this week

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LEON NEAL/GETTY IMAGES

GPs are at "breaking point," leaders warn

General practices are "reaching breaking point" because of the "intense" workload facing doctors and staff, the country's most senior GP leaders have warned.

The warning came as new figures from NHS Digital showed that practices in England delivered almost five million more appointments in March than the month before and nearly three million more than in March 2019.

Richard Vautrey, chair of the BMA General Practitioners Committee, said the figures underlined the huge efforts practices were making and the pressure on staff. He said, "GPs and their teams are consistently telling us they're busier now than they have ever been, and this data—which does not include a large proportion of the vaccine programme undertaken by practices, nor a vast amount of other daily tasks—backs this up."

The figures came as the BMA's latest tracker survey of GPs and hospital doctors, published this week, found that thousands were considering leaving the NHS in the next year because of exhaustion, stress, and burnout caused by working without respite during the pandemic. Half the respondents (2099 of 4240) said they planned to work fewer hours in the next 12 months, 25% (1065) said they were "more likely" to take a career break, 21% (882) said they were considering leaving the NHS for another career, and 32% (1352) were considering early retirement.

Vautrey said the survey results should serve as a "wake-up call" to the government. "Our calls must be listened to and our workforce truly valued," he said. "This means giving GPs the respite they need and access to proper breaks to ensure no more feel forced to leave a career they've worked so hard to achieve."

NHS Digital's data show general practices delivered an estimated 28.4 million appointments in March, up from 23.5 million in February and 25.6 million in March 2019. The latest data included some covid vaccinations (1.24 million in March), but most vaccination appointments were logged in different systems. This March 15.9 million appointments (56%) were face to face, 11.4 million (40%) were telephone consultations, and the rest by other means such as video consultations or home visits.

Commenting on the appointment figures, Martin Marshall, chair of the Royal College of General Practitioners, said, "Good progress has been made to encourage medical students to choose general practice,

(Continued on page 172)

Richard Vautrey (inset) called on the government to give GPs the respite they needed "to ensure no more feel forced" to leave the profession

LATEST ONLINE

- Covid-19: Hancock ordered by court to share messages about deals for PPE worth £650m
- Students overlooked for vaccine in favour of family members at Dublin hospital
- Many more people could benefit from blood pressure lowering drugs, say researchers

SEVEN DAYS IN

UK plans autumn booster vaccine rollout as it buys 60 million more Pfizer doses

The UK will roll out a covid booster vaccine at the beginning of autumn to protect the most vulnerable people ahead of winter, the Department of Health and Social Care has announced. The vaccines taskforce has secured an extra 60 million Pfizer-BioNTech doses, which will be used alongside the other vaccines already purchased.

Details on how the programme will work have not yet been made public, though the DHSC said the booster will be given according to clinical need and to the results of clinical trials assessing the effect of mixing approved vaccines.

The UK has secured deals for 517 million doses of eight vaccines or candidate vaccines for a population of 67 million people. These include 100 million doses each of Pfizer and AstraZeneca, 60 million Novavax, 30 million Janssen, and 17 million Moderna. From the candidate vaccines the UK has secured 100 million Valneva doses, 60 million of GlaxoSmithKline and Sanofi Pasteur, and 50 million CureVac.

The new deal came as WHO criticised the "shocking imbalance in the global distribution of vaccines" and called for distribution to be fairer.

"On average, in high income countries almost one in four people have received a covid-19 vaccine. In low income countries it's one in more than 500," WHO director general Tedros Adhanom Ghebreyesus said in a press conference earlier this month.

Elisabeth Mahase, *The BMJ* **Cite this as: *BMJ* 2021;373:n1116**

Assisted dying

Hancock asks for data on suicide in terminally ill

MPs and campaigners welcomed a request from England's health secretary, Matt Hancock, for more data on suicides by terminally ill people and the possible effect that the ban on assisted dying is having on these cases. Hancock made the pledge to the All Party Parliamentary Group on Choice at the End of Life in light of new figures from the Office for National Statistics, which suggest that one suicide in seven is by someone with experience of cancer or neurological, heart, or lung disease.

Legal news

Spire failed to tell patients of poor treatment

The private hospital group Spire Healthcare pleaded guilty to breaching the duty of candour in failing to give four patients prompt explanations about their inadequate treatment by a consultant orthopaedic surgeon. This was the first case to be brought by the Care Quality Commission against a private healthcare provider for breaching the duty of candour. Spire was fined £5000 and ordered to pay a £120 victim surcharge, as well as £14 984 in costs, at Leeds Magistrates Court.

Covid-19

India "should consider postponing" elections

In an open letter published in *The BMJ*, trustees of the South Asian Health Foundation called for India to ban mass gatherings, impose strict lockdowns, and consider postponing its upcoming election as the country struggles to cope with a huge surge in covid-19 cases and deaths. "India invoked an exemplary lockdown during the initial wave of covid-19 and it is perhaps now a time to consider whether the benefits of a lockdown outweigh the benefits of an immediate election," they wrote. "Mass gatherings need to stop urgently."

Pfizer-BioNTech seek child vaccine approval

The German newspaper *Der Spiegel* reported that the Pfizer-BioNTech vaccine could be available for children aged 12 to 15 as early as June. Uğur Şahin (below), cofounder of BioNTech, said it would submit the vaccine to the European Medicines Agency this week for approval for this age group. The companies were also testing the vaccine on children as young as 6 months old, he said.

Body weight is linked to risk of severe disease

A study that was based on more than 6.9 million people living in England, including more than 20 000 patients with covid who were admitted to hospital or died during the first wave, found that the risk of worse outcomes started rising in people with a BMI above 23, which is considered to be in the healthy range. The risks of hospital admission were 5% higher with each unit increase in BMI, and the risk of admission to intensive care was 10% higher with each unit increase, researchers reported in the *Lancet Diabetes & Endocrinology*. The effects were greatest in people under 40.

US to send 60 million AstraZeneca doses abroad

The Biden administration announced that the US would send as many as 60 million doses of the AstraZeneca coronavirus vaccine to countries in need—

effectively conceding that this vaccine would never be offered to the US public. Where the doses will go is not clear, but concern is widespread that uptake in recipient countries could be harmed by the perception that the US is giving away a vaccine that its own people refused to take.

High cholesterol

New NICE approval is set to benefit thousands

People with high cholesterol who are unable to use statins and whose cholesterol is not well controlled with ezetimibe can now be offered bempedoic acid with ezetimibe, after it was approved by NICE. About 70 000 adults in England with primary hypercholesterolaemia or mixed dyslipidaemia will benefit from the change, said NICE.

MEDICINE

International aid

UK funding cuts "will harm global health security"

UNAIDS said that the UK's proposed reduction in its annual funding of the agency from £15m in 2020 to £2.5m in 2021 would disrupt provision of HIV prevention and treatment services around the world. The ability of young women and girls to access sexual and reproductive health and rights would also be affected, it warned, as would the upholding of human rights of some of the most marginalised people, including LGBTQ+ people in low and middle income countries, ultimately reducing global health security.

UK cuts will hamper global HIV treatment, UNAIDS warns

CQC rating

Independent mental health hospital is "inadequate"

The Care Quality Commission rated an independent hospital in Nottinghamshire, Priory Hospital Arnold, as inadequate and placed it in special measures after it found that people were being cared for in an unsanitary environment. Inspectors found human waste, blood, and dried food on floors and walls of the hospital, which cares for adults with chronic mental health needs. Toilets were dirty, and a bag of urine, which had been left for several days, was found. Without sufficient improvement the CQC will use its powers further to protect patients from the risk of harm.

NHS England

Chief executive to step down this summer

Simon Stevens, who has confirmed that he is stepping down as chief executive of NHS England at the end of July, has been widely praised for his contribution to the NHS. Victor Adebowale, chair of the NHS Confederation, said that Stevens "made the case for investment in health and healthcare with determination and skill." Nigel Edwards, Nuffield Trust chief executive, said that Stevens had, "through a difficult period of pressures and an all consuming national pandemic, steadily advanced a strategic vision and longer term reforms" towards cooperation across health and social care.

Tobacco control

US will ban menthol cigarettes within the year

The US Food and Drug Administration set out plans to ban menthol in cigarettes—the last allowable flavour—and all flavours in cigars within the next year, which it hopes will help reduce the number of young

people who start smoking, increase the chances of people quitting, and tackle health disparities. About 30% of the cigarettes sold in the US are menthol flavoured, and research has shown that banning them would lead an additional 923 000 smokers to quit, including 230 000 African Americans, in the first 13 to 17 months of a ban.

