this week

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"Race health inequity needs radical action"

There is a clear and overwhelming case for radical action on racial inequity in England's healthcare system, a review has concluded. The damning report, commissioned by the NHS Race and Health Observatory, found "widespread" ethnic inequalities across a range of health services, with some communities found to have particularly poor access, experiences, and outcomes.

For too many years the health of people from ethnic minorities has been negatively affected by a lack of appropriate NHS treatment, poor quality or discriminatory treatment from staff, missing data on ethnic monitoring, and a lack of appropriate interpreting services, the report said. Many people from ethnic minorities may delay or avoid seeking help because they fear racist treatment from NHS professionals, it added.

"It is clear that existing evidence on the stark health inequalities faced by ethnic minority communities has not led to significant change," said Habib Naqvi, director of the observatory. "By drawing together the evidence and plugging the gaps where we find them we have made a clear and overwhelming case for radical action on race inequity in our healthcare system."

Chaand Nagpaul, the BMA's chair of council, called the review a "shocking indictment of the scale of harm that racism is causing millions of people in the UK."

"This can no longer be ignored: there is a moral duty to put this right as a matter of urgency," said Nagpaul. "The government must openly acknowledge structural racism within the NHS and the barriers it creates. Those responsible for our health service must develop a cross government action plan with tangible outcomes, timescales, and agreement across the NHS."

The review's findings contrasted with those of a government commissioned report issued last year that dismissed the notion that structural racism may have contributed to poor health outcomes among ethnic minority groups during the covid pandemic. That report was widely criticised by health and NHS leaders, who said the findings did not match the experience of staff and patients.

For the observatory's review, researchers from the universities of Manchester, Sheffield, and Sussex screened more than 13 000 research papers, spanning a 10 year period, with 178 studies included in the final rapid review. Discussion groups were also held with people working with diverse communities.

Some of the largest inequalities were found in mental healthcare, where treatment of

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Patients and staff from ethnic minorities are being negatively affected by race inequalities in the NHS, says the review

LATEST ONLINE

- GP who faked patient consultations is suspended for 12 months
- Judge quashes junior doctor's erasure for "failure of fairness"
- Medical leaders urge ministers to end UK's dependence on fossil fuels

SEVEN DAYS IN

Changes to consultants' local clinical excellence awards are set to be imposed

The government and NHS Employers are set to impose changes to the consultants' local clinical excellence awards (LCEA) scheme this April after talks on reforming it broke down.

Consultants' representatives, the BMA, and the Hospital Consultants and Specialists Association have been in talks for two years about how to make the awards fairer. The breakdown followed changes to the scheme announced at the end of last month, which the BMA described as "not positive ones for consultants."

The aim of revisions was to make the awards more accessible to under-represented groups, including women, doctors from ethnic minorities, and younger consultants, but consultants' leaders have warned that the intended reforms will do the opposite.

Vishal Sharma (left), chair of the BMA's Consultants Committee, said the proposed changes to the way the LCEA was funded would result in a postcode lottery, with some trusts having very little to spend on the awards and younger consultants losing out.

Some improvements were secured, including ensuring successful applicants who worked part time received a full award, but ultimately the scheme would not deliver the primary aim of tackling inequality, said Sharma.

Ingrid Torjesen, *The BMJ* Cite this as: *BMJ* 2022;376:o371

Covid-19

Oestrogen may link to mortality in older women

Oestrogen levels may be linked to risk of death from covid among older women, as higher levels seem to protect against severe infection, research in *BMJ Open* found. The Swedish researchers suggested that randomised controlled trials could look at supplemental hormone treatment to curb the severity of covid after menopause.

All restrictions removed in Northern Ireland

Northern Ireland's health minister, Robin Swan, was due on 15 February to announce the lifting of the small number of restrictions still in place, which he said would become guidance. These included wearing a mask in public places, for businesses to have measures in place to limit virus transmission, the use of covid certification in nightclubs and indoor venues, and limits on the number of people meeting indoors in homes.

Pandemic has harmed US cancer outcomes

The American Association for Cancer Research called for an extra $4.1bn (£3bn) and an expansion of Medicaid to help detect and treat cancer, after a report found that the pandemic had impaired referrals for preliminary cancer diagnoses and led to an 11% increase in US patients having inoperable or metastatic cancer diagnosed in 2020. Nearly 10 million patients missed cancer screenings in the first six months of the year. Ethnic

minority people were particularly badly hit, with surgery for prostate cancer, for example, falling by 91% among black patients but 17.4% among white patients.

General practice

BMA calls for revised GP contract in England

At a meeting on 10 February the BMA's General Practitioners Committee for England passed a motion calling for the government to enter negotiations for a "refreshed, fit-for-purpose" GP contract, beyond the five year agreement ending in 2023-24, to support the independent contractor model. The motion was passed after the committee discussed the latest proposals from NHS England for this year's changes, noting that the current five year deal was reached long before covid-19 and acknowledging the additional and unprecedented challenges the pandemic brought for practices.

Integrated care

White paper "risks overestimating benefits"

A new government white paper on integrated care may risk overestimating the impact of structural changes and must deal with workforce and funding issues, experts warned. The white paper sets out plans to integrate health and social care in England as part of wider reforms laid out in the government's Health and Care Bill. Nigel Edwards, chief executive of the Nuffield Trust, said that the paper had "admirable aspirations" but he added, "Previous attempts at integration show that it alone does not deliver financial savings, bolster social care, or reduce hospitalisations as much as the government would hope."

Litigation

Drug companies fined for deal on prochlorperazine

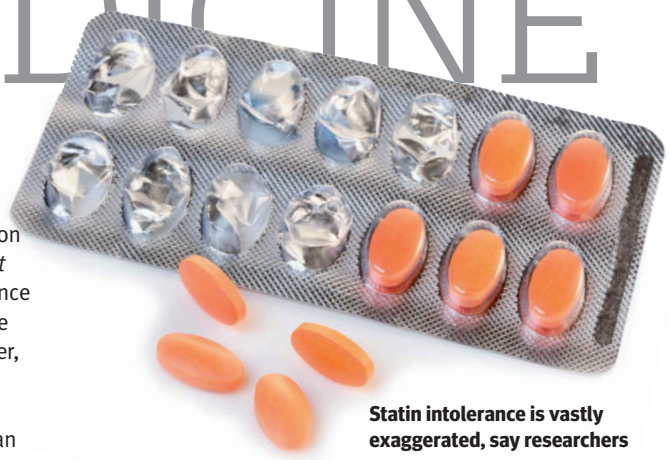
The UK Competition and Markets Authority fined drug companies more than £35m for an illegal arrangement under which a competitor was paid not to launch an antinausea drug, leading to a 700% price rise over four years. Under the arrangement, which restricted competition in the supply of prochlorperazine 3 mg dissolvable tablets to the NHS, Alliance Pharmaceuticals appointed the drug company Focus as its distributor, while the wholesaler Lexon and the drug company Medreich were paid a share of the profits Focus earned from selling Alliance's product. In return, Lexon and Medreich agreed not to compete in the supply of prochlorperazine tablets in the UK.

Elective care

Ending two year waits is "big challenge"

The Royal College of Surgeons of England warned that the NHS faced a "big challenge" to clear the two year waiting list for consultant led hospital treatment by July, as pledged in the elective recovery plan. A record 20 065 people had been waiting more than two years for treatment in December 2021, with more than six million people on the list overall. Fiona Myint (left), the college's vice president, said, "These figures show just how stretching the government's targets are."

MEDICINE



Statin intolerance is vastly exaggerated, say researchers

Statins

Intolerance is "overdiagnosed"

A study of more than four million patients in the *European Heart Journal* found the true prevalence of statin intolerance worldwide to be 9.1%. The lead researcher, Maciej Banach, on behalf of the international Lipid Expert Panel, said, "Our findings mean we should evaluate patients' symptoms very carefully, first to see whether symptoms are indeed caused by statins and, second, to evaluate whether it might be perceptions that statins are harmful—the so called nocebo or drucebo effect—which could be responsible for more than 50% of all symptoms."

