this week

JUSTIN BIEBER page 423 • **BMA SEXISM REVIEW** page 424 • **UNVIABLE TRIALS** page 426

MARK THOMAS

Omicron subvariants drive new covid wave

NHS leaders fear a rise in covid hospital admissions will force the service to divert its recovery efforts

The UK now seems to be at the start of a new wave of covid infections driven by the rise of two omicron subvariants, BA.4 and BA.5. Cases and hospital admissions are now rising sharply, figures show.

The latest data from the Office for National Statistics, released on 17 June, show that covid infections were up 43% week on week. The infection survey for the week ending 11 June showed that an estimated 1 in 50 people in England would test positive for covid, up from 1 in 70 the week before. In Scotland the figure is now 1 in 30 people and in Northern Ireland and Wales, 1 in 45.

The percentage of people testing positive rose in all English regions except the north east, where the trend was uncertain. The percentage of people testing positive increased in all age groups.

Speaking at an Independent SAGE meeting on 17 June, Kit Yates, senior lecturer in the department of mathematics at Bath University, said, "It is pretty much official from the latest ONS data that the UK has entered the next wave of covid."

Latest NHS England data showed that hospital admissions with covid were rising sharply across England, up 31% week on week. Admissions rose by between 20% and 42% in all English regions. The total number of beds occupied by people with confirmed covid cases in English hospitals was 5008 on 16 June, up from a low of 3800 on 1 June. This was far lower than in April, however, when more than 16 000 beds were occupied. The intensive care unit and high dependency unit admission rate remained low in the week ending 12 June.

Saffron Cordery, interim chief executive of NHS Providers, said NHS trust leaders were monitoring the situation closely. "We are, thankfully, nowhere near the peaks seen during the worst of the pandemic. But if admissions go up dramatically because of a new wave of infections caused by new omicron variants this summer, the NHS may have to take its foot off the recovery accelerator and divert efforts and capacity into looking after people with covid once again. Clearly, we all want to avoid this."

The ONS said the increase in people testing positive was "likely caused by infections compatible with omicron variants BA.4 and BA.5." Latest data from the Covid-19 Genomics UK Consortium show that BA.4 and BA.5 are now at 50% of sequenced cases in England.

Jacqui Wise, Kent

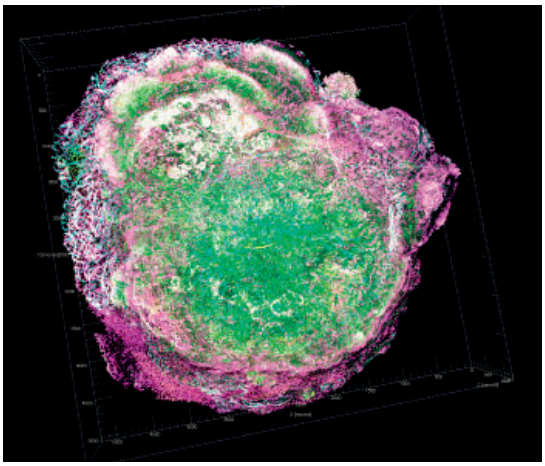
Cite this as: *BMJ* 2022;377:o1506

LATEST ONLINE

- WHO to rename monkeypox to prevent stigma
- Disgraced surgeon Paolo Macchiarini is convicted over experimental trachea surgery
- Government's tobacco plan must tackle link between mental health and smoking, say psychiatrists

SEVEN DAYS IN

NICE recommends new targeted treatment for early breast cancer



SPL

NICE has provisionally approved a treatment for early breast cancer that it says will benefit around 4000 patients in England. Final draft guidance published on 17 June gives provisional approval of abemaciclib in combination with hormone therapy as an option after surgery. It is recommended for people with hormone receptor positive, HER2 negative, node positive early breast cancer at high risk of recurrence who have had surgery to remove a tumour.

Abemaciclib, taken as a twice daily pill, is also called Verzenios and is manufactured by Eli Lilly. It is a CDK4/6 inhibitor and works by targeting and inhibiting proteins in cancer cells that allow the cancer to divide and grow.

The recommendation follows trial results showing that people being treated with abemaciclib and hormone therapy had a more than 30% better chance of their cancer not returning after surgery, when compared with those who just had hormone therapy.

The drug normally costs £2950 for a packet of 56 tablets of 150 mg, but the company has agreed a confidential NHS discount, NICE said.

Gareth Iacobucci, *The BMJ* Cite this as: *BMJ* 2022;377:o1491

Covid-19

Vaccine patent deal is criticised by charities

Charities and campaigners condemned the terms of an agreement by governments at the World Trade Organization on patents for covid vaccines in developing countries. Max Lawson, co-chair of the People's Vaccine Alliance and head of inequality policy at Oxfam, said, "This is absolutely not the broad intellectual property waiver the world desperately needs to ensure access to vaccines and treatments for everyone, everywhere. The EU, UK, US, and Switzerland blocked that text. Put simply, it is a technocratic fudge aimed at saving reputations, not lives."

Under 5s in US offered Pfizer and Moderna jabs

The US Centers for Disease Control and Prevention and the Food and Drug Administration approved both the Pfizer-BioNTech and the Moderna covid vaccines for children aged 6 months to 5 years—the last group eligible for vaccination in the US. The CDC's director, Rochelle Walensky (right), gave approval on 18 June after previous approval by advisory committees and the FDA. She recommended vaccination for about 20 million children in the 6 month to 5 year age group, using whichever of the two vaccines is available.

Government accepts most of MPs' recommendations

The Commons Health and Social Care Committee chair, Jeremy Hunt, and his Science and Technology Committee chair counterpart, Greg Clark, welcomed the government's acceptance of most of the 38 recommendations made by the committees' joint parliamentary inquiry into the handling of the pandemic. But the MPs criticised the government for not fully meeting the call for additional social care funding and not tackling specific concerns over preventing infection. "We remain doubtful that ministers have learnt this lesson," they said.

Racism

Leaders report widespread discrimination across NHS

Over half of senior health leaders from ethnic minority backgrounds in England are considering leaving the NHS because of their experience of racism at work, a national survey of 123 senior managers, directors, and chief executives found. The survey by the NHS Confederation, which mirrors the findings of a recent BMA survey of doctors, found that 57% of senior leaders from ethnic minority backgrounds had experienced verbal abuse and behaviour targeting their racial, national, or cultural heritage at least once in the past three years, and 22% said that this had happened five times or more.

General practice

Partnership model "viable with proper resources"

Doctors giving evidence to MPs have defended the independent contractor model of GP partnership, arguing that it allows for innovation and greater accountability to patients provided that it is resourced properly. At the Health and Social Care Committee's inquiry into the future of general practice the committee chair, Jeremy Hunt, asked witnesses to respond to the government's reported plans to abolish the GP partnership model by 2030. Mike Holmes, a GP partner in York and vice chair for membership at the Royal College of General Practitioners, said, "The partnership model is viable when resourced properly."

Sickle cell disease

NHS campaign aims to boost public awareness

NHS England launched a campaign to increase awareness of the key signs and symptoms of sickle cell disease, which disproportionately affects people from black African and Caribbean backgrounds. The campaign is aimed at emergency care staff who may see people experiencing a "sickle cell crisis," as well as carers and the wider public. The NHS is also launching a staff training programme on the condition and the symptoms of a crisis, such as severe pain, fever, one sided paralysis, difficulty walking, and confusion.

Type 1 diabetes

Inquiry into eating disorders in diabetes

A parliamentary inquiry into eating disorders in type 1 diabetes was launched on 17 June by the All Party Parliamentary Group for Diabetes. It will hear from academics, clinicians, charities, and patients.

MEDICINE

Air pollution

UK government is not on track to hit targets

The National Audit Office has warned that, despite falling emissions, UK government policy is inadequate to achieve targets to reduce air pollution. The Department for Environment, Food and Rural Affairs warned that rising energy bills may increase domestic wood burning, that ammonia emissions have stayed at 2007 levels, and that 64 local authorities have potentially breached nitrogen dioxide limits. The agency warned that the government was not effectively communicating air quality issues to the public. People cannot easily access local air quality information, but air pollution in the UK causes 28 000 to 36 000 deaths a year.

