GP pledge: Javid admits he won’t deliver

The government is not on track to hit its target of 6000 more GPs by 2024-25, health secretary Sajid Javid has admitted.

Speaking to MPs on the Health and Social Care Committee on 2 November, Javid said, “I’m looking at what more we can do. But I’m not going to pretend we’re on track.” He went on to highlight the “unimaginable pressures” that general practice has been facing. “We’ve got to look at other ways we can support GPs, it’s got to be about investment in recruitment as well,” he said.

The Conservative Party had promised the additional GPs ahead of the 2019 general election, as part of a pledge to provide 50 million more appointments in GP surgeries every year. This pledge followed former health secretary Jeremy Hunt’s promise of 5000 more GPs by 2020—a target that was also missed.

The health secretary’s admission comes as an analysis by the Nuffield Trust found that, while the number of GPs in England had risen by 1385 (as of June 2021) since the 2019 general election, the number of full time, fully qualified GPs had actually decreased by 105.

In a blog post Nuffield researcher Lucina Rolewicz wrote, “At the time of writing, we would have expected an increase of over 1700 more full time, fully qualified GPs over this period for the government to be on track to meet its commitment.” She wrote that historically there had been only a few instances where the annual increase in GPs had been greater than 1200—which is the average yearly increase needed to reach the target of 6000 more GPs over five years.

She said that national figures also hid substantial local differences in staffing levels. “Our analysis shows large differences in much of London and the south east compared with other regions in England,” Rolewicz wrote. “Higher numbers of patients per GP are evident in areas such as Thurrock (2373 patients per GP) compared with the north west, where the Wirral has only 1318 patients per GP.”

When pushed on what the government will do in the short term, Javid told MPs that there will be a plan released by the end of the year which will tackle both the NHS and social care workforce in the short term.

On 3 November the government was to launch the “Made with Care” recruitment campaign encouraging people to work in social care in England, where there are more than 105 000 vacancies.

Abi Rimmer and Elisabeth Mahase, The BMJ
Cite this as: BMJ 2021;375:n2666

Sajid Javid (inset), England’s health secretary, told MPs the government would not hit its manifesto target of 6000 more GPs by 2024-25
Inequality led to thousands of adverse birth outcomes in black and Asian women

Socioeconomic inequalities account for an estimated quarter of stillbirths, a fifth of preterm births, and a third of births with fetal growth restriction, found the National Maternity and Perinatal Audit of NHS birth records in England from April 2015 to March 2017.

The audit found that an estimated two thirds (63.7%) of stillbirths and half (55%) of births with fetal growth restriction among black women from the most deprived neighbourhoods could have been avoided had they had the same risks as white women living in the most affluent 20% of neighbourhoods.

Among South Asian women, half (53.5%) of stillbirths and nearly three quarters (71.7%) of births with fetal growth restriction were potentially avoidable, estimated the research published in the Lancet.

The government has pledged to halve stillbirths and neonatal death rates and reduce levels of preterm birth by 25% by 2025, but the report’s joint lead author Jan van der Meulen said, “National targets to make pregnancy safer will only be achieved if there is a concerted effort by midwives, obstetricians, public health professionals, and politicians to tackle broader socioeconomic and ethnic inequalities.”

Elisabeth Mahase, The BMJ  Cite this as: BMJ 2021;375:n2662

Covid-19
Booster for vulnerable people available sooner
Certain vulnerable people can now be given covid booster vaccines sooner than six months after their second dose where this makes operational sense, after updates were made to the “green book.”

This will, for example, allow care home residents to be vaccinated in the same session, as long as at least five months have elapsed since their second dose. It may also help other vulnerable groups, such as housebound patients, so that they can have their flu and covid vaccines at the same time.

Poor response to vaccine in blood cancer patients
Just 31% of patients with blood cancer who hadn’t previously been infected with SARS-CoV-2 developed neutralising antibodies against the delta variant after receiving two doses of the Pfizer or AstraZeneca covid vaccine, compared with 62% of patients with solid cancers, the Capture study found. Among the 585 patients with different types of cancer the response was 68% overall in those who had the Pfizer vaccine and 50% in those who had AstraZeneca’s, researchers reported in Nature Cancer.

NHS financing
Greensill early payment schemes no benefit to NHS
Two advance payment schemes offered by the collapsed financing company Greensill Capital were not as popular as predicted and offered no material benefits to the NHS, the National Audit Office found. The Pharmacy Earlier Payment Scheme allowed community pharmacies in England to be reimbursed for prescriptions earlier than normal, and the Employer Salary Advance Scheme allowed NHS trust employees to receive a proportion of their salaries before payday without charge. Uptake of both schemes was much lower than expected, and while the cost to the taxpayer was minimal, in some cases it led to trusts switching to a paid salary advance scheme.

General practice
Appointments rise by 4.7 million in a month
GPs in England provided an extra 4.7 million appointments in September to total just under 28.7 million, up from 23.9 million in August. Face-to-face appointments have also risen by more than a quarter, from 13.7 million to 17.3 million, said NHS Digital. Richard Vautrey, chair of the BMA’s General Practitioners Committee, said the rise in face-to-face appointments should “equivocally put to bed the demoralising and inaccurate narrative that GPs are no longer seeing patients in person.” Vautrey has announced he will step down as chair of the committee this month after four years in the role.

BMA polls GPs on industrial action
GPs in England are being asked whether they would be willing to take industrial action, as the government had “failed to work together on a rescue package.” The BMA is undertaking an indicative ballot to ask GPs whether they would take four types of action. These are disrupting appointment data collection that the BMA fears may be used for “naming and shaming” practices; not fulfilling the contractual requirement to provide covid vaccination exemption certification; disengaging from the primary care network direct enhanced service, either outside the opt-out period or during the next opt-out period; and not complying with NHS England’s requirement to submit GPs’ earnings data. The news came after the BMA’s GP committee said it was seeking approval from BMA Council to ballot GPs. The results of the indicative ballot will be known next month.

Allergies
“Appoint national tsar” to improve care, say MPs
The All Party Parliamentary Group for Allergy and the National Allergy Strategy Group called for the appointment of a national clinical leader for allergy, a new national strategy, and better training for doctors. Hospital admissions for anaphylaxis increased by 615% in the 20 years to 2012, from one to seven cases per 100 000 people a year. Jon Cruddas (left), Labour MP and chair of the all party group, said, “The time has come for the government and the NHS to give allergy the priority it deserves and to recognise the true burden it can place on those who are affected and their families and wider communities.”
Guidance from the MHRA on e-cigarettes could lead to them being prescribed in England

Prescribing
E-cigarettes could be prescribed on NHS
England could soon become the first in the world to prescribe e-cigarettes to help cut smoking rates, as the MHRA is to publish guidance on medicinally licensed e-cigarette products that can be prescribed. Once a product receives approval clinicians would be able decide if it would be appropriate to prescribe. Non-smokers and children are still strongly advised against using e-cigarettes, as they contain nicotine and are not risk free.

Vaccinations
US and China prepare to jab younger children
The US is likely to begin offering the Pfizer covid vaccine to children aged 5-11 from this week after a Food and Drug Administration advisory committee voted by 17 to zero, with one abstention, to recommend emergency authorisation in that age group. China approved its Sinovac vaccine for children aged 3-17 in June and has been vaccinating mostly young children with extra risk factors. Some local governments have announced all children aged 3-11 will be required to get their shots to attend school.

HRT prescribing cycles will be lengthened
The UK government will lengthen the prescribing cycles for hormone replacement therapy, so patients will have to order fewer prescriptions, potentially only once a year. The changes have been proposed through a private member’s bill that has reached its second reading in the House of Commons. The government is also looking to combine two hormone treatments into one prescription, which would affect 10% of HRT users. Currently, HRT can be classed as two medicines if it contains progesterone and oestrogen, so patients may be charged twice for one course.