Inequalities

Research aims to tackle structural health inequities

The independent NHS Race and Health Observatory is commissioning research to evaluate the gaps in provision for ethnic minority communities and offer evidence based recommendations for change. The observatory is looking to commission four reviews that tackle inequalities in mental health provision for people from Gypsy, Roma, and Traveller (above) communities, as well as access to precision medicine, communications in maternal care, and health inequalities faced by people with learning difficulties from minority ethnic backgrounds.

Public health

Only one in three take up cervical screening

The government launched a campaign to urge patients who are eligible for cervical screening not to ignore invitations. In March 2021 nearly a third (30%) of eligible individuals were not screened. A survey of 3000 patients found embarrassment was the most common reason for not attending (42% of respondents), followed by those who "kept putting it off" (34%) or were "worried it would be painful" (28%).

Wine labelling is "woefully inadequate," say experts

The Alcohol Health Alliance UK called for better labelling on alcoholic drinks after an analysis found wine from the 10 leading brands in the UK contained as much as 59 g of free sugars per bottle. None of the 30 products had sugar content on the label—information that is required for all non-alcoholic drinks. Government guidelines recommend no more than 30 g of free sugars a day for an adult, which can be contained in two medium glasses of wine.

Short daily exercise at 70 shows benefits

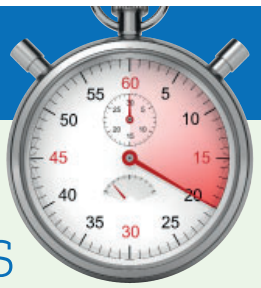
Twenty minutes of moderate to vigorous daily exercise in early old age (70-75) may stave off major heart disease in late old age (80+), research published in *Heart* showed. Italian researchers drew on data from the Progetto Veneto Anziani, a study of 3099 Italians aged over 65. They concluded, "These results suggest policies should be targeted at promoting physical activity in mid- and early late life."

Cite this as: *BMJ* 2022;376:o379

OMICRON

Around **3000** volunteers will take part in a clinical trial to test a Moderna omicron variant vaccine. Half will receive the omicron specific vaccine and half will receive the standard Moderna covid vaccine (Spikevax).

[National Institute for Health Research]



SIXTY SECONDS ON . . . MPs AND STATISTICS

YOU CAN PROVE ANYTHING YOU WANT WITH STATS

Some say so. But we've faced so many during the pandemic that it's not always been easy to interpret them.

AT LEAST WE CAN RELY ON MPs NOT TO GET THINGS WRONG

Don't be too sure. A survey by the Royal Statistical Society (RSS) found that almost half of MPs were unable to answer a simple probability question correctly.

HOW SIMPLE?

A total of 101 MPs were asked the question: if you toss a coin twice, what's the probability of getting two heads? Only 52% gave the correct answer of 25%.

AN AVERAGE PERFORMANCE. DO THEY NEED A CRASH COURSE?

This was an improvement from when the RSS polled MPs with the same question 10 years ago, when only 40% got the correct answer. But RSS chief executive Stian Westlake said the latest results highlighted that "more needs to be done to ensure our elected representatives have the statistical skills needed for the job."

HAS THE PANDEMIC HELPED TO RAISE STANDARDS?

It wouldn't seem so. Last year complaints to the UK Statistics Authority about the use of statistics almost tripled, with 72% of cases relating to health and social care, and 97% of those relating to covid-19.

ANY NOTABLE CULPRITS?

The former health secretary Matt Hancock received a ticking off from the watchdog over the way he described covid testing data. The prime minister has also been censured over his use of crime statistics.

SURELY NOT? WHAT WERE THE ODDS ON THAT?

Short, you would imagine.

DID THE LATEST SURVEY TELL US ANYTHING ELSE?

Politicians who have been in power for longer performed better than those elected more recently. But, given recent events, we may not find out if Boris Johnson's handling of stats is like a fine wine.

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2022;376:o377

(Continued from page 253)

people from black ethnic groups was particularly poor. Evidence indicated that barriers to seeking help were rooted in a distrust of primary care and mental healthcare, as well as a fear of being discriminated against. One study showed that black children were 10 times as likely as white British children to be referred to child and adolescent mental health services by social service teams rather than their GP.

In maternal healthcare, the report said there were some positive relationships with staff, particularly midwives, but this was far from the norm. Women without English language skills often lacked access to good quality interpreting services. Overall, the review of maternal care found evidence of negative interactions, stereotyping, disrespect, discrimination, and cultural insensitivity, leading to some women from ethnic minorities feeling "othered," unwelcome, and poorly cared for.

The review also found evidence of inequalities in the NHS workforce. It found evidence of ethnic minority staff enduring racist abuse from other staff and patients. This was particularly stark in black groups. An ethnic pay gap was found to affect black, Asian, mixed, and other groups and, to a lesser extent, Chinese staff.

The review also pointed out that research studies using clinical data often had substantial amounts of missing ethnicity data. For example, only one study investigated health inequality in the care of ethnic minority newborn babies.

The report made several recommendations, including ensuring that patients' ethnicity was recorded in all NHS interactions; improving statistics to monitor clinical outcomes in ethnic minority populations; investing in interpreter services; building trust with ethnic minority groups and community organisations; and investing in research to understand the effects of racism on healthcare.

The lead investigator, Dharmi Kapadia, a lecturer in sociology at Manchester University, said, "The evidence on the poor healthcare outcomes for many ethnic minority groups across a range of services is overwhelming and convincing. The time for critical action on ethnic inequalities in healthcare is now."

Jacqui Wise, Kent

Cite this as: *BMJ* 2022;376:o382

RESEARCHERS screened over 13000 research papers, spanning a 10 year period, with 178 studies included in the final rapid review

AstraZeneca accused of withdrawing diabetes drug to protect wider interests

The drug company AstraZeneca has withdrawn the type 1 diabetes indication for dapagliflozin because of fears that required changes to its label would cause confusion among doctors when prescribing it for other conditions.

The company removed the indication for 5 mg dapagliflozin in October after UK and EU medicines regulators advised that—despite there being no new safety or efficacy concerns—an inverted black triangle would need to be added to the label to signify that additional monitoring was required when the drug was prescribed.

AstraZeneca said in its announcement the changes "might cause confusion among physicians treating patients with type 2 diabetes, heart failure with reduced ejection fraction, or chronic kidney disease."

But the Juvenile Diabetes Research Foundation, a non-profit organisation that funds type 1 diabetes research, said AstraZeneca's actions were driven by a "commercial conflict of interest," as other, larger groups of patients had been prioritised at the expense of those with type 1 diabetes.

Speaking to *The BMJ*, the foundation's policy director, Hilary Nathan, said, "Dapagliflozin is an important treatment for people with type 1 diabetes in helping to reduce blood glucose levels and prevent the heightened risk of longer term cardiovascular and renal complications. We believe there is a commercial conflict of interest that is driving such decision making. In particular, we are concerned that the decision to withdraw this treatment lacks clinical scrutiny and regulatory oversight to

Mild covid risks long term heart problems

Infection with SARS-CoV-2 can cause cardiovascular problems for up to a year, not just in the acute phase, a large study has found.

The authors reported in *Nature Medicine* that one year after infection people were at higher risk of cardiovascular disease, including cerebrovascular disorders, dysrhythmias, ischaemic and non-ischaemic heart disease, pericarditis, myocarditis, heart failure, and thromboembolic disease. Even those who had not been admitted to hospital with covid were at risk, but this increased with the severity of the infection.

These risks might manifest even in people at low risk of cardiovascular disease

Those who had had covid had a 72% increased risk of heart failure, 63% of heart attack, and 52% of stroke when compared with controls.