Clinical research

STEM workforce "must be more diverse"

MPs have been told of an "urgent" need to increase diversity in the science, technology, engineering, and mathematics workforces, which are currently highly unrepresentative of some parts of the population. Giving evidence to the Commons Science and Technology Committee on 15 June, the science minister, George Freeman, acknowledged concerns that participation by people from more deprived and disadvantaged backgrounds, some ethnic minority backgrounds, and women and girls, had persisted at a low level for many years. "I absolutely recognise that picture and the urgency of it," he said.

Emergency care

Ministers "can't use covid as excuse for crisis"

NHS performance data from NHS England showed that in May 2022 some 40% of patients attending major emergency departments waited more than four hours to be admitted, transferred, or discharged. Sarah Scobie, the Nuffield Trust's deputy director of research, said, "The health secretary claimed [on 15 June] the pandemic was the root cause of the 'A&E crisis,' but the government cannot hide solely behind covid-19. In reality, this key target has not been met since July 2015, and the root causes can be traced back to over a decade ago."

As electricity bills rise there are fears domestic wood burning will increase

NICE guidelines

Drug boosts chance of kidney transplant success

NICE recommended a new treatment that increases the chance of a successful kidney transplant. In final draft guidance published on 16 June NICE recommended imlifidase (also known as Idefirix and made by Hansa Biopharma) for people waiting for a kidney transplant who are highly sensitised to human leucocyte antigens (HLAs)—including some people from ethnic minority backgrounds and patients who have been pregnant—to prevent the body rejecting the donor organ. The company estimates that more than 100 people are eligible for imlifidase in England and Wales.

Cite this as: *BMJ* 2022;377:o1508

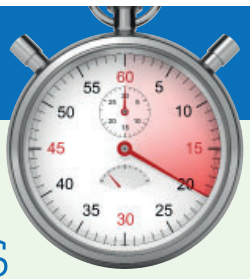
WAITING TIMES

In England

12735

people had been waiting more than two years for hospital treatment in April, down from a high of

23778 in January 2022. But the waiting list has risen overall to a record high of 6.48 million people *[NHS]*



SIXTY SECONDS ON . . . **JUSTIN BIEBER**

NEWS JUSTIN?

Yes. Canadian pop superstar Justin Bieber made waves this week by revealing on Instagram that he has been diagnosed with Ramsay Hunt syndrome (RHS).

THAT SOUNDS SERIOUS

It is, particularly for a singer. RHS is a cause of facial droop, where the nerve (cranial nerve VII or facial nerve) that supplies the muscles in the face stops working properly. His is a textbook case—the entire right side of his face can't move. As a result, Bieber has had to cancel several live tour dates. The condition is treatable, though. If antiviral drugs, steroids, or painkillers are given within three days of symptoms appearing, around 70% of patients make a full recovery.

HOW HAVE THE BELIEBERS REACTED?

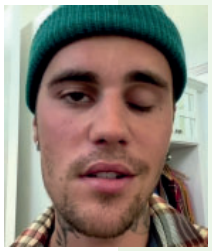
There was speculation from fans as to whether Bieber has had a stroke, but a closer look at his video shows otherwise. His right eyebrow isn't moving with his left, a classic sign of a lower motor neuron pathology—the forehead is innervated from both sides of your central nervous system, so if you have a stroke, those muscles are spared, and the other side of your brain compensates.

ARE DOCTORS CONFIDENT OF THE CAUSE?

The singer's condition is caused by varicella zoster virus (shingles) and can potentially happen to anyone who has had chickenpox. More concerningly, the news sparked a wave of antivaccine conspiracy theories on social media, claiming that his condition was caused by covid vaccination.

SO AS BIEBER SANG: NO SENSE?

Indeed. Confusion and panic among fans has been worsened as people mix up facial palsy, like that in RHS, with Bell's palsy. Not helping is the fact that clinicians often use the term Bell's palsy interchangeably with facial palsy.



HARD TO BELIEB

I know. And as music and culture magazine *Rolling Stone* pointed out, "Bieber's case may be more of an argument for vaccines than against them. There are widely available vaccines for chickenpox and shingles, with the former being 90% effective at preventing chickenpox."

Joy Hodkinson, *The BMJ*

Cite this as: *BMJ* 2022;377:o1492

All male candidate lists for senior BMA posts highlight lack of progress, say female leaders

The BMA has defended its record on promoting equality, after an all male list of candidates for the top elected posts of chair of council and treasurer sparked claims that it has been too slow to act over alleged "institutional sexism."

Leading female doctors said they were "very disappointed" with what seemed to be a lack of meaningful change at the BMA when it came to removing barriers to women since a review into sexism and sexual harassment in its ranks by Daphne Romney QC was published in 2019.

The four candidates to succeed Chaand Nagpaul as the BMA's chair of council are Phil Banfield, a consultant in obstetrics and gynaecology in North Wales, Tom Dolphin, a consultant anaesthetist in London, Vishal Sharma, a consultant cardiologist in Liverpool, and David Wrigley, a GP in Carnforth, Lancashire. The two candidates for the BMA's new treasurer are Peter Holden, a GP in Matlock, Derbyshire, and Trevor Pickersgill, a consultant neurologist in Cardiff.

I don't think the BMA has accepted it has a problem with institutional misogyny
Fay Wilson

The shortlist emerged as a progress report, shared with *The BMJ*, documented the progress the BMA said it had made to embed Romney's recommendations (see below).

Fay Wilson, an elected member of the BMA's GP committee and a former member of the BMA council, told *The BMJ*, "The four man candidate line-up for the council and the two man line-up for treasurer tell you all you need to know. I don't think the BMA has accepted it has a problem with institutional misogyny. The candidate line-ups are just another symptom of it."

Romney's review heard evidence of an "old boys' club" culture in which women were undermined, bullied, and in some instances sexually harassed. The review recommended steps to improve behaviour and widen representation, such as diversity and equality training for all members and a time limit for committee appointments.

Zoe Norris, a senior BMA GP committee representative who gave evidence to the Romney review, also criticised a "lack of progress" and warned of the signal being sent by the BMA having no women standing

Romney review: "Real, meaningful progress is being made"

EXCLUSIVE The BMA has produced a report charting the progress it has made to embed the recommendations from Daphne Romney's 2019 investigation into sexism and sexual harassment at the organisation.

The report, shared with *The BMJ* ahead of its publication this week, came as the BMA faces mounting pressure to act on Romney's findings and as leading female doctors told *The BMJ* (above) that the process of responding to the landmark inquiry was taking too long.

Latifa Patel, the newly elected chair of the BMA's representative body, said the report showed a commitment to making "real and meaningful progress" to improve the culture but acknowledged that "there is plenty still to do."

The report, *Improving Culture and Inclusion at the BMA*, highlights a rise in the proportion of female members in BMA leadership positions (committee chairs and deputy chairs), from 29.3% in March 2019 to 36.9% in March 2022.

Analysis for the BMA by independent auditors (summarised in the report) found that 55% of the Romney recommendations had been implemented so far, 18% partly implemented, 18% outstanding, and 9% with "deliverables to be identified"

But, amid concerns that women were still heavily outnumbered on the council and that this could be deterring many from standing, data for elections to council show that the proportion has barely risen at all: there has been just a half percentage point increase in the number of women, to 38% of members elected in 2022, from 37.5% in 2018.

Across all committees the percentage of female members rose from 36.7% in 2019 to 41.8% in 2022.

In her review Romney made 31 recommendations covering the broad areas of culture, calling out, listservers used by elected members, the resolution process, and committees.