Emergency medicine
Antibullying staff campaign is launched
The Royal College of Emergency Medicine is launching an antibullying campaign, RespectED, to raise awareness and tackle a rise in bullying, harassment, and incivility among emergency department staff. The college says the behaviours create a toxic working environment, affecting morale and the delivery of safe care. The campaign encourages staff members to look at their own behaviour and to speak up and challenge poor behaviour if they see or are subjected to it.

Tobacco
UK “fails to stop industry interfering in policy”
The UK has not made progress in preventing the tobacco industry from interfering in policy and legislation, the UK Tobacco Industry Interference Index showed. The UK scored 32 out of a possible 100—compared with 26 in 2019, when it was ranked first. The report found the UK had continued to offer companies opportunities to use corporate social responsibility programmes to open the door to policy makers.

Cite this as: BMJ 2021;375:n2653

KIDNEY DISEASE
Between 2000 and 2015
200 000 admissions to hospital for renal disease in Brazil can be attributed to rising temperatures, leading researchers to call for more strategies to tackle climate change
[The Lancet Regional Health—Americas]

SO, IT’S A RED LIGHT FOR HONEYCOMB MAKING?
Yes, and as we enter the season of Guy Fawkes, Diwali, and Halloween, doctors are warning against other potential sources of burn injuries too. The British Society for Surgery of the Hand has reminded people to take extra care when handling fireworks, lighting bonfires, and carving pumpkins.

Cite this as: BMJ 2021;375:n2640

THAT SUCKS!

This is no Greek odyssey. We’re talking about Squid Game, the South Korean dystopian drama that has taken the internet by storm, recording 111 million views in less than a month and making it the biggest series launch on Netflix. It chronicles 456 debt ridden contestants’ participation in a series of children’s games for a cash prize—or death if they lose.

I HAVE AN INKLING THERE’S MORE TO SAY ON THIS . . .
Indeed. The recreation of some of the games has prompted concerns about health and safety. One, the “honeycomb challenge,” entails using a needle to cut a shape out of a honeycomb toffee disc without breaking it. It’s gone viral on social media.

SOUNDS MORE LIKE A TREAT THAN A TRICK?
It’s causing havoc in burns units and emergency departments. The Korean sweet, also known as dalgon or ppopgi, is traditionally made by heating sugar and baking soda on a ladle over a naked flame. One video on how to make it has racked up 87.9 million views. But one false move and things can go easily wrong.

Guidance from the MHRA on e-cigarettes could lead to them being prescribed in England

Pat Lok, The BMJ
**Covid hits quarter of vaccinated people in households with case**

Vaccination reduces but does not eliminate the risk of covid transmission within households, a study published in *Lancet Infectious Diseases* has found. It showed that among household contacts of someone who tested positive one in four vaccinated and 38% of unvaccinated contacts became infected. Transmission depended not only on the susceptibility of contacts but also on the infectivity of cases, and although vaccination reduced susceptibility it did not seem to reduce infectivity: the risk of transmission to vaccinated contacts was similar regardless of whether the index case was vaccinated or not. The study followed 205 household contacts of people who tested positive for delta and who experienced mild symptoms or were asymptomatic. Most household contacts (62%) had been doubly vaccinated, 19% had received one vaccine dose, and 19% were unvaccinated. Contacts provided swabs for PCR testing daily for 14-20 days. The median length of time since vaccination was 101 days among contacts who were infected and 64 days among uninfected contacts, suggesting that protection begins to wane earlier than expected, the researchers told a press conference on 28 October.

Ajit Lalvani, chair of infectious diseases and director of the NIHR Health Protection Research Unit in Respiratory Infections at Imperial College London, said, “What we found, surprisingly, was that by three months after the second vaccine dose the risk of acquiring infection was high compared with being more recently vaccinated.”

PCR data for some of participants showed that viral load declined more rapidly among vaccinated people than among the unvaccinated but that there seemed to be no difference in the peak viral load. Lalvani said the faster rate of decline in viral load helped explain why vaccinated people get fewer symptoms, have quicker resolution of symptoms, and have much lower risk of having severe disease. The modelling showed, however, that vaccination did not affect the time people spent “in the window of highest infectiousness” during peak viral load and only partially prevented delta transmission, he added.

Some 53 of the 205 household contacts returned a positive PCR test during the study, including 31 of 126 (25%) who were doubly vaccinated and 15 of the 40 (38%) unvaccinated contacts.

---

**Exercise should be set by ME/CFS patients, says NICE**

Graded exercise therapy (GET) should no longer be used to treat patients with myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome (ME/CFS), says NICE in long awaited updated guidance.

Patients may still be offered exercise programmes provided they aren’t based on fixed incremental increases. Instead, programmes should be based on patient centred energy management, which is a self-management strategy led by the patient with support from a specialist team, the guideline advises.

Energy management should consider all types of activity (cognitive, physical, emotional, and social) and help patients learn to use the amount of energy they have, while reducing their risk of post-exertional malaise or worsening their symptoms by exceeding their limits. Cognitive behavioural therapy (CBT) has sometimes been assumed to be a cure for ME/CFS, the guideline acknowledges. Now it should be offered only to help people manage their symptoms, improve their functioning, and reduce the distress of having a chronic illness.

The final 2021 guideline shows a change of emphasis from the 2007 guideline, which said that CBT and GET should be offered to people with mild or moderate CFS/ME as the interventions with the clearest research evidence of benefit. Rather than a focus on specific treatments, the guidance says, patients should receive support tailored to agreed goals, and a range of approaches should be used, depending on the patient’s preferences and priorities.

**Resignations**

The final guideline is very similar to the draft recommendations published in 2020, which were welcomed by patients’ groups and representatives, who had lobbied for years for the 2007 guideline to be changed.

This August the proposed final guideline led to the resignation of three members of the guideline committee, and several royal colleges raised concerns about the advice and the processes used to review the evidence. As a result NICE delayed publication.

The guideline was finally published on 29 October after a round table

---

**Doctors in rogue breast surgeon’s hospital “failed to prevent harm”**

The former chief executive and the medical director of the NHS trust where the jailed breast surgeon Ian Paterson worked are facing allegations of failing to prevent harm to patients, at a medical practitioners tribunal hearing that opened last week.

Mark Goldman, chief executive of the Heart of England NHS Foundation Trust from 2001 to 2010, and Ian Cunliffe, its medical director from 2007 to 2010, face rarely brought charges that they failed in their duty as doctor managers. Paterson is serving a 20 year prison sentence after being convicted of 17 counts of wounding with intent and three counts of unlawful wounding from 1997 to 2011. He subjected more than 1000 patients to unnecessary and damaging operations over 14 years before he was stopped.

In Paterson’s main job as a consultant surgeon with the trust he carried out unapproved “cleavage sparing” mastectomies that left tissue behind, risking the return of cancers. Goldman and Cunliffe failed to recognise the significance of the
meeting on 18 October with a range of patient and professional organisations to discuss the concerns. Commenting on the guidance, Alastair Miller, a consultant physician in infectious disease and internal medicine, said, “It is unfortunate that NICE continues to misrepresent GET as ‘fixed incremental increases in physician activity or exercise,’ whereas in practice the approach in most CFS/ME clinics has been to tailor increasing activity to the individual’s needs in line with their current recommendations.

“It is unfortunate so much emphasis is given to working ‘within current energy limits’ rather than a gentle and controlled pushing of those limits. However, it is to be welcomed that clinics will still be able to provide appropriate personalised activity and exercise programmes for those patients in whom it is felt to be appropriate.”

Relieving symptoms
The final guideline emphasises that, while ME/CFS symptoms can be managed, the condition currently has no cure, either pharmacological or non-pharmacological. Miller commented, “They say that exercise [or] activity cannot be regarded as a ‘cure’ for CFS/ME, and yet they accept it may relieve symptoms, which could potentially improve longer term outcomes.

The final guideline lists the symptoms of ME/CFS as debilitating fatigue that is worsened by activity, as well as post-exertional malaise, unrefreshing sleep or sleep disturbance, and cognitive difficulties (“brain fog”), and it says diagnosis can now be confirmed after three instead of six months of persistent symptoms, which could potentially improve longer term outcomes.