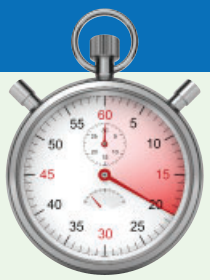
Cite this as: *BMJ* 2021;373:n1128

NHS LEAVERS

The proportion of UK doctors considering early retirement in April was **32%** (1352 of 4258 respondents), more than double the figure last June, when it was **14%**

[BMA survey]

SIXTY SECONDS ON . . . CONCUSSION IN FOOTBALL



WHAT'S THE SCORE?

A large study of US high school football (or, should we say, soccer) players has found that teenage girls face almost double the risk of concussion playing the game than teenage boys do. The authors said their findings were relevant to growing concern about the consequences of sport related concussion (SRC), including the possible increased risk of dementia, which is still being investigated.

"REFEREE, WE NEED A STRETCHER"

Notably, the study, which examined three years of data from 40 000 female teen players and 44 000 males in Michigan, found boys were 1.5 times as likely as girls to be substituted with a documented SRC.

WHY THE DIFFERENCE?

Authors of the study, published in *JAMA Network Open*, suggested the likelihood of being removed from the field was linked to the presence of an athletics trainer. If a trainer was involved in the initial assessment athletes with concussion were considerably more likely to be removed from play.

HOW WERE THE FINDINGS EXPLAINED?

The paper said it was unclear whether differences in reporting symptoms or physiological differences between male and female athletes were at play. But it noted, "Female soccer athletes have lower neck strength and girth compared with male athletes, with these variables inversely associated with linear and rotational head acceleration after soccer ball heading."

SHOULD GIRL HEADERS BE RED CARDED?

Not necessarily. Lead author Abigail Bretzin called only for "sex specific approaches to participation and concussion management," adding that more research was needed.

IS THERE ANY OTHER FIELD RESEARCH?

This week it was reported that 50 former professional rugby players were being recruited to a study to examine whether they are more likely to show early warning signs of dementia. A separate study of UK rugby players recently identified a method of accurately diagnosing concussion by using saliva, which it is hoped could be used to reduce the risk of missing concussions in sport and other settings.

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2021;373:n1119

(Continued from page 169)
but we also need to see comprehensive plans to keep existing and experienced GPs in the workforce, protecting them from burning out by addressing 'undoable' workloads."

Vautrey said the data also contradicted false perceptions that practices were seeing fewer patients. "This narrative, categorically proven wrong by [the] data, is extremely damaging at a time when morale is already reaching rock bottom," he said.

Open letter to patients

Last week the Ivy Grove Surgery in Derbyshire provided an example of the strain facing some practices in a 16 page open letter to its patients about the huge demand it was facing and the resulting risk of staff burnout. The surgery said it would be reducing its use of video consultations as it had seen a doubling of demand over recent months, with some patients submitting several requests a day.

The practice told *The BMJ*, "We are aware of the stir our letter has caused but have also been overwhelmed by the kind feedback from patients, and the many encouraging messages of support we have received from GP surgeries all around the country. We feel that open and honest debate about demand and workload in general practice is vital. If this letter goes even a little way towards sparking some much needed discussion then it will have been a good thing."

Vautrey added, "The unseen reality is that those pre-pandemic, once full, reception areas are now overflowing virtual waiting rooms, with the GP team working non-stop throughout the week. It's therefore vital NHS England and the government are honest about the pressures on general practice, provide clear guidance about what services are available across the NHS and when it is appropriate to use them, and also to plan properly for the future."

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2021;373:n1139

MARK THOMAS

Most people admitted to hospital after vaccination were infected before immunity could develop

The majority of vaccinated people who were admitted to hospital for covid-19 were probably infected shortly before or around the time of their vaccination, highlighting the importance of maintaining social distancing and understanding that immunity develops over time, researchers have said.

The International Severe Acute Respiratory Infection Consortium Clinical Characterisation Protocol (ISARIC4C) analysed UK hospital admissions after the start of the covid-19 vaccination rollout. As of 10 April 3842 of the 99 445 inpatients enrolled in the study had been vaccinated.

The researchers found that 40% (729) of 1823 who developed covid-19 symptoms did so 0-7 days after vaccination and a further 19% (352) developed symptoms 8-14 days after. The median incubation period for

Can the antivirals taskforce deliver home covid treatments by the autumn?

The government's newly launched antivirals taskforce aims to find at least two effective treatments against covid-19 for home use this year, in either a tablet or capsule form. The hope is that these treatments could prevent future waves of infections and limit the effect of new viral variants, especially over the winter.

What will the taskforce do?

Health secretary Matt Hancock said, "Modelled on the success of the vaccines and therapeutics taskforces, which have played a crucial part in our response to the pandemic, we are now bringing together a team to supercharge the search for antiviral treatments and roll them out as soon as the autumn."

Details on how the new taskforce will operate are scarce, but the vaccine taskforce brought together academia, industry, and government officials together with a ringfenced budget and a "clear and dedicated ministerial approval process to govern spending commitments."

Do antivirals work against respiratory viruses?

Two antivirals are recommended in the UK for treating influenza: oseltamivir (Tamiflu) and zanamivir (Relenza). However, there has been much controversy over the mass stockpiling of oseltamivir by many governments after the 2009 H1N1 flu pandemic and the lack of evidence to support its use. A 2009 Cochrane review found many of the studies used to support its efficacy were unpublished, which led to a four year campaign—much of it through *The BMJ*— to release the clinical trial data.

We are now bringing together a team to supercharge the search for antiviral treatment Matt Hancock

The subsequent Cochrane review found that both oseltamivir and zanamivir shortened the duration of symptoms of influenza-like illness by less than a day and that oseltamivir did not reduce hospital admissions. Concerns were also raised over oseltamivir's harm profile. WHO recommended restricting its use to critically ill hospital patients, but many countries, including the UK and US, still recommend its use elsewhere.

Public Health England disagrees that antivirals are ineffective for flu, criticising Cochrane for not including observational data. The agency tells health professionals they must not be "deterred from prescribing neuraminidase inhibitor drugs as a result of confusion over efficacy."

Meanwhile, in Japan the antiviral drug favipiravir, which

SARS-CoV-2 is around five days, meaning it is likely many of these patients were infected before immunity developed.

The report said it was possible that "elderly and vulnerable people who had been shielding may have inadvertently been exposed and infected either through the end-to-end process of vaccination, or shortly after vaccination through behavioural changes where they wrongly assume they are immune."

Vaccination failure

However, 12% (211) showed symptoms 15-21 days after vaccination and 29% (526) more than 21 days after vaccination. These cases could be due to vaccination failure. The team emphasised that this was not an unexpected finding, as the vaccines were not 100% effective, and that the absolute numbers of vaccinated people being admitted to hospital 21 days after a first dose were "tiny."

The researchers reported that, among the people who developed symptoms more than 21 days after vaccination, 113 (of 400) died with covid-19 (28%). Of these, 82 were in the "frail elderly" group.

Deborah Dunn-Walters, chair of the covid-19 taskforce at the British Society for Immunology, said the results showed the "importance of maintaining social distancing, even after vaccination, to minimise the risk of contracting SARS-CoV-2 before immune protection is active."

She added, "A very small number of people were hospitalised 21 days post-vaccination, and it's these people that we need to examine in more detail to understand why the vaccine did not afford them full protection."

Elisabeth Mahase, *The BMJ*

Cite this as: *BMJ* 2021;373:n1127

The results show the importance of maintaining social distancing, even after vaccination
Deborah Dunn-Walters

is also being investigated in the UK's Principle trial, has been licensed for treating novel or re-emerging influenza viruses since 2014. The treatment works by inhibiting the RNA polymerase, stopping the virus from replicating.

Baloxavir marboxil, an oral antiviral for the treatment of influenza A and B, is also approved in Japan and the US. In randomised controlled trials favipiravir was found to result in a similar time to alleviation of symptoms as oseltamivir. However, baloxavir was associated with greater reductions in viral load one day after the start of treatment, compared with placebo or oseltamivir.

What drugs are being investigated for covid?

Early in the pandemic a combination of two antiviral drugs, lopinavir and ritonavir (Kaletra), normally used to treat HIV, was investigated for use in patients with covid-19. But randomised controlled trials found no benefit in adult hospital patients.

Remdesivir was targeted at the start of the pandemic. Originally created to treat hepatitis C and respiratory syncytial virus in 2009 but found to be ineffective, it was then tested against Ebola virus in 2014. Again, the results were disappointing.

