

this week

ENERGY BILLS page 338 • **NITROUS OXIDE** page 340 • **MONKEYPOX** page 342



STEFAN ROUSSEAU/AFPI/GETTY

Truss's priority has to be NHS, say doctors

Liz Truss, the new prime minister, must act decisively on the key challenges facing the NHS and social care or face an “uncontrollable crisis” this winter, doctors’ leaders have warned.

The most pressing item in Truss’s in-tray will be tackling soaring energy bills that will have severe health implications if people, particularly if they are elderly or clinically vulnerable, are forced to choose between food and heating.

During the Conservative leadership contest the NHS received relatively little attention, but in her acceptance speech on Monday Truss pledged to “deliver on the National Health Service.” However, she will have to square this with her promise to reverse the rise in national insurance, which aimed to provide cash to help clear the backlog of procedures after covid and in the longer term to pay for better social care.

In a letter to Truss, the BMA chair of council, Philip Banfield, outlined the extreme pressure facing the NHS, with record waiting times, ambulances queuing outside emergency departments, delayed discharge because social care is overwhelmed, and plummeting staff numbers.

Banfield urged Truss “not to see this problem from Whitehall or through

sanitised visits” but through the eyes of NHS staff, who were “taking the unenviable decisions over which patient to prioritise and which to leave waiting in distress.”

Richard Murray, chief executive of the King’s Fund, also called for urgent action. “If Liz Truss doesn’t prioritise action to shore up health and care services, she can expect the NHS and social care to slide even deeper into crisis.”

With more than 130 000 posts in secondary care in England vacant, Banfield warned that more must be done to retain healthcare professionals. In his letter he told Truss that reconsidering the recent pay award and tackling pension taxation were crucial to boosting staff morale.

Saffron Cordery, interim chief executive of NHS Providers, called on Truss’s government to provide a “fully funded long term workforce plan for the NHS sooner rather than later.” She added that the failure to fully fund this year’s below-inflation pay awards was a factor in trusts finding it “increasingly difficult to recruit and keep vital health workers.”

Cordery also called on Truss to deliver a commitment to build 40 hospitals by 2030.

Jacqui Wise, Kent
Cite this as: *BMJ* 2022;378:o2166

Liz Truss takes the applause of Tory MPs on becoming PM. The BMA has warned her to act urgently or the NHS will face an “uncontrollable crisis”

LATEST ONLINE

- WHO: Only half of world’s healthcare facilities have basic hygiene services
- Italy and Mexico turn to Cuban doctors to fill gaps in underserved regions
- White House says US public must have free and immediate access to government funded research



SEVEN DAYS IN

Disconnecting energy supplies can be “life threatening,” NHS chief warns



Clinically vulnerable people are being admitted to hospital after having their energy supplies disconnected, an NHS executive has warned the UK’s energy regulator.

Samantha Allen (left), chief executive of NHS North East and North Cumbria Integrated Care Board, wrote to Ofgem on 2 September to raise “serious concerns” over electricity and gas services being disconnected as a result of non-payment.

“It is my understanding that those people deemed clinically vulnerable cannot have their energy supply disconnected,” Allen wrote. “Having their energy supply terminated will be life threatening for some people.” She added that this will also place additional demand on the “already stretched health and social care services.”

The letter came after a report warned that 15 million people in the UK, or 55% of households, were expected to experience fuel poverty by January 2023.

Allen urged the regulator to work with energy suppliers to ensure that their lists of clinically vulnerable patients are “fully updated frequently and checked before considering terminating supply.” She also called for energy companies to adopt a similar policy to water companies, whereby domestic supplies cannot be cut off.

● OPINION, p 358

Elisabeth Mahase, *The BMJ* Cite this as: *BMJ* 2022;378:o2156

Covid vaccines

Moderna sues Pfizer over vaccine technology

The vaccine manufacturer Moderna is suing the US drug company Pfizer and its German partner, BioNTech, for patent infringement of mRNA technology used in the first covid-19 vaccines, which it says it developed before the pandemic. Moderna alleges in a lawsuit filed in the US and Germany that the companies copied two key elements of its intellectual property. The first is a “chemical modification” whereby a vaccine “avoids provoking an undesirable immune response,” and the second relates to the way both of the covid vaccines target the spike protein. Early in the pandemic Moderna said that it would not enforce patents of its covid vaccine, to help other drug companies develop their own vaccines.

England’s HRT tsar returns to vaccine role

The head of the government’s taskforce on hormone replacement therapy has returned to her role overseeing the vaccine taskforce, ahead of the rollout of the omicron booster programme this month. Madelaine McTernan was asked to take on the HRT role in April to tackle serious supply issues.

Four months later the access to HRT products has improved, but shortage protocols—which limit dispensing to three months’ supply and allow specified alternative products to be supplied if necessary—will remain in place for 12 HRT products, including some gels and creams that contain oestrogen.

UK begins booster campaign in care homes

The UK began its latest coronavirus vaccine booster campaign this week. From Monday 5 September around 1.6 million care home residents and staff and housebound people became eligible for the autumn dose. And from 7 September the NHS is inviting around seven million people, including over 75s, people who are immunosuppressed, and health and care workers, to book their covid booster vaccine. The programme will use Pfizer’s bivalent vaccine along with the Moderna bivalent vaccine to target both the omicron variant and the original covid strain.

US rolls out omicron specific boosters

The US plans to roll out coronavirus

vaccine boosters reformulated against the omicron variant. The Food and Drug Administration authorised updated boosters from Pfizer-BioNTech and from Moderna on 31 August. An expert advisory committee convened by the Centers for Disease Control and Prevention voted 13-1 to recommend their use. The Pfizer booster is authorised for use in people aged 12 and over and Moderna’s for over 18s. Both boosters will be offered to all eligible groups immediately.

Smoking

Vaping hits record levels among British adults

The proportion of adults in Britain who use e-cigarettes has increased this year to 8.3%, the highest rate ever, said a report from Action on Smoking and Health. It found that 4.3 million people used e-cigarettes, 57% of them ex-smokers. Only 1.3% of people who have never smoked a cigarette are current vapers. E-cigarettes are especially popular with young people: 11% of 18-24 year olds use them, the highest rate by age group.

Cigarette and drug use fall in young people

The percentage of schoolchildren aged 11-15 who smoke cigarettes has decreased to 3%, from 5% in 2018, show data from NHS Digital. Only 12% reported having ever smoked, down from 16% in 2018 and the lowest level ever recorded. The percentage of young people taking drugs has also fallen: 18% of pupils reported having ever done so, down from 24% in 2018. But vaping has increased, with 9% of secondary school pupils either regularly or occasionally using e-cigarettes in 2021, up from 6% in 2018.



Infectious disease

Legionella caused deaths in Argentina

The Pan American Health Organization has said that *Legionella* is the cause of a cluster of pneumonia cases associated with a health clinic in the province of Tucuman, Argentina. So far 11 cases have been identified, including four deaths of patients with comorbidities. The Argentina Ministry of Health and provincial health authorities are working to identify the source of infection and to implement appropriate control measures.



MEDICINE

Food safety

Listeria is linked to ready-to-eat smoked fish

The Food Standards Agency, Food Standards Scotland, and the UK Health Security Agency are reinforcing advice to vulnerable groups such as over 65s, anyone pregnant, or people with weakened immune systems to ensure that ready-to-eat smoked fish is thoroughly cooked before they eat it. This refers to chilled smoked fish products that would not normally be cooked at home before being eaten. Fourteen cases of listeriosis have been identified in England and Scotland since 2020, including eight this year, and most people affected report having eaten ready-to-eat smoked fish.



Vulnerable people are warned to cook smoked salmon after eight listeriosis cases this year

Pensions

Consultation begins on NHS pension changes

The government has launched a consultation on pension changes to make it easier for retired and partly retired NHS staff to return to the workforce or continue working over winter. Since March 2020 some of the pension scheme's rules on retiring and returning have been suspended, but these measures apply only until 31 October. The consultation will gather views on extending them to 31 March 2023 to help bolster the workforce ahead of winter.