Ingrid Torjesen, London
Cite this as: BMJ 2021;375:n2643

THE FINAL guideline is very similar to the draft recommendations published in 2020, which were welcomed by patients’ groups and representatives, who had lobbied for years for the 2007 guideline to be changed.

lack of informed consent for these mastectomies, the GMC alleged.

The GMC claimed that Goldman, who retired in 2010, failed to promote a blame-free culture for reporting clinical concerns and neglected to promptly inform the trust’s board that the multidisciplinary team had been performing poorly for many years.

Goldman and Cunliffe are charged with failing to report Paterson to the GMC and failing to stop him carrying out breast surgery from June to December 2007 or, alternatively, to enforce his verbal agreement to stop doing cleavage sparing mastectomies.

The managers, the GMC alleged, failed to formally report to the trust’s board on the progress of investigations into the surgeon’s practice after receiving nine reports from December 2007 to May 2009.

The GMC claimed they failed to share the reports’ concerns and recommendations with other clinicians in the multidisciplinary team and allowed Paterson to review and refer patients himself and to be involved in discussions after introducing a protocol to identify patients for cleavage sparing mastectomy.

The hearing, listed for 60 days, is scheduled to run until February 2022.

Guide “understates role of exercise and CBT,” say royal colleges

Medical leaders have questioned NICE’s ME/CFS updated guideline for downplaying the importance of activity and exercise in managing the condition. They say the guideline understates the connection between mental and physical health, does not reflect how exercise therapy is used in practice, and fails to represent the positive discussions that leaders have had with patients’ groups.

In their joint statement seven heads of royal colleges and faculties said, “The published guideline contains some positive changes, but these do not go as far as we would have liked and understate the importance of activity and exercise in the management of ME/CFS and the connection between people’s mental and physical health. We also do not think the changes represent the positive discussions that have been had with patient groups.

“As in many chronic conditions, people’s mental and physical health are intrinsically linked. This guidance risks undermining the importance of these links by dismissing the potential of treatments such as CBT as of less value in alleviating symptoms than pharmacological interventions.”

Disquiet
The leaders, including Andrew Goddard (below) of the Royal College of Physicians, Martin Marshall of the Royal College of General Practitioners, and Adrian James of the Royal College of Psychiatrists, said that while there was disquiet among doctors and some patient groups about how the evidence was assessed, “the important thing now is that services are commissioned in a safe and effective way that does not disadvantage any patients.”

They pointed out to those commissioning services that “GET as defined in the guidance is not reflective of the personalised paced exercise programmes that are used in the NHS. These have provided benefit to many patients and should not be discontinued. However, we recognise that the phrase GET is unhelpful and this terminology should be dropped to allow clinicians to work with their patients in a more productive way.”

They added that CBT was a valuable treatment and that services should ensure patients have access to this and other psychological therapies.

Zosia Kmietowicz, The BMJ
Cite this as: BMJ 2021;375:n2647

the bmj | 6 November 2021
meeting on 18 October with a range of patient and professional organisations to discuss the concerns.

Commenting on the guidance, Alastair Miller, a consultant physician in infectious disease and internal medicine, said, “It is unfortunate that NICE continues to misrepresent GET as ‘fixed incremental increases in physician activity or exercise,’ whereas in practice the approach in most CFS/ME clinics has been to tailor increasing activity to the individual’s needs in line with their current recommendations.

“It is unfortunate so much emphasis is given to working ‘within current energy limits’ rather than a gentle and controlled pushing of those limits. However, it is to be welcomed that clinics will still be able to provide appropriate personalised activity and exercise programmes for those patients in whom it is felt to be appropriate.”

Relieving symptoms
The final guideline emphasises that, while ME/CFS symptoms can be managed, the condition currently has no cure, either pharmacological or non-pharmacological. Miller commented, “They say that exercise [or] activity cannot be regarded as a ‘cure’ for CFS/ME, and yet they accept it may relieve symptoms, which could potentially improve longer term outcomes.

The final guideline lists the symptoms of ME/CFS as debilitating fatigue that is worsened by activity, as well as post-exertional malaise, unrefreshing sleep or sleep disturbance, and cognitive difficulties (“brain fog”), and it says diagnosis can now be confirmed after three instead of six months of persistent symptoms, which could potentially improve longer term outcomes.

Ingrid Torjesen, London
Cite this as: BMJ 2021;375:n2643

THE FINAL guideline is very similar to the draft recommendations published in 2020, which were welcomed by patients’ groups and representatives, who had lobbied for years for the 2007 guideline to be changed

lack of informed consent for these mastectomies, the GMC alleged.

The GMC claimed that Goldman, who retired in 2010, failed to promote a blame-free culture for reporting clinical concerns and neglected to promptly inform the trust’s board that the multidisciplinary team had been performing poorly for many years.

Goldman and Cunliffe are charged with failing to report Paterson to the GMC and failing to stop him carrying out breast surgery from June to December 2007 or, alternatively, to enforce his verbal agreement to stop doing cleavage sparing mastectomies.

The managers, the GMC alleged, failed to formally report to the trust’s board on the progress of investigations into the surgeon’s practice after receiving nine reports from December 2007 to May 2009.

The GMC claimed they failed to share the reports’ concerns and recommendations with other clinicians in the multidisciplinary team and allowed Paterson to review and refer patients himself and to be involved in discussions after introducing a protocol to identify patients for cleavage sparing mastectomy.

The hearing, listed for 60 days, is scheduled to run until February 2022.

Clare Dyer, The BMJ
Cite this as: BMJ 2021;375:n2613

Guide “understates role of exercise and CBT,” say royal colleges

Medical leaders have questioned NICE’s ME/CFS updated guideline for downplaying the importance of activity and exercise in managing the condition. They say the guideline understates the connection between mental and physical health, does not reflect how exercise therapy is used in practice, and fails to represent the positive discussions that leaders have had with patients’ groups.

In their joint statement seven heads of royal colleges and faculties said, “The published guideline contains some positive changes, but these do not go as far as we would have liked and underestimate the importance of activity and exercise in the management of ME/CFS and the connection between people’s mental and physical health. We also do not think the changes represent the positive discussions that have been had with patient groups.

“As in many chronic conditions, people’s mental and physical health are intrinsically linked. This guidance risks undermining the importance of these links by dismissing the potential of treatments such as CBT as of less value in alleviating symptoms than pharmacological interventions.”

Disquiet
The leaders, including Andrew Goddard (below) of the Royal College of Physicians, Martin Marshall of the Royal College of General Practitioners, and Adrian James of the Royal College of Psychiatrists, said that while there was disquiet among doctors and some patient groups about how the evidence was assessed, “the important thing now is that services are commissioned in a safe and effective way that does not disadvantage any patients.”

They pointed out to those commissioning services that “GET as defined in the guidance is not reflective of the personalised paced exercise programmes that are used in the NHS. These have provided benefit to many patients and should not be discontinued. However, we recognise that the phrase GET is unhelpful and this terminology should be dropped to allow clinicians to work with their patients in a more productive way.”

They added that CBT was a valuable treatment and that services should ensure patients have access to this and other psychological therapies.

Zosia Kmiotowicz, The BMJ
Cite this as: BMJ 2021;375:n2647
NHS gets £5.9bn funding boost in autumn budget to tackle waiting lists in England

The NHS in England received a £5.9bn funding boost to tackle record high waiting lists in the chancellor’s autumn budget last week.

The 2021 budget report states that £2.3bn will be used to increase diagnostic capacity, including 100 community diagnostic centres, while £2.1bn will support the “innovative use of digital technology.”

The NHS will be expected not only to clear the backlog but also to provide around 30% more elective activity by 2024-25 than before the pandemic, the document said. This is despite the Health Foundation estimating that it would cost as much as £16.8bn from now to 2024-25 just to enable the NHS to clear the backlog of people waiting for routine elective care, return to the 18 week waiting time target, and treat millions of patients who had been expected to receive care during the pandemic but did not.

