadowing, some authentic simulation exercises, and building on those experiences as their knowledge develops.

"One of the sessions we're running towards the end of the first year is about discharging a patient into the community from a hospital setting, with students from multiple professions working out the problems to provide a safe discharge, to understand what each role does and to see it working."

This will all build on work already done by physician associates and colleagues in occupational therapy and in nursing and midwifery, among others, adds Nicholson.

It's about learning to work in teams to the benefit of a patient
Sandra Nicholson

We're trying to change something that is so traditional and ingrained
Andreas Xyrichis

It does make you more amenable to working in a team
Issy Walker

Medicine left behind

It does seem that other professions, including nursing and pharmacy, have adopted such an approach more commonly in the undergraduate space, says Anderson, with medicine lagging behind. Some of this may be due to medicolegal issues, with doctors bearing the responsibility of medical decision making.

One of the major barriers to interprofessional education identified by CAIPE in a paper in 2009 and a later review was the professional identity tied up in everyday practice. "We cannot change this without medicine fully buying into it," Anderson says. "What we're trying to do through interprofessional education is flatten that hierarchy and say that, actually, the best care for the patient depends on recognising the value we each bring." She believes the profession is waking up to this.

Issy Walker has just finished a medical degree at Nottingham University, where she was one of the first students to experience training through its Centre for Interprofessional Learning. Once or twice a year they were set a task or project with other healthcare students. "It gave us an appreciation of what others do early on, and it does make you more amenable to working in a team."

Walker says it could go further, including in clinical skills simulations where medical students have to take the role of a nurse or healthcare assistant. "It would have been really useful to do this with other professions."

The centre's director, Maria Kordowicz, says her team is working across nine health and social care undergraduate programmes, and this includes working with clinical skills teams on how best to "provide an enhanced IPE [interprofessional education] experience."

She adds, "We are also increasingly making connections with local health trusts and NHS England to deliver advisory and team development support around interprofessional working in practice."

Schwartz rounds: flattening hierarchies

One model of interprofessional learning gaining ground in the UK is Schwartz rounds. These are group forums that give staff members an opportunity to reflect on the emotional and social aspects of working in healthcare. A session is often based on a theme, and stories are shared by participants. Evidence indicates that the sessions reduce psychological distress and improve staff wellbeing and teamwork.

Although they are more likely to be found in hospitals, primary care settings and universities are also starting to adopt the approach as a way to better understand the perspectives of other health professionals.

Rini Paul, a GP in north London and teacher development lead at King's College London, says that what started as a small Schwartz round project in 2016 is now open to health and social care professionals across five boroughs in north and central London. "We were the first people to do it in community, in a primary care setting, and they're just different from any other spaces for GPs or as a medic that I've been to, because of the flattening of hierarchies."

King's is also in the second year of running a pilot for students across medicine, dentistry, nursing, adult and child mental health, physiotherapy, and pharmacy. Numbers are small because it's not mandatory and it is hard to explain the value to those who have not experienced it, Paul says. "There's lots of evidence that, while it's not about problem solving, what happens is that they go back onto placements and maybe approach things slightly differently. I think it breaks down a lot of those silos."

Paul adds that her team has secured more funding for the rounds to continue in the community—and they will be doing six sessions a year for the moment, all online. "The thing I found frustrating is that our Schwartz rounds in primary care were put on hold in the pandemic despite the fact everyone talks about supporting the workforce, yet this is absolutely the kind of thing our workforce needs."

We work across nine health and social care undergraduate programmes
Maria Kordowicz

Our job is to create students who can understand what flexibility looks like
Laura Chalmers

Management should be included among all the other clinicians
Mateen Jiwani

From shared learning to collaborative practice

For the past 20 years Aberdeen and Robert Gordon Universities have worked together on collaborative learning that now includes 13 professions. It starts in year 1, with 1500 students witnessing a dramatic portrayal of a very distressed patient being turned away from a general practice for being abusive. Students then break into teams to discuss the scenario from several angles, before returning to view an alternative ending to the scenario.

Laura Chalmers, head of the Centre of Collaborative and Interprofessional Practice at Robert Gordon University, says that over time they have moved from doing a bit of shared learning to proper collaborative practice throughout the curriculum. "It's much more indepth around the inherent skills that it takes to consult and to think together, to actively listen, and to make collaborative decisions."

They can't teach just for working in the NHS, she adds. "We have to teach them to be open, have empathy, and be able to adapt constantly to working in different teams. Our job is to create students who can understand what flexibility looks like."

Their most recent development is to place a team of different healthcare students into a placement in a general practice in a deprived area to "function together."

And before the covid-19 pandemic Chalmers visited Germany to see an interprofessional training ward, a clinical ward where students from more than one healthcare profession collaborate in caring for patients, a model used more widely in other European countries, including Sweden. "I am about to resurrect the conversation about interprofessional training wards, because there's definite evidence of the impact that it gets patients out of hospital faster," Chalmers says.

"It takes a lot of courage for people to let go of the governance part of that, but we are working on a model with the health board around how we can make that happen."

Regulatory and policy support

What happens at undergraduate level should be the scaffold allowing further progress after qualification, says Xyrichis, including in things such as interprofessional training wards—but that takes funding. "Even though the whole thing started in the UK," he says, "we've now been taken over by countries like the US and Australia, mainly because there's more buy-in from regulators and the policy that nudges people along." This includes the different professions coming together to agree a consistent message, as well as sharing the best practice.

In its 2014 review, CAIPE concluded that sustained progress would depend on "concerted support from governmental, commissioning, regulatory and professional bodies in partnership with providers." It is now "lobbying hard" on the need to quantify the amount of interprofessional learning that must happen, Anderson says. It is in the process of writing standards that it hopes will be adopted, as well as updating the review of the evidence base.

"At the moment, the GMC, NMC, and Healthcare Professionals Council just said that you must offer it—it's a tickbox," she says. "But actually, what is the quality, how much have you offered, and is it fit for purpose? Those are the questions we are asking."

Although ad hoc continuing professional development is often based on simulations, these are often geared to doctors and perhaps not done as well as they could be in terms of teams learning from each other, says Anderson. The use of interprofessional education at the postgraduate level—and not just multiprofessional learning, where teams do courses together—is something that needs "much more attention," she thinks. Examples of best practice are therefore hard to come by, but one gaining ground is the proliferation of interprofessional Schwartz rounds and their move into primary care (see box page 17).

Including managers

Mateen Jiwani, a GP with an interest in digital health and healthcare management, says one of the things most often absent in interprofessional education is putting managers together with clinicians. "We teach a certain way because we think that's what you need, but the problem is that people don't understand what's happening around them, and what other people are doing and involved in, and how to make that a better system for patients."

He adds, "If people start training together, chances are that when they're working together they've got a better relationship. If you're going to fix the system overall that should include management among all the other clinicians.

"I think the pandemic made a big difference because on the wards there was no hierarchy any more," Jiwani says. Doctors, nurses, healthcare assistants, and other members of the team were all working outside their usual roles. "That has made a difference for the good—it's whether we sustain it."

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Cite this as: *BMJ* 2022;377:o1547