Life expectancy

US has steepest fall in a century—almost three years

Life expectancy in the US fell for the second year running in 2021, said the Centers for Disease Control and Prevention. Life expectancy at birth has shrunk by almost three years, from 78.8 years in 2019 to 77.0 years in 2020 and then to 76.1 years in 2021. The groups most severely affected were Native Americans and Alaskan Natives, whose life expectancy has fallen by around six and a half years since 2019; from 2020 to 2021 alone it fell from 67.1 years to 65.2 years.

War in Ukraine

Healthcare facilities are targeted by Russia

Russia has carried out at least 500 attacks on Ukrainian health services since February, said WHO. Physicians for Human Rights said the Russians were targeting the health system as a war strategy, as they had done in Syria, and must be held accountable for violating international law. Christian



de Vos, the group's director of research and investigations, said the reported attacks "call out for justice and accountability."

Workforce

Almost one in 10 NHS posts are vacant

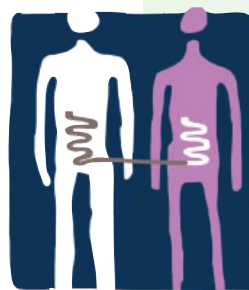
At the end of June 132 139 NHS roles (9.7%) were vacant, up from 105 855 at the end of March. The previous highest number for full time equivalent staff was 111 864, at the end of June 2019. Vacancies include 46 828 nursing posts (11.8% vacancy rate) and 10 582 doctors' posts (7.3%). NHS Providers' interim chief executive, Saffron Cordery, said the figures were "staggering and further proof that the NHS simply doesn't have enough staff to deliver everything being asked of it."

Cite this as: *BMJ* 2022;378:o2159

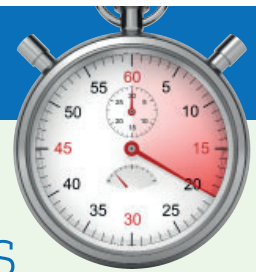
BACKLOG

Even without the pandemic, the NHS in England would have expected to see a waiting list of around 5.3 million people at the end of May 2022

[*QualityWatch, a joint programme by the Nuffield Trust and the Health Foundation*]



SIXTY SECONDS ON... FAECAL TRANSPLANTS



EVERYTHING COMES DOWN TO POO

Hundreds of people with recurrent bacterial infections could be treated with gut bacteria taken from a healthy donor's poo, after NICE recommended the treatment for recurring *Clostridium difficile* infection.

A GUT REACTION

C difficile infections can occur when the balance of bacteria in the bowel changes and can lead to diarrhoea. Infections range from mild to life threatening, and although they are often the result of taking antibiotics they are also initially treated with antibiotics.

(GRAM) POSITIVE NEWS

NICE has said a faecal microbiota transplant (FMT) will now be offered to people in England who have had two or more *C difficile* infections without successful treatment. The aim is to restore a healthy population of bacteria by delivering intestinal bacteria to the stomach or colon—either through an inserted tube or by an oral pill.

WHAT'S THE EVIDENCE?

Clinical evidence presented to NICE indicates an FMT could resolve up to 94% of infections. In four of the five randomised controlled trials they looked at—which included 274 adults—more infections were resolved with FMT than with antibiotic treatment. In the other trial no difference was seen.

FEELING FLUSH

NICE has said the treatment could save the NHS thousands of pounds, with modelling showing that FMT is cheaper than almost all the antibiotic options. As a bonus, the recommendation could also lead to a reduction in antibiotic use. NICE's interim director of medical technology, Mark Chapman, said, "Use of this treatment will help reduce the reliance on antibiotics and in turn reduce the chances of antimicrobial resistance."

POO'S IDEA?

FMT was first used 1700 years ago in China to treat patients with food poisoning or severe diarrhoea. Despite being considered a medical miracle as it brought patients back from the brink of death, the treatment didn't catch on, probably because the human faecal suspension was administered orally.

Elisabeth Mahase, *The BMJ*

Cite this as: *BMJ* 2022;378:o2152

Guidance on confirming infant deaths is reviewed after court case

Guidelines for confirming death in young babies are being reviewed amid concerns about a case in which an infant began to breathe after a diagnosis of brain stem death.

Guy's and St Thomas' NHS Trust applied to the High Court in June for a declaration that 2 month old "A" was dead and for authorisation to withdraw his ventilation and treatment. The boy had sustained a profound hypoxic ischaemic brain injury after a cardiac arrest. But before the case came to court a nurse observed him breathing spontaneously, and the declaration was rescinded.

At a High Court hearing in July Mr Justice Hayden appointed an independent expert, Joe Brierley, a paediatric intensivist at Great Ormond Street Hospital, to help understand why the brain stem

Baby A has raised important questions as to the confidence that can be placed in the code of practice

Mr Justice Hayden

tests were unreliable. Brierley found A to be deeply unconscious, with no response to stimulation, no purposeful movement, and with a Glasgow coma score of 3, the lowest possible. In his report Brierley said that most cases in world literature where infants who had been verified dead from neurological criteria and were later found to be alive involved errors in the test performance. But this was not so in A's case, as the tests were performed entirely in line with the Academy of Medical Royal Colleges' code of practice.

Complex parts of the brain

Brierley explained in his report that the brain stem was less likely than the more complex parts of the brain to be damaged by lack of oxygen and blood flow. As for A, it was now clear he had sustained a severe level of damage to the brain, demonstrated by MRI and electroencephalography, he said.

Hayden said the boy was dying, and continued ventilation would only protract death. Therefore, ventilation should be withdrawn and palliative care provided. He added that the case had raised "real and important questions as to the confidence that can be placed in the code of practice for the diagnosis and confirmation of death in cases involving infants."

An academy spokesman said a panel reviewing its 2008 guidance was expected to report in 2023. In the meantime, in the light of A's case, a subgroup would consider paediatric issues.

Clare Dyer, *The BMJ* Cite this as: *BMJ* 2022;378:o2124

Doctors warn use of nitrous oxide by young people is an "epidemic"

Doctors have warned that they are seeing a rise in neurological complications among young people as a result of use of nitrous oxide, commonly known as laughing gas. It has become an increasingly popular recreational drug at festivals, nightclubs, and parties. Used to induce laughter and hallucinations, the gas is not illegal to possess and can be purchased online in the small silver canisters known as "whippits."

Doctors voiced concern after seeing more users with neurological complications after inhaling from large canisters, 80 times the size of whippits.

David Nicholl, a consultant neurologist and clinical lead at

Birmingham City Hospital, who has shared a TikTok video about recreational use of nitrous oxide, said, "In the last 20 years, a consultant would maybe see one or two cases, but then it started picking up in the pandemic, so during lockdowns we would maybe see a case every couple of months or so but now we see one every week.

"I would describe it as an epidemic, and that's not just me saying that: colleagues would too, because we are seeing a lot more of these cases."

Nicholl added, "I think some patients are aware of the risks and complications, and some aren't, and I think that's down to its common name, 'laughing gas,' which sounds trivial. There's less awareness that with

Each UK nation needs overarching patient safety lead, report urges

A new patient safety chief should be appointed in each of the four UK nations to oversee health and social care and tackle the currently "fragmented and complex" system, experts have urged.

The Professional Standards Authority for Health and Social Care (the body that oversees the 10 statutory bodies that regulate health and social care professionals in the UK, including the GMC) called for what it described as a radical rethink to improve safety in care. In a report published on 6 September it recommended the appointment of an independent health and social care safety commissioner (or equivalent) for each UK country.

These commissioners would identify current and potential risks across the system, it said, and instigate necessary action across organisations. The role needs to be much broader than that announced for England in July by

the Department of Health and Social Care, said the authors.

Such a role was needed, they argued, because the currently "fragmented and complex" patient and service user safety framework meant that concerns raised could fall between organisations or were left unmet because of jurisdictional issues or insufficient powers.

The Westminster government is currently considering reform of the regulation of healthcare across the UK and of social care in England. In July it appointed its first ever patient safety commissioner for England to promote patients' interests and improve the safety of drugs and medical devices.

The report says that although there have been improvements in health and care professional regulation over the past two decades there was a "disheartening recurrence" of failings and national scandals continued to emerge. It also





ALMOST 9%
of 16-24 year olds said they had taken nitrous oxide in the previous year, up from **6.1%** in 2012-13

taking an overdose there is a risk of side effects. Essentially, by inactivating vitamin B₁₂, nitrous oxide can lead to a paraparesis via myelopathy due to B₁₂ affecting the posterior columns of the spinal cord. It can also cause neuropathy again via B₁₂ deficiency. B₁₂ can be normal, depending on the assay, so doctors may check methylmalonic acid which is markedly raised.”

raises concerns about persistent, large inequalities in access to and experience of UK healthcare services and says that the system as a whole needs to improve data collection.