The number of patients waiting for routine procedures, such as hip replacements and cataract surgery, is set to exceed 13 million.

It is not yet clear whether this funding is new money, on top of the promised £5.4bn over six months that was announced at the beginning of September, to help tackle the waiting lists and immediate pressures from the covid pandemic. The investment will be partly funded by the new health and social care levy, a rise in national insurance contributions.

Saffron Cordery, deputy chief executive of NHS Providers, welcomed the latest announcement but said that there were “still significant questions on whether the NHS will be able to meet the government’s manifesto pledge to upgrade 70 hospitals and build 40 new ones, given the lack of clear, long term funding commitments beyond 2024-25.”

She added, “We await confirmation of the money that will be available to providers to tackle the £9.2bn maintenance backlog that’s built up.”

Workforce
One major area missing from the budget is the workforce. Fiona Donald, president of the Royal College of Anaesthetists, said, “With increasing workforce gaps and poor levels of retention, the announcements still leave us in the dark as to where the NHS will get the staffing capacity to support the urgently needed increase in elective surgery. Promises of increased funding for medical school places are positive for NHS sustainability in the long term, but to start making a dent in the backlog we need more trained staff soon.”

Cordery added that NHS trust leaders would be “disappointed and frustrated” to see no multiyear increase in Health Education England’s budget for education and training. “Workforce shortages and the resulting unsustainable workload on existing NHS staff are currently the health service’s biggest problem,” she said. “They can only be tackled with a robust, long term workforce plan and increased longer term investment in workforce expansion, education, and training, none of which are currently in place.”

Social care
Social care is another area that policy leaders think has been overlooked. Nigel Edwards, chief executive of the Nuffield Trust, said, “Increases of 3% across all local government services are welcome, but they are not enough to address the disastrous situation in social care. The sector will face a stark choice between trying to improve access to care and support for people, and simply trying to stabilise the system in which care providers are on their knees, hampered by a devastating shortage of staff.”

Charles Tallack, assistant director of the Health Foundation’s Research and Economic Analysis for the Long Term (REAL) Centre, said, “Yet again, adult social care looks to be one the biggest losers in today’s spending review.

For a decade social care funding has barely risen in real terms.

“Today’s settlement for local government may be just enough to meet demographic pressures but will do nothing to tackle the high levels of unmet need, persistent workforce shortages and recruitment difficulties, and the precarious position facing many providers.”

Pensions
The BMA saw the budget as a missed opportunity to tackle the issue of pension taxation, which could have helped to keep thousands of doctors working for the NHS.

Vishal Sharma, chair of the BMA’s pensions committee, said that the current lifetime annual allowance remained a powerful driver of early retirement, at a time when workforce
“Freezing duty on alcohol undermines plans for healthier tax system”

Alcohol misuse experts have warned that the government’s reforms of alcohol taxes are undermined by the decision to freeze alcohol duty for another year, which they said could encourage more alcohol consumption.

The government unveiled plans to overhaul the current alcohol duty system in its autumn budget. It will tax stronger types of alcohol more heavily to make the system fairer and healthier.

“Outdated and complex”
In his budget speech Rishi Sunak said the current system was “outdated, complex, and full of historical anomalies” and that the changes would see drinks taxed in direct proportion to their alcohol content.

The new approach would involve reducing the number of bands at which different duties are levied from the current 15 to just six, with common thresholds for each set of bands across product categories. Under the new rates all drinks above 8.5% alcohol by volume would have the same rate of duty. The cost of a bottle of rosé wine, for example, would be reduced by 23p, while strong beer would become more expensive.

The government hopes to have the new system in place from February 2023, after a public consultation that will launch soon and run until 30 January. Sunak said, “The alcohol duty regime will undergo a major simplification, overhauling an outdated system full of historical anomalies, making the regime fairer and more conducive to product innovation in response to evolving consumer tastes.

“Alcohol will be taxed in a progressive manner, ensuring higher strength products incur proportionately more duty, tackling the problem of harmful high strength products being sold too cheaply.”

The chancellor also announced that a planned increase in alcohol duty will be frozen and “draught relief” introduced, meaning a 5% cut to the tax on drinks served from pumps, such as beer and cider.

Ian Gilmore, chair of the Alcohol Health Alliance UK—a coalition of more than 60 organisations—welcomed the announcement, adding, “We have long campaigned for changes to the way alcohol is taxed to ensure that:

WE HAVE LONG CAMPAIGNED FOR CHANGES TO THE WAY ALCOHOL IS TAXED TO ENSURE THE STRONGEST, MOST HARMFUL DRINKS ALWAYS COST THE MOST, AS THEY CAUSE THE MOST DAMAGE TO SOCIETY”

The strongest, most harmful drinks always cost the most, as they cause the most damage to society.”

However, he added, “The decision to once again freeze alcohol duty is totally misguided. Deaths caused by alcohol reached record highs in 2020, and making alcohol even cheaper will only deepen the health inequalities that this government has promised to tackle.”

Richard Piper, chief executive officer of the campaigning charity Alcohol Change UK, said the new system would be “fairer, more consistent, and geared towards promoting public health.” But he said that the freezing of this year’s alcohol duty was “yet another missed opportunity to significantly reduce the harm caused by alcohol and to cover the costs of that harm.”

Public health
Colin Angus, senior research fellow for the Sheffield Alcohol Research Group at the University of Sheffield, told The BMJ the chancellor’s announcement was broadly good news for public health. “Making simple comparisons with minimum unit pricing is tricky. The new system is more effectively targeted because it links the duty payable on a product directly to the amount of alcohol it contains. However, it does not prevent the sale of cheap alcohol in the way that minimum unit pricing does, particularly not with the low rates of duty announced for cider under the new system,” he said.

“There is a good public health argument that the combination of a tax system based on alcohol content and minimum unit pricing is perhaps the optimal approach.”

Adrian O’Dowd, London
Cite this as: BMJ 2021;375:n2630

Elisabeth Mahase, The BMJ
Cite this as: BMJ 2021;375:n2637

We await confirmation of the money available to providers to tackle the £9.2bn maintenance backlog Saffron Cordery

We’re still in the dark as to where the NHS will get the staff to support the urgently needed rise in elective surgery Fiona Donald

Increases of 3% across local government aren’t enough to address the disastrous situation in social care Nigel Edwards

capacity in the NHS needed to be maximised to deal with the backlog of patients requiring treatment after the covid pandemic. He added, “It’s all very well announcing almost £6bn worth of capital investment for the NHS, but without plans to increase staffing or, crucially, to ensure we retain the doctors we have, the impact on the huge backlog of patients needing care will be minimal.

“Pension tax has a major impact on doctors’ ability to care for their patients. It can lead to the perverse outcome that many doctors may face financial detriment if they undertake additional work or work for longer in the NHS. As a result, doctors have been left with little alternative but to reduce their working hours, at a time when waiting lists are at their highest for many years.”

Elisabeth Mahase, The BMJ
Cite this as: BMJ 2021;375:n2637
After a three year pause, nationwide house-to-house polio vaccinations are to restart in Afghanistan on Monday, after the UN reached agreement with the Taliban. Women will also be allowed to carry out the programme.

These female health workers were able to vaccinate children in the southern city of Kandahar last year as neither the Taliban nor Islamic State were then in control of the area. Elsewhere the ruling parties have attacked frontline vaccination workers as western spies, and some tribal leaders have spread the myth that the vaccine causes infertility, causing polio cases to rise significantly.

According to Unicef 56 new cases of polio were reported in Afghanistan last year, the highest number since 2011. Pakistan is the only other country in the world where the disease still kills and maims children.

“This decision will allow us to make a giant stride in the efforts to eradicate polio,” said Hervé Ludovic De Lys, Unicef’s representative in Afghanistan.