The researchers wrote that the increased risks "were evident regardless of age, race, sex, and other cardiovascular risk factors, including obesity, hypertension, diabetes, chronic kidney disease, and hyperlipidemia; they were also evident in people without any cardiovascular disease before exposure to covid-19, providing evidence that these risks might manifest even in people at low risk of cardiovascular disease."

The researchers used the US Department of Veterans Affairs database to build a cohort of 153 760 people who had survived the first 30 days of infection between March 2020 and January 2021.

They said health systems must prepare to deal with possible big problems in future. In the UK more than 16 million people have been infected by the virus.

Janice Hopkins Tanne, New York

Cite this as: *BMJ* 2022;376:o378

Better stakeholder engagement with those living with the condition by industry is needed
Sufyan Hussain

We're disappointed a solution couldn't be found that allowed the drug's continued safe use
Simon O'Neill

establish the impact on health outcomes for people with type 1 diabetes."

The foundation also warned the move set a precedent by which a commercially driven drug company can remove access to a drug without any scrutiny of potential conflicts of interests or cross sector consultation.

Simon O'Neill, Diabetes UK's director of health intelligence and professional liaison, said, "We're disappointed AstraZeneca and MHRA could not find a solution that allowed people living with type 1 diabetes to continue to use the drug safely. If it was possible to find a way of doing so, without causing potential confusion to people with diabetes or healthcare professionals, then we would like to see dapagliflozin reinstated."

Sufyan Hussain, a member of the foundation's scientific advisory council, said the way the withdrawal was handled showed that "better stakeholder engagement with those living with the condition by industry is needed." He told *The BMJ*, "Efforts to understand those affected and preserve the option in type 1 diabetes or those with hybrid type 1 and type 2 diabetes phenotypes, such as considering different branding with a licence in type 1 diabetes, could have been explored. While there is a cost, it may have allowed a positive step for all involved."

Hussain added he would like to see more transparency and better communication of the decisions that drug companies make.

AstraZeneca did not respond to the accusation it had prioritised larger and more profitable patient groups over patients with type 1 diabetes. It told *The BMJ* that the decision had been agreed with the MHRA and the EMA after discussions about product information changes needed after approval for dapagliflozin 5 mg specific to type 1 diabetes, "which might cause confusion among physicians treating patients with type 2 diabetes, heart failure with reduced ejection fraction, or chronic kidney disease."

Alison Cave, the MHRA's chief safety officer, said, "Before we made our own communications, we talked to diabetes charities to understand their concerns and how best we can reassure patients."

Elisabeth Mahase, *The BMJ*
Cite this as: *BMJ* 2022;376:o373

TIMELINE

- In September 2019 dapagliflozin—the first adjunct therapy to be prescribed to people with type 1 diabetes in the UK and EU—was licensed for people with type 1 diabetes who had a BMI >27 to help with hyperglycaemia and weight loss. The Juvenile Diabetes Research Foundation has estimated that around 1300 people with the condition in the UK were prescribed dapagliflozin up until October 2021.
- As part of the approval AstraZeneca was required to conduct and submit the results from a post-authorisation safety study of diabetic ketoacidosis. This is a known side effect occurring in at least one in 100 patients. The study found no new safety problems.
- But the EMA and MHRA advised AstraZeneca that it would need to add an inverted black triangle to the product labelling. In October 2021 AstraZeneca voluntarily withdrew the type 1 diabetes indication.
- In December 2021 the MHRA published guidance for healthcare professionals on dapagliflozin, in which it stated that the "removal of the type 1 diabetes indication is not because of any new safety concerns." It advised that, after stopping dapagliflozin, frequent blood glucose monitoring is recommended and that an increased insulin dose may be needed.

Show evidence for lifting covid measures, doctors tell PM

Doctors and scientists have warned the prime minister that SARS-CoV-2, and not politics, should dictate the pace at which the UK lifts measures to contain the pandemic.

They expressed their concern after Boris Johnson's announcement in parliament on 9 February that he intended to end all remaining restrictions four weeks early if "encouraging trends" continued. The move would see measures, including the requirement to self-isolate after a positive test result, ending as early as 24 February.

Penelope Toff, chair of the BMA's public health medicine committee, said, "With case rates still incredibly high and hundreds of deaths each day, the suggestion that self-isolation may be removed this month runs contrary to good public health practice. We must question on what scientific basis this decision is being made, and the government needs to show the evidence behind its proposals."

It is wise to ramp measures down gradually and up rapidly
Iain Buchan

In the days after the announcement No 10 confirmed the decision had been prompted by a recent fall in rates of hospital admission and was not based on the advice of the SAGE advisory group.

But many scientists have said that declining admission rates could not be interpreted as a sign that the virus no longer presented a danger.

Iain Buchan, chair of public health and clinical informatics at Liverpool University and a SAGE member, emphasised the need for caution. "It is wise to ramp measures down gradually and up rapidly, guided by data on the prevailing biology, behaviours, and environments," he told *The BMJ*.

Marian Knight, professor of maternal and child population health at Oxford University and an occasional adviser to SAGE, said her main worry was indirect consequences of an early end to restrictions. "We're still seeing large numbers of pregnant women admitted to hospital with covid," she told *The BMJ*, adding, "Anything that makes women less confident in attending their routine antenatal and postnatal visits is of concern."

A No 10 spokesperson said any plan to lift restrictions would be subject to independent advice.

Adele Waters, *The BMJ*
Cite this as: *BMJ* 2022;376:o383

NEWS ANALYSIS

Is antivaccine sentiment affecting routine childhood immunisations?

With uptake of the MMR vaccine falling in the UK, **Emma Wilkinson** examines whether antivaccination sentiment around covid-19 has played a part in discouraging parents from protecting their children

Despite being in a fairly deprived and diverse area of Sheffield, the Wincobank Medical Centre has always achieved good uptake of childhood immunisations. This year, however, the centre will be penalised financially because of declining immunisation rates and new payment structures.

Anne Noble, a GP partner, recently wrote reminders to parents whose child had missed an immunisation. But while doing so she noticed the practice nurses had already had detailed conversations with them.

"This is anecdotal, but we're finding quite a lot of parents saying they have researched the [MMR] vaccine and are refusing it," Noble told *The BMJ*. "Covid vaccine hesitancy seems to have impacted on it, unfortunately. There seems to be a loss of trust, which is both sad and worrying."

Falling coverage

On 1 February the UK Health Security Agency warned that coverage of the first dose of the measles, mumps, and rubella vaccine had dropped below 90% in 2 year olds. By age 5, uptake of two doses had dropped to 85.5%—well below the World Health Organization's 95% target needed for elimination of measles.

The latest quarterly figures show very small declines in uptake in England from July to September 2020, and uptake continued to decline over the next year.

And it's not just MMR: small decreases have been seen in coverage of other childhood vaccines, including the combined diphtheria, hepatitis B, Hib, polio, tetanus, and whooping cough vaccine, as well as those for rotavirus and meningitis B. But MMR is the one that public health officials worry about most because of historically lower uptake and the risks of outbreaks.

We ought to try a bit harder: bring vaccination clinics to the community centre, the mosque
Greg Fell

We really need to know what people's concerns are: is it trust in vaccination, or are they very busy and not coping?
Farzana Hussain

Impact on deprived areas

Anthony Gore, a GP and clinical director for young people and maternity commissioning at NHS Sheffield Clinical Commissioning Group, said that MMR rates seemed to have fallen further in more deprived areas. In Sheffield this disparity is particularly stark because there's a clear divide between two halves of the city, but it would be replicated around the country, he added.

It's not clear exactly how much the antivaccine sentiment over covid is feeding into routine childhood immunisations, as these deprived areas have always struggled to get good uptake—covid included. "They are also the areas where, if MMR uptake falls, you can guarantee you will get a measles outbreak, and if you get a measles outbreak a child will die," said Gore.