National strategies

The report highlights serious staff shortages and calls on the four UK governments to collaborate on a coherent strategy for the regulation of professionals and to support delivery of national workforce strategies.

Caroline Corby (left), chair of the authority, said, “The upcoming reforms to the powers and governance of the healthcare professional regulators will help but won’t fully solve these complex problems.”

A health department spokesperson said, “In July we appointed our first

He also said it was important for users to know that taking vitamin B₁₂ would not prevent neurological complications, a belief often circulated among nitrous oxide users.

The 2019-20 Crime Survey for England and Wales found that almost 9% of 16-24 year olds said that they had taken nitrous oxide in the previous year, up from 6.1% in 2012-13.

Other doctors have taken to social media to raise awareness, including Nikos Evangelou, a University of Nottingham neurologist, who tweeted, “On call for Nottingham Neurology, and I realised there is an epidemic of [nitrous] oxide induced spinal cord and nerve damage. Terrifying to see paralysed young people from laughing gas canisters.”

There was a mean number of five deaths a year involving nitrous oxide in England and Wales from 2012 to 2017, show data from the Office for National Statistics.

Zainab Hussain, *The BMJ*
Cite this as: *BMJ* 2022;378:o2155

ever patient safety commissioner for England. The Office for Health Improvement and Disparities was also set up to examine how best to reduce unacceptable health disparities.”

The Scottish government said it was committed to a patient safety commissioner who will “develop a systemwide view of healthcare in Scotland.” The Welsh government said it was establishing an independent Citizen Voice Body, to represent “the voices of the people of Wales for health and social care matters.” A spokesperson for Northern Ireland’s health department said it was considering “the remit of a patient safety commissioner role” and the “merits of such a function.”

Adrian O’Dowd, London
Cite this as: *BMJ* 2022;378:o2165

PROPOSED BRIEF FOR ROLE

The new safety commissioner role should span public and private provision, be independent of governments, and be able to:

- Tackle inequalities by identifying risks for protected characteristic groups
- Look for emerging risks in how care is funded and delivered
- Spot risks relating to workforce shortages, and
- Identify unintended risks arising from existing or proposed national approaches to patient and service user safety.

FIVE MINUTES WITH . . .

Anthony Harnden

Deputy chair of the Joint Committee on Vaccination and Immunisation discusses flu and the covid vaccine

We are potentially going to have a very big influenza outbreak this winter because collectively we’ve had quite low flu numbers for the past five or six years and therefore population immunity levels will be low.

This year’s flu season was much earlier in Australia, and it was children that were getting quite a lot of flu and we’re expecting that might happen here. We’ve recommended that all over 50s, people with underlying illnesses, and those between 2 years old and secondary school age be offered the vaccine. It would be really good to see high uptake, because there’s very good evidence that if children are getting it they will transmit it.

One of the issues with a combined flu and covid-19 vaccine is that covid still hasn’t morphed into a seasonal illness, so we’re still getting spikes in the summer. I think it will eventually morph so we can have a seasonal vaccine for it.

There’s no theoretical reason why the vaccines can’t be combined in the future.

In terms of the bivalent covid-19 vaccine, to a certain extent we’re chasing a thing that is changing all the time. That’s not to say that the updated vaccines don’t have added advantage. But not hugely, because these are drifts in the virus, not major shifts. If we happen to have a major variant that produces very different characteristics in terms of outcomes, then we may be in a situation where we do need a variant vaccine desperately—but we’re not there.

Omicron is the latest shift from delta and transmits more easily but gives a milder illness. And, so, we may get a variant that is more infectious but gives milder illness, or we may get something—hopefully not—that becomes more transmissible and gives a more severe illness. Then things become a bit more critical.

What we’re quite clear about is that even the original vaccines still produce really good protection against severe disease, so the imperative should be to get vaccinated, rather than worrying about the particular type of vaccine.

Anthony Harnden was speaking as part of the Royal Society of Medicine’s Covid-19 Series: The Bivalent Vaccine

Elisabeth Mahase, *The BMJ* Cite this as: *BMJ* 2022;378:o2164



THE ORIGINAL VACCINES STILL PRODUCE GOOD PROTECTION AGAINST SEVERE DISEASE

BRIEFING

MONKEYPOX

What we know about the outbreak so far



With WHO declaring the virus a public health emergency of international concern, **Mun-Keat Looi** explains the current state of the global cases

We have known from the beginning this vaccine would not be a silver bullet

Rosamund Lewis

? Which countries have declared a public health emergency?

The World Health Organization declared monkeypox a public health emergency of international concern (PHEIC) on 24 July. Since then only the US, which accounts for more cases than anywhere else in the world, has done so. The Biden administration made the call on 4 August, just days after the cities of New York and San Francisco announced their own, in a bid to free up access to funding and expand the workforce and vaccines, as well as raise public awareness.

At the time of writing, more than 35 000 cases have been reported in 92 countries, with 12 deaths.

“Almost 7500 cases were reported last week—a 20% increase over the previous week, which was also 20% more than the week before,” said WHO’s director general, Tedros Adhanom Ghebreyesus, at a press briefing on 18 August. Almost all cases were in Europe and the Americas.

? What are the symptoms?

The symptoms that presented before this year’s outbreak still stand. As a *BMJ* Best Practice guide states: “Patients typically present with a characteristic rash that progresses in sequential stages at the same stage of development over all affected areas of the body. It may be associated with fever, lymphadenopathy, backache, and myalgia.”

On 22 July the largest study of confirmed monkeypox cases to date identified new clinical symptoms that were similar to those of syphilis and other sexually transmitted infections and could easily lead to misdiagnosis. These included single genital lesions and sores on the mouth or anal mucosa. The study, published in the *New England Journal of Medicine*, found that 95% of 528 patients from 16 countries presented with a rash, 73% with anogenital lesions, and 41% with mucosal lesions. One in 10 of the patients had only a single genital lesion, and 15% had anal or rectal pain (or both).

A smaller study of London cases, published in *The BMJ* on 28 July, found that penile swelling and erectile dysfunction were among symptoms not normally associated with the disease. Of 197 patients who tested positive for monkeypox from May to July, 71 reported rectal pain and 31 penile swelling. Eight of 20 hospital admissions were for anal or rectal pain and five for penile swelling.

? What’s the vaccine situation?

The smallpox vaccine Jynneos (also known as MVA) is the only one licensed for monkeypox and is valid in the US, Canada, the EU, and the UK. The licence is based on animal studies and immune responses in humans, rather than on clinical studies. Critics point out that the main study used for indicating efficacy—reported as 85%—is from the 1980s and looked at a different, more powerful, type of vaccine than the ones used today.

No randomised controlled clinical trials of the vaccine have been conducted on infected humans, although some early data are now emerging from its use in current

outbreaks. In a preprint released in August, French doctors administering it as post-exposure prophylaxis to 276 people reported that 12 developed a monkeypox infection—10 within five days of vaccination and two after more than 20 days.

Shortages of Jynneos owing to unprecedented demand have hit headlines over the summer. There are many issues, one of which is that it is made by only one company, Bavaria Nordic, at its Denmark plant. It claims that to do otherwise would take too long and be too complicated. However, Rolf Sass Sorenson, a company vice president, told an investor call on 17 August it was talking with others about third party technology transfer. The UK Health Security Agency said two days earlier it was experiencing a shortage but that 100 000 more doses were due to arrive this month. As of 10 August, around 27 000 people in the UK had been vaccinated.

Because Jynneos is normally an emergency stockpile drug against smallpox, countries had different volumes of doses, and—in an echo of the vaccine hoarding seen in the covid pandemic—new orders, of which 12 million are stored in Denmark, have been tied up largely by a handful of high income countries. The UK and the US have some of the largest, with the US expecting 500 000 doses this year and 2.5 million doses next. The US has supported Bavarian Nordic’s vaccine development for nearly 20 years, pumping in close to \$2bn, the *New York Times* reported.