Last year remdesivir trials began against covid-19 and initial evidence indicated it shortened recovery times for severely ill patients, leading to the US, EU, and UK recommending its use. However, WHO's Solidarity trial reported the drug had little or no effect on mortality at 28 days and did not delay the need for ventilation. Researchers are now looking at whether remdesivir can benefit moderately ill patients.

Molnupiravir, a drug that inhibits RNA virus replication, is undergoing phase II and III clinical trials to see whether it aids sustained recovery or reduces hospital admissions or deaths in patients with covid-19.

Another treatment being trialled is PF-07321332, an oral antiviral from Pfizer. Although the phase I trial only started in March, the company said it had shown potent antiviral activity in vitro against SARS-CoV-2.

Is the timeline realistic?

As some antiviral drugs are undergoing trials, the aim to have two rolled out before the end of the year is possible, although it relies heavily on positive results.

Janet Scott, who is leading a trial of favipiravir in Glasgow, said, "With concerted effort it is possible to have results by the autumn. We cannot promise a positive outcome, of course; results will be what they will be."

Elisabeth Mahase, *The BMJ*

Cite this as: *BMJ* 2021;373:n1077

One dose "cuts risk of spreading virus by up to 50%"

MARK THOMAS

Adults who tested positive for SARS-CoV-2 three weeks after receiving one dose of the Pfizer or AstraZeneca vaccine were 38-49% less likely to pass the virus on to their household contacts than people who were unvaccinated, a preprint released by Public Health England has shown.

The research team said that protection was seen from around 14 days after vaccination, and levels were similar regardless of age of cases or contacts.

PHE said this protection was on top of the reduced risk of a vaccinated person developing symptomatic infection in the first place, which was around 60-65% four weeks after one dose of either vaccine.

"This is very promising," said Deborah Dunn-Walters, the British Society for Immunology's covid-19 taskforce chair and professor of immunology at Surrey University. But she added, "We must not be complacent. It is still very important for us all to get two doses of the covid-19 vaccine to ensure we receive the optimal and longest lasting protection, both for ourselves and our communities."

Emerging evidence

A total of 552 984 residential households with 2-10 people where there was at least one case were included in the study. In households where the index case was not vaccinated before testing positive, the study found 96 898 secondary cases from 960 765 household contacts (10.1%).

Elisabeth Mahase, *The BMJ*

Cite this as: *BMJ* 2021;373:n1112

In households where the index case received the AstraZeneca vaccine 21 days or more before testing positive, 196 secondary cases were seen in 3424 contacts (5.72%). With the Pfizer vaccine (one dose 21 days or more before testing positive), 371 secondary cases were found in 5939 contacts (6.25%)

NEWS ANALYSIS

Why is India having a covid-19 surge?

The country's infections set new pandemic records in April, with more than 300 000 positive tests each day for a week. **Kamala Thiagarajan** looks at the many unanswered questions

On 26 April India saw the highest daily tally of new SARS-CoV-2 infections ever recorded in the world, 360 960, taking its pandemic total to 16 million cases, second only to the US, and with more than 200 000 deaths.

The devastating second wave comes a year after the country imposed one of the most rigid lockdowns in the world—and just three months since its health ministry declared infections and mortality were at an all time low.

What's causing this wave, and why is it worse than the first?

After the first wave people dropped their guard, said Chandrakant Lahariya, an epidemiologist who helped write India's national covid vaccine policy. "In some of the worst hit states, like Delhi and Maharashtra, community transmission was so rampant that there have been several localised waves," he said. Media reports have blamed lax social distancing and mask wearing, alongside political rallies for recent elections and religious events such as the Kumbh Mela (below), in which hundreds of thousands of Hindus gathered at the Ganges river.

"The government was easing restrictions by what seemed to be the end of the first wave," said V Raman Kutty, an epidemiologist and honorary chairman of the non-profit organisation Health Action by People in Thrissur, Kerala. "Malls and theatres opened; there were sporting events, elections, and religious events. Politicians even made the unsupported claim that India had beaten the pandemic."

DANISH SIDDIQUI/REUTERS/ALAMY

A report in the *International Journal of Infectious Diseases* last December concluded that the transmission rate fell significantly during the first lockdown but warned that lockdown was only a temporary measure. The authors recommended ramping up testing and self-isolation to prevent secondary infections, yet India's testing rate remains among the lowest in the world. Comparisons are difficult, as India doesn't release daily test numbers for the country as a whole, but the health ministry said a total of 1.75 million samples had been PCR tested by 27 April. The UK performs 500 000 PCR tests a day.

Then there is India's health infrastructure, already troubled before the pandemic and now overwhelmed.

On 11 May 2020, soon after the first lockdown was lifted, the government's policy think tank NITI Aayog analysed the country's covid-19 response. It found a severe dearth of medical equipment such as testing kits, PPE, and ventilators. It also noted the long running shortages of emergency healthcare and professionals: the ratio of doctors to patients was 1:1445 and of hospital beds to people 0.7:1000, with a ventilator to population ratio of 40 000 to 1.3 billion.

In the latest crisis, medical supplies and oxygen are being imported from 15 countries and aid organisations. Devi Prakash Shetty, a cardiac surgeon and chairman of the Narayana Health chain of medical centres, has estimated that India would need about 500 000 ICU beds and 350 000 medical staff in the next few weeks. At present it has only 90 000 ICU beds, almost fully occupied.

India is also struggling to vaccinate its population of 1.36 billion, despite boasting one of the largest pharmaceutical manufacturing capacities in the world.

Earlier, individuals were affected, but now whole families are contracting covid
Chandrakant Lahariya

The two variants may have additive effects in making the virus less sensitive to antibodies
Ravi Gupta

Official statistics are often doctored to suit the political bosses
V Raman Kutty

Why did India's infections drop at the start of 2021?

This remains unknown, but Kutty said it was likely to have been the true tapering off of the first wave, with positive tests falling.

But the testing numbers may not tell the whole story. "Official statistics in India are often doctored to suit the political bosses, and there was tremendous pressure to report less," Kutty told *The BMJ*, adding that there is a lack of transparency in the figures for infections and mortality. "One hardly knows who is responsible for them. It is definitely dependent on the number of tests done, and in many states it could be argued that not enough tests were done. However, the numbers of deaths are a more robust indicator, and in the first wave deaths seem to have been less compared with other countries. The second wave is a totally different story."

With a reported 16 million cases, the actual number of deaths is likely to be much higher, Lahariya said. "Testing was limited, and so many who weren't tested were admitted [to hospitals]. When these patients die, their deaths are not recorded as covid-19 deaths," he said, adding that death can also occur after discharge.

How does the second wave differ from the first?

"Earlier, individuals were affected, but today whole families are contracting covid," said Lahariya.

A study in *Lancet Global Health* in February indicated that the first wave infected up to 50% of people in urban areas. The second wave seems to be spreading more to rural areas, where people have long distances to travel to get to health centres. In the state of Punjab, records show that over 80% of patients have severe symptoms once they arrive, because of travel delays.

People aged 30-50 who go out to work seem also to be especially

affected by this wave, at least in New Delhi. Anecdotal reports suggest more deaths among younger people this time, said Kutty, but the scale isn't clear because so many infected people have no symptoms.

There have been high profile reports of reinfections. For instance, the chief minister of the southern state of Karnataka, B S Yediyurappa, tested positive for SARS-CoV-2 twice in nine months. In March 2021 a study in *Epidemiology and Infection* reported a reinfection rate of 4.5% among 1300 people, with a large proportion having shown no symptoms the first time.

Are new variants to blame?

Variants first identified in South Africa (known as 20H/501Y or B.1.351), Brazil (P.1), and the UK (B.1.1.7) are circulating in India, alongside a distinct new Indian variant (B.1.617) first identified in October. All are likely to be a factor, but the extent of involvement of each is as yet unknown.

"The B.1.617 variant has spread rapidly in parts of India, apparently dominating over previously circulating viruses in some parts of the country," said Ravi Gupta, professor of clinical microbiology at Cambridge University, who is studying these variants. "B.1.1.7 is dominating in some parts, and B.1.617 has become dominant in others, suggesting both may have an advantage over pre-existing strains."

Scientists are concerned about two mutations in B.1.617 (E484K and L452R), which have led it to be dubbed a "double mutant." Gupta said that the L452R mutation is in a key area of the spike that is recognised by antibodies after vaccination or infection. E484K also has this effect. "The worry is that the two may have additive effects in making the virus less sensitive to antibodies," he said.