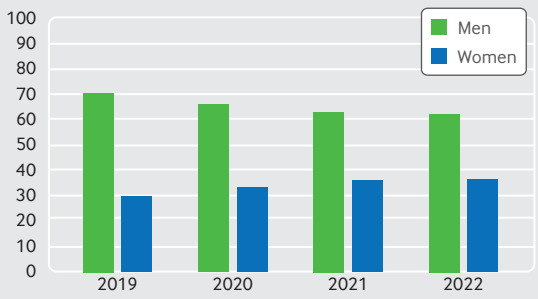
The BMA set up a Culture Inclusion Oversight Group in November 2019 with a broader remit to consider inclusion across all diversity strands.

The report noted that the England GP Committee has elected its first female chair from an ethnic minority background. It added that the new intake of council members was the "most ethnically diverse council in BMA history."

But Fay Wilson, an elected member of the BMA's GP committee and a former member of BMA council, said the progress report lacked the detailed action plan expected.

She added, "I doubt if this report will do much to stifle the dismay among women in the BMA who feel dismayed by what has been happening for the last few years."

A BMA spokesperson said, "While the report shows all the positive progress that has been made, we still have a long way to go and we will continue to talk and work with our members and staff and report on our progress annually"



% of BMA committee chairs and deputy chairs who are men or women

Matthew Limb, London

Cite this as: *BMJ* 2022;377:o1527

as chair of council. She told *The BMJ*, "We continue to have the main trade union for the medical profession that in no way reflects the demographic of doctors in the UK among its senior leadership team. It seems unlikely to achieve this in the next five years, based on the current shortlist."

Helena McKeown, a former chair of the BMA's representative body, who stepped down last year, and who helped establish a new BMA network for elected women in 2019 in response to Romney's report, said, "One of my aspirations [for the network] was that every election for a chair of a committee or council would have at least one female candidate, so I'm very disappointed because I don't feel I achieved what I set out to do."

In a joint statement, Rachel Podolak and Neeta Major, the BMA's two recently appointed co-chief executives, said it would be "remiss" to view the candidate line-ups as a setback for equality at the organisation. They said, "The recent council election had seen a significant increase in the representation of ethnic minority members, including women from an ethnic minority background, and the percentage of seats held by men had fallen below 60% for the first time.

"In the past three years the representation of women has increased right across the BMA's committees, including into positions of leadership.

They added, "GPCE [GPC England] has elected its first woman chair from an ethnic minority background. Our medical ethics committee, international committee, patient liaison group, and public health medicine committee have all appointed or elected women chairs. Our junior doctors committee and medical students committee are also chaired by women."

The BMA also confirmed that Latifa Patel, an ST7 paediatric respiratory trainee in the north west of England, has been elected chair of the association's representative body.

Matthew Limb, London

Cite this as: *BMJ* 2022;377:o1525

One of my aspirations was to have at least one female candidate. So I am very disappointed
Helena McKeown

BMA COUNCIL seats held by men fell below **60%** for the first time in recent elections

ACTIONS THE BMA SAID THAT IT HAD TAKEN TO IMPLEMENT DAPHNE ROMNEY'S 2019 REPORT

- Creating a BMA network of elected women to help and support elected women members
- Hosting training to improve culture and launching a BMA Speak Up Guardian Service in June 2020 to allow committee members and staff to discuss matters relating to "work grievances, whistleblowing, bullying and harassment, staff safety, and anything that doesn't feel quite right at the BMA"
- Introducing additional warning procedures over use of listservers
- Updating committee standardised standing orders to include a limit to the number of committees that a person can be elected to from within a committee—this will be in place from June 2022

Omicron infection is a poor booster to covid immunity, study finds

People infected with the omicron variant show poor immunity boosting against future SARS-CoV-2 infection, researchers have found.

This may explain why breakthrough and repeat infections have been a common feature of the omicron wave, even among triple vaccinated people, said the research team.

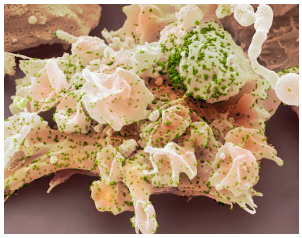
Omicron is "an especially stealthy immune evader," said Danny Altmann, study coauthor from Imperial College London. "Not only can it break through vaccine defences, it looks to leave very few of the hallmarks we'd expect on the immune system," he said. "It flies under the radar, so the immune system is unable to remember it."

Blood samples were examined from 731 UK healthcare workers who received three doses of mRNA vaccine and had different SARS-CoV-2 infection histories, to investigate antibody, T cell, and B cell immunity against omicron.

The study, published in *Science*, found that people with no prior infection who then had omicron showed enhanced cross reactive immunity to previous variants—with enhanced B and T cell immunity against the alpha, beta, gamma, and delta variants—but they showed reduced boosting against the omicron itself.

Participants previously infected with the alpha variant showed a less sustained antibody response against omicron. People infected during the pandemic's first wave and then again with omicron lacked any immune boosting, the study found.

The lead author, Rosemary Boyton of Imperial College's Department of Infectious Disease, said, "A concern is that omicron could potentially mutate further into a more pathogenic strain or become better able to overcome vaccine protection. In this scenario, people who have had omicron infection would be poorly boosted against future infection."



The authors emphasised that vaccination remains effective against severe disease but warned that the effect of many reinfections on long term health, including long covid, is not known.

Jacqui Wise, Kent

Cite this as: *BMJ* 2022;377:o1474

NEWS ANALYSIS

How will UK clinical research be affected by the forced closure of "unviable" trials?

The government's move to shut down studies that have little chance of being completed has prompted a mixed reaction. **Shaun Griffin** reports

ADRIAN WROTH

The reduction in studies able to recruit effectively and close on time during the pandemic has prompted a "research reset" programme

The Department of Health and Social Care for England recently wrote to research sponsors and funders urging them to shut down "unviable" research to help tackle the NHS backlog and workforce pressures resulting from the covid pandemic. It advised them to "review their portfolios of research in the NHS and take firm action on studies that are struggling to deliver" because they weren't meeting participant recruitment targets, they lacked staff capacity, or the scientific question was no longer pertinent.

The letter stated, "We have asked the National Institute for Health and Care Research Clinical Research Network (NIHR CRN) to identify studies that are behind their targets and potentially 'at risk' of closure," warning that if substantial improvements could not be achieved it would "seek to move to nationally mandated action."

The substantial reduction in the number of studies able to recruit effectively and close on time during the pandemic has prompted what the health department has dubbed its "Research Reset" programme.

In a statement a spokesperson for the department said that clinical research had been "vital in our fight against covid and is essential in saving thousands of lives." They added, "To ensure the NHS research system continues to recover from the pandemic, we have asked sponsors and funders to conduct a review of their research—focusing on studies that are most viable, which will give as many as possible the chance of succeeding."

Although some people have welcomed the move to reduce waste and focus on limited capacity where it can add greatest value, there are caveats concerning how the viability of trials is to be determined.

Role of NHS trusts

Concerns have also been raised that the implementation of the policy by NHS trusts is already detracting from their role in approving important new clinical research.

Nikola Sprigg, professor at the University of Nottingham Stroke Trials Unit, was concerned about the policy's unintended consequences. Sprigg said, "The NIHR CRN do a fantastic job and are the envy of our international collaborators, but the very scale of this initiative is potentially impeding the type of practice changing research that it is meant to facilitate. Research and innovation teams at many of the 100 UK hospitals due to participate in a trial we lead have told us they do not have capacity to do so at present, while this review is being undertaken."

Sprigg's study, called TICH-3, aims to determine whether a commonly used drug can be used to treat haemorrhagic stroke in emergency departments. Sprigg added, "My fear is that the research reset programme could lead to a focus by R&I [research and innovation] teams on studies recruiting large numbers of participants quickly—to questionnaire studies, for example. As a result, more complex studies like TICH-3 that may only recruit one or two patients per month in emergency situations may be judged as not feasible.