The EU’s Health Emergency Preparedness and Response Authority (HERA) is reportedly struggling to secure new stocks. Many countries on the continent are short of vaccines despite several having stockpiles in



AS OF
10 August, around
27 000
people in the
UK had been
vaccinated

case of a smallpox outbreak. This has led to patients crossing borders: *Politico* has reported on patients travelling from Brussels to a clinic in France. Similar anecdotes have emerged in US states.

Africa, the only continent where monkeypox is endemic, has no access to the vaccine, although a clinical trial of Jynneos is under way in the Democratic Republic of the Congo. The Africa Centers for Disease Control and Prevention is in “very advanced discussions” with multilateral institutions and non-African governments to purchase stocks. Its acting director, Ahmed Ogwell, said on 11 August there were no discussions with the private sector because all available doses had already been bought up, *AP News* reported.

WHO has issued warnings calling for donations and fairness. “We remain concerned that the inequitable access to vaccines we saw during the covid-19 pandemic will be repeated and that the poorest will continue to be left behind,” said Tedros at the 18 August WHO briefing.

It also warns that vaccines are not a panacea. “The fact we’re beginning to see some breakthrough cases tells us the vaccine is not 100% effective, whether preventive or post-exposure,” said Rosamund Lewis, WHO’s technical lead for monkeypox. “We have known from the beginning this vaccine would not be a silver bullet.”

The agency emphasised the importance of other interventions, including reducing the number of sex partners in high risk groups and giving time for the vaccine to generate a maximum immune response, usually two weeks after the second dose.

? What’s happening in the US?

The country with the most cases has been plagued by problems with testing, messaging, and the distribution of drugs and vaccines, with the White House under fire for “bungling” the response—an accusation that comes as the US Centers for Disease Control and Prevention admitted to failures during the covid pandemic. Various agencies at local, state, and national levels have blamed federal mismanagement and bureaucracy, particularly in

distributing vaccines from the national emergency stockpile. Some quarters are also calling for another smallpox vaccine, ACAM2000, which is also held in the national stockpile, to be considered.

On 18 August the Biden administration announced it would accelerate rollout, making 1.8 million additional doses of Jynneos and 50 000 courses of the antiviral Tpoxx (tecovirimat) available. Additionally, the CDC said it was launching a pilot programme to make 50 000 vaccine doses available at events with high attendance of gay and bisexual men.

The urgency of the situation has led the US Food and Drug Administration to grant emergency approval for a fractional dosing or “dose sparing” strategy, where a fifth of a single dose is administered subcutaneously just under the skin, in an effort to stretch out existing stocks. The European Medicines Agency made a similar move on 19 August, as did the UK Health Security Agency on 22 August.

Florida was already rationing its stocks by issuing only the first of the two shots normally required. But Bavarian Nordic is said to harbour concerns about this strategy, while other experts say the need for training in the fractional dosing technique will complicate the rollout, especially at a time when the country is still experiencing high levels of covid-19 and much of its health workforce is burnt out from the pandemic.

The US has an order of one million doses of Jynneos, but these may not get into people’s arms until 2023. Doses are stored in Denmark, though the White House is in talks with several companies to bottle (“fill and finish”) the stock in the US to speed up the process. Even so, it could still take three to six months, says *Politico*.

A similar quagmire is preventing patients from accessing the antiviral Tpoxx, the only drug treatment for monkeypox. It is approved by the FDA under an emergency authorisation based on animal studies, on condition it could be sold only to the Strategic National Stockpile. The CDC also ruled it could be prescribed only if a patient also enrolled in a clinical study. This has meant a hugely bureaucratic process. Writing in *STAT*

News, two doctors said it meant hours of paperwork for a single patient and that the vast majority of the stockpile’s doses had yet to be distributed.

The worry is that the virus is increasingly likely to become endemic in the US, making elimination extremely difficult.

? What’s happening in Africa?

There are spillover cases in countries that don’t usually see the disease, but 80% are in countries where the disease is endemic. Unlike the global outbreak, transmission still seems to be through contact with animals, and the Africa CDC has said that no evidence yet shows transmission between men who have sex with men is driving changes.

The demographic split of cases is also more evenly split than in Europe and the Americas. In a WHO press conference on 4 August it was revealed that 60% of the 350 cases were in men and 40% in women.

? Will the disease be renamed?

The disease was first identified in laboratory monkeys but actually infects a variety of animals—monkeys are not even the main reservoir of the virus (which remains unknown).

In June WHO admitted the name was unhelpful in efforts to combat the outbreak and said it would look into relabelling the disease to reduce stigma. That has proved easier said than done. In a nutshell, it involves renaming the actual virus and, separately, the disease. The International Committee for the Taxonomy of Viruses oversees virus nomenclature, and adopting a name like “the orthopoxvirus monkeypox” could work. But renaming the disease is more difficult. Once a disease is named it enters the International Classification of Diseases and is assigned a code, which is used worldwide, so a name change has many repercussions, including on data already collected.

WHO did rename the virus’s two common variants—now known as clade I and clade II, removing references to central and west Africa, respectively.

Mun-Keat Looi, *The BMJ*

Cite this as: *BMJ* 2022;378:o2058



There are no discussions with the private sector because all available doses have been bought
Ahmed Ogwell

We remain concerned the inequitable access to vaccines we saw during the covid-19 pandemic will be repeated

Tedros Adhanom Ghebreyesus



THE BIG PICTURE

Flood health fears for 33 million Pakistanis

With a third of Pakistan inundated by floods, affecting more than 33 million people, public health experts fear a rise in waterborne and mosquito-borne diseases.

Malik Muhammad Umair, a public health expert, told *The BMJ*, “With limited access to safe drinking water, the biggest threat is from waterborne diseases such as diarrhoea, typhoid, and cholera. Also, increased mosquito breeding may lead to high numbers of malaria and dengue cases, which Pakistan has already been grappling with.”

Of Pakistan’s 154 districts, 116 have been affected by heavy monsoon rains that began in mid-July. Official figures put the death toll at 1162 so far.

Amid criticism that the government isn’t doing enough, prime minister Shehbaz Sharif has pledged 10 billion Pakistani rupees (£40m) for affected areas and has asked for more international help.

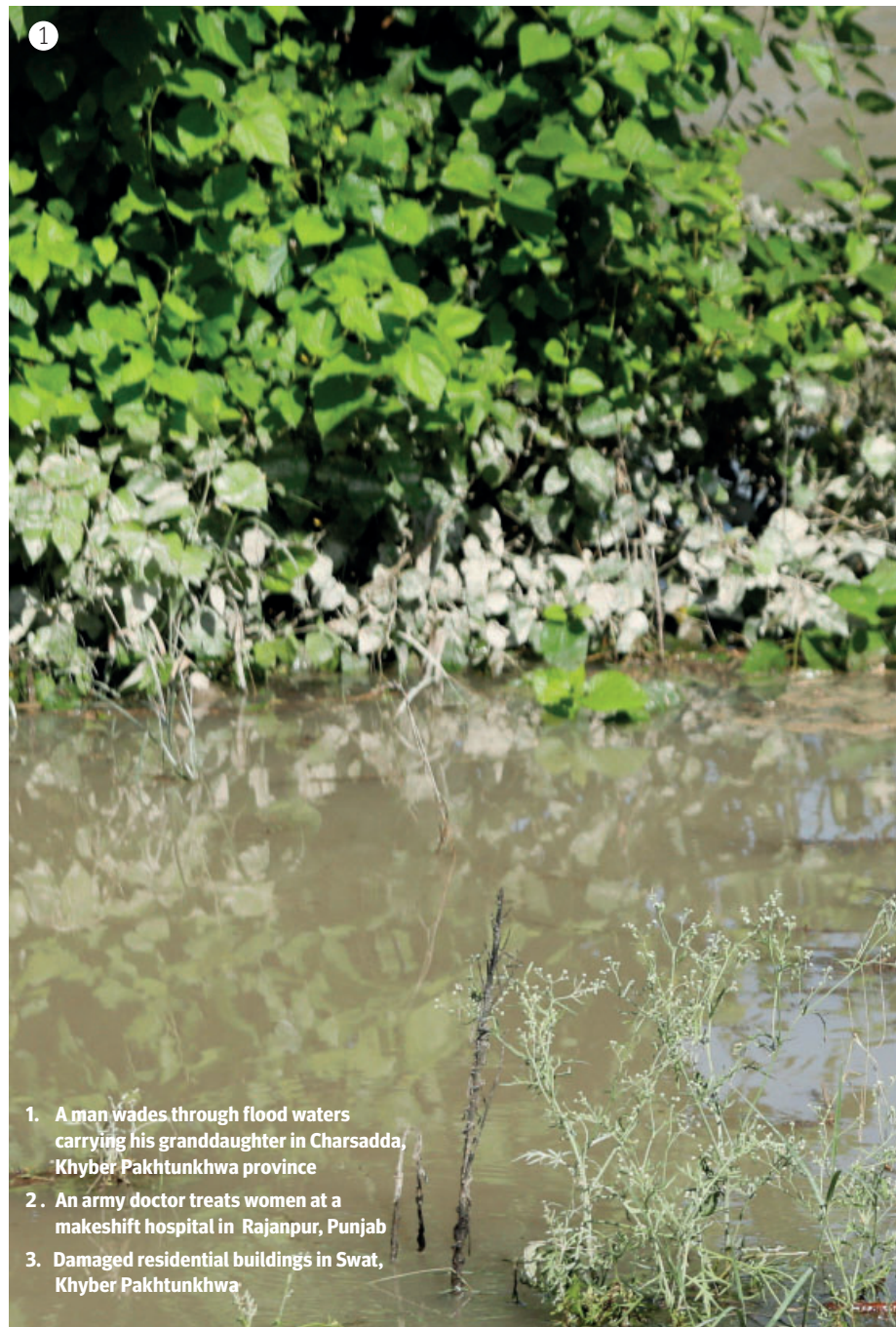
Around half of the villages in northwestern Khyber Pakhtunkhwa province are not accessible because roads and bridges have collapsed. Medical teams have had to swim to victims, and local relief agencies have supplied food to more than 30 000 people, as well as makeshift tents and medical care.