One recent international study found that people's trust in government was linked to covid vaccine uptake. Fluctuations in childhood vaccination may be for complex reasons, partly related to access to care during the pandemic, as separate research in 2020 found some confusion among parents over whether services were still open.

Yet GPs in deprived areas now face being penalised financially at a time when they may need extra resources to improve uptake. This is because some immunisations, including MMR, have been added to the Quality and Outcomes Framework (QOF), where GPs have to hit 95% uptake to get the full payment.

Gore said that this change now seemed like a very bad idea, as practices that have to work the hardest will have fewer resources. He added that they wouldn't be able to do it alone and called for concerted national and local campaigns to improve uptake.

"Childhood immunisation rates look like they're being affected by general chitchat in social media and antivaccine messages that were specific to covid," he said. "We need to start the pushback against that idea."

Awareness may be part of the problem. Research commissioned by the Department of Health and Social Care showed that almost half of parents were not aware of the serious complications of measles, and only four in 10 knew that measles could be fatal.

Farzana Hussain, a GP in Newham, east London, began carrying out drive-through vaccinations at the start of the pandemic when she realised uptake was falling. The practice is still having to work incredibly hard to hit QOF targets, and percentage uptake is currently in the low 90s."We have an admin person who spends an hour a week calling parents, and without it I think we'd be at 50%," Hussain told *The BMJ*. "Most say yes, they will come in, and then never turn up.

"We really need to know what their concerns are—is it trust in vaccination, or is it that they are very busy and not coping? It can take a lot for someone to tell you, and everyone probably has their unique reason."

Lessons from covid

Provisional data in England and Wales show almost 700 measles cases in 2020. In 2018, outbreaks led to 2557 cases and two child deaths. This is not a disease of the past, but it could be.

Greg Fell, Sheffield's director of public health, said lessons could be learnt from the covid vaccination campaign. "For some people, these are difficult to access services, so we

DAVID GEE / ALAMY

probably ought to try a bit harder," he said. "Not just to run a vaccination clinic in a surgery a mile away but bring it to the community centre, bring it to the mosque, and work with those community leaders. That's being organised now."

And although work during the pandemic has overcome some hesitancy about covid vaccines, Fell said that serious antivaccination messages had not been properly tackled. "Historically, we've been reluctant to publicly take on those messages because it creates a lot of noise, and people get more confused in the crossfire," Fell said. "We're all going to have to reflect on how well we've done that, locally and nationally."

It is quite difficult as we don't have any solid data: we have the uptake figures, but we don't have the attitudinal stuff
Helen Bedford

Lack of data

Helen Bedford, professor of child health at UCL Great Ormond Street Institute of Child Health, highlighted that vaccine uptake guidance from NICE was due later this year but that the underlying reasons for declining vaccination rates would be complex. "It is quite difficult at the moment, as we don't have any solid data: we have the uptake figures, but we don't have the attitudinal stuff," she said.

Bedford identified the massive shortage of health visitors, many of whom were redeployed in the pandemic, as a factor. It's also worth noting that vaccine uptake has increased in Scotland, she added.

"With health visitors, it's young families missing out on those early contacts—where you talk about vaccination, encourage parents to take it up, and remind them about it," she said. "That's one issue that I think is really important."

Emma Wilkinson, freelance journalist, Sheffield

Cite this as: *BMJ* 2022;376:o360

"Covid staff absences are still stretching NHS hospitals"

Staff absences resulting from covid-19 are continuing to place acute care hospital services under high pressure, medical leaders have told *The BMJ*.

Official data show that an average of 70 000 hospital trust staff in England were absent from work in the week ending 30 January, 28 000 (40%) of whom were off because of covid-19. On 18 and 19 January *The BMJ* visited University Hospitals Coventry and Warwickshire NHS Trust (UHCW) to speak to leaders and staff about workforce pressures (see video on bmj.com).

In the seven days to 19 January UHCW had an average of 644 staff absent, 275 (43%) of whom were absent because of covid. Since then, staff absences have remained high: the latest available data for the week ending 30 January showed an average of 680 staff absent, 40% (269) from covid.

These numbers were a small decrease from the time of the peak of the omicron variant in early January: from 3 to 9 January an average of 1000 staff were absent at the trust, 52% (515) from covid.

But leaders at the trust told *The BMJ* that pressure remained a problem. Kiran Patel, chief medical officer at UHCW, said, "We're quite concerned about making sure we have enough staff to run all of our services, and we are concerned because of the impact of isolation of staff who either have tested positive or have family members who have tested positive for covid and need to take time off work.

ONE CASE OF COVID IN A HOUSEHOLD IS CAUSING US TO MAKE SOME REAL LAST MINUTE CHANGES TO OUR ROTAS
Ed Hartley

"And of course, that happens in an unplanned manner, so it's a sudden loss of staffing at scale. That makes it increasingly difficult to plan and schedule services, and we're doing that on a day-by-day basis at the moment."

Ed Hartley, a consultant and clinical director for the emergency department at Coventry, said the number of staff absent because of covid had made this year much harder than previous winters.

"We are used to staff suffering from short term sickness, coughs and colds, and bugs," he told *The BMJ*. "But at the moment, with covid, one case of covid in the household means that one member of staff might be off for five to seven days. It's causing us to make some real last minute changes to our rota."

In a survey of 1016 healthcare staff published last week by YouGov, 95% said their workplace had recently been affected by staff shortages resulting from covid. This included nearly half (48%) who said their workplace had been affected to a "great" extent and 37% who said it had been affected to a "moderate" extent. Only 3% said that they had not been affected

National situation

The workforce pressures are not confined to Coventry. Healthcare workers in NHS hospitals were the most likely to say that they had been "greatly" affected (55%), compared with 46% in mental health trusts, 41% in community services and local authorities, and 37% at general practices.

Of the NHS staff whose workplace had been affected by staff shortages, 71% said that current staff were working overtime or doing extra shifts to make up the missing hours, 38% said that their workplace was bringing in agency staff to cope with shortages, and 36% said that staff were being redeployed from nearby locations to assist.

Some 18% said that recently retired staff had returned to work to help, while a further 9% said that their workplace was using volunteers to fill gaps.

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2022;376:o350

PATRICK DOYLE/REUTERS/ALAMY

THE BIG PICTURE

“Freedom convoy” shuts down Ottawa

A counter-protester in Ottawa on 10 February (left) urges anti-vaxx truckers and their supporters to end their protest against Canada’s covid vaccine mandates and lockdowns.

The capital’s mayor, Jim Watson, declaring a state of emergency, described the situation as a “siege of our downtown area.”

There are fewer than 8000 protesters in the so called Freedom Convoy (below), but their more than 500 heavy trucks and other vehicles have made it almost impossible for the police to dislodge them from the roads.

Hospitals have moved from eight hour to 12 hour shifts as staff struggle to get to work, while patients fearful of crossing the protest zone are cancelling appointments, and fewer are visiting emergency departments, Ottawa’s hospitals said.

Healthcare workers have felt especially targeted by the protesters and are being told not to travel in their work clothes. Two ambulances have reportedly been attacked with stones.

The fundraising website GoFundMe raised nearly C$10m (£5.8m) towards the protests, but organisers have announced that most of this will be returned after police provided evidence that the “previously peaceful demonstration has become an occupation.”