"Our study took three years to get funding and is poised to answer a hugely important question. I'm concerned that more complex trials like this risk being shut down because R&I departments don't have capacity to review in a timely way, and hospital doctors don't have time to deliver the studies, meaning potentially lifesaving treatments don't get tested properly."

NIHR said it was working with funders and sponsors to target studies failing to meet "certain criteria" for review and action that could include closure, in line with Health Research Authority guidance, or provision of more up-to-date data.

Christopher McDermott, professor of translational neurology at Sheffield University, said, "There are currently huge issues with delivering trials, and the ambition is to ensure that UK trial capacity is being used effectively.

"The success of the plan will be determined by the information used to determine trial viability, but it is essential that this information is contextualised alongside the importance of the research question, the investment to date, the potential impact of the findings, and the nature of the study population."

In addition to reviewing feasibility of current studies, Sprigg suggested that streamlining the process of approval and setup of studies—as has been done with covid trials during the pandemic—could also help the UK test potential new treatments more quickly.

Nick Meade, policy director at the

MORE COMPLEX studies like **TICH-3** that may only recruit one or two patients per month in emergency situations may be judged as not feasible Nikola Sprigg

Genetics Alliance, said, "At face value, this move to stop non-viable clinical trials is a positive one. However, a lot rests on how viability is determined and that the chosen definition takes into account the realities of the indicated condition and the clinical environment.

"We are reassured by the NIHR's explanation, which indicates they are taking into account the special challenges that come with research into rare conditions, and we hope that rare diseases are not disproportionately affected by closures of trials.

"We also hope that participants in any clinical trial that is stopped as part of this programme are treated fairly and ethically, and measures are taken to ensure they have access to the treatments they need."

Difficult time

A spokesperson for UK Research and Innovation said, "We understand that the pandemic has been a difficult time for researchers conducting clinical studies, especially those not studying covid-19, with many studies that were started before the pandemic forced to suspend recruitment in healthcare settings for the duration.

"Following the unprecedented disruption caused by the pandemic, we support DHSC, NIHR, and the NHS's efforts to evaluate where studies are no longer viable and to enable the clinical research system to more rapidly recover. We are working closely with DHSC to ensure that the best research continues to be supported for the benefit of the health of the UK population."

The Health Research Authority, the body that authorises and monitors studies, has issued guidance to the researchers on the NIHR initiative. With the policy still in its infancy, the HRA said that it was yet to see an increase in trial terminations.

Shaun Griffin, London

Cite this as: *BMJ* 2022;377:o1497

There are currently huge issues with delivering trials, and the ambition is to ensure that capacity is being used effectively
Christopher McDermott

BBC probe prompts review of GP service provider's use of less qualified staff

The Care Quality Commission is reviewing material revealed by an undercover BBC investigation that claimed the UK's largest provider of NHS GP services was using less qualified medical staff to see patients without ensuring they were adequately supervised by GPs.

Operose Health, which is owned by the giant US healthcare company Centene, serves almost 600 000 patients across 70 surgeries in England.

"Cheaper" than GPs

The makers of the BBC *Panorama* programme said they had uncovered evidence that less qualified staff were preferred on grounds of cost. The manager at one of Operose's practices in London told an undercover reporter that they hired physician associates because they were "cheaper" than GPs.

Panorama's analysis of NHS data also showed that Operose employs six times as many physician associates as the NHS average and operates with half the number of GPs, at 0.6 full time equivalent GPs for every 2000 patients, which compares with an average across England and Wales of 1.2.

In a statement, Rosie Benneyworth, the CQC's chief inspector of primary care, said, "Delivering safe, high quality care means ensuring that each of these roles has the right training, and is working within their competency, and that there are systems in place that deliver proper supervision. "We take all concerns raised with CQC seriously. We are reviewing the material shared with us and will be following up as appropriate."

Operose told *Panorama* that it was not over-reliant on physician associates at the practice. However, one physician associate there told the undercover reporter, "You get used like a GP," adding that they were "getting used to it." When asked about contact with GPs, another said, "Sometimes I hardly ever see a GP. When I first started it was more, now I hardly speak to them."

"WE ARE REVIEWING THE MATERIAL AND WILL BE FOLLOWING UP" CQC

Sam Everington, a senior practising GP working at an unconnected practice, told *Panorama* he was concerned for the safety of patients and was worried that physician associates were saying they were not receiving the supervision they needed.

A member of the practice's administration team told Jacqui Wakefield, the *Panorama* reporter, that they believed there to be a backlog of thousands of medical reports, test results, and hospital letters on a system used by about 30 Operose general practices, while another said that "it's frequent you see ones that are five to six months old."

Everington told *Panorama*, "If a letter destined for the GP is not being acted on for six months, that is a massive risk to patients, both in terms of the development of a more serious disease and them dying earlier. The government needs to send in CQC and do an in-depth investigation on this practice. They are putting profits, money, ahead of quality of care. And that will have an impact," he added.

In a statement to *Panorama*, Operose Health said a clinical lead GP was on site at the London practice most of the time to help answer questions from physician associates and denied being over-reliant on them. It also said it always operated in patients' best interests.

Operose added that its document workflow helped to ensure that clinicians received accurate and well coded documentation in a timely manner and that the process was audited monthly for quality and safety. It denied that profit was being put ahead of patient care.

In response to a request for a statement from *The BMJ*, an Operose Health spokesperson said, "It is deeply disappointing that the BBC decided to deliberately mislead and secretly record our GP practice staff, including junior members of the team, to cover a story they report on almost every day—a national shortage of GPs.

"The CQC currently rates 97% of our practices as good or outstanding. We are recruiting a new GP at the rate of one every nine days and are investing over £1m this year in sector leading GP salaries to help recruit and retain GPs in a very competitive market."

Shaun Griffin, London

Cite this as: *BMJ* 2022;377:o1488

THE BIG PICTURE

Dressed to impress … and raise awareness

In the absence of the Queen, this year's Royal Ascot risked being less fashionable and glamorous than in previous years. But the arrival of hundreds of saree wearing doctors and other professionals turned the premier horse racing event into an even more colourful spectacle.

The women, many of whom work in the NHS and are members of a group called Doctors in Sarees, not only wanted to showcase their culture at one of the fashion highlights of the season but also hoped, as one of the group tweeted, that it would be "a little nudge towards fostering belonging."

Dipti Jain, a doctor based in Sussex, who helped organise the event, told news agencies, "We are saree loving girls, and the idea came up after setting up a charity to help artisans and weavers, especially after the pandemic in India."

Alison Shepherd, *The BMJ* Cite this as: *BMJ* 2022;377:o1512

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EDITORIAL

Long term implications of covid-19 in pregnancy

We must characterise the risks and take urgent steps to reduce harm

Complications in pregnancy, including maternal and perinatal deaths, increased with each wave of the covid-19 pandemic. But 40% of women giving birth have still not received a first dose of vaccine[2] despite a positive benefit-risk profile, endorsement in guidelines, and public health campaigns.

Meanwhile the JCVI has chosen not to include pregnant women in its interim autumn booster plans.[3] Strategies for treating covid-19 in pregnancy and potential long term complications are also underused.[1] A large portion of the diffidence for both vaccination and treatment in pregnancy stems from the continued exclusion of pregnant women from much of the pre-approval drug development process. This results in delayed or even absent data on benefit-risk profiles and a dangerous spiral of indecision.[4]

The public health implications for postpartum women are unclear, but some key considerations are increased cardiovascular risk, including in future pregnancies; the impact of long covid; and the effect of ethnic and socioeconomic inequalities that widened during the pandemic.[4] Covid-19 during pregnancy substantially increases the risk of pre-eclampsia,[5] which could increase cardiovascular disease later in life.[6]

The UK is ideally placed to define these risks more precisely, taking a life course approach and using NHS data in either anonymised or consented cohorts. Observational studies to understand covid-19's long term effect in babies have begun, but a deeper understanding of the biological mechanisms at play and effects on whole populations are needed.[8]

Global preparedness frameworks continue to overlook risks to pregnant women and babies during epidemics. Beyond covid-19, this neglect had tragic consequences for women affected by the Zika and Ebola outbreaks. Intrauterine exposures to maternal covid-19 could reach 20 million a year globally, according to recent estimates.[9] This, coupled with lessons from previous antenatal viral infections, means the possibility of long term neurological or neurodevelopmental harms from covid-19 warrant close attention.