The Indian SARS-CoV-2 Genomics Consortium, a group of 10 national laboratories, was set up in December 2020 to monitor genetic variations in the coronavirus, particularly B.1.1.7, but the lack of testing and sequencing capacity is hindering efforts. Government data show that India has sequenced less than 1% of its positive samples, compared with 4% in the US and 8% in the UK.

SOPA/ALAMY

People wait to be vaccinated at the Madhyamgram Rural Hospital in Kolkata last month

What do we know about the Indian variant's spread in the UK?

Public Health England has identified several cases of B.1.617 in the UK, mostly linked to travel. This led the UK government to add India to its travel red list.

The number of B.1.617 genomes detected in the UK has risen in the past few weeks, Sharon Peacock, professor of public health and microbiology at the University of Cambridge and director of the Covid-19 Genomics UK Consortium, told the Science Media Centre. "Even though this is at or less than 1% of the genomes sequenced in the UK overall, the upward trend in cases warrants action while ongoing uncertainties over the level of threat posed by this variant are evaluated."

How will the crisis affect India's vaccine rollout?

India launched its vaccine drive on 16 January 2021, mostly relying on Covishield, a version of the Oxford-AstraZeneca vaccine produced by the Serum Institute of India. A smaller number of people get India's domestically developed Covaxin, manufactured by Bharat Biotech. The government had set a target of vaccinating 250 million people by July. So far about 117 million people have been vaccinated and around 17 million have received two doses.

The government has stopped exports of Covishield, a decision that has affected vaccine rollouts all over the world, including the global Covax initiative. Reports allege the government has approved a $610m (£440m) grant for the Serum Institute of India and Bharat Biotech to ramp up production in the days ahead, which critics said should have been done before the second wave.

Approval and import of other vaccines have been slow, with the likes of Pfizer facing requests for further domestic clinical trials. The government could have allowed more vaccines to be imported, for the large segment of the urban population who may be willing to pay the price, said Kutty. "It would ease the pressure on the public infrastructure, which is under great strain."

In the face of the crisis the government has approved the use of Russia's Sputnik V, and five Indian manufacturers have been authorised to produce more than 850 million doses a year, with the first doses due on 1 May.

As infections have risen, hospitals have been running out of vaccines. Kutty said that shortages were one thing; another is how fast India is able to vaccinate. "I think our [health] infrastructure at present may not be able to do it fast enough even if there were enough supplies of vaccines. The government has to plan a real campaign to cover as much of the population in as short a time as possible."

And although vaccines for people over 45 and frontline medical workers have been paid for by the federal government, doses for other age groups have to come out of local budgets. State governments have been asked to negotiate with vaccine manufacturers directly to purchase the stocks they need, a move criticised as arbitrary and discriminatory between states, as they have widely different budgets and healthcare systems.

I estimate India will need about 500 000 ICU beds and 350 000 medical staff in the next few weeks Devi Prakash Shetty

Kamala Thiagarajan, Tamil Nadu

Cite this as: *BMJ* 2021;373:n1124

THE BIG PICTURE

Record of historic rollout

These pictures, showing how a 92 year old man was able to get his covid vaccine, are among a collection of photographs showcasing the people behind the UK's vaccination effort.

Gavin Chestnutt, a GP partner at Ballycastle Medical Practice, Country Antrim, took a ferry to Rathlin Island to give Duncan Smythe his first jab in March.

Taken by Liam McBurney, the photographs are in a series of images (see bit.ly/2RgkmJx) taken with Jude Palmer and Glenn Edward of people receiving vaccines at mobile units, care homes, and pop-up sites across the UK.

Alison Shepherd, *The BMJ* Cite this as: *BMJ* 2021;373:n1125

EDITORIAL

Rehabilitation after critical illness

Essential for all intensive care patients, not just people recovering from covid-19

The burden of illness experienced by patients who survive critical illness is well documented.[1 2] The symptoms are collectively known as post-intensive care syndrome and can include long term physical impairments such as muscle weakness, weight loss, breathlessness[3]; cognitive impairment[4]; and psychological symptoms such as depression[5] or anxiety.[6] Those recovering from covid-19 are also more likely have additional respiratory sequelae.[7-9] Furthermore, deficits in quality of life can persist for up to 12 years after critical illness[10] with many people unable to return to work.[11]

In 2009 guidance from the National Institute for Health and Care Excellence (NICE)[13] outlined the requirements for optimum rehabilitation services after critical illness. However, these guidelines failed to translate into improved support for all patients, with national survey data from 2014 indicating that less than a third of intensive care units offered follow-up when recommended, and even fewer hospitals offered post-hospital discharge rehabilitation programmes.[14] Patients and families must cope alone or rely on their primary care professionals, who may have limited experience supporting patients after critical illness.

The patient voice

There is much to admire in how the patient voice has highlighted the longer term effects of covid-19 and made the case for community rehabilitation. NHS England has invested heavily, establishing 60 multidisciplinary clinics nationwide to support patients recovering from covid-19.[15] However, a recent study identified no discernible difference between the rehabilitation needs of patients with covid-19 and those admitted to intensive care with other critical illnesses.[16] The authors highlight this inequality of access and suggest that heightened awareness may be contributing to better rehabilitation services for patients with covid-19.[16]

Deficits in quality of life can persist for up to 12 years after critical illness

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Providing consistent rehabilitation services is challenging. Lack of high quality evidence about the most effective approach is a problem for commissioners and service managers, for example.[14-18] New services need adequate funding and staffing with experienced clinicians from multiple specialties.Robust processes and tools are required to screen all patients for post-intensive care syndrome. Enhanced links between hospitals and primary care are essential to facilitate the transition to community settings and ongoing rehabilitation. Engagement from NHS management and other stakeholders such as commissioners, clinicians, and integrated care systems is key to successful delivery.

Serious consequences

Lack of adequate rehabilitation has serious consequences for individuals and risks increasing costs to the NHS, particularly from unplanned readmissions to intensive care units.[19] Consistent with the 2009 NICE guidance,[13] rehabilitation should be provided to all patients after critical illness, not just those with covid-19.

Services should include healthcare professionals who recognise the diversity of physical and mental health problems that can follow a critical illness and be supplemented by high quality, comprehensive, and individually tailored information for patients and relatives to guide recovery.[20] Research to determine the most clinically and cost effective rehabilitation strategies should be a priority, with collaboration between patients, funders, and researchers to identify and address evidence gaps.

Many guidelines on rehabilitation for patients with covid-19 have been published in the past year, but just two have considered broader services for people recovering from critical illness. Firstly, the National Post-ICU Rehabilitation Collaborative developed a framework for assessing the needs of patients stepping down from intensive care.[21] Embedded in the framework is the "post-ICU presentation screen," a validated tool that identifies individual rehabilitation requirements and can be adapted as needs change.[16 22] Secondly, the Faculty of Intensive Care Medicine published provisional guidance from its "life after critical illness" programme, recommending follow-up, including assessment of rehabilitation needs.[23] Further work on implementation is now required, with meaningful patient input to inform and develop models based on user experience.

Management of critically ill patients in intensive care units requires expert multidisciplinary teams to ensure best outcomes. The same approach is needed to support the rehabilitation of all patients after discharge from intensive care and hospital, with consistent pathways of care across the country to ensure all patients achieve their best possible recovery.

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EDITORIAL

Control pollution, protect children, save lives

Coroner urges action to prevent further asthma deaths

Asthma outcomes in the UK are among the worst in the world,[1 2] but little is done except endlessly to rewrite guidelines that are largely ignored. The leading cause of asthma deaths in children is fragmented clinical care[3]—fragmented because asthma attacks are treated as isolated events rather than markers of underlying risk that must be addressed.[4 5] Asthma is a serious chronic condition and should be treated as such.[6]

On 21 April, a London coroner issued a regulation 28 report after an inquest ruled that environmental pollution had made a material contribution to the death of a 9 year old girl, Ella Adoo-Kissi-Debrah, who lived near the congested South Circular Road in south London. Regulation 28 reports signal that action must be taken, in this case to prevent any future deaths from air pollution.

The coroner identified three areas of concern: first, that the UK (and the EU) permits levels of air pollution more than double those allowed by World Health Organization guidelines; second, public awareness of sources of information about pollution remains low, along with awareness of how to reduce exposure; and, thirdly, the risks of air pollution are inadequately communicated to parents and families.

Response demanded

The coroner rightly demanded a response from government agencies and professional bodies, including Health Education England and the Royal Colleges of Physicians, General Practitioners, and Paediatrics and Child Health, as well as from guideline developers the National Institute for Health and Care Excellence and the British Thoracic Society.