Alison Shepherd, The BMJ

Cite this as: BMJ 2021;375:n2656
Tackling overprescribing

Long overdue with a lot to do

The UK government recently published its long awaited review led by the chief pharmaceutical officer to evaluate overprescribing in England. It revealed how NHS spending on medicines increased sharply from £13bn in 2010–11 to £18.2bn in 2017–18. Over one billion prescription items were dispensed in primary care alone, with an estimated 10% being “overprescribed”—that is, not needed or wanted by the patient, potentially more harmful than beneficial, or having more appropriate alternatives.

The negative consequences for patients are clear: a fifth of hospital admissions among adults over 65 are the result of adverse effects of prescribed drugs. But overprescribing has substantial environmental impact too. Currently 25% of the NHS’s carbon footprint comes from medicines.

A key recommendation of the report is cultural change to reduce reliance on medicines. We live in an era in which there is virtually “a pill for every ill”: the British National Formulary contained around 250 drugs in 1949; today it comprises over 18,000. Thus it is more practical, convenient, and often cheaper to take prescribed drugs than explore non-pharmacological interventions.

Furthermore, clinical “inertia” means that risk from passive continuation of unnecessary medicines seems to be more acceptable than that from active changes or harm from undertreatment. Such attitudes are reinforced by time pressures on prescribers and limited awareness and availability of social prescribing, which improves health and wellbeing by connecting people to community services.

Interestingly, the report places limited emphasis on educating and empowering patients to know more about their medications or to take ownership of their therapy. Such patient-centred engagement may help inform shared decision making, manage expectations, and improve adherence, which is consistently absent from the report.

Continuing medicines education for all healthcare professionals is critical to reducing overprescribing but is also missing from the report. Teaching on prescribing has been taken seriously in undergraduate medical curriculums in the UK since the prescribing safety assessment was introduced in 2014. But much more is required to raise awareness of overprescribing and to develop, evaluate, and implement effective interventions to tackle it. Equally pressing is the need for more evidence and guidance on how best to withdraw inappropriate medication (deprescribing).

System wide changes

The new overprescribing review rightly highlights system-wide changes needed to improve digital records, increase their accessibility to patients, and ensure interoperability between care systems. At a time when general practitioners are struggling to meet patient needs, recommending 30 minute consultations for structured medication reviews and greater numbers of clinical pharmacists is welcome but will require substantial new funding.

The report’s focus is very much on primary care and community pharmacists, encouraging them to “challenge” prescribing practice in secondary care. For example, patients are often prescribed more medicines on discharge than they were on admission, and an opportunity to rationalise treatment is missed.

Hospital experts in medicines management and optimisation such as senior clinical pharmacists and pharmacologists have a pivotal role in reducing overprescribing, including leading deprescribing initiatives locally and regionally, and need to be better used.

Other promising developments given insufficient attention in the report include point-of-care testing in the community—to help guide use of antibiotics, for example; use of artificial intelligence to develop predictive algorithms to guide individualised selection and management of medicines; and the potential of pharmacogenomics in “precision prescribing” to maximise benefits and minimise harms.

In addition, legislative and regulatory changes are required to ensure that priority is given to new drugs that are clearly better than existing treatments rather than those that are simply “non-inferior.” Similarly, a move away from target driven funding of primary care and towards incentives that encourage comprehensive individual medication reviews is overdue.

Overall, this report includes several commendable recommendations. But there remains much to do before high quality individualised prescribing becomes a reality. With a concerted and collaborative national effort, good leadership, and adequate funding, it need not be a bitter pill to swallow.
Lack of data is holding back much needed improvements to services

A total of 5691 deaths by suicide were registered in England and Wales in 2019, substantially more than in previous years. Records of deaths by suicide have their problems, but at least a clear system is in place. The recording of suicidal or self-harm ideation, however, is much less clear and robust, despite the fact that suicidal ideation is one of the strongest risk factors for death by suicide. Poor data are hampering efforts to care for those affected.

Suicidal crisis involves overwhelming distress with suicidal thoughts or a suicide attempt. It is characterised by severe emotional pain, for which death seems to be the only option. Risk of self-harm is often heightened during a crisis, and people seemed to be at “high” risk need rapid care to minimise potential harm.

Emergency departments are often the first point of contact for people experiencing suicide related distress, but while data are available on attendances for self-harm, no comparable data exist for suicidal crisis. In England, more than 200,000 presentations with self-harm are recorded in emergency departments annually. Hospital figures underestimate suicide related admissions, however, because of inconsistencies in coding within and between sites.

Accurate detection and documentation of suicidal crisis is critical to understanding future risk and to improving services. The current coding system, ICD-10 (international classification of diseases, 10th revision), includes diagnostic codes related to suicide attempts, self-harm, and suicidal ideation. However, in practice, the code for suicidal ideation (R45.81) is rarely used. Guidelines state that this code should be used only if the clinician is certain there is no underlying mental disorder. Consequently, attendances for suicidal crisis are often coded as depression or anxiety disorder. Coding is further complicated by the recording of only one diagnosis. One study found that 90% of attendances had only one recorded diagnosis, so identifying people who attend with mental ill health and an unrelated primary diagnosis code (such as laceration) is not possible.

Administrative challenges in coding self-harm in emergency departments are often obscured by inconsistent coding and delays in entering information onto systems, and over 10% of all incidents are not included in basic emergency records. The Emergency Care Data Set was introduced in 2017 in an attempt to address these problems and includes a larger and more specific list of over 1000 clinical terms to capture patient data (SNOMED CT). Although SNOMED codes have been used in Australian studies to obtain suicide related data, and some argue they improve the quality of information, their value in recording suicidal ideation remains unknown.

Numbers underestimated

Given limitations in current coding practices, the number of emergency department attendances for suicidal crisis is probably much higher than official NHS statistics suggest. Data should therefore be used with caution until a more standardised approach is implemented.

Research and development in monitoring systems for suicidal crisis should be a priority for health services, and a national data collection tool is urgently needed to ensure accurate and timely data collection in emergency departments. As a first step, new coding systems could be piloted in a small number of hospitals to ensure their search terms and screening procedures are robust.

Improved detection and recording of suicidal crises will support service developments such as the care concordat, which aims to provide better access to mental health services in England. Better data could be used to inform policy and developments in crisis care and to tackle the implementation gap between policy and services.

Finally, pandemic related factors, such as reduced services and social isolation, were reported more frequently by patients needing emergency care for self-harm during lockdown in England. Evidence suggests self-harm and suicidal thoughts increased during the first month of the pandemic, although the long term impact of the pandemic on suicide rates is still unknown. The predictive power of suicidal ideation as a risk factor for suicide varies between studies, and our suggestions to standardise recording across health organisations would help clarify and quantify the association.

Major changes to coding practices would be a substantial challenge for emergency departments and researchers. However, prioritising such work could result in considerable benefit for patients, including more efficient targeting of resources and interventions to areas with the highest prevalence of suicide related behaviours.
WHO in its present incarnation is not fit for purpose

The World Health Organization is needed now more than ever, but it is stymied by lack of funds and its vulnerability to politics. These can be fixed, and must be urgently, writes Anthony Costello

Debate about the World Health Organization’s future has never been more important. The Economist estimates that the pandemic has killed up to 18.2 million people. The economic crisis induced by the pandemic is a terrible setback to health, development, and poverty alleviation. The International Monetary Fund suggests $22tn (£16tn) will be lost in the period 2020-25—the deepest shock to the global economy since the second world war and the largest contraction of national economies since the Great Depression. Up to 125 million people have been pushed into extreme poverty.

WHO faces enormous and growing challenges: covid-19, vaccine apartheid, emerging infections, increased food emergencies, disruption to health systems, a pandemic of non-infectious conditions such as obesity, cardiovascular disease, diabetes, and mental ill health, and the objective of universal health coverage, to say nothing of the routine plagues of HIV, tuberculosis, malaria, and childhood pneumonia. Above all, WHO must respond to a deteriorating climate crisis, the greatest global health threat in our century, which imperils the future of our children and young people.