Owen Dyer, Montreal

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EDITORIAL

Regulatory decisions diverge over aducanumab

FDA's accelerated approval for the US is a controversial outlier

The European Medicines Agency refused marketing authorisation for aducanumab (Aduhelm), a monoclonal antibody targeted at amyloid β, in December 2021. It noted that "although Aduhelm reduces amyloid beta in the brain, the link between this effect and clinical improvement has not been established."[1] Furthermore, it concluded "studies did not show that the medicine was sufficiently safe," citing reported side effects including brain swelling and bleeding. This decision contrasts with that of the US Food and Drug Administration, which granted the drug accelerated approval in June 2021.[2]

The FDA's approval of aducanumab for treatment of Alzheimer's disease was based on a reduction in amyloid β plaques during clinical trials. It has been one of the most consequential and controversial regulatory decisions in recent years.[3] The FDA's peripheral and central nervous system drugs advisory committee voted almost unanimously against approval, and three panellists resigned following the decision.[4 5]

A reduction in amyloid β plaques is known to be an unreliable surrogate for cognitive improvement or delayed clinical decline in adults with dementia, and critics argue this endpoint should not be used to justify accelerated approval.[6 7] The FDA also allowed a generous nine years for confirmatory trials with clinical outcomes. The FDA acting commissioner has called for an independent review of interactions between Biogen and FDA during the approval process, casting further doubt on the rigour and validity of authorisation.

The cost of treatment has also caused problems. Biogen announced an initial annual cost of $56 000 (£42 000) per patient, over 10 times the price recommended by the independent Institute for Clinical and Economic Review.[12] Although reimbursement decisions in the US usually follow FDA approvals, several leading healthcare providers and insurers have declined to use or fund aducanumab. In December 2021, Biogen announced a 50% reduction in the annual cost.[13]

KRISTOFFER TRIPPLAAR/ALAMY

A reduction in amyloid plaques is an unreliable surrogate for cognitive improvement or delayed clinical decline

The FDA and EMA have a high degree of concordance (>90%) in marketing authorisation decisions.[14] The divergence over aducanumab is therefore surprising, and it is important to consider possible reasons.

Different approaches

Typically, the FDA approves new drugs earlier than the EMA.[15] In the case of aducanumab, the EMA application was submitted 115 days after that to the FDA. This delay may have permitted an application with more mature clinical and safety data, including data from Biogen's phase III clinical trials showing that 41.3% of patients who received a high dose (10 mg/kg) of aducanumab experienced brain swelling or bleeding compared with 10.3% in the placebo group.[16] Furthermore, in 2018 the EMA adopted revised guidelines for the "clinical investigation of medicines for the treatment of Alzheimer's disease."[17 18] This guidance emphasises the need for clinical trials to show cognitive, functional, and global benefit. Authorisation of aducanumab would have been inconsistent with this recommendation.

New drug approvals require "substantial evidence" of efficacy, typically through a demonstration of how patients feel, function, or survive. Early approval pathways are intended to strike a careful balance to allow patients access to promising new therapies earlier, with confirmatory evidence later. FDA's accelerated approval pathway has permitted early access to transformative new therapies such as imatinib for chronic myelogenous leukaemia. However, in the early approval of aducanumab, the FDA is being overzealous, as the link between surrogate endpoint and improvement in symptoms or cognition has not been established, and is even refuted.[6 7]

The divergence in opinion between the EMA and FDA is significant and may reflect the EMA's more cautious and scientifically grounded approach to accelerated pathways. Less than a week after the EMA decision, a Japanese health ministry advisory subgroup recommended deferring the decision on aducanumab, echoing similar efficacy and safety concerns and advising "effectiveness and safety should be re-examined through proper clinical trials."[19]

With Biogen intending to appeal the EMA verdict and multiple new anti-amyloid drug hopefuls (such as donanemab) nearing regulatory submission, the debate about this approval could shape neurodegenerative drug development for many years.[11] Fostering greater engagement and harmonisation between global medicine regulators in their assessments would ensure regulatory standards and public trust are maintained.

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EDITORIAL

Gambling Act review

A test case for the UK government's commitment to public health

The UK government is taking a fresh look at gambling. A white paper, expected in spring 2022, will propose an update of the 2005 Gambling Act. This is welcome news: we now know far more about the damage done by gambling in the UK, including financial distress, relationship breakdown, and suicide.[1-3] But this knowledge will translate into meaningful action only if the new law recognises that the contemporary gambling landscape is a threat to public health.[4] We set out three tests that a truly public health focused law, based on principles of equity, collective responsibility, and human rights,[5] should meet.

First, the law should consider all gambling related harms on the population. Current responses to the potential for harm, mostly industry funded, characterise gambling as just another leisure activity offering "fun," with any harms affecting only the few who continue to gamble after the fun stops.[6 7]

Concepts relevant to use of data and evidence in gambling policy debates

- At the time of the passage of the Gambling Act 2005, the House of Commons Culture Media and Sport Committee stated: "There is a decision which the government needs to take about its policy for the regulation of commercial gambling. Like the decision whether to put a new drug onto the market, the question is whether, in the absence of agreed evidence that the product is safe, the government should be cautious about giving it the go ahead, or, in the absence of agreed evidence that the product is unsafe, the government should allow further deregulation, letting competition, as Sir Alan Budd [chair of the Gambling Review Body] recommends, safeguard price and quality for the consumer. The key issue is that at present there is insufficient evidence on which to make judgments about safety."[11]
- Absence of evidence of harm should not be conflated as evidence of absence of harm
- A downward trend in harm does not signify that an issue is no longer of public health concern
- Small studies that do not reach statistical significance can still provide useful insights into mechanisms of harm or potential intervention effectiveness
- Single studies are not definitive and do not prove causation, which requires a coherent and plausible body of evidence made up of multiple studies from multiple fields.

Spiral into destitution

Of course we must support those who enter a vicious downward spiral into destitution, but this ignores the many others who barely avoid this fate and those harmed by another's gambling.

With a looming cost of living crisis, is it really acceptable for many families to contribute substantial amounts of their diminishing disposable income to gambling companies, exploited by pervasive advertising holding out illusory prospects of winnings? As accounts emerge of families forced to choose between heating their homes and feeding themselves, we cannot stand back while their hopes are exploited to benefit the industry through the "coercion of circumstance."[8]

Second, the law should recognise that those responsible for creating harms to health should not be involved in decisions about how to prevent these harms, given the obvious conflict of interest. We do not allow tobacco companies to design tobacco control policies, yet the gambling industry, through the organisations it funds, shapes our responses to the harms.[6 7]

As with other harmful commodities such as tobacco and alcohol, the industry narrative emphasises "downstream" measures, helping those at risk of, or affected by, "problem gambling", rather than tackling the upstream "causes of the causes," in particular its own activities, including sophisticated marketing of highly addictive products.[9] A public health approach would learn from the growing research on commercial determinants of health and how concepts such as corporate social responsibility are often abused.[10]

Third, legislation should adopt the precautionary principle. When there is reason to believe something is damaging to health, the burden of proving lack of harm lies with those who profit from it. Experience has taught us the dangers of waiting for evidence of harm to become so clear that action becomes inevitable, a process often delayed because those causing the harm endeavour to undermine the emerging evidence (box).[12 13]

The review is a once in a generation opportunity to reframe an activity that has shattered many lives

A rich evidence base on corporate behaviour is available to draw on. Harmful industries attempt to define what constitutes evidence, typically demanding unattainable standards of proof or dismissing evidence that captures the often indirect and contextually bounded associations that characterise real world human activities.[12 13] These tactics are familiar to those working on environmental toxicology, in which what counts as proof of danger is highly contested.[14] Lack of definitive evidence cannot be a licence for inaction.

The current review is a once in a generation opportunity to reframe an activity that has shattered many lives, but it will succeed only if it reframes gambling. Just as we have a Food Safety Act and a Clean Air Act, we need a Prevention of Gambling Harms Act. This would redirect our focus from people's behaviour and vulnerabilities towards a responsibility on us all, and the government that we look to for our protection, to make sure that the necessary safeguards are in place. If the gambling industry can convince us that its products are indeed harmless, so be it. Otherwise, just as health professionals are required to "first do no harm," it is reasonable to ask the same of others.