The association between environmental pollution and asthma attacks is well described,[7] and Ella's death was a tragedy for her and her family. Even if Ella had survived, she would have experienced lifelong adverse effects from her early exposure to air pollution. Ella was almost certainly harmed by pollution before she was born; maternal exposure to environmental pollution during pregnancy is associated with asthma[8] and impaired lung function[9] in children. Exposure in childhood then leads to a slowing of lung growth,[10] and these double hits mean that Ella could not have attained her normal lung potential. Failure to attain a normal final lung capacity by your early 20s carries a 26% risk of chronic obstructive pulmonary disease[11] and an increased risk of premature cardiovascular and all cause morbidity and mortality.[12 13]

The harms of air pollution in childhood are completely irreversible, leaving a lifelong legacy

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Finally, when children growing up on polluted streets become parents themselves, their children are also born with abnormal lung function with all the attendant risks.[13] The harms of air pollution in childhood are completely irreversible, leaving a lifelong legacy.

Effective action is possible, however. In California, successive pieces of legislation improving air quality have been associated with improved lung growth in school age children.[14] Levels of air pollution dropped substantially during pandemic lockdowns,[15] and these positive changes must inspire similar legislative action elsewhere, including the UK.

Scandalous

The coroner at Ella's inquest heard evidence that exposure to any level of environmental pollution is unsafe. Yet successive UK governments have persistently and scandalously ignored WHO targets. Why should heavily polluting vehicles be allowed to pay as little as £12.50 a day to drive through areas where pregnant mothers, babies, and young children live? The London mayor has been widely acclaimed for the city's low and ultra-low emission zones, but much more could be done both in London and in other cities. Serious consideration should be given to extending congestion charging areas, with especially high charges for large polluting vehicles.

Ella died from a potentially preventable acute asthma attack because her right to breathe clean air was ignored. But at the time of her death, it was already too late to do anything about the chronic lung damage endured by her and her peers. Her death from air pollution is a stark illustration of health inequality and should prompt urgent government action, including legislation to reduce pollution levels to below WHO targets.

The professional bodies named by the coroner must add the harmful effects of pollution to mainstream undergraduate and postgraduate teaching, and provide immediate guidance on how to communicate risk about pollution to patients and families. This regulation 28 report must not become yet another missed opportunity to prevent avoidable deaths from asthma in the UK.

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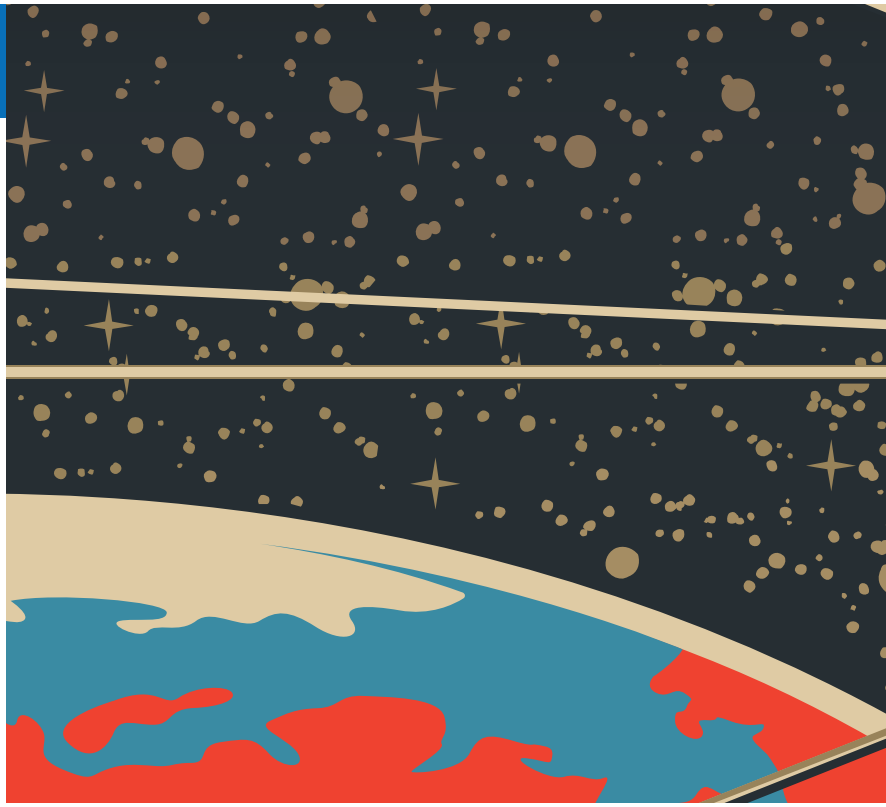
ESSAY

Covid-19: Sputnik vaccine rockets, thanks to Lancet boost

Journals risk being used in place of regulators when they publish studies of novel vaccines that have not yet been officially authorised. **Chris van Tulleken** argues that peer review is inadequate to decide the risk benefit ratio of new drugs



Last August President Vladimir Putin announced Sputnik V, a vaccine developed by Russia's Gamaleya National Center of Epidemiology and Microbiology. Putin's claim that it had gone through "all the necessary trials" did not seem to be backed up by the information on the Russian language registration certificate, which said that just 38 participants had received the vaccine.

International responses ranged from concern to derision. By granting approval to a vaccine before results from large phase III randomised trials were available, the Russian government seemed to be taking two immense risks. The first was a risk of direct harm to large numbers of people. Bad vaccines don't just fail to protect, they might have serious adverse effects including making subsequent infection more dangerous through antibody associated disease enhancement, a phenomenon previously seen with SARS and MERS coronaviruses. Second, if people were harmed, public confidence in the vaccination programme and future investment in covid-19 vaccine development and uptake might be jeopardised. Trust in vaccines is easily bruised and recovers slowly.

A month later, the first peer reviewed Sputnik V data were published in the *Lancet*: two non-randomised, open label studies, each of 38 people. No serious adverse events were reported, and the vaccine seemed to induce robust immune responses in participants.

Neither the Lancet nor the Sputnik team have provided either the data from which the figures were generated or individual patient data

Phase I and II trial data concerns

Enrico Bucci was one of the first people to spot inconsistencies in this paper. Bucci runs an Italian research integrity company, and just three days after the publication he posted an open letter expressing concern that participants seemed to have identical values for different variables. He also noted identical repeating patterns of data points in separate groups of participants.

These findings seemed important, so I signed Bucci's open letter, with more than 40 other scientists. Then, with 15 others, we wrote a letter, which the *Lancet* published, requesting access to the data from which the figures were generated.

The Sputnik team responded, saying that the patterns in the data were "coincidences associated with the discreteness of the data, as well as with the small number of participants in the groups" and confirmed that individual participant data would be made available on request to the letter's lead author and that "after approval of a proposal, data can be shared through a secure online platform."

Initially, this was reassuring. The *Lancet* is enthusiastic about open data. Its website says, "We envision a global research community in which sharing de-identified data becomes the norm," and a September 2020 editorial said that "authors must endeavour to validate their conclusions with data that are accessible to readers, so that analyses can be reproduced. The *Lancet* journals will continue to hold authors and editors accountable for the data published in our pages, and we encourage our readers to do the same."

But, despite these assertions, neither the *Lancet* nor the Sputnik team have provided either the data from which the figures were generated or individual patient data. The *Lancet* declined to respond specifically to questions about whether they would uphold the data sharing agreement or whether they had even requested more data from the Sputnik team. It did publish a brief correction amending the paper without explanation, which seemed to be in response to the letters but made no reference to them.

Phase III data concerns

After a flurry of stories, press interest in the concerns around Sputnik V waned until the publication of an interim report on the phase III study on 2 February 2021, again in the *Lancet*.

The paper reported an efficacy of over 90% in 14 964 vaccinated adults and was followed by favourable editorials in the journal. One announced: "Sputnik V covid-19 vaccine candidate appears safe and effective" and said that "another vaccine can now join the fight." A

second editorial applauded Russia "for their efforts in making their vaccine available and affordable to countries across the globe."

But once again, the paper was followed by an open letter of concern from Bucci, who drew attention to a large number of minor errors that would not be expected in a study of such importance. On a Kaplan-Meier plot, for example, hundreds of people whose data were available at day 20 were not included in the analysis at day 10. In another data table in the appendix, the numbers didn't add up to the reported total. Later, in an online response to *The BMJ*, Bucci and a group of international authors pointed out the improbable consistency of vaccine efficacy values reported at interim analyses.