The World Health Organization, which has said around 890 Pakistani health facilities have been damaged, has diverted mobile medical camps and delivered nearly two million water purification tablets.

Nadeem Jan, who led Pakistan’s polio eradication programme in Khyber Pakhtunkhwa, warned of the effects on children’s nutrition in the province, where every second child (an estimated 800 000 under the age of 5 years) is failing to thrive because of malnutrition.

Sonia Sarkar, New Delhi, India

Cite this as: *BMJ* 2022;378:o2141



1. A man wades through flood waters carrying his granddaughter in Charsadda, Khyber Pakhtunkhwa province
2. An army doctor treats women at a makeshift hospital in Rajanpur, Punjab
3. Damaged residential buildings in Swat, Khyber Pakhtunkhwa





FAYAZ AZIZ/REUTERS/ALAMY; SHAHID SAIED MIRZA / AFP/GETTY; AHMAD KAMAL/XINHUA/ALAMY

Depression is not caused by “chemical imbalance”

But antidepressants remain an effective treatment for many

A recent umbrella review of evidence for the serotonin theory of depression¹ was widely reported in UK media as showing that depression is not caused by low levels of serotonin or a “chemical imbalance,” casting doubt on the use of selective serotonin reuptake inhibitor (SSRI) antidepressants by millions of people.²⁻⁵

The polarising debate that ensued risks undermining the evidence based treatment of depression and causing harm to people who take or need SSRI antidepressants. Critics of the review and its coverage noted that study selection was incomplete, as an omitted 2021 meta-analysis had concluded that changes in blood biochemistry, notably of L-tryptophan, were associated with depression.⁶ The umbrella review was dismissed as nothing new and limited because peripheral and indirect measures of serotonin concentration or activity tell us nothing about activity at receptors between neurons in the brain.⁷ Psychiatrists argued that use of SSRIs is not based on the simplistic theory that low serotonin causes depression but on clinical trial evidence.^{6,7}

Others, however, including the review’s lead author, interpreted the findings to imply that antidepressants do not work, suggesting they are barely distinguishable from placebos and may just numb emotions.^{8,9} These contentions are not supported by evidence, went beyond the findings of the review, and were not expressed in its conclusions.¹ They could encourage sudden antidepressant cessation, causing withdrawal symptoms and risking relapse.

Public reaction on social media included fear, guilt, and feeling stigmatised for taking antidepressants on the one hand, and anger at experts’ dismissal of patients’ legitimate medication concerns on the other.

How should patients and



JOHN GREIM/SPL

Open and honest discussion with patients about the remaining uncertainties is essential

clinicians navigate these challenges? First and foremost, good evidence from randomised controlled trials shows that antidepressants are effective in treating people with new episodes of both less severe and more severe depression.¹⁰⁻¹² Around 25% of trial participants taking antidepressants experience a substantial effect, compared with around 10% taking placebos.¹⁴

False belief

However, the review discusses an important point—that most of the public believes the chemical imbalance theory is established,¹⁵ and this is probably because general practitioners use it to justify prescribing antidepressants, although the only evidence cited to support this assertion was a small online survey.¹⁶ While most GPs surveyed acknowledged chemical imbalance as one possible cause of depression, they ranked it last among 13 biological, psychological, and social factors, suggesting they believed in a much broader overall model of depression.¹⁶

Unfortunately, the chemical imbalance explanation may have encouraged long term use of SSRIs because it falsely implies a serotonin deficiency needing long term replacement, perhaps for life. This false belief was identified in 10 qualitative studies of barriers and facilitators to discontinuing antidepressants when appropriate.¹⁷ Therefore we should not tell people

with depression that antidepressants correct an imbalance or deficiency of serotonin, or that they will necessarily need long term treatment.

Open and honest discussion with patients about the remaining uncertainties is essential. We do not know why antidepressants work well for some people and not others, or why they cause harm to some people, not others. Research into their biological and psychosocial mechanisms of action must continue. Trial evidence makes clear that the effect of antidepressants is on average modest.¹⁰ The National Institute for Health and Care Excellence (NICE) therefore recommends that psychological therapy should be offered first (if available) to people with a new episode of less severe depression unless they prefer antidepressant treatment, and that people with more severe depression are given a combination of antidepressant and psychological treatment.¹²

NICE recommends that clinicians advise people taking antidepressants for a first episode to take them for at least six months after recovery.¹² People needing treatment for a second episode of depression are at greater risk of relapse after discontinuation, particularly if symptoms persist that are serious enough to impair daily activities, or their depression has an ongoing underlying cause. They may be advised to continue antidepressants for two years before considering stopping treatment again.¹²

Trust between the prescriber and the person with depression is of paramount importance for a good outcome. An initial time frame for treatment should therefore be agreed, with frequent contact until symptoms have receded.¹² Personal continuity of care should be offered at six monthly regular reviews of longer term treatment.¹²

Cite this as: *BMJ* 2022;378:o1993

Find the full version with references at <http://dx.doi.org/10.1136/bmj.o1993>

Tony Kendrick, professor of primary care, University of Southampton
A.R.Kendrick@Southampton.ac.uk

Susan Collinson, specialist TB case worker, Homerton University Hospital NHS Foundation Trust, London

Escalating drug related deaths in the UK

A fundamental reorientation in approach is needed

The escalating rates of drug related deaths in the UK constitute a public health crisis.¹ Recently released figures for 2021 show 3060 deaths related to the use of illicit drugs in England and Wales and 1330 in Scotland.^{2,3} Although Northern Ireland's 2021 figures are yet to be released, a record numbers of deaths occurred in 2020.⁴ The most damning indictment of the UK's response to drugs is that these figures are no longer surprising because rates have increased for more than a decade to among the highest in Europe.^{2,5} This unconscionable loss of human life cannot be allowed to continue.

The UK government's 2021 drugs strategy, *From Harm to Hope*, highlighted that current approaches are not effective in reducing drug related harm.⁶ But its proposed solutions are echoes of the failed measures that have led to the current crisis. A fundamental change in approach of the UK's response to drugs is urgently required.

The current response is increasingly inconsistent with international efforts to reorientate domestic policies to approach drug use through a lens of public health rather than criminality. As the Lancet Commission on Public Health and International Drug Policy highlighted, not only have repressive drug policies failed to reduce drug related harm, they have caused incalculable harm to marginalised communities.⁷ The 2018 UN Common Position On Drugs calls for countries to adopt public health approaches, putting "people, health, and human rights at the centre."⁸

Human rights

The UK strategy does not mention the term "human rights," and the government's proposed framework of escalating sanctions for drug possession⁹ will be deleterious for



This unconscionable loss of human life cannot be allowed to continue

the rights of people who use drugs, probably increasing the number of people receiving sanctions that may escalate to criminal charges.

