

this week

CHILD PROTECTION page 340 • COVID REBOUND page 341 • GMC UNDER FIRE page 342



Recorded violent incidents at GP clinics double in five years

EXCLUSIVE The number of violent incidents at general practices recorded by the police has almost doubled in the past five years, a *BMJ* investigation has found.

Crime figures obtained from police forces around the UK show that violent incidents at GP surgeries and health centres have increased every year since 2017. Worryingly, the figures also show a near doubling of assaults that cause physical harm.

The rise in violent incidents and abuse aimed at GPs and their staff is causing some to leave their jobs, GPs have warned. “We have to try to address this because it leads to burnout of our staff, demoralisation, and staff leaving the service altogether,” said Richard Vautrey, a GP in Leeds and former chair of the BMA’s General Practitioners Committee.

GP leaders said the “appalling” figures showed how assaults, harassment, and other forms of abuse aimed at doctors and staff had worsened during the pandemic, as services came under increased pressure and some sections of the media perpetuated the idea that GP services were “closed.”

A recent survey by the medical defence organisation MDDUS found three quarters

of GPs had faced a rise in verbal abuse or aggression from patients, leading to a big increase in work related stress. The UK conference of local medical committees recently proposed that practices be given greater powers to remove patients immediately from their list if they abused GPs and staff, including verbally.

Richard Van Mellaerts, a GP in Kingston upon Thames and an executive officer for the BMA’s GP Committee, said the figures obtained by *The BMJ* matched the experiences of doctors in primary care clinics, including his own. He said, “I regularly hear abuse directed at reception staff in my practice. We’ve had to call the police several times over the last year.

“I know GPs who have been attacked, their reception area has been damaged, and their consultation room wrecked. It is absolutely appalling. Any single instance of abuse or violence or harassment towards any GP or any NHS staff is one too many, and it should never be tolerated. It is tremendously sad that we’re seeing this.”

The BMJ sent freedom of information requests to the UK’s 45 police forces

(Continued on page 338)

Police records show the number of crimes of violence and harassment in surgeries has soared since 2017

LATEST ONLINE

- Oklahoma governor signs strictest ban on abortion in the US
- University of California to pay out nearly \$700m over gynaecologist accused of sexual abuse
- Treasury must act to avert huge tax bills for GPs, warn medical accountants



(Continued from page 337)

for the number of recorded crimes committed at general practices and how each crime was categorised. By the time of publication 42 forces (93%) had sent responses, 32 of which (71%) were able to provide complete and comparable data for the past five years.

The figures show a near doubling of violent incidents over the past five years. In total the 32 police forces recorded 1068 incidents of violence at health centres and GP surgeries in 2021-22, up from 791 in 2020-21 and from 586 in 2017-18 (below). These figures include all incidents defined in the category of “violence against the person,” which includes all forms of assault and harassment.

Within this number were 182 assaults resulting in injury last year—the highest for five years and almost double the 98 recorded in 2017-18.

Also within this number, recorded incidents of stalking and harassment at GP surgeries have almost tripled, with 223 instances last year, up from 85 in 2017-18. This was largely driven by a surge in malicious communications, which can include sending letters or emails and which rose from 25 in 2017-18 to 92 last year.

As well as a rise in violence, public order offences such as threatening behaviour rose by 24% last year, from 438 in 2020-21 to 541, and were up 40% on five years ago (387).

The most recent NHS staff survey figures show that 14% of staff experienced at least one incident of physical violence from patients, service users, relatives, or other members of



We appreciate patients’ frustrations and upset, but those frustrations need to be channelled into holding governments to account

Richard Van Mellaerts

the public in the past 12 months, while 28% experienced at least one incident of harassment, bullying, or abuse. But the survey covers only trusts and does not give a clear picture of incidents at GP surgeries.

Vautrey said the police figures represented only a fraction of incidents in general practice. “It’s often daily abuse that staff are having to deal with,” he told *The BMJ*. “It can sometimes generate much more significant incidents that are reported to the police. But the figures from the police are just the tip of a much, much bigger iceberg, and many staff have almost accepted that this is part and parcel of that role, which is simply not acceptable in itself.”