Complications in pregnancy, including maternal and perinatal deaths, increased with each wave of the pandemic

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A recent case-control study reports that maternal SARS-CoV-2 infection is associated with an increased incidence of neurodevelopmental disorders in babies, particularly disorders of motor function or speech and language in the first 12 months after delivery, even after the higher risk of preterm delivery associated with covid-19 is taken into account.[10] Babies born to women vaccinated during pregnancy, particularly during the third trimester, benefit from transplacental transfer of maternal antibodies and are 61% less likely to be admitted to hospital with covid in the first six months.[11]

Keeping ahead of covid-19

The UK's Recovery trial enrolled pregnant women receiving hospital treatment, providing critical data to inform guidelines.[14] To keep pace with the emerging variants, Recovery now needs to move beyond repurposed drugs and evaluate newer monoclonal antibody treatments. Monoclonal antibodies are strong therapeutic candidates in pregnancy because of their high efficacy, minimal off-target activity, and limited placental transfer.[4] The summary of product characteristics for the recently approved prophylactic Evusheld (tixagevimab and cilgavimab) cautiously allows use in pregnancy and is a welcome addition to protective options for pregnant women.

Using the extensive post-marketing pharmacovigilance data already available in pregnancy to update information on labels and in summaries of product characteristics of currently used drugs, including covid-19 vaccines and treatments, could be a swift and powerful step towards improved prescribing in pregnancy. Updating the globally endorsed International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines[19] to ensure safe, effective, and high quality medicines are developed and that the process appropriately includes pregnant and breastfeeding women would fundamentally transform this area.

Covid-19 in pregnancy increases the risk of severe complications for both mother and baby. The long term implications are unknown, but emerging signals warn of substantial public health threats. To counter high vaccine hesitancy in pregnancy we must end the default exclusion of pregnant women from the rigorous regulated drug development process and implement systematic, long term, population-wide surveillance of infected and non-infected people.

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EDITORIAL

Initial antimicrobial treatment of sepsis

Pragmatic framework from the royal colleges should support, not dictate, clinical decision making

Sepsis is a life threatening organ dysfunction caused by a dysregulated response to infection.[1] Early treatment with appropriate antimicrobials may improve outcome, but antimicrobial overuse can cause harm and contribute to antimicrobial resistance.[2 3] The multiple guidelines, statements, recommendations, and standards around the choice and timing of antimicrobials are often contradictory and open to challenge.[4-6] Consequently, the UK Academy of Medical Royal Colleges convened a working group led by the Faculty of Intensive Care Medicine to issue recommendations on the initial antimicrobial management of patients with sepsis.[7]

The resulting statement focuses on the challenge of identifying patients most likely to benefit from early antimicrobial treatment. Early treatment makes sense if patients risk dying from a dysregulated response to infection, but as the report highlights, pre-existing conditions often have a role in sepsis related deaths.

The statement includes a lengthy and helpful narrative review of the literature and highlights the challenges of an overwhelmingly observational evidence base. There is welcome recognition of the importance of comorbidities, frailty, and patient preference in determining treatment decisions, including treatment intensity limits and end-of-life care—something often missing in previous guidance.

The key elements of the statement are two clinical decision support frameworks to guide management based on likelihood of infection and illness severity, using NEWS2 (national early warning score, version 2) for adults and the paediatric early warning system for children.[9 10] These are pragmatic choices based on current use in healthcare and lack of evidence that any of the alternatives are superior, rather than strong evidence for the scores. NEWS2 predicts risk of adverse outcome with reasonable accuracy but may not predict benefit from early antimicrobial treatment.[11] Patients often have a raised baseline score, so clinicians need to use their judgment to determine the extent to which abnormal early warning scores reflect serious infection or pre-existing conditions.[12] The statement appropriately advises that early warning scores should support and not replace clinical judgment.

MARK THOMAS

Implementation of arbitrary time targets risks unintended consequences such as misdiagnosis

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Assessing risk

Each framework recommends actions for different risk groups within one, three, and six hours, based on the reviewed evidence. Only patients with the highest severity scores require antimicrobial treatment within one hour. Longer timescales should facilitate more targeted use of antimicrobials, but only if diagnostic tests are completed in a timely manner. Assessment of patients with suspected sepsis is challenging, and many are ultimately found to have a non-infectious condition.[14] The formerly mandated four hour benchmark for treating pneumonia in the US shows how implementation of arbitrary time targets risks unintended consequences such as misdiagnosis and inappropriate antimicrobial use.[15]

It is not clear how the proposed framework aligns with the current emergency care pathway, which typically involves triage before definitive clinical assessment, or how it is deliverable in an emergency care system with prolonged waiting times. Emergency departments can achieve the one and three hour targets only if people with suspected sepsis are prioritised, which may mean that other patients with time critical conditions wait longer.

The statement ends by inviting national and local organisations to consider introducing and auditing the sepsis clinical decision frameworks but does not say how they should do this. Any discrepancies between clinical decisions and framework recommendations could simply reflect the appropriate use of clinical judgment. Audit requires a robust clinical standard, yet the narrative review reveals the uncertainty and weakness of the evidence. We should be cautious about inferring that discrepancies between practice and recommendations reflect poor care.

Overall, the statement represents a pragmatic approach that reflects the complexity of clinical decisions and limitations of the evidence base. Clinical judgment is essential when applying uncertain evidence to complex patients. The best approach might be to use the frameworks to direct senior clinicians to the most urgent patients and then let them (rather than the framework) make treatment decisions. Ultimately, organising and resourcing the emergency care system to deliver timely clinical expertise is the key to improving sepsis care.

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HOW TO READ THIS DIAGRAM

Each bubble represents a day. The area of the bubble represents the number of people in hospital with covid-19 that day, relative to the size of the country:

People in hospital, per 100 000 population: 15, 30, 45, 60

Measure introduced | Measure ends | Similar measures

DATA BRIEFING

How the covid-19 pandemic has differed across the UK's four nations

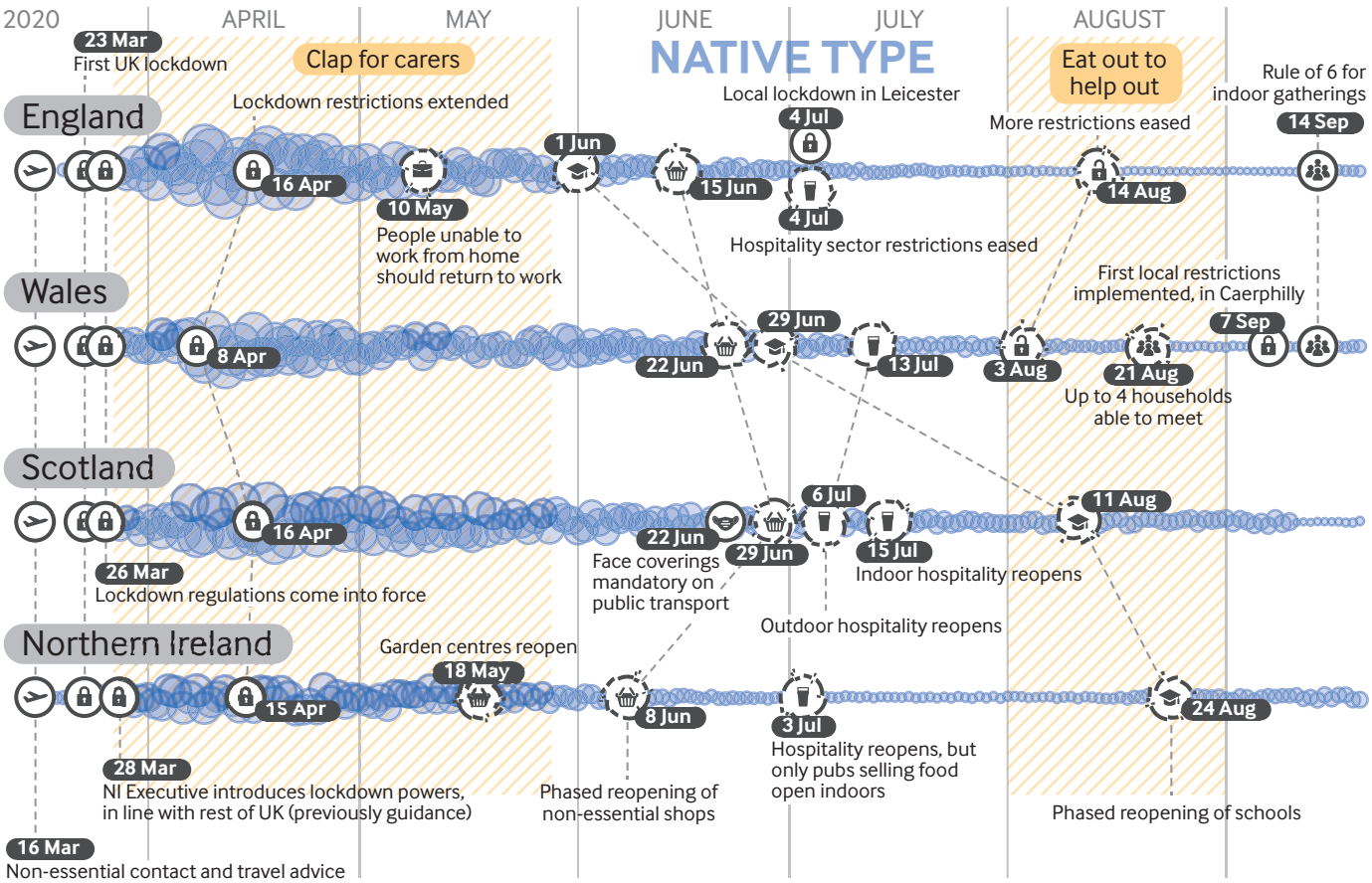
And what can it tell us about the relative effectiveness of the varying measures and guidance they put in place? The Nuffield Trust's **Sarah Scobie** analyses the data

We examined trends over the first two years of the pandemic in terms of the proportion of the population with covid-19 (from the Office for National Statistics' infection survey), people in hospital with covid per head of population (on diagram), and the number of deaths registered with covid-19 mentioned on the death certificate per head of population (see box for sources and www.bmj.com for an interactive version of the diagram including cases and deaths).

Similarities

In broad terms, the shape of the pandemic in each country has been similar. Big shifts seem to have been driven by the course of

Visit www.bmj.com for an interactive version of this diagram that allows exploration of cases and deaths as well as hospitalisations



the virus, such as the arrival of the alpha variant and the exceptionally transmissible omicron variant, and the introduction of vaccines and treatments, which have reduced the risk of severe disease and increased survival even when this occurs.

The extent to which high case rates translate into hospital admissions and deaths also depends on demographic and social factors. Case rates have varied between occupational, age, ethnic, and socioeconomic groups. These factors vary across the UK. For example, Northern Ireland has a younger population and Wales an older population than England and Scotland. England's rates of cases, admissions, and deaths have been higher in ethnic minority groups, reflected in the greater impact of covid-19 in London, the north west, and the Midlands relative to other parts of England.

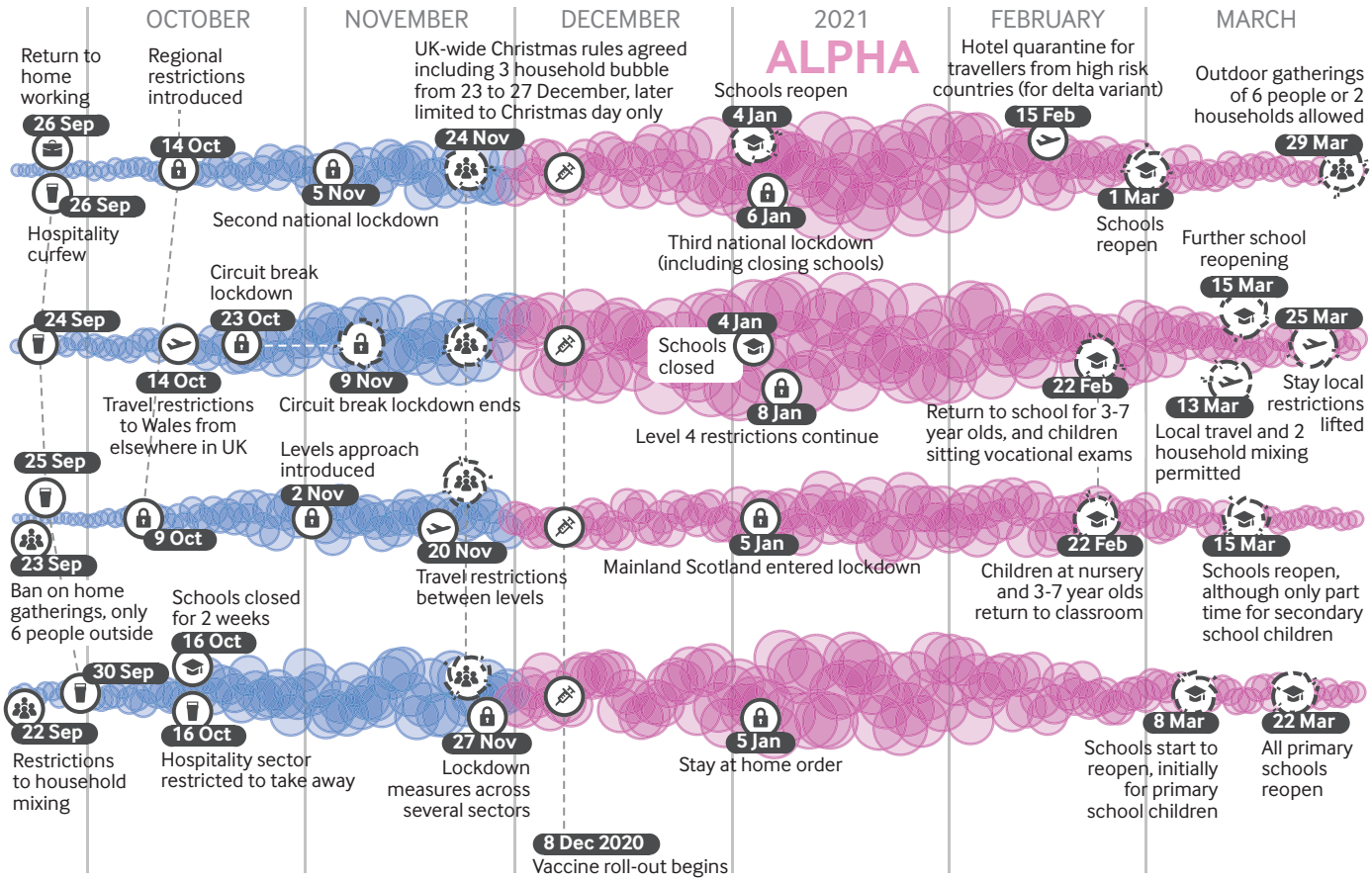
The extent to which high case rates translate into admissions and deaths depends on demographic and social factors

LYNSEY ADDARIO/GETTY IMAGES

Divergences

Although the overall course of the pandemic has been similar across the UK, there have been instances when the countries' trajectory has diverged.