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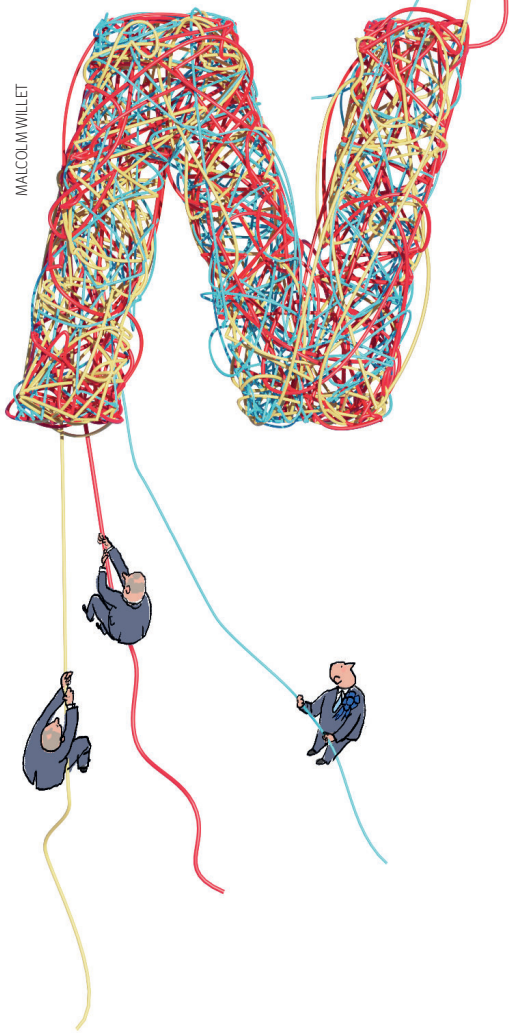
BRIEFING

Ten things you need to know about the health and care bill

Tom Moberly asks what doctors need to know about the first big overhaul of the NHS in England since 2012



MALCOLM WILLET

The clock is ticking

The new Health and Care Bill is the first major legislative reform of the NHS in England in a decade, and contains measures on the NHS, social care, and public health. The bill is scheduled to become law by April, although there are doubts this deadline will be met.

The proposed legislation is currently being examined by the House of Lords, and any amendments that are agreed then need to be taken to the House of Commons. The NHS's latest planning guidance has pushed back the deadline for when the new NHS structures would be established on a legal basis by three months to July 2022.

It is a story of two halves

The bill consists of two big sets of legislative changes that are designed to perform two quite different functions but have been lumped together.

The first is largely to tidy up the mess left by Andrew Lansley's Health and Social Care Act 2012—promoting integration and collaboration over competition, ending requirements around enforced competition, and introducing legal and organisational changes to close the gap between how the current system was set up and how it is now working. These changes will make it easier to renew contracts with those providers that are seen to be doing a sufficiently good job, without having to go out to the market before awarding a contract.

The second is to give the secretary of state more control over local health services. This is thought to be a response to ministers' frustration with the independence afforded to local health systems and their own relative lack of control over the delivery of their priorities for the NHS.

The bill also includes measures to allow the merger of arm's length bodies and to change the cap on care costs for social care.

It provides the legal foundations for new structures

The proposed legislation will establish integrated care systems as statutory bodies. These replace clinical commissioning groups.

Integrated care systems already exist in non-statutory form in 42 areas. The bill will put them on a statutory footing and create integrated care boards as new NHS bodies.

Each system will be made up of two organisations: an integrated care board and an integrated care partnership. The board will be responsible for controlling most NHS resources, while the partnership will be a collaboration through which the NHS, local authorities, and other organisations make decisions about local health plans.

The structure and membership of integrated care boards is one of the most hotly debated aspects of the proposed legislation. This is because the bill opens up the possibility of private service providers sitting on the boards.

The bill imposes certain mandatory members and sets out the structure. It then largely leaves it up to clinical commissioning groups to determine as they draw up constitutions for their replacements.

We need more detail to know if it will work as intended

Encouraging collaboration, rather than competition,fits with the NHS direction of travel over the past decade. But that does not mean the new legislation will deliver exactly what proponents of further integration and collaboration want.

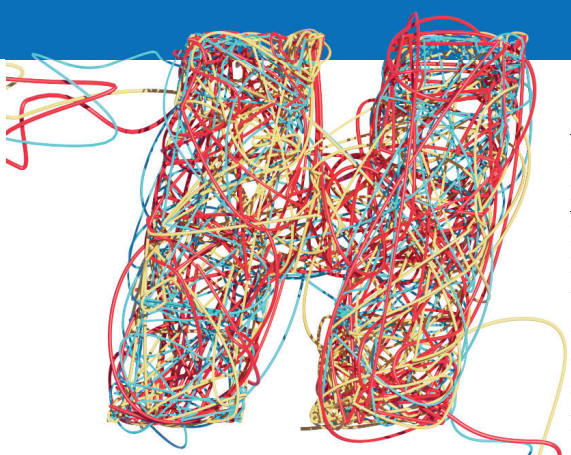
The BMA argues that the bill should ensure adequate clinical engagement throughout integrated care systems. And National Voices wants patients to be working closely with healthcare organisations and local government within integrated care systems.

The Health Foundation points out that, even though encouraging collaboration makes sense, the advantages are often exaggerated. "The benefits of these changes should not be overstated and there is a risk that the new NHS structure is complex, vague, and not adequately designed to support the bill's aims for better integration between NHS and wider services," it warns.

The BMA and others want changes to stop the NHS being privatised

The BMA, the Labour Party, the campaigning group Keep our NHS Public, and others fear that the bill could allow contracts to be awarded to private providers without appropriate scrutiny. The BMA is lobbying for amendments to strengthen the proposed replacement for mandatory competition and to protect the NHS from the unnecessary involvement of the private sector. "We want the NHS to be the default option for the provision of NHS services, so that contracts are not simply handed to private providers," it says.

It also wants to stop private companies from being able to sit on NHS boards and



is calling for amendments to prevent corporate private providers from sitting on integrated care boards and influencing commissioning decisions.

For Mark Dayan and Helen Buckingham of the Nuffield Trust the bill is not likely to lead to a widespread corporate takeover. Rather, they say, removing requirements to tender all large contracts, allowing contracts to be rolled over, and having local health bodies working together "actually herald a less competitive, less marketised NHS." They argue that the question of whether the bill will privatise the NHS is not an issue and that focusing on this will distract people from properly examining other aspects of the legislation.

Ministers' power grabs could prioritise politics over patient care

The BMA, the King's Fund, NHS Confederation, and NHS Providers warn that the new powers being given to the secretary of state could create a health service in which decisions are taken to suit party politics rather than patients. This is because the bill requires that the secretary of state be notified of any changes in local services, and it allows them to step in and take decisions themselves on these changes.

The concern is that there are no safeguards specified in the bill as to when the powers to take decisions away from local health organisations would be enacted. This could mean local decisions about the configuration of health services are held hostage to national political matters.

The constitution select committee of the House of Lords also raised concerns about the proposals. "This could alter the balance between the government's constitutional responsibility for the provision of healthcare and providers' ability to function in a manner that can respond effectively to local needs," the committee said.

It doesn't tackle staff shortages, inequalities, or social care issues

Despite being the first major reform of the NHS for a decade, medical organisations, think tanks, and charities have pointed to a long list of problems that the bill does not do enough to tackle, including workforce shortages, health inequalities, and the problems in social care.

Medical royal colleges, the BMA, and NHS Confederation have described the absence from the bill of any provision for long term workforce planning as a "glaring omission." The BMA wants to "make government accountable for safe staffing" and it is calling for a requirement to be introduced for the government to undertake regular workforce assessments and to be accountable for ensuring the NHS has adequate numbers of staff.

On health inequalities, the provisions in the bill "amount to more of the same," according to the Health Foundation, and are a missed opportunity both to acknowledge the NHS's role in influencing wider determinants of health and to broaden the duties placed on the government to tackle inequalities.