People who use drugs face extreme levels of stigma—negative stereotyping leading to marginalisation and discrimination.^{10,11} The negative health effects of stigma are well documented, including those related to delayed engagement with healthcare and other services for fear of judgment and poor treatment.¹⁰ The strategy's position on stigma is incoherent. While indicating the need to minimise the stigma of addiction, it advocates for stigmatising, punitive measures.⁶

A notable proportion of the public hold negative views about people who use drugs¹⁴—views that are feasibly shared by those in positions of power. Research shows that stigmatising attitudes towards people who use drugs are associated with support for measures that punish drug use and a lack of support for public health oriented interventions.^{15,16} Aside from the more obvious effects of stigma on people who use drugs, stigma may pervade decision making, perpetuating ineffective and harmful responses.

An essential component of stigma involves separating those who are being labelled ("them") from those doing the labelling ("us").¹¹ This may lead some people to disassociate

themselves from the drug related deaths crisis. However, this is our crisis—it is our compatriots, neighbours, and family members who continue to die. It is a crisis we must all confront, not through redoubled efforts to stigmatise people who are using drugs—people who are dying unnecessarily—but by fundamentally reorienting our approach.

Public health lens

We must adopt a public health lens and minimise the factors associated with harmful patterns of use, such as socioeconomic deprivation and adverse childhood experiences.^{17,18} We must consider the negative effects of punitive policies with dubious justification when there are better recourses to reduce harm.⁷ We must use evidence appropriately, in lieu of rhetoric about evidence being "at the heart" of reiterations of failed policy approaches.⁶ We must allow for innovative interventions, such as overdose prevention centres, with appropriate legislative amendments to accelerate their introduction.¹⁹

And finally, we must question what evidence we are looking for. Combating drug use has seemingly become an end in and of itself, as opposed to prioritising the reduction of drug related harm. The UK has been a leader in public health approaches to hepatitis C virus and HIV, providing needle exchange and treatments for people who inject drugs.^{20,21} Drug use is a risk factor for negative health outcomes. By treating it as such rather than as an immoral or criminal act, our management of drugs would be more coherent with our management of every other public health concern. A mandate for this must be given now; each delay costs lives, and allowing it to continue is scandalous.

Cite this as: *BMJ* 2022;378:o2005

Find the full version with references at <http://dx.doi.org/10.1136/bmj.o2005>

Maggie Rae, president, Epidemiological and Public Health Section, Royal Society of Medicine, London maggiemrae@outlook.com

Joshua Howkins, public health specialty registrar

Adam Holland, public health specialty registrar, University of Bristol

NHS PAY

How an “unfunded” pay deal will affect doctors, patients, and the NHS

The government has committed to a higher than proposed pay award for staff—but no new money to cover the rise.

Andrea Chipman asks what this will mean for trusts who will have to find £1.8bn

What does “unfunded” mean here?

In July, the government’s pay review body said that it would increase NHS workers’ salaries in 2022-23 by more than the 3% initially proposed in the autumn budget—but the government has promised no new money to back up the additional salary increase.

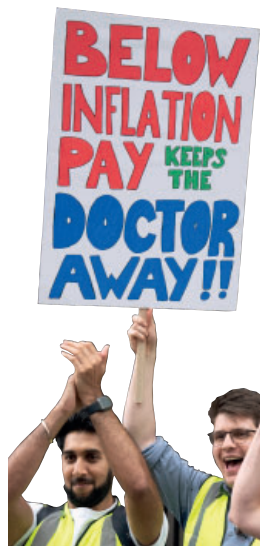
The extra pay will therefore need to be covered by the existing NHS budget, further tightening the financial straitjacket the health service is working under. The NHS Confederation has calculated the unfunded amount to be around £1.8bn.

Where will the additional money come from?

Sally Gainsbury, senior policy analyst at the Nuffield Trust, explains that the 3% pay rise that was originally promised is transferred from NHS England to NHS commissioners, who add it to the payments they make to trusts to cover trust activities. The additional pay rise will have to be financed from the trusts themselves, at a time when they are already having to make very large savings. Budgets set aside by trusts for service transformation are likely to come under pressure, although Gainsbury adds that “there is not a huge amount of wriggle room.”

Anita Charlesworth, director of research and the REAL Centre at the Health Foundation, says, “The higher cost of energy and soaring inflation are already reducing the value of the NHS budget set out at the [latest] spending review: current estimates point to a real terms cut between £4bn and £9.4bn.

“Integrated care systems are already facing demanding efficiency targets of over £5.5bn—around 5% of total system allocations—as a way to respond to the fall in the real value of the NHS settlement. It is therefore not realistic to assume further savings or efficiencies can be brought in to deal with new pressures, such as pay increases, rising inflation, or new service demands.”



MIK VALICIA/LAWY

What will trusts target to make savings?

The primary way to cover a pay rise that the health service cannot afford is to employ fewer people, says Gainsbury, adding, “I don’t think people will be sacked, but the NHS needs to be taking on more staff. There will be more temporary stopgaps.”

Capital investment also could take a big hit, says Charlesworth, given the precedent of a decade of austerity in the 2010s, when the Department of Health and Social Care started reallocating capital spending to revenue spending.

“Capital investment is used to pay for things like new diagnostic equipment and much needed repairs and upgrades to existing buildings and facilities,” she explains. “These are crucial to reduce critical infrastructure risks and to enable a higher diagnostic and treatment capacity.”

The risks of avoiding much needed infrastructure repairs were highlighted early this August, when a health minister acknowledged that 34 hospital buildings in England had concrete roofs that were in danger of collapsing.

In addition, NHS trusts are likely to try to reduce covid-19 measures for which they have already received extra ringfenced funding from the government, to reallocate this to cover funding shortages. Gainsbury says, “I suspect some of that covid-19 money is already propping up ‘business as usual’ rather than paying for extra covid measures.”

What might be the implications for services and patients?

Elective care waiting lists, which hold around 6.7 million patients in England, are likely to suffer the most from the additional pressure as the health service refrains from filling significant gaps in staffing. The effect of the pay deal that will be most obvious to patients is therefore the continued backlog in elective care, as empty medical posts remain unfilled because of cost constraints.

Staffing woes are exacerbated by low morale and knowing the increase represents a pay cut in real terms given the sharp rise in inflation. Unions reacted angrily to the pay review body’s July announcement after demanding rises matching inflation—which could reach 13% later this year, the Bank of England has predicted.



The substantial real terms pay cut junior doctors face this year has implications for their motivation, morale, and retention

The pay review body's revised pay deal for NHS staff provides more than a million healthcare workers—including nurses, midwives, and paramedics—with a pay rise of £1400, around 4%. Cleaners and porters receive 9.3%, while doctors out of training and dentists get 4.5%. The Royal College of Nursing has said that it will ballot members in advance of possible strike action.

Even with the pay rise, the current inflation rate of 9.4% means a real terms pay cut for most workers. Nurses working in NHS trusts face a basic pay cut of £1400-£2500 on average per full time equivalent, with the exact size of the cut depending on the rate of inflation.

A report from the Health and Social Care Select Committee, published on 25 July, found that the staffing crisis in the health system was seven times worse than suggested by official figures, with current vacancies for as many as 50 000 nurses and more than 12 000 doctors.

Individual services have already warned of potential economising. The Royal College of Radiologists, in a press release that followed the pay rise announcement, noted that the NHS was already under pressure to cut investment in expanding diagnostic capacity and new technologies, including improved IT infrastructure, both of which are needed to tackle the existing backlog. Decades of underfunding have also left a 30% shortfall of clinical radiologist consultants in England, which is set to climb to 39% by 2026, the royal college says.

Finally, there is the overall impact on NHS services that are still reeling from covid-19 and related backlogs, while facing pressure from the government to claw back some of the extraordinary additional investment made in the NHS during the pandemic.

The unfunded pay rise could also further exacerbate equity issues among patients, says Gainsbury, noting that the number of self-payers turning to the private sector is already growing, with many likely to be less complex patients who are better off and have been referred early.