In the first wave Northern Ireland had far fewer deaths and hospital admissions. Lockdown restrictions were similar across the UK at this time. One possible explanation for the divergence is that lockdown began at a slightly earlier stage in the pandemic in Northern Ireland, reducing the size of the peak there. In the second wave Scotland had relatively fewer cases, hospital admissions, and deaths than England and Wales. Scotland also had the most consistent set of restrictions in place between September and December 2020, which may have helped to delay the spread of the alpha variant (which was dominant in England by the



LIAM MCBURNEY/PA/ALAMY

beginning of December but not in Scotland until January 2021).

Northern Ireland had a slightly later peak in this wave, which may have contributed to lower mortality, as a result of the vaccination programme reducing severe disease. The younger population may also have been a factor in its lower cumulative mortality.

From the middle of 2021 to February 2022 Northern Ireland had consistently higher rates of hospital admission than elsewhere, although case rates and mortality have been broadly similar. This suggests that hospital care for patients with covid may have been organised differently in Northern Ireland, resulting in a higher admission rate. Another possibility is that hospital acquired covid-19, which has been a significant concern, may be a particular problem in its hospitals.

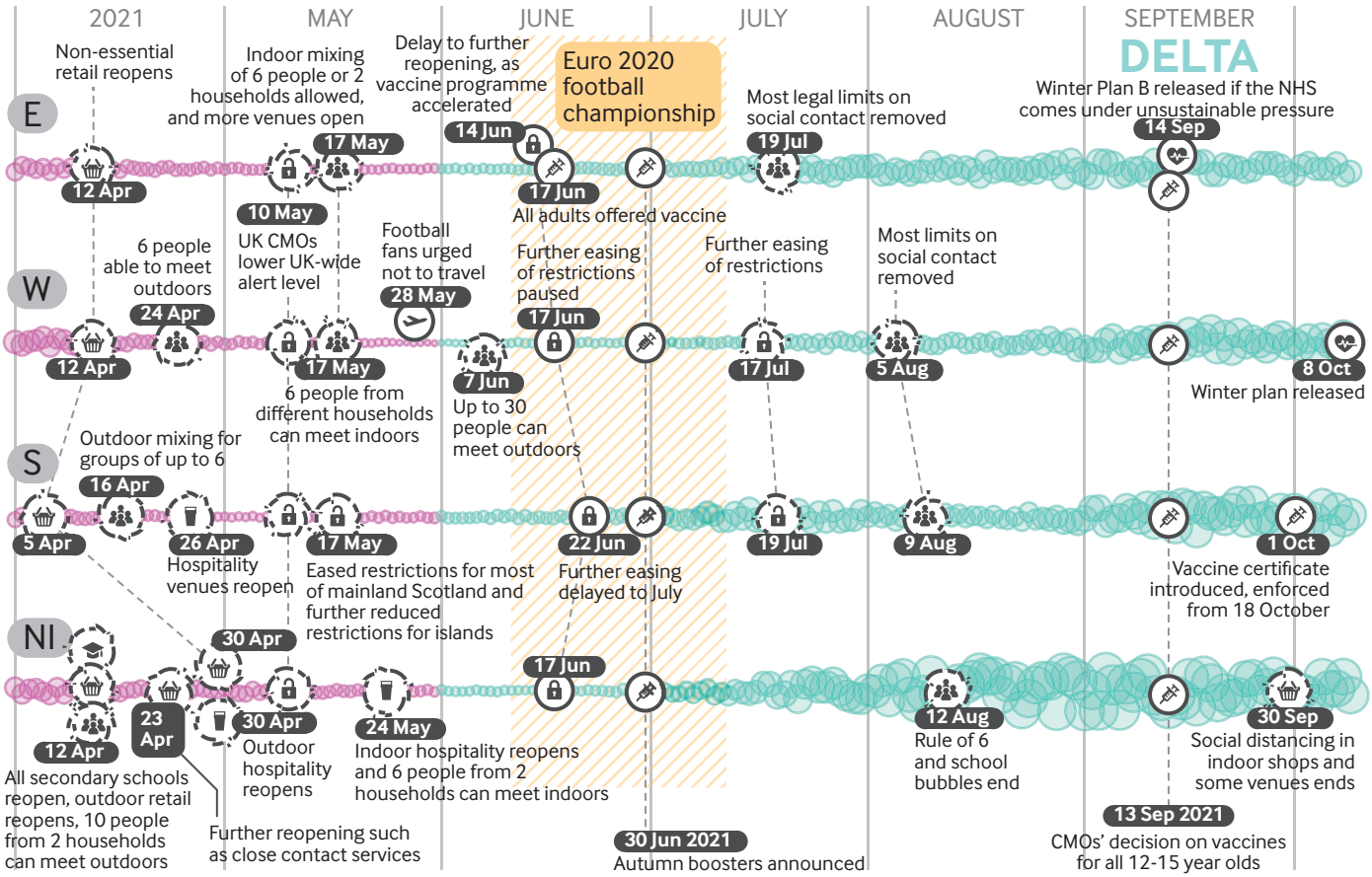
In February and March 2022 Scotland had the highest case rates and a rapid increase in hospital admissions, despite retaining restrictions longest in response to omicron.

Impact of policy differences

It is hard to pick out the direct effects on outcomes of the differences in restrictions and guidance in place in each country.

Although legal requirements may have differed, each country has shared the same evidence base and scientific advice. For example, the Scientific Advisory Group for Emergencies and the Joint Committee on Vaccination and Immunisation provide advice to all UK countries. Many aspects of the response have also been UK-wide, including the vaccine programme, approach to foreign travel, and most aspects of economic support.

Furthermore, although health is a devolved function, close collaboration between the four chief



medical officers, combined with consistent scientific evidence, resulted in similar public health messaging across the UK. So, although England did not introduce new restrictions in December 2021, warnings from its chief medical officer, Chris Whitty, affected people's behaviour nonetheless.

From the current evidence it is difficult to say whether one UK country's policies worked much better or much worse than the others over the first two years of the pandemic. For example, while tighter restrictions in the second wave in Scotland coincided with reduced circulation and severe disease, the reverse has been the case in more recent months, despite recent stronger guidance applied there. This could reflect the scale and enforcement needed for interventions to make a difference—or the tendency for behaviour to be consistent across the UK, even without legal requirements.

Looking ahead

There is no room for complacency in the UK's response to covid-19.

Further variants have the potential to reduce the protection from vaccines and previous infection. And evidence is increasing of the disease's long term effects on health. The milder disease seen in recent months is still leading to persistent health problems.

The pandemic is still very much ongoing. Understanding the reasons for inequalities between different population groups in their experience during the pandemic remains an urgent challenge, so we can reduce inequalities in the future. Alongside inequalities between ethnic groups and according to levels of deprivation, international data indicate that the UK has unusually high excess mortality in younger age groups.