In terms of social care, the Nuffield Trust points out that the bill "does little to tackle the severe and worsening crisis" in social care. "The admirable goal of the NHS working better with social care will not be achieved if the sector is failing to deliver basic support, as is the case today," it says.

The King's Fund argues that the change to the cap on social care costs is "regressive" as those who will benefit most are those who are already well off. It is calling for this change to be dropped from the bill.

It has no champion and no clear narrative explaining its purpose

Some of the concerns about the bill stem from its conception as a legislative tidying up exercise, led by Simon Stevens when he was chief executive of the NHS and onto which Matt Hancock grafted a ministerial power grab when he was health secretary. With Simon Stevens and Matt Hancock no longer in post, their successors will want to implement their own plans which may be at odds with the bill's direction of travel.

Health Secretary Sajid Javid was reported to have pushed for the bill to be delayed or scrapped, only to be over-ruled by Prime Minister Boris Johnson. And Javid has already set out plans, such as for academy-style hospitals, that appear to be at odds with the bill's push for NHS organisations to collaborate more closely and for ministers to be able to intervene in local service reconfigurations.

The changes are unhelpful given current workload pressures

Critics of the bill argue that it will not solve the big problems facing the NHS, such as staff shortages and a broken social care system—why then impose additional work on a service that is already struggling to recover from the pandemic?

"It is wrong to implement wholesale reform while the country is still fighting the covid-19 pandemic, the NHS is facing a significant backlog of care, and doctors have had little time to scrutinise the details," the BMA says.

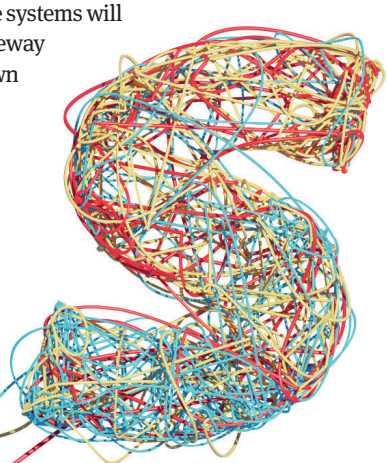
Its proponents would say, however, that the changes introduced by the bill are not additional work, but rather that the bill legislates for what the service is already doing, while removing pointless requirements to pretend that a competitive system still exists.

There is still time to shape the changes

As the parliamentary process grinds on, the BMA wants members to contact MPs and peers. "We need your support in telling policymakers that the Health and Social Care Bill is the wrong bill at the wrong time and encouraging them to support the amendments we are calling for," the BMA says.

In the end, whether the bill makes a difference to patients or not will depend to some degree on how the health service engages with the changes. "Tangible differences in patients' experiences will depend on how local organisations, leaders, and clinical teams implement these changes," the King's Fund says.

The BMA is encouraging members to lobby their local integrated care systems directly. "Integrated care systems will be left a lot of leeway to make their own decisions about how they work, including who sits on boards."



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VACCINATION

Data holes and distrust hamper Russia's covid vaccination programme

The country's regulators have approved three homegrown vaccines, but clinical trial results have been hard to obtain, and the public are hesitant to get their shots, reports **Polina Loseva**

In August 2020, President Vladimir Putin announced that the Ministry of Health had approved use of Sputnik V, the first Russian developed vaccine against SARS-CoV-2, for people at high risk. Russia was between two waves of infection; lockdowns were over, restrictions had been relaxed.

No trial data were published for Sputnik V. Only a couple of reports were available about the phase I and II trials, in which mostly military men reported feeling well after vaccination, and vaccine developers from the Gamaleya Institute injected themselves as the pre-clinical trials started. According to a statement from the Association of Clinical Research Organisations (a Russian non-profit organisation that includes drug companies) testing was "a gross violation of the very foundations of conducting clinical trials, Russian legislation, and generally recognised international norms." Still, Putin offered reassurance to the public by declaring that one of his daughters (he never mentioned her name) had already received her shot and had a high antibody titre.

This was not enough to convince the Russian public: less than 40% would agree to get vaccinated, according to periodic independent polls (fig 1).

Data for the phase I and II trials were later published in the *Lancet* in September 2020, and raised further questions. Critics noted the small cohort size and limited characterisation of the convalescent plasma controls, but also suspicious patterns that appeared repeatedly in several figures. "It seems to us," a group of scientists wrote in a note of concern, "that on the grounds of simple probabilistic evaluations, the fact of observing so many data points preserved among different experiments is highly unlikely."

A phase III trial was expected to shed light on these issues. Meanwhile, the first health workers received their first doses.

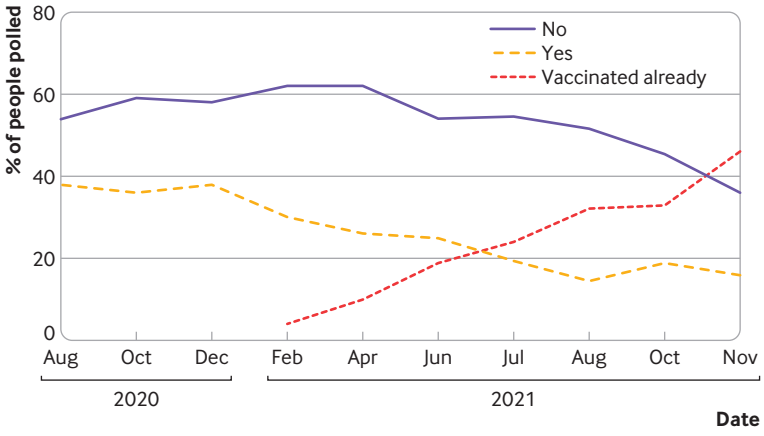

Fig 1 | Percentage of people willing to get a Russian vaccine. Source: Levada Center

Critics noted the small cohort size and suspicious patterns that appeared repeatedly in several figures

The preliminary phase III trial data were released on 11 November, just days after Pfizer/BioNTech and Moderna declared their candidate mRNA vaccines to be effective in phase III trials. Sputnik V's effectiveness, claimed as 92%, was similar to that of Pfizer/BioNTech and Moderna. President Putin announced a national vaccination campaign on 2 December, hours after the UK had made a similar declaration. "I know the industry and the [medical] network are generally ready," Putin said, "Let's take this first step."

Within a few days, healthcare workers and teachers were able to get jabs, and within a month, older people, social workers, and journalists. By mid January, vaccination became available to everyone, which effectively brought clinical trials to a halt. Trial participants, unsure which group they were in, started to ask for the guaranteed medicine. But among the wider public, demand for the vaccine appeared low.

In February 2021, the developers of Sputnik V claimed in a paper in the *Lancet* that the vaccine "showed 91.6% efficacy against covid-19 and was well tolerated in a large cohort." Yet, according to one poll, about 20% of Russian citizens were willing to travel abroad to get a foreign vaccine instead. Another 40% intended to wait for a foreign vaccine to be approved and available in Russia. At the time of writing, none are.

A year on, the Ministry of Health still refuses to publish long term data on Sputnik V, as these results "contain commercially confidential

ANTON NOVODEREZHKIN/TASS/ALAMY

information." The ministry also avoids disclosing the death rate among vaccinated people, citing the "impracticality" of doing so, "as this data does not reflect any interrelation between the lethal case and the vaccination and may provoke negative attitude towards vaccination." Data on side effects and virus neutralisation were available only as part of a study from Argentina.

Data scrutiny

By spring 2021, about 3% of Russians had received covid vaccines (compared with almost 30% in the UK). More than 60% of those polled said they had no trust in the Russian vaccination campaign.

Two more Russian developed vaccines received swift domestic approval with no clinical data. Both became widely available just as the phase III trials began.

EpiVacCorona—the patent for which is held by a group including the head of the Russian Federal State Agency for Health and Consumer Rights—consists of artificially synthesised protein subunits. CoviVac—developed by the Chumakov Institute—is a classic "dead" virus preparation. The absence of viral vectors in both vaccines led experts to suggest that they would be less likely to cause side effects than the adenovirus based Sputnik V. Many people rushed to get a shot of EpiVacCorona or CoviVac, which created queues and shortages never seen for Sputnik V.