“There is already pressure on trusts to remove people from waiting lists,” she says. “Those sorts of measures need a lot of scrutiny to ensure that it isn't a recipe for making sure that less articulate people aren't pressured into giving up their slot on the waiting list.”



It isn't realistic to assume more savings or efficiencies can be brought in
Anita Charlesworth



The Treasury will probably find a way to meet some of the shortfall
Sally Gainsbury

What's the likely impact on public perception?

The British public have generally been supportive of improving salaries for NHS staff, says Gainsbury, especially at a time when the average wage settlement in the rest of the economy has been slightly higher than in the health service.

At the same time, taxpayers will see the new 1.25% health and social care levy coming out of their pay packets. The government has said that the levy will raise £39bn over the next three years, with the aim of putting “health and care services on a sustainable footing” by helping to tackle covid-19 backlogs and create more sustainable services—although it has provided little detail about how the money will be divided and allocated.

A poll by Savanta ComRes, published in the *Mirror* just before the announcement of the pay deal, found that some 55% of respondents supported an above inflation wage rise for health staff. It also found that 85% believed decent pay was critical to maintaining adequate staffing levels and patient care.

How will doctors be affected?

While there is not always a clear cut relation between wages and staff retention, doctors could be affected by broader staff morale. This is especially true if stagnant waiting lists and high job vacancies put renewed pressure on the working conditions of health providers who are already exhausted by two years of a pandemic.

Junior doctors in England are excluded from this year's award and will receive a pay increase of only 2% under a multi-year pay deal agreed before the pandemic, Charlesworth notes, adding that the substantial real terms pay cut they face this year has implications for their motivation, morale, and retention.

What next?

Ultimately, further negotiation is likely between the NHS and the Treasury over the £1.8bn shortfall in salaries, says Gainsbury, adding, “My expectation is that the Treasury probably will find a way to meet some of it, but the NHS will have to put up a fight.”

Andrea Chipman, freelance journalist, Nottingham andreachipman1@gmail.com
Cite this as: *BMJ* 2022;378:o2092

Broken Horizon: how Brexit left UK science struggling for funds and collaborations

Leaving the EU has introduced visa requirements, customs regulations, and led to the loss of funding, all of which has heavily impacted medical and health researchers in the UK. **Eva Amsen** reports

One of the biggest effects of Brexit has been exclusion of the UK (including Northern Ireland) from the Horizon Europe funding, to which the country would have contributed approximately £2bn a year.

It was initially on track to be admitted to the research framework as an associate country, which would have allowed UK researchers to apply for European Union funding such as European Research Council (ERC) grants. But when negotiations on the Northern Ireland Protocol stalled, the UK didn't meet Horizon's requirements for association, and UK based ERC grant awardees were given a few months to move to an EU country or to decline funding.

"It wasn't a hard choice, because you can't decide within two months to just

move to Italy," says Tamar Makin, programme leader at the MRC Cognition and Brain Sciences Unit at the University of Cambridge. Under the UK government's alternative solution, she and 114 other UK researchers agreed to return their ERC grants in full and had their funds matched by UK Research and Innovation, a non-departmental government body that directs research and innovation funding, which plans to continue to support researchers as long as the UK isn't associated to the Horizon programme.

As a result, she hasn't experienced funding delays and can still carry out her planned research, which investigates how the brain can control prosthetic limbs or augmentative body parts—but she won't have all the benefits of the international grant she initially applied for. "The flexibility of UK Research and



I've got a good track record, but I can no longer lead
Trish Greenhalgh

Innovation is not the flexibility of the ERC by any stretch," she says; for example, the ERC allows grant holders to move countries. But more than that, the EU has a track record of funding innovative high risk, high reward research, and the loss of this funding stream will have major consequences for some researchers.

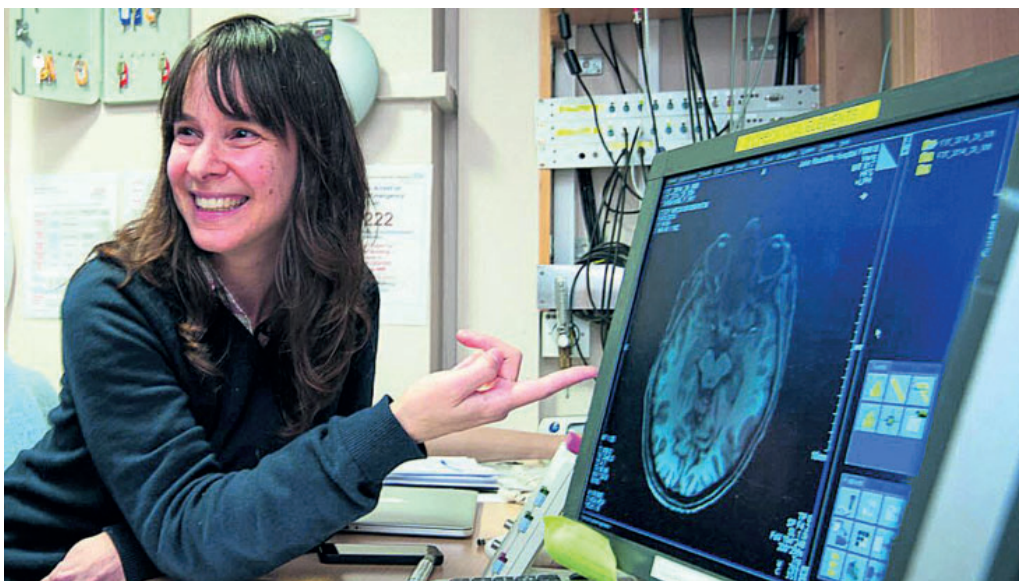
Loss of leadership and expertise

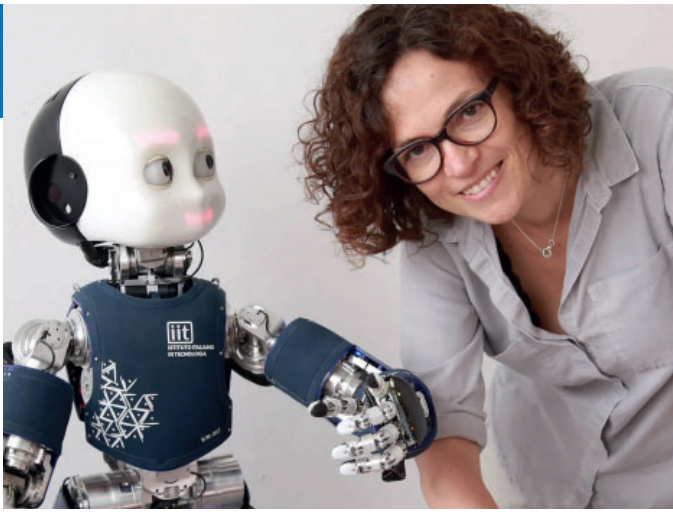
Trish Greenhalgh, professor of primary care health sciences at the University of Oxford, had been planning to apply for an ERC Synergy grant in the autumn for a project researching complex change in health related fields. But with the UK now considered a "third country" outside of Horizon Europe, she can no longer act as the main researcher in charge of such a project. "I've got a good track record, but I can no longer lead," she says.

Participation is still possible, but another group will have to manage the application and any funding that it leads to. That also means losing out on Oxford University's expertise in managing the administration of such large research grants. "If you're going to get €10m, you want the most experienced people keeping an eye on the governance," says Greenhalgh.

What worries her most is that the UK, she says, is less likely to fund the ethnographic methodologies that she planned to use. Co-creation research methods, where partner communities work together with researchers to develop new

You can't decide within two months to just move to Italy
Tamar Makin





knowledge, are highly valued by the EU, but not so much nationally. “As a medic who does a lot of social science research, the loss of the ERC funding stream is devastatingly bad.”

And not only could UK based funding possibly overlook some key areas of medical and health research that the EU was keen to fund, but a national funding stream is overall less likely to encourage international collaborations, which could gradually affect the international status of UK researchers.

Still, the UK’s participation in Horizon Europe might be far from over—on 17 August the UK launched dispute resolution proceedings against the EU, hoping to force participation in the programme. “The EU is in clear breach of our agreement, repeatedly seeking to politicise vital scientific cooperation by refusing to finalise access to these important programmes,” Liz Truss, then UK foreign minister, said in a statement.