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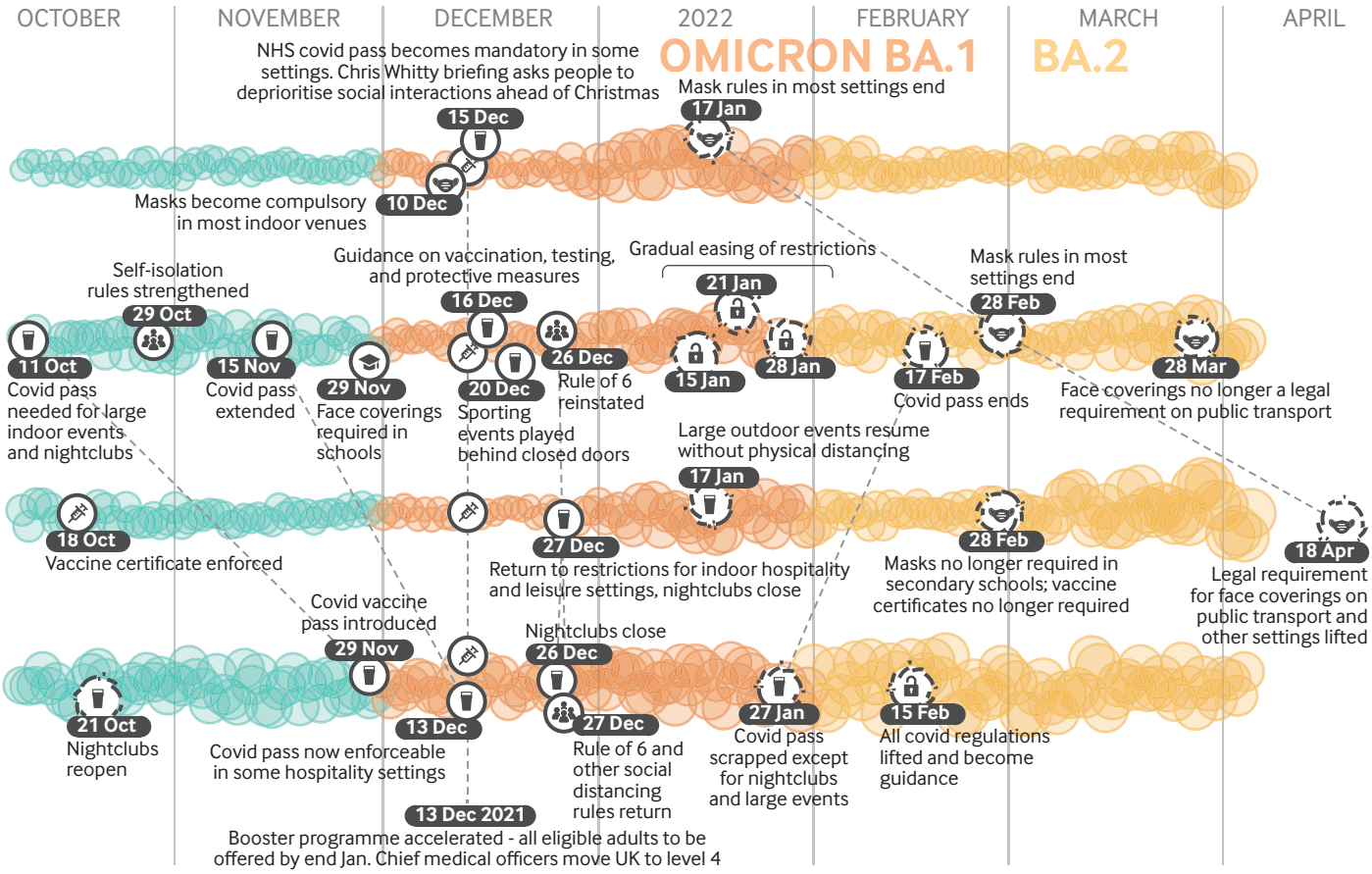
It is difficult to say whether one UK country's policies worked much better or much worse than the others

Data notes and sources

- Information about cases during the first wave is incomplete, because only limited testing was available, and surveillance studies such as the ONS covid-19 infection survey had not started. Case rates from the ONS infection survey are the most robust measure of infections across the four nations, because it is based on random surveys and is not affected by variation in testing programmes or by access to tests, which had an impact on daily reported cases. Source: Office for National Statistics covid-19 infection survey.
- Number of people in hospital with covid-19 has been used, rather than admissions, because the definition for admissions in Wales includes suspected cases and is therefore less comparable. Sources: UK covid dashboard, ONS mid-year population estimates 2020.
- Covid-19 death registrations are those in which it is mentioned anywhere on the death certificate, including in combination with other health conditions. Sources: UK covid dashboard, ONS mid-year population estimates 2020.



CLIMATE CRISIS

Indian construction starts to tackle extreme heat

SOPA/ALAMY

South Asia is suffering some of its worst heatwaves in a century. The public health implications are exacerbated by an infrastructure that is not designed to cope. **Kamala Thiagarajan** reports

For years, Revathi Pechi, 43, worked for 10 hours every day in a windowless two room shed with an asbestos roof. She, along with other men and women in the same room, suffered from nausea, dizziness, and a constant dull headache. It would intensify in the summer months, she explained.

"The ventilation was so poor that I felt suffocated," she says. "And I experienced an overwhelming tiredness."

India has recorded its hottest temperatures in 120 years since March 2022, as the country grappled with a series of intense and prolonged heat waves. On 28 March, temperatures in New Delhi topped 43°C, sparking fires in the city's landfills and exposing the slum residents of Ghazipur in particular to acrid smoke. Over central India during April, the average maximum temperature during the day was 38.04°C, the highest it's ever been since 1901. According to reports, more than 7000 people with heat rash (miliaria) were treated in the city of Nagpur, Maharashtra, at the heat wave's peak.

Yet there's one aspect that's often overlooked and which affects lower income communities the most: construction, housing, and roofing materials. "Either at work or at home, people spend much of their lives under shelter," says Thekkumkara Surendran Anish, associate professor of community medicine at the Government Medical College in Thiruvananthapuram, Kerala. "Depending on the construction material used and the exposure, in times of heat stress, it can have significant health impacts."

Ketki Gadre is an independent consultant for Mahila Housing SEWA Trust, a women led non-governmental organisation exploring climate related stress on housing in low income neighbourhoods. Gadre is involved in a survey on heat stress affecting women doing "home based work," running small cottage industries, across the country. In early May, she visited 20 homes in Ahmedabad and 15 in Vadodora, both in Gujarat.

In many of the homes surveyed, the interior temperature can go up to 52°C, she says. Most are poorly ventilated, with a single door, no windows, and a roof made of asbestos or tin. Overcrowding is a problem too, with a three bedroom home housing up to 20 people.

In addition to the loss of productivity and rising electricity costs during a heat wave, there are hidden health consequences too. "The women workers surveyed say they frequently suffer from nausea, higher blood pressure, lethargy and in some cases, have even collapsed from the heat and had to be taken to emergency rooms," Gadre says.

Invisible illnesses

And like Pechi, many have not received medical treatment, adding to the invisibility of heat related illnesses and their potential link to hazardous construction. According to the World Health Organization, globally 125 million people are directly exposed to asbestos in their workplace every year, and one million workers are estimated to die from asbestos related disease.

It's not as if India is unaware of the health dangers: since 2009, Indian Railways has been phasing out asbestos and replacing it with metal roofs in 8000 stations across India. However, cooling solutions for school, and homes have not been adequately dealt with.

The effects of rising heat will be felt most by the most vulnerable. At 33-34°C, a worker operating at moderate work intensity loses 50% of their work capacity, according a report from the International Labour Organisation. The most vulnerable to heat stress are migrant workers in the agriculture and construction sectors, and workers in cottage industries. Projections based on a global temperature rise of 1.5°C by the end of the 21st century, and on workforce trends, suggest that by 2030, productivity loss from heat stress is expected to affect 80 million people worldwide, 34 million in India, the report says.

Building awareness in a country that is used to enduring heat is critical

Hospital measures

In 2010, hospitals weren't ready to treat heat sickness, says Dileep Mavalankar, director of the Indian Institute of Public Health in Gandhinagar, Gujarat, but now strategies used in Ahmedabad are expected to be adapted by state governments nationwide. One of these is creating cooling wards.

In 2011, a study on air conditioning found that with growing energy costs, only an estimated 8% of households in India have access to air conditioning. Physically cooling a person when body temperatures exceed 40°C is important, says Mavalankar. "Ambulances during heat waves should be equipped with ice-packs," he says. "Cooling wards should comprise air-conditioned rooms, access to ice-packs, staff trained to identify heat rashes, cramps, and the difference between heat exhaustion and heat stroke," he says. Access to drinking water in workplaces, especially if they're outdoors, and places that hire daily wage labourers is another important consideration, says Anish.

In the long term, solutions such as cool roofing technologies are expected to make a difference. Non-governmental organisations like the Mahila Housing Trust are providing microloans for solar reflective paint used on roofs across six Indian states.

Building awareness in a country that is used to enduring heat is critical, experts believe. "Reducing exposure is best, because even with treatment, mortality is high. People should know in the years to come that heat can kill," says Mavalankar.

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