But WHO in its present form is not fit to meet these challenges. It needs systemic reform to build the confidence of the world’s citizens and states, to attract funds, and to build global scientific networks.

Hamstrung budgets

WHO is a member state organisation, with a democratically elected director general and clear accountability each year to the World Health Assembly of states. On paper, it is the most accountable part of the UN. For more than 20 years though, health funding has bypassed WHO, and been diverted to less accountable bodies such as the Global Fund, UNAIDS, and the Global Financing Facility. The current annual financial settlement for WHO is wholly inadequate—little more than the budget for my university. For 2018-19, annual revenue averaged $2841m but increased by 38% in 2020 owing to $1966m eventually provided for emergencies including covid.

In the 1970s, three quarters of WHO funding came from assessed contributions by member states, but the proportion has fallen to below 10%, a derisory $379m in 2020. The rest comes from voluntary contributions by countries and philanthropists tied to myriad projects and conditions (see chart above right).

On 5 February 2020 Tedros Adhanom Ghebreyesus called for $675m to support a global response to covid-19. A month later WHO had received just $1.2m

WHO had received just $1.2m, “from Ireland, thanks to Mike Ryan (WHO’s head of emergencies, who is Irish).”

It beggars belief that two months into a global pandemic, member states had failed so miserably to finance WHO. In May 2021 the Independent Panel on Pandemic Preparedness, chaired by Helen Clark and Ellen Johnson-Sirleaf, recommended that member states immediately increase contributions to two thirds of the WHO budget. Such a small budget cannot possibly cover the breadth of global health challenges handled by WHO, which has headquarters in Geneva and six regional offices in the Americas, Europe, Africa, eastern Mediterranean, South East Asia, and the western Pacific.

For one thing, WHO’s data collection and analysis function, critical for policy and rapid response, requires urgent strengthening around the world. The often conflicting data received from various UN sources and universities can confuse our understanding of health and disease. Research coordination across regions needs far greater attention and cannot be mixed with politics. Much stronger emergency capacity could help build resilience to pandemics and climate change, and focus on humanitarian needs.

Genuine reform of WHO could bring enormous benefits for health and economic security, but member states must engage proactively, take on active scrutiny and oversight of the organisation, and learn first hand the value of increased funding for effective health. For example, an IMF proposal to vaccinate 60% of the world’s population against SARS-CoV-2 by 2022 would cost $50bn but return $9trn in economic benefits, a return-on-investment ratio of 180:1.
Soon after he became director general, Tedros called in management consultancies McKinsey, Boston Consulting Group, Deloitte, Preva Group, Seek Development, and Delivery Associates to implement a wide ranging reform process.

Certainly, he has simplified and focused the mission objectives of WHO down to three: emergencies, universal health coverage, and health promotion. But millions of dollars were spent with little apparent impact. Core funding has not increased and member states remain largely inactive. Financial cuts have led the director general to ban all external appointments, potentially diminishing creativity and the energy of contrarian ideas.

For decades, WHO has struggled with three major organisational challenges: a rigid financial straitjacket maintained by its member states; a blurring of its scientific, technical, and political/diplomatic functions; and a federation of regional office fiefdoms led by locally elected directors without mobility of technical staff.

Major reforms could re-energise WHO, attract new funds, and ensure better global health security. I recommend three key changes that others have suggested before.

First, a new, permanent and independent executive board from member states should be resident in Geneva to hold WHO accountable and incentivise new funding. It would restore the engagement of powerful member states with WHO and replace the current system of assistant director generals (who are appointed by the director general). The largest donor countries should be represented on this permanent body. Political appointees should no longer be involved in managing WHO directors and scientific processes. WHO funding could more than double as a result of greater confidence among donor nations.

Second, there should be a clear split in WHO’s political and technical functions. The director general should manage the political and diplomatic functions, such as support for regional offices, relations with member states, and management of emergency responses.

The director general’s secretariat could coordinate annual accountability to member states at the World Health Assembly, not only of WHO but of all UN health activities (World Bank, Global Fund, UNDP, UNAIDS, Unicef, and others). Accountability is fragmented. These other bodies are often accountable to unelected boards, yet they spend large amounts of taxpayer money. The director general should be elected by secret ballot of member states and should serve a single seven year term as recommended by the recent Independent Review.

An independent WHO scientific director should oversee the science and norms of the organisation, including research, collection, and analysis of global health data, the development of global and regional disease control and prevention networks, evaluation of country programmes, and WHO research groups. The person should not be a political appointee but an internationally distinguished scientist, competitively selected, with strong experience in effective senior administration, and a commitment to build or strengthen networks of scientific excellence globally, in Geneva and in each of the six regions.

The scientific director would be independent, report separately to a board of scientists, and be appointed by member states at the World Health Assembly. They would oversee and respond to global health data and analysis, the evaluation of programmes, new research findings, the evidence basis for prevention and control of diseases, and updated guidelines. They would also have a seven year single term of office, but not coterminous with the political director general. The appointed person would be accountable to the chair of the executive board of member states but work closely with the director general on a par with regional directors.

With new funds, the work to improve quality of health data, evaluation, and research across WHO, and through global and regional networks, could be supported by advisory boards of global experts—science, biostatistics, economics, evaluation, implementation science, and social and behavioural science. With a new scientific leader and separation of science from policy, funding for WHO-linked pandemic and disease prevention and control could increase dramatically from member states and foundations. The Framework for Engagement with Non-State Actors will protect issues from conflicts of interest. Global and regional scientific meetings would regularly liaise with the world’s best scientists, mostly online, to share data, discuss important topics, and respond quickly to threats.

Finally, WHO must strengthen regional centres with expanded mobility of staff. Its current regional structure is commendably devolved, but suffers from a lack of mobility and limited funding. Member states in the regions usually lobby for WHO appointments from their own ministry and/or politically connected officials. Regional directors are elected, not appointed by the director general, so—they being dependent upon regional country votes for re-election—they are incentivised to employ people only from the region. With little movement between regions, or even from Geneva to regional or country offices (unlike organisations such as Unicef, where appointments are made from the centre), parochial thinking and local nepotism are major risks.

For the same reason, WHO should encourage staff to spend time in different regions from their country of origin. The director general and member states should approve a quota—maybe 30%—of non-regional programme and technical staff in each region, with all staff appointments for five years, renewable based on appraisal.

In some ways, these three reforms could reinforce each other and break the vicious cycle of lack of confidence in WHO by its member states, inadequate donor finance because of a perceived decline in technical, data, and scientific expertise, and regional office insularity. It is time for member state nations to step up, to help WHO to reform radically, and to give it the heft and finance to coordinate effective solutions for global health. Failure to respond now risks millions of lives and trillions of dollars in the future.

Anthony Costello, professor of global health and sustainable development, University College London anthony.costello@ucl.ac.uk

Cite this as: BMJ 2021;375:n2644

Reform
Covid passes are a tool enabling individuals to prove that they are either fully vaccinated against the coronavirus, have immunity from a previous infection, or have recently tested negative for covid-19. Asking people to prove their health status before entering a crowded or enclosed environment potentially reduces the risk of covid being spread, by restricting entry to people with a reduced risk of having covid.

Properly implemented “covid passes” can provide reassurance to the public, and especially to vulnerable people, that all reasonable steps have been taken to ensure the people they are mingling with are virus free. These passes are the most accurate tool at our disposal for limiting transmission and avoiding further blanket lockdowns.

The UK government’s Events Research Programme, while limited in some respects, provides grounds for optimism that tools such as a covid pass will help to limit transmission at mass events: in phase I of the programme, only 28 cases of covid-19 were detected in 7764 participants who completed the full testing requirements.

**Reduced cases**

At the Tony Blair Institute for Global Change we carried out an analysis based on a June 2021 model of the virus’s spread, created by researchers at Imperial College London for the UK’s Scientific Advisory Group for Emergencies (SAGE). This showed that if the government had opted to make covid passes mandatory for crowded indoor settings in England since restrictions were lifted, this could have reduced cases and deaths by as much as 30%.