Bucci was not alone. Vasiliy Vlassov, a professor at the National Research University Higher School of Economics in St Petersburg, also wrote an open letter referencing the *Lancet*'s brief correction of the previous paper, which, he said "has exacerbated distrust." He pointed out that, unlike vaccines authorised by a major regulator, the Sputnik team was unique in being the only major vaccine developer not to release its full trial protocol.

The *Lancet* subsequently issued a correction for the phase III trial, again amending some of the anomalies. The overall impression is that of inadequate peer review and editorial processes that failed to detect what seem to be obvious errors in reporting the results of this high profile research.

Most of the 40 countries using the vaccine ahead of EMA authorisation are countries without well resourced, independent regulators

The Lancet as cheerleader

These obvious errors and the uncritically glowing editorials would be worrying enough under normal circumstances. But they are particularly concerning given that, at the time of publication of the phase III trial, no major regulator had even received an application for marketing. By comparison, every other covid-19 vaccine with a phase III trial published in a high impact journal had already been submitted to or authorised by a major regulatory authority. The European Medicines Agency only began reviewing the Sputnik team's application on 4 March, a month after the *Lancet* publication.

Meanwhile, the publications in the *Lancet* are being used to great effect by the Sputnik V marketing team and its primary investor, Russian Direct Investment Fund. The *Lancet* paper has been cited on Sputnik's popular Twitter and Instagram feeds, in every press release, and in multiple interviews. The vaccine website claims: "Sputnik V's efficacy and safety results are validated by internationally peer reviewed data published in the *Lancet*" (https://sputnikvaccine.com/).

And the paper seems to have given other countries confidence. Before publication of the phase III trial, 16 countries had authorised Sputnik V for use—now, over 40 have authorised it. Hundreds of millions of doses have been ordered and, according to the Sputnik team, millions of doses have been given.

Most of the 40 countries using the vaccine ahead of EMA authorisation are low and middle income countries without well resourced, independent regulators. Understandably, because of the desperate global shortage of vaccines approved by a major regulator, they may have had no choice but to rely on the *Lancet*'s vetting of the science. But despite its international reputation, is the journal's peer review process adequate for this?

Peer reviewing the pandemic

Clinicians and researchers are trained to trust in the power of peer review. Such faith was on display when Pfizer released interim trial results in a press release, ahead of journal publication.

Richard Horton, editor in chief of the *Lancet* expressed the same sentiment: "On the Pfizer covid-19 vaccine: publishing interim results through a press release is neither good scientific practice nor does it help to build public trust in vaccines. An announcement should come with full publication of a peer-reviewed research paper in a scientific journal."

Horton's statement indicates a misunderstanding of the reasons for press releasing important results—companies around the world are legally obliged to disclose major new developments to investors without delay—as well as a misplaced confidence in journal peer review. The *Lancet* might be expected to exercise extra caution when it comes to papers on covid-19 or vaccines.

In summer 2020 both the *Lancet* and the *New England Journal of Medicine* published—and then retracted—major covid-19 studies based on a fraudulent dataset. And the *Lancet* made a similar mistake on a 1998 paper linking the MMR vaccine to autism, which remained in the literature for 12 years and contributed to the resurgence of measles around the world.

The widely recognised inability of traditional journal peer review to detect errors and fraud is hardly surprising. After a manuscript is selected for external review beyond the editorial team, it will typically be seen by two or three reviewers and a statistician. Turnaround times might be quick, and reviewers are almost always unpaid and, being international experts, busy. Usually

BIOGRAPHY

Chris van Tulleken is an infection doctor at University College London Hospital and an honorary associate professor at UCL in the division of infection and immunity. He also works as a broadcaster covering science and health for children and adults on the BBC (including the double BAFTA winning Operation Ouch). Much of his academic and broadcasting work focuses on conflicts of interest and research integrity.

a few hours are spent reviewing a paper, and occasionally post docs are roped in for additional scrutiny. At well resourced journals, further internal review and detailed editing will be done before acceptance and publication, but fast tracking topical and important findings might mean that corners are cut. After the retraction in summer 2020, Horton talked to the *New Yorker* about the stresses of publishing in the pandemic. "I don't think we've had the capacity easily to deal with it [the increase in submissions], and that has stretched all of us," Horton said. "Inevitably, in moments like that, you get very, very anxious about mistakes."

The editors and peer reviewers of the Sputnik V paper are likely to have had only the 20 or so pages of PDF documents that were ultimately published. The *Lancet's* website makes it clear that, like many journals, it does not have access to "raw data related to research studies."

Such limitations affect trust in journal publications generally but are most concerning when published data on important public health interventions, such as vaccines, have not yet been scrutinised by a stringent regulator.

The regulatory process

The regulatory process has its flaws and critics. It is fundamentally similar to peer review in its purpose—to scrutinise a received submission—but the scope and scale is orders of magnitude larger.

At most journals, peer review is undertaken over a few hours, by two or three anonymous, unpaid experts, without publicly declared interests and without access to underlying data. By contrast, the EMA and other major regulators typically use named teams of in-house and external experts, all with declared interests and expertise in different critical aspects of a new product. The regulator also has unlimited access to all the non-clinical, clinical, and manufacturing data. They frequently audit the sponsor and inspect research and manufacturing sites. If they choose to exercise it, they have the power to look at individual patient charts to verify data.

RESPONSE FROM THE *LANCET*

Prior to publication, *The BMJ* provided the *Lancet* with a list of allegations contained in this article regarding the *Lancet*'s publication of the Sputnik V trials. We received the following response from Emily Head, media relations manager:

"This research was independently peer reviewed by international experts on covid-19 and vaccines, including a statistical reviewer. At the *Lancet* journals, our editors treat communication with authors as confidential, and details of peer review including dates and peer review comments are not shared publicly.

"All publicly available information for Lancet articles is published with the article, in the Supplementary Materials or Linked Articles sections on the article webpage. In addition, explanations of any errors that have been corrected within an article are provided in the Department of Error notice.

"Our policies on peer review, data access, and corrections are available here: https://www.thelancet.com/publishing-excellence."

The application for regulatory authorisation is not simply a vast data dump. It's an orchestrated, collaborative process, governed by hundreds of pages of law and guidelines. Typically, meetings will begin before a submission, and drug developers can then be given formal guidance about every aspect of study design.

In terms of transparency, the EMA has published public assessment reports for the covid-19 vaccines they have authorised. These are over 150 pages long and detail the logic leading to authorisation. They include legal obligations on the sponsor to resolve any data discrepancies. In addition, the EMA has published thousands of pages of data from the submissions.

Compared with this extensive and well documented process, peer reviewed publication, even in a highly reputed publication such as the *Lancet*, is a relatively low bar to clear. Yet, since the extraordinary initial announcement, everything about Sputnik V has seemed worthy of detailed scrutiny by a journal.

The vaccine was developed at an institution in a country with no substantial track record of vaccine development and was intensively marketed without being submitted for authorisation to a major regulator. These things alone might have raised the need for exceptional caution in publishing the results of a phase III vaccine trial. Yet the *Lancet* chose to accompany publication with favourable editorials that made no mention of the need for regulatory scrutiny. After publication, credible concerns around the data were raised, and the *Lancet* has been unable to enforce the data sharing commitments made by the authors.

It is unclear exactly when the EMA will render its judgment on Sputnik V, especially considering the concerns about clotting problems that have since emerged with vaccines using similar adenovirus vector platforms. If it is authorised, Sputnik V will be a boost to global health, an idea which the *Lancet*, under Richard Horton, has championed with a radical approach. Perhaps their early endorsement of Sputnik is consistent with this, but, just as this episode raises questions about the *Lancet*'s commitment to open data, it also raises questions about the depth of the other commitments that they place under the banner "the best science for better lives."

If Sputnik is not authorised, much more serious questions will surface, about the avoidable harm driven by overconfidence in journal peer review and the more far reaching damage to the public's fragile confidence in other vaccines that are truly safe and effective.

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ESSAY

Ticking the ICE box: the future of doctor-patient communication in a post-covid world

Phil Whitaker revisits the model of "ideas, concerns, and expectations" founded by his GP mentor and wonders how the internet and life after the pandemic will impact on consultation room interactions

One of my favourite apocryphal stories is the doctors' surgery with the dead tree stump in the middle of the car park. The stump remained there for years, until eventually the practice manager decided to get rid of it. When the contractors' chainsaws began cutting the desiccated wood, hundreds of green FP10 prescription forms fluttered out from the hollow middle.