The true immunogenicity of EpiVacCorona appeared to be lower than declared–70% versus 100%

In March 2021, the Kremlin announced that Putin had been vaccinated. Officials declined to name the vaccine, stating only that all three available vaccines were effective and reliable. Only one report on the phase I and II trials for EpiVacCorona appeared by the end of March in *Infection and Immunity*, a Russian journal founded by an institution under the Russian Federal State Agency for Health and Consumer Rights, which also manages Vector, the developer of EpiVacCorona. The report stated that the vaccine had "100% immunogenicity", although the data were impossible to verify. Vector used its own test system to assess the antibody titre and claimed that no other system was suitable for such measurements. However, as no culture test results were provided, it remains unknown whether those antibodies actually protected the cells from infection.

By June 2021, several citizen science groups (groups of specialists collaborating separately from the government) had reported their data on EpiVacCorona and CoviVac. The true immunogenicity of EpiVacCorona appeared to be lower than declared (70% versus the 100% claimed in official statements). Moreover, as a preprint stated, "immunisation with this vaccine did not lead to emergence of neutralising antibodies in healthy volunteers." Two further preprints have since been issued (one by a group of epidemiologists from St Petersburg, the other by a scientist and a science journalist), both claiming negative efficacy for EpiVacCorona. This could also be because of the small size of the cohort studied, or because of the tendency in vaccinated people to be less cautious about spreading infection, preprint authors suggested.

The immunogenicity of CoviVac also appears to be lower than officially claimed (less than 50% versus the 75% claimed). But, as the citizen scientist reported, it does seem to work well as a primer or booster for Sputnik V. The developers of CoviVac have issued a preprint on the phase I-II trials,but developers of both vaccines have still to present clinical data from phase III.

Mandatory vaccination

In June 2021, Putin disclosed it was the Sputnik V vaccine he had received, rebutting rumours that it had been Pfizer or Moderna. But Russians had other worries: the delta variant had emerged, pushing the government to introduce mandatory vaccination.

First, companies were obliged to get 60% of their staff vaccinated and

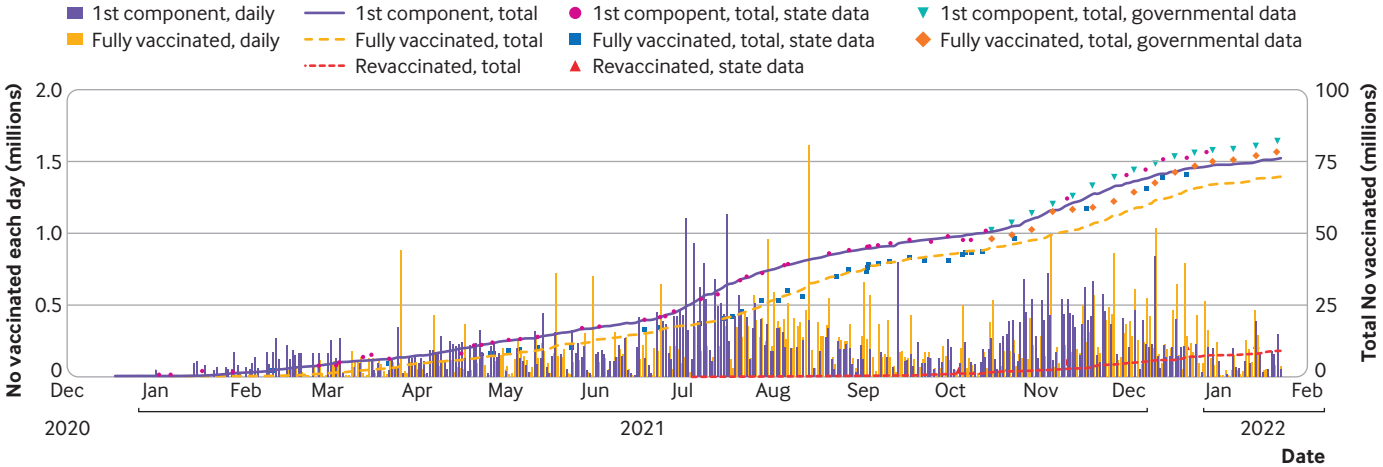

Fig 2 | **Rate of vaccination in Russia**

Fig 3 | Number of websites selling fake vaccination certificates. First peak corresponds to introduction of QR codes. Second peak corresponds to point at which the QR code law was introduced. Source: Novaya Gazeta

DIMITAR DILKOFF/AFP/GETTY IMAGES

another 30% to work remotely. Then, a QR code covid passport system was introduced: a code was generated for every person vaccinated, recovered, or recently tested negative. This was required to access public places, except for grocery stores, pharmacies, and public transport, although implementation varied across regions.

These measures seemed to work. Vaccination numbers reached 15% of the population by July and 35% by the end of August 2021 (fig 2). However, the true number of people vaccinated is a point of contention: trade in fake vaccination certificates peaked as the QR codes were introduced, with certificate prices as high as several thousand roubles (£100).

After a short respite, case numbers started to rise again, and autumn 2021 brought new restrictions and lockdowns. In early November, a fourth wave of covid-19 provoked another period of "non-working days"—the term the Russian government uses instead of "lockdown." To ensure greater consistency between regions, the government proposed plans to unify QR code requirements for access to public places, and separately for intercity and international travel. This sparked anger and sometimes unrest around the country. According to the National Anxiety Index survey (which ranks issues by the volume of discussion in social networks and media) by the end of 2021, Russians feared the QR code system more than SARS-CoV-2.

Less than 50% of the Russian population is vaccinated (most with Sputnik V), although the real rate might be lower

Russia enters 2022 with three two-shot vaccines (and one booster, Sputnik Light, which is a single dose of the normally two-dose Sputnik V). Sputnik V has proved to be effective, though lacks long term data. EpiVacCorona appears to be ineffective, and the effectiveness of CoviVac is still unknown. No other vaccines are accepted to obtain a QR code.

At the time of writing, less than 50% of the Russian population is vaccinated (most with Sputnik V), although the real rate might be lower. According to Viktor Kabanov, who analyses vaccination statistics for the "Watching COVID-19" Facebook community, "the rough estimate of fake certificates is by order of millions" (fig 3). The QR code laws are being continuously postponed as much of the Russian population remains opposed to restrictions.

Meanwhile, the pandemic continues. As of January 2022, the government reported more than 300 000 deaths from covid-19. Studies that include excess mortality suggest that the real number is more than a million, which would place Russia as the highest worldwide (in absolute numbers).

Parallels with flu

Russia's approach to developing and distributing the covid vaccine looks much like its strategy for influenza. In the past, Russia developed several flu vaccines, which—like their covid counterparts—were approved despite a paucity of available data. One such vaccine was registered for use despite being shown to be ineffective against previous strains of flu. Others contain less than three times the amount of antigen recommended by the World Health Organization to stimulate an immune response. These vaccines include adjuvants that are supposed to compensate for antigen deficiency; however, at least one of those—azoximer bromide—is of unknown efficacy.

Flu vaccination in Russia is mandatory only for certain groups, such as teachers and healthcare workers. The number of flu related deaths has not been published for several years. The latest public data, issued by the Ministry of Health in 2019, indicated several hundred victims yearly.

Fewer than 50% of Russians are vaccinated against flu, a rate similar to that for covid-19. In 2019 it was reported that fewer than half of Russian citizens planned to get a flu vaccine. A survey noted greater trust in foreign shots, although these have been in short supply in Russia for several years; and none are available at present.

Flu season usually ends around May in Russia, but covid has no such timeline. With the omicron variant spreading quickly, the country is encountering more than 150 000 cases daily (the previous peak was 41 335 cases in autumn 2021).

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