As with all public policy interventions, safeguards are needed if covid passes are to be used widely. In some settings it may be justifiable to require individuals to have been fully vaccinated against covid, such as those caring for vulnerable people. For others, proof of a reduced risk of covid due to one or more factors (prior infection, vaccination, or a recent negative test) may be sufficient. Including these factors as relevant indicators of health status will help ensure that people who are unable to get vaccinated are not unduly excluded. Indeed, phases II and III of the Events Research Programme in England allowed participants to show either evidence of vaccination or a negative lateral flow test result to gain entry to a venue.

In addition, if passes are legally required, legislation should clearly limit their use to managing the current covid pandemic and should include a “sunset” clause so that the order expires automatically if it is not renewed, as in Denmark and Israel. The requirement to use a pass can also be “switched off” when prevalence of the virus drops below an agreed threshold.

**Protecting data**

In the longer term, a much wider and more detailed debate is needed about how democratic societies can make the best use of health data to benefit the common good while protecting individuals’ privacy, but we need rapid action now if we hope to get the coronavirus under control globally.

It’s essential that covid passes are designed and implemented in such a way as to protect personal health data and maximise privacy. Existing technology allows users to prove their health status without disclosing any further details (such as the date or type of vaccination) to the verifying party. Data amassed by health authorities should be managed and stored in compliance with high standards of protection, while the pass itself could exist as a credential on the user’s phone, updated periodically.

To be most useful, covid passes need to be internationally interoperable, where the pass a citizen uses to enter a sports stadium or cinema in their home country can also be used to board a flight or pass through border controls. The Good Health Pass Blueprint provides a road map for achieving this, and national governments should make delivering this a top priority as part of their strategy for beating the pandemic.

In the context of rising cases or, worse, a new and more dangerous variant, a covid pass is the best mechanism we have to target restrictions and avoid the need for another hard lockdown. Ultimately, faced with further spikes, we either force everyone to stay at home or we require only those with the virus to do so.
DEFINITIONS OF COVID PASSES

Articles on this subject use many different terms such as health pass, covid pass, vaccine passport, or green pass, and they often conflate different types of passes/passports.

In this debate we distinguish between a "vaccine passport," which is a document or app showing evidence of vaccination status only; and a "covid pass," a document or app showing evidence that a person has either a lower risk covid status based on their vaccination record, a recent negative lateral flow or PCR test, or a positive antibody test (showing that they had the infection previously and have some level of immunity).

The implications of relying on vaccine status alone are different from allowing all three of the above measures or a combination.

We should consider not just how such tools are used now but how they might be used in the future, by different political regimes.

Imogen Parker, associate director, Ada Lovelace Institute, London
iparker@adalovelaceinstitute.org

Support for covid passes has been building since early in the pandemic, and it’s easy to understand the attraction: if you could have a more precise understanding of risk you could engineer a better balance between restrictions to control the pandemic, as well as freedoms for personal liberty and economic recovery.

Unfortunately, it’s not that simple. Communicating vaccination or test status tells us something about risk, but it doesn’t prove people are free or safe from the virus. In August the outdoor Boardmasters Festival in Cornwall used vaccine passports with additional testing but still became a “superspreader” event, incubating almost 5000 cases. Given the variants and the heterogeneity of immune response, vaccine passports can’t give a perfect assessment of risk at an individual level.

Indeed, some experts have warned the move towards a system of personal risk scoring could undermine public health by treating a collective problem as an individual one: giving someone a green light to social participation could encourage them to ignore the contextual risk and potentially reduce compliance. Of course, this might need to be weighed against incentivising uptake by requiring compliance.

Like more traditional public health measures such as mask wearing or distancing, passports may reduce risk but can’t guarantee safety. Unlike masks or social distancing, however, they introduce profound risks into society.

Three risks

The most obvious risk arises through segregation, which could introduce barriers to economic and social participation. If a pass were to be based on vaccination status some people may find it hard to prove this to required standards, perhaps because they were unwilling to be vaccinated, but they may also be unable to have the vaccine or may have been vaccinated abroad, as part of a trial or with a brand that may not be covered. A pass based on access to covid testing comes with its own barriers, including availability and cost.

Second, normalising third party policing of individuals’ status could contribute to additional barriers for minority ethnic people, who already face over-policing, or for people with insecure citizenship who may be concerned about being co-opted into an identity system.

This plays out globally: if countries start using passports for normal participation in events, activities, and travel, only those people who are willing and able and have access to jabs or tests accepted in different countries will be allowed to take part—exacerbating inequalities of access, from testing and vaccines to economic recovery.

A third risk is the creation of enduring surveillance technology in response to what we hope will be a timebound crisis. Technology justified for emergencies has a habit of becoming normalised, as one member of the Ada Lovelace Institute’s expert deliberation on the subject put it: “Once the road has been built, good luck not using it.”

Digital tools make data easy to share, and this benefits health research, but they could also allow personal information to be shared with police or insurance companies. And the tools are easy to adapt: systems that include tests and vaccinations could be expanded to incorporate other risk factors or conditions, from blood pressure to mental health, or to move beyond health to incorporate ethnicity or sexuality. We should consider not just how such tools are used now but how they might be used in the future, by different political regimes.

No such thing as risk-free

The pandemic doesn’t offer risk-free interventions, and our institute’s research doesn’t rule out passports as a valid tool to help transition from lockdowns. It does call for transparent scientific foundations, including models on their public health effects in comparison with other tools and in the context of infection rates and variants; technical design standards; and a clear, specific, and limited purpose.

Beyond the tool itself, any scheme needs the right sociotechnical design: the legal regime, including “sunset” clauses to shut systems down if they’re not renewed; ethical considerations and policy structures to govern and mitigate potential harms; and the means to enable rights and redress.

To create the technical, operational, legal, and policy infrastructure required, policy makers should pause to calculate whether investment in passports might prove to be a technological distraction from the best mechanism available for us to reopen societies safely and equitably: global vaccination.

Cite this as: BMJ 2021;375:n2571
Pfizer’s covid vaccine trial: researcher blows the whistle on data integrity concerns

Revelations of poor practices at a Texan company working on a phase III study raise questions about handling of data and regulatory oversight. Paul D Thacker reports

Last autumn Pfizer’s chairman and chief executive, Albert Bourla, released an open letter to the billions of people around the world who were investing their hopes in a safe and effective vaccine to end the pandemic. “As I’ve said before, we are operating at the speed of science,” Bourla wrote, explaining to the public when they could expect a Pfizer vaccine to be authorised in the US.

But, for researchers who were testing Pfizer’s vaccine at several sites in Texas during that autumn, speed may have come at the cost of data integrity and patient safety. A regional director who was employed at Ventavia Research Group has told The BMJ that the company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer’s pivotal phase III trial. Staff who conducted quality control checks were overwhelmed by the volume of problems they were finding.

After repeatedly notifying Ventavia of these problems, the regional director, Brook Jackson, emailed a complaint to the US Food and Drug Administration (FDA). Ventavia fired her later the same day. Jackson has since provided The BMJ with dozens of internal company documents, photos, audio recordings, and emails.

On its website Ventavia calls itself the largest privately owned clinical research company in Texas and lists many awards it has won for its contract work. But Jackson has told The BMJ that, during the two weeks she was employed at Ventavia in September 2020, she repeatedly informed her superiors of poor laboratory management, patient safety concerns, and data integrity issues.

Photographs
Jackson is a trained clinical trial auditor who previously held a director of operations position and came to Ventavia with more than 15 years’ experience in clinical research coordination and management. Exasperated that Ventavia was not dealing with the problems, Jackson documented several matters late one night, taking photos on her mobile phone. One photo, provided to The BMJ, showed needles discarded in a plastic biohazard bag instead of a sharps container box. Another showed vaccine packaging materials with trial participants’ identification numbers written on them left out in the open, potentially unblinding participants. Ventavia executives later questioned Jackson for taking the photos.