Loss of partners and movement

In anticipation of the Brexit referendum in 2016, the Royal Society analysed how EU funding affected research collaborations. It found that 58% of publications about ERC funded research included researchers from different countries, whereas an average of 48% of publications that mentioned UK funding included international teams. That’s not a huge difference, but it also found that research papers including authors from multiple countries

received more citations, pointing to an objective career benefit from such collaborations.

Agnieszka Wykowska, professor in social cognition at the Italian Institute of Technology, told *The BMJ* that they are not looking for UK partners for their EU-wide collaborative research projects anymore. She expects that the UK will be part of EU research projects again in the future but points out that ongoing delays might prevent association in the current Horizon programme, which runs until 2027. That’s a long time for the UK to be excluded by default from EU research projects.

Since Brexit, it’s not easy for British medical experts to take a brief working visit to collaborators in the EU or for EU citizens to come to the UK for a few months. “The most painful process for us at the moment is having to arrange visas for anyone who wants to visit the lab, even for a short term internship,” says Makin. Greenhalgh has similar concerns. “The thing that I’m most gutted about is the loss of opportunities for young researchers,” she says. She collaborates with a group in Norway and had envisioned early career researchers on the different teams regularly visiting each other’s research groups to exchange ideas.

It’s still possible to keep such exchanges going, but they now require a lot more planning. The same is true for hiring staff from the EU, which the Nuffield Trust flagged as one of six key changes in health and social care in the UK after Brexit.

I expect the UK will be part of EU research projects again

Agnieszka Wykowska

Research and development

Despite new challenges for hiring staff, MedCity (an organisation set up to drive growth in health and life sciences sector in London) found a surprisingly resilient early research and development sector in London in 2020, when they surveyed the local industry. “We’ve seen a growth in demand of life science real estate space,” says Neelam Patel, chief executive officer of MedCity. Even after the relocation of the European Medicines Agency from London to Amsterdam in 2019, biomedical research seemed to be doing okay—at least in the capital. Patel points out, however, that it’s difficult to separate the effects of covid-19 from those of Brexit.

An Association of the British Pharmaceutical Industry report noted the number of commercial clinical trials in the UK went down from 667 to 508 between 2017 and 2020. “Clinical trials are a major indicator for us in terms of understanding research activity and the levels of growth and economic investment,” says Patel. “Even though clinical trials have been declining across the UK, London is still pretty strong in terms of the volume of research.”

We’ve seen a growth in demand of life science real estate space

Neelam Patel



New restrictions imposed on the movement of goods across the UK border are making it more challenging for international clinical trials. Additional customs checks since January 2021 can delay the shipment of investigative medical products or cause them to get stuck in border control for a long time, where they will need to be kept at the



The UK is still a very important scientific location

Krisztina Varga

right temperature. “Safeguarding a temperature controlled environment can be very expensive,” says Krisztina Varga, chief executive officer of Oximio, which provides logistics services for clinical trials. To mitigate high costs and unnecessary delays, Oximio now plans as few British border crossings as possible in the logistics of trials involving parties in the UK, and it recommends that trial organisers account for extra time in planning the details of collaborative trials between UK and EU partners.

Despite logistical and hiring challenges, Varga is optimistic about the role of the UK in international clinical trials. “The UK position in the healthcare industry has not changed whatsoever,” she says. “It’s a very important scientific location.”

Patel also notes that industry is still very interested in maintaining a presence in the UK but adds: “That doesn’t mean that we need to be complacent about it by any means.”

Eva Amsen, freelance journalist, London
eva@evaamsen.com

Cite this as: *BMJ* 2022;378:o2087

Leeds trials “end-of-life doulas” to ease pressure on beds and GPs

A pilot scheme in the city is tackling the care and administrative needs of elderly patients in the community, reports **Sally Howard**

NHHS West Yorkshire Integrated Care Board (ICB) is piloting a novel approach to support end-of-life patients in the community in Leeds. The project includes a digital tool to help GPs identify patients nearing the end of life, improvements to advance care planning, and £50 000 funding for “end-of-life doulas.”

It is estimated that 1.5 million older people have some unmet care needs, with the number projected to rise to 2.1 million by 2030 should governments fail to act, Age UK says. This has a knock-on effect on hospitals—as elderly people are admitted to hospital for want of other care—and general practice. GPs are being asked to undertake life administration for the elderly, including ensuring a patient is taking their medication, and to administrate advance care planning and NHS continuing healthcare (funding for domiciliary and social care) applications. They are also fielding calls from lonely patients and from worried family members. End-of-life doulas can provide this sort of support.

Care and death at home

Leeds’s 2021 health and wellbeing strategy noted that 37 000 older people experience social isolation and loneliness in the city. Care is often organised around single illnesses rather than all an individual’s needs and many people are treated in hospitals when care in their own homes and communities would be better for them.

The ICB’s pilot, which began earlier this year, will offer 1500

hours of funded end-of-life doula support over the course of a year, with all NHS professionals being able to refer into the service, including GPs and hospital palliative care consultants. It is fully funded by the ICB and involves Leeds Palliative Care Network and St Gemma’s Hospice. The number of patients the funding will cover will depend on the level of support each person needs, but it works out at just over £33 an hour.

Gill Pottinger, a Leeds GP and the clinical lead for end of life at NHS West Yorkshire ICB, says the pilot was inspired by the rise in patients who wanted to die at home rather than in hospital during the pandemic. This has carried over to the present, with a 20% increase in patients who would prefer to die at home.

“At the very end of life, patients have their fast track continuing care assessment in place but we wanted to provide the doula service as something to help before this point, with things like advance care planning,” Pottinger says. She adds that doulas are particularly helpful in cases where patients have no family, or family is overseas.

“We might offer completely emotional support for one client, and practical and administrative

It is estimated 1.5 million older people have some unmet care needs

help for someone else,” says Emma Clare, a director of End of Life Doula UK, which is involved in the Leeds pilot. “This can range from helping with advance plans to refuse treatment, to getting power of attorney arrangements in place and liaising with a patient’s GP if that is what they want us to do—or just doing the washing up.”

Disappearance of home helps

Clare says the job—which she stresses is “in fact nothing new, since this work has always been performed by societies”—plugs a gap left by the disappearance of home helps and wider family, as the current social care model leaves those at the very end of their life with a range of unmet needs, particularly practical and administrative.

“I don’t think people realise the administrative burden on dying and very elderly people,” says end-of-life doula Diane Roberts, “with the need to apply, for example, for NHS continuing healthcare and personal independence payments—and the fact care at end of life can fall between many NHS trusts.”

RETHINKING THE SOCIAL CARE GAP

Other novel solutions include:

- London’s end-of-life paramedics, who are trained to help patients who wish to die at home
- Urgent community response teams, which provide critical care to help people stay at home, are available at seven “accelerator sites” including West Yorkshire, Leicestershire, and south east London
- Community initiatives such as compassionate communities, and the Frome model: projects that seek to build networks integrated with healthcare services to lessen pressure on emergency services.



Roberts is not involved in the Leeds pilot but has worked in the role in Buckinghamshire for three years, and undertakes a range of tasks for her clients from filling in forms to cooking batch meals or simply holding their hand and providing comfort. Like many of the end-of-life doulas trained by End of Life Doula UK’s sister organisation Living Well Dying Well, she is a former nurse—many others are midwives.

While the Leeds pilot is NHS funded, End of Life Doula UK also fundraises to subsidise services for those who cannot afford to pay full private rates. There are 230 members of End of Life Doula UK with around 100 doulas practising, Clare estimates. Rates are between the doula and the patient or their carer, at around £20–£25 an hour.

Data from Leeds are being compiled with the Open University and will track outcomes such as reductions in hospital admissions and whether patients died in their preferred place, as well as gathering feedback from healthcare professionals and carers. Results will be published in 2023.

End of Life Doula UK hopes to use these to inform future collaborations with other trusts, whether charitably or NHS funded. Leeds is the first trust, but three others have made inquiries. “Caring for people in life transitions has taken various forms through human history,” says Clare, “from extended families to home helps. But there’s very much a gap for this form of care today.”

Sally Howard, freelance journalist, London sal@sallyhoward.net
Cite this as: *BMJ* 2022;378:e1836