It is an unforgettable image: patient after patient coming out from consulting with the doctor and depositing the prescription they've just been given in the old tree stump before heading on their way. The moral of the tale: the yawning gulf that often exists between what patients want from encounters with their doctors and what the doctors assume should be the outcome.

How do we ensure that anyone leaving our consulting room with a treatment recommendation—be it a drug, an operation, or a lifestyle change—actually believes it is something they should agree to? And in the manner and for the duration that we have advised? Equally important is how we identify and satisfy those who want or need something different from us.

ICE forms

The concept of ICE (ideas, concerns, and expectations) was first articulated in *The Consultation*, the 1984 text that helped revolutionise understanding of what goes on when a patient goes to see a doctor. One of the four authors was Peter Tate, who went on to be my GP trainer when I entered primary care in the early 1990s.

Tate, together with psychologist David Pendleton and fellow GP trainers Theo Schofield and Peter Havelock, had analysed hundreds of videotaped consultations conducted by a cohort of experienced GPs. Most of the doctors were fulfilling the time honoured paternalistic role of the physician, arriving at a medical diagnosis and prescribing a treatment to an essentially passive patient, but around 10% had honed a completely different style. They were interested in the sense that their patients made of their symptoms and situations—their ideas, concerns, and expectations—and they used various techniques to draw this information out.

Having understood their patients' perspectives, these doctors were able to answer important questions such as "What has led this patient to consult about this problem at this point in time?" and to define how much or little overlap there might be between a patient's health beliefs and the way a physician views things. Not only did this equip them to make more nuanced and holistic diagnostic formulations, they were also able to tailor their explanations and advice to the person in front of them. Each patient centred consultation represented one fewer FP10 in the proverbial tree stump in the car park.

The questions helped equip the doctors to make more nuanced and holistic diagnostic formulations

ICE flow

Had the concept remained confined to an academic textbook, it is unlikely to have propagated far. But Tate understood that the way to create the change was to introduce ICE to new generations of doctors who had yet to fix their consulting style and who would be receptive to novel thinking. In 1994, he published *The Doctor's Communication Handbook*, a distillation of the insights he'd gained through his work with the Pendleton group. It quickly found a place on most GP registrars' recommended reading lists.

Tate had also become an examiner for the Royal College of General Practitioners. In collaboration with other progressives, such as Steve Field, Roger Neighbour, and David Haslam, he pushed for consultation skills to become formally

BIOGRAPHY

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incorporated in the GP training curriculum. And on the basis that people will pay due attention to something if they know they are going to be tested on it, he led the complex process of devising methods of assessing those skills as part of the college's membership examination.

For many years this involved registrars submitting video recordings of sample consultations. This approach gave way to the Clinical Skills Assessment, which seeks to test the same competencies under examination conditions using actors to role play carefully devised clinical encounters.

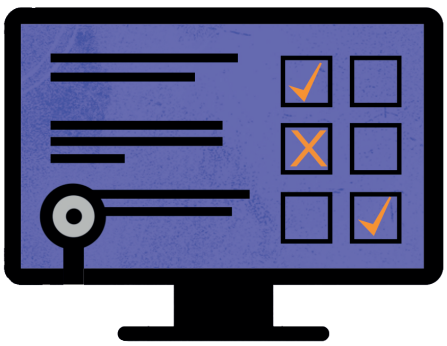
The concept of ICE has seeped out of general practice and become embedded in wider UK medical education. My daughter is now a clinical medical student; her clerking routinely incorporates a section on the patient's ICE alongside the traditional components of the medical history—presenting complaint, previous medical history, social history, and so on—that I learnt a generation ago.

The revolution Tate helped usher in is the bedrock on which the emerging field of shared decision making is founded, and it represents an essential counterbalance to the impersonalising tendency inherent in the uncritical application of that other great reforming movement of the late 20th century, evidence based medicine. ICE has been pivotal in the demise of the paternalistic doctor and the reinvention of the physician as the patients' expert ally.

Ticking the ICE box

Although the ubiquity of ICE seems like a success story, I wonder if sometimes it paradoxically prevents the goal it was supposed to achieve—true patient centredness. As an educational supervisor, I work with numerous GP registrars and foundation programme doctors. They are all aware that they should attempt to elicit patients' ICE, but what training they've received has been decidedly lacklustre. Most have been taught simply to ask bald questions like: "What do you think is wrong?" or "What were you hoping I would do about this?" Direct and to the point, but I've lost count of the times I've watched patients' faces betray their bemusement or disbelief. "You're the doctor!" is the frequent response. And that other ignoble classic, "What are you worried about?" can come across as crass, making it seem like the doctor thinks that the patient's problem is trivial and that they are overreacting.

Consultation skills are about much more than giving patients a chance to explain their ICE



These moments in consultations can be jarring for patient and doctor alike and undermine a doctor's apparent competence. Small wonder that eliciting ICE has become for many younger doctors an awkward exercise to be got through as quickly as possible, rather than an opportunity for genuine curiosity and connection.

As educators, we should be doing so much better by our trainees. A simple awareness that patients usually research their symptoms can be used to open ICE conversations much more obliquely and naturally—asking, for example, "Many people read about their symptoms online—have you found anything out?" Health matters are frequently extensively discussed at home or among friends, so why not ask: "What do your family think about it all?" Responses to such indirect questions usually require further exploration; the picture that emerges will often generate a far more nuanced appreciation of that patient's unique situation.

These kinds of enquiries communicate the doctor's interest and avoid inadvertently implying ignorance.

Consultation skills are about so much more than giving patients a chance to explain their ICE. People may be reticent or embarrassed about revealing their perspectives, or they may be unaware of concerns lurking in their subconscious.

The half beat of hesitation or the shift in body language can indicate that there is more to be uncovered—subtle signs that are lost if the focus is purely on ticking the ICE box and moving on. Direct questioning is too blunt a tool in such circumstances; other skills such as reflection or responding to a fleeting cue are required. We need to teach our trainees to be alert to subtext and the subliminal, not simply to take at face value that which is readily verbalised.