Early and inadvertent unblinding may have occurred on a far wider scale. According to the trial’s design, unblinded staff were responsible for preparing and administering the study drug (Pfizer’s vaccine or a placebo). This was to be done to preserve the blinding of trial participants and all other site staff, including the principal investigator. However, at Ventavia, Jackson told The BMJ that drug assignment confirmation printouts were being left in participants’ charts, accessible to blinded personnel. As a corrective action taken in September, two months into trial recruitment and with around 1000 participants already enrolled, quality assurance checklists were updated with instructions for staff to remove drug assignments from charts.

In a recording of a meeting in late September 2020 between Jackson and two directors, a Ventavia executive can be heard explaining that the company wasn’t able to quantify the

The email highlighted more than 100 outstanding queries older than three days
types and number of errors they were finding when examining the trial paperwork for quality control. “In my mind, it’s something new every day,” a Ventavia executive says. “We know that it’s significant.”

That Ventavia was not keeping up with data entry queries is shown by an email sent by ICON, the contract research organisation with which Pfizer partnered on the trial. ICON reminded Ventavia in September 2020, “The expectation for this study is that all queries are addressed within 24hrs.” ICON then highlighted more than 100 outstanding queries older than three days in yellow. Examples included two individuals for which “Subject has reported with Severe symptoms/reactions . . . Per protocol, subjects experiencing Grade 3 local reactions should be contacted. Please confirm if an UNPLANNED CONTACT was made and update the corresponding form as appropriate.” According to the trial protocol a telephone contact should have occurred “to ascertain further details and determine whether a site visit is clinically indicated.”

Worries over FDA inspection
Documents show that problems had been going on for weeks. In a list of “action items” circulated among Ventavia leaders in early August 2020, shortly after the trial began and before Jackson’s hiring, a Ventavia executive identified three site staff members with whom to “Go over e-diary issue/falsifying data, etc.” One of them was “verbally counseled for changing data and not noting late entry,” a note indicates.

At several points during the late September meeting Jackson and the Ventavia executives discuss the possibility of the FDA showing up for an inspection. “We’re going to get some kind of letter of information at least, when the FDA gets here . . . know it,” an executive states.

The next morning, 25 September, Jackson called the FDA to warn about unsound practices in the clinical trial at Ventavia. She then reported her concerns in an email to the agency. That afternoon Ventavia fired Jackson—deemed “not a good fit,” according to her separation letter. Jackson told The BMJ it was the first time she had been fired in her 20 year career in research.

Concerns raised
In her 25 September email to the FDA Jackson wrote that Ventavia had enrolled more than 1000 participants at three sites. The full trial (registered under NCT04368728) enrolled around 44 000 participants across 153 sites that included numerous commercial companies and academic centres. She then listed a dozen concerns she had witnessed, including:

- Participants placed in a hallway after injection and not being monitored by clinical staff
- Lack of timely follow-up of patients who experienced adverse events
- Protocol deviations not being reported
- Mislabeled laboratory specimens,
A history of lax oversight

When it comes to the FDA and clinical trials, Elizabeth Woecnker, president of Citizens for Responsible Care and Research Incorporated (CIRCARE), says the agency’s oversight capacity is severely under-resourced. If the FDA receives a complaint about a clinical trial, she says the agency rarely has the staff available to show up and inspect. And sometimes oversight occurs too late.

In one example CIRCARE and the US consumer advocacy organisation Public Citizen, along with dozens of public health experts, filed a detailed complaint in July 2018 with the FDA about a clinical trial that failed to comply with regulations for the protection of human participants. Nine months later, in April 2019, an FDA investigator inspected the clinical site. In May this year the FDA sent the trialist a warning letter that substantiated many of the claims in the complaints. It said, “[i]t appears that you did not adhere to the applicable statutory requirements and FDA regulations governing the conduct of clinical investigations and the protection of human subjects.”

“There’s just a complete lack of oversight of contract research organisations and independent clinical research facilities,” says Jill Fisher, professor of social medicine at the University of North Carolina School of Medicine and author of Medical Research for Hire: The Political Economy of Pharmaceutical Clinical Trials.

Ventavia and the FDA

A former Ventavia employee told The BMJ that the company was nervous and expecting a federal audit of its Pfizer vaccine trial.

“People working in clinical research are terrified of FDA audits,” Jill Fisher told The BMJ, but she added that the agency rarely does anything other than inspect paperwork, usually months after a trial has ended. “I don’t know why they’re so afraid of them [the FDA],” she said. But she said she was surprised that the agency failed to inspect Ventavia after an employee had filed a complaint: “You would think if there’s a specific and credible complaint that they would have to investigate that.”

In 2007 the Department of Health and Human Services’ Office of the Inspector General released a report on FDA’s oversight of clinical trials conducted between 2000 and 2005. The report found that the FDA inspected only 1% of clinical trial sites. Inspections carried out by the FDA’s vaccines and biologics branch have been decreasing in recent years, with just 50 conducted in the 2020 fiscal year.

- Vaccines not being stored at proper temperatures, and
- Targeting of staff for reporting these types of problems.

Within hours Jackson received an email from the FDA thanking her for her concerns and notifying her that it could not comment on any investigation that might result. A few days later Jackson received a call from an FDA inspector to discuss her report but was told that no further information could be provided. She heard nothing further in relation to her report.

In Pfizer’s briefing document submitted to an FDA advisory committee meeting held on 10 December to discuss an application for emergency use authorisation of its vaccine, the company made no mention of problems at the Ventavia site. The next day the FDA issued the authorisation.

In August this year, after the full approval of the vaccine, the FDA published a summary of its inspections of the company’s pivotal trial. Nine of the trial’s 153 sites were inspected. Ventavia’s sites were not listed among the nine, and no inspections of sites where adults were recruited took place in the eight months after the December 2020 emergency authorisation. The FDA’s inspection officer noted: “The data integrity and verification portion of the BIMO [bioresearch monitoring] inspections were limited because the study was ongoing, and the data required for verification and comparison were not yet available to the IND [investigational new drug].”

Other employees’ accounts

In recent months Jackson has reconnected with several former Ventavia employees who all left or were fired from the company. One of them was one of the officials who had taken part in the late September meeting. In a text message sent in June the former official apologised, saying that “everything that you complained about was spot on.”

Two former Ventavia employees spoke to The BMJ anonymously for fear of reprisal and loss of job prospects in the tightly knit research community. Both confirmed broad aspects of Jackson’s complaints. One said that she had worked on more than four dozen clinical trials in her career, including many large trials, but had never experienced such a “helter skelter” work environment as with Ventavia on Pfizer’s trial.

“I’ve never had to do what they were asking me to do, ever,” she told The BMJ. “It just seemed like something a little different from normal—the things that were allowed and expected.”

She added that during her time at Ventavia the company expected a federal audit but this never came.

After Jackson left the company problems persisted at Ventavia, this employee said. In several cases it lacked enough employees to swab all trial participants who reported covid-like symptoms, to test for infection. Laboratory confirmed symptomatic covid-19 was the trial’s primary endpoint, the employee noted. (An FDA review memorandum released in August this year states that across the full trial swabs were not taken from 477 people with suspected cases of symptomatic covid-19.)

“I don’t think it was good clean data,” the employee said of the data Ventavia generated for the trial. “It’s a crazy mess.”

A second employee also described an environment at Ventavia unlike any she had experienced in her 20 years in research. She told The BMJ that, shortly after Jackson was fired, Pfizer was notified of problems at Ventavia with the trial and that an audit took place.

Since Jackson reported problems with Ventavia to the FDA, Pfizer has hired the company as a research subcontractor on four other vaccine clinical trials (covid-19 vaccine in children and young adults, pregnant women, and a booster dose, as well as an RSV vaccine trial; NCT04816643, NCT04754594, NCT04955626, NCT05035212). The advisory committee for the Centers for Disease Control and Prevention is set to discuss the covid-19 paediatric vaccine trial on 2 November.