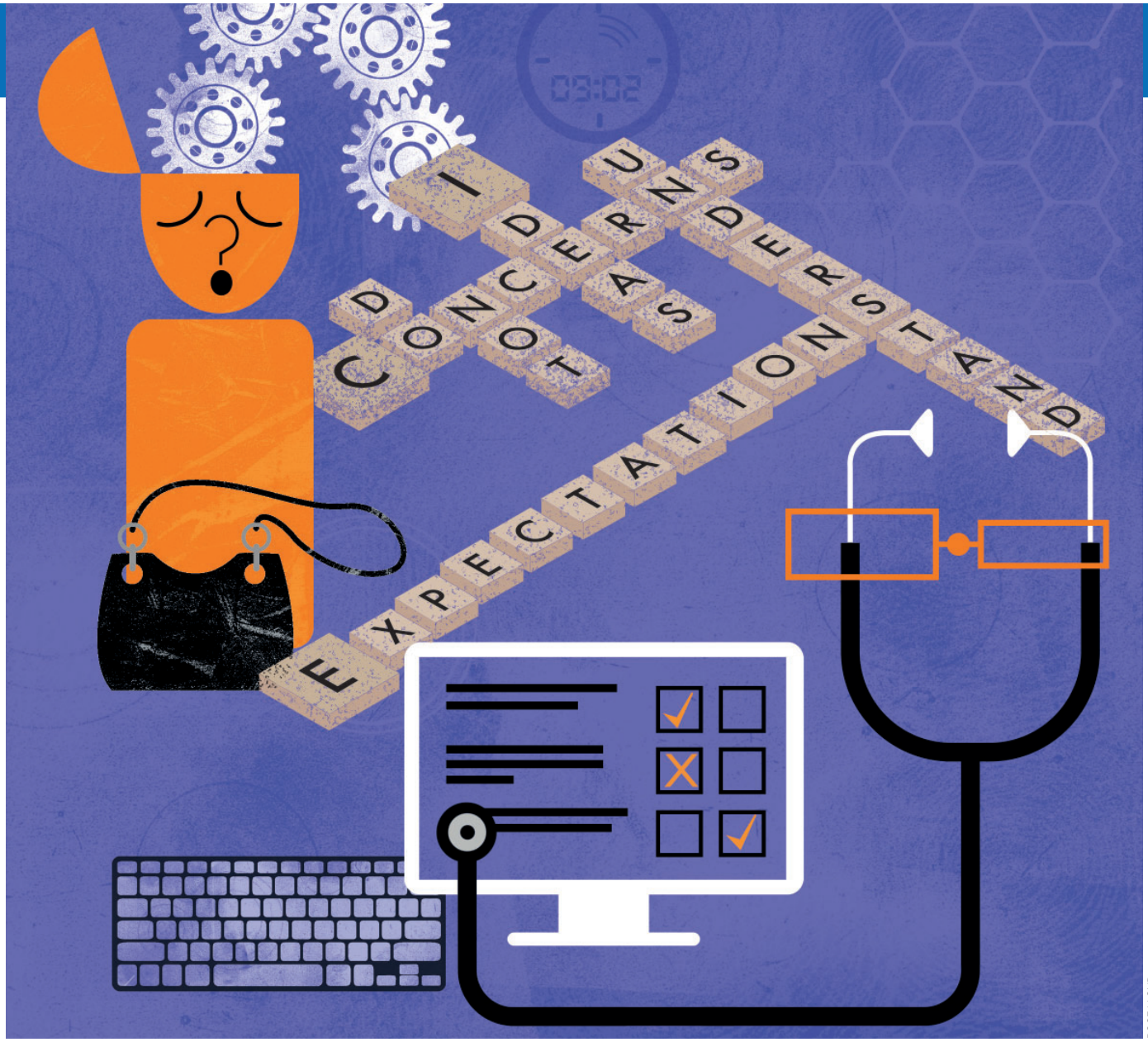
The future of ICE

In another generation, we may have far less need for artful skills to uncover patients' perspectives. In recent years, I have been struck by the increasing number of patients who explain their ICE unprompted in their opening remarks. It seems likely that the altered way we are practising as doctors is having a parallel training effect on our patients.

There have been wider societal changes as well: culturally, we are far more assertive and sceptical in our dealings with professionals. When the concept of ICE was first articulated, the world wide web was but a twinkle in creator Tim Berners-Lee's eye; now, the internet puts masses of medical information in anyone's reach. On occasion, this helps in aligning patients' health beliefs with doctors' perspectives. More often, though, the information that patients discover lacks context.

One of our chief tasks in the future might be to negotiate understanding as to why what seems to make perfect sense in the literature doesn't apply. We are increasingly going to have to work in partnership with patients to navigate the areas of uncertainty and risk—and the related issues of constrained resources and potential iatrogenic harm—that doctors have traditionally managed tacitly on behalf of both patients and the NHS.

The field of artificial intelligence is starting to have an impact.



ROSE LLOYD

Patients' ICEs are more commonly being shaped by the output from symptom checker algorithms, which are of variable quality. The worst will sometimes generate bizarre differentials, and even the best are firmly constrained in the biomedical model. When patients have received seemingly authoritative artificial intelligence diagnoses, broadening their understanding to incorporate psychosocial factors is likely to become more challenging.

Covid-19 has accelerated other changes. The NHS has switched wholesale to a "telephone first" model of consultation to limit viral transmission. When the pandemic is over, this shift to remote consulting—be it telephone, video, email, or messaging—is likely to stick. Coupled with the ongoing governmental prioritisation of ease of access over continuity of care in the English NHS, this threatens the loss of much that we currently value about general practice. Remote consulting with random clinicians is convenient and adequate for transactional problems, or for supplying generic information, but as it becomes normalised, so will the idea that primary care is a transactional, impersonal discipline—for both patients and practitioners. Are we sleepwalking back to the era of tree stump medicine?

Are we sleepwalking back to the era of tree stump medicine?

We have barely begun to consider the effect of remote consulting on the provision of holistic care. Other consulting skills seem more pressing: how to exclude serious illness in a person on the other end of a telephone, for example. Yet properly divining patients' ICE remains as important as ever, as does the forging of rapport and genuine doctor-patient partnerships.

Are these possible remotely in any but the simplest scenarios? How do we practise good medicine without the non-verbal signals and signs—from both patient and doctor—that comprise the majority of human communication and that guide us unconsciously as we attempt to negotiate shared understandings with those who seek our care?

Tate's *Doctor's Communication Handbook* is now in its eighth edition, coauthored with Francesca Frame, a GP from Cambridgeshire who brings contemporary experience to the material. Tate is well into his retirement, but his cause is far from over.

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BRIEFING

How the JCVI sets who gets a vaccine and when

The Joint Committee on Vaccination and Immunisation is a crucial player in the UK's covid vaccination programme. **Jo Best** reports on its role and recommendations during the pandemic

It's a constant review process as we learn more about the virus and the vaccine Wei Shen Lim

What is the JCVI?

The 16 experts who make up the independent Joint Committee on Vaccination and Immunisation advise UK health departments, help develop immunisation programmes, and identify gaps in knowledge about vaccines and immunisation strategy. During the pandemic they have advised who should receive a vaccine and when. (The Vaccines Taskforce advises on which vaccines to buy.)

The health secretary sets the committee's remit and appoints JCVI members on the advice of the Department of Health and Social Care (DHSC) and Public Health England. The DHSC uses the advice to set policy, which the NHS puts into practice. The JCVI typically meets three times a year, but the covid-19 subcommittee has been meeting about twice a week.

Who sits on the JCVI?

Members are mostly from universities and public health bodies with backgrounds in virology, infectious diseases, epidemiology, general practice, respiratory medicine, and pharmacology; one or two are lay members. The chair, Andrew Pollard, professor of paediatric infection and immunity at Oxford University, recused himself from the committee's covid-19 work because of his involvement in the development of the Oxford AstraZeneca vaccine. Wei Shen Lim, a consultant respiratory physician at Nottingham University Hospitals NHS Trust, chairs the covid-19 subcommittee.

No conflicts were recorded in the most recently published subcommittee minutes.

How does it make recommendations?

It considers scientific and clinical data, existing recommendations, expert advice, modelling, attitudinal research, and evidence from charities. It can request unpublished data from vaccine manufacturers.

"Usually, decisions are made with a lot of information that's already known," Lim told *The BMJ*. "Whereas in the pandemic we're making decisions sometimes with information that is just out, and that is difficult." For covid-19 it has considered disease epidemiology and characteristics, risk factors, demographics, occupational exposures, vaccine inequalities, clinical trial data, and vaccination modelling.

"The speed of deployment is so much greater a factor for a mass vaccination programme," Lim said. Usually, the NHS has months to plan vaccination programmes, he said. "As we learn more about the pandemic, the virus, and the vaccine, it's a constant review process for any decision we've made."

What has it recommended for covid-19?

EU and UK regulators have not set age restrictions for the AstraZeneca vaccine after finding that blood clots could be a "possible" and "extremely rare" side effect, but the JCVI has said that healthy adults under 30 should be offered an alternative where possible. (No causal relation has been established.)

Revised advice on dosing recommends prioritising first doses over second doses and recommends a maximum of 12 weeks between doses. While the manufacturers Pfizer and AstraZeneca stated that second doses should be given three weeks after the first, the JCVI advises a longer interval to increase the number of first doses that could be given. This was controversial as the NHS initially scheduled second doses for three weeks after the first, only to switch once the JCVI amended its advice at the end of December, following an increase in cases involving the B117 variant, which was suspected to be more transmissible and deadly. The JCVI does not recommend mixing doses from different manufacturers.

How were prioritisation decisions reached?

In the first phase of the vaccine programme, the JCVI recommended nine priority groups that should be vaccinated first, including people over 50, clinically vulnerable people, and patient facing healthcare workers, with people in care homes and their carers the highest priority. Interim advice for the second phase recommends further prioritisation by age: 49 to 40 year olds, then 39 to 30 year olds, then all other adults.

The committee decided not to designate people from ethnic minorities, who are at greater risk of hospital admission and mortality, as priority groups. It argued that prevalent comorbidities and social factors increase such risks and that existing priority groups already include those at increased risk. It recommends increased promotion of vaccines to people in high risk groups.

The JCVI initially said that a second phase could prioritise vaccination by occupation but in February decided that this "would be more complex to deliver and may slow down the vaccine programme, leaving some more vulnerable people at higher risk unvaccinated for longer."

"Unvaccinated people who are at increased risk of severe outcomes from covid-19 on account of their occupation, male sex, obesity, or ethnic background are likely to be vaccinated most rapidly by an operationally simple vaccine strategy," the committee said.

Does JCVI respond to public opinion?

"It's important to hear what the public wants, but we also have to be aware of what is scientifically valid," says Lim. Confusion surrounded calls for people with learning disabilities to be prioritised, and people on the GP Learning Disability Register are now in priority group 6. But this was a change in NHS practice, not a change to JCVI advice. People at severe risk, including those with learning disabilities, are generally already in priority groups because of comorbidities or being in residential care.

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