Why is it happening?

Van Mellaerts said that, as well as the police and courts taking action against perpetrators of violent crime, to tackle the problem it was important to understand why the increase in abuse and violence was happening.

“Some sections of the media have driven a view that general practice was closed during the pandemic, which is of course the opposite of the truth,” he said. “Unfortunately, that opinion has been adopted by some people, and that’s been a driver for some of the aggression. That’s not been adequately quashed by the government, which could have taken the opportunity to be more supportive of general practice.”

“In addition, the number of remote and telephone consultations has gone up dramatically, and some patients are finding that difficult to comprehend, which can then feed into the narrative of general practice being closed. Plus there are simply fewer GPs doing more and more, so it’s no surprise that some patients are finding it difficult to access the care they need. This never excuses any kind of violence . . . but it is vital that the government grasps hold of

some of these issues and solves them in order to nip this in the bud.”

Vicious circle

As well as being deeply distressing, the rise in violent incidents and abuse will only exacerbate the staff shortages that are contributing to difficulties in accessing care, leaders warned.

Vautrey has recently been working with NHS officials in West Yorkshire on a patient facing campaign called Leaving a Gap, which aims to explain the consequences of abusing GPs and their staff. He said, “The risk is that this constant and repeated abuse leaves people unwilling to do the job, and we’re not then able to recruit people to replace them. That makes the problem worse because we’ve got fewer staff to be able to respond to the needs of patients, and their concerns increase, so this becomes a real vicious circle.”

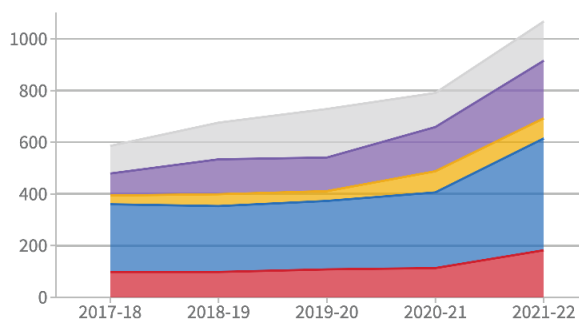
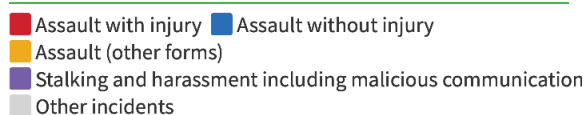
“The intent of the campaign is to highlight these things to patients, to try to encourage them to be much more kind and considerate and understanding of our hard pressed workforce and to understand the consequences of repeated abuse.”

Van Mellaerts said his own practice had lost reception staff because of the way they had been treated. “We had two reception staff who both left within a fortnight because they could not stand how they were spoken to every day on the telephone and face to face by patients,” he said. “These are people who had come to work in general practice and had been genuinely interested in the work, and they found themselves ground down in such a short period of time that they couldn’t tolerate it.”

“We appreciate patients’ frustrations and upset with delays in their care, but those frustrations need to be channelled into holding governments to account—[so] that they invest appropriately in general practice and



NUMBER OF VIOLENT INCIDENTS RECORDED IN UK HEALTH CENTRES AND GP SURGERIES



solve these systemic issues—not taken out on their GPs and practice staff.”

Prosecutions

In 2020 the NHS joined forces with the Metropolitan Police Service and the Crown Prosecution Service to launch Operation Cavell, a pilot scheme that aimed to increase the number of convictions for attacks on healthcare staff by assigning a senior officer to review all reports of assaults and hate crimes against NHS staff. It has now been rolled out more widely.

Data from the Ministry of Justice show that in 2021 there were 17 043 prosecutions on the charge of assault on an emergency worker, of which 13 422 cases were convicted. This compares with 13 392 prosecutions and 10 626 convictions in 2020, and 11 257 prosecutions and 9350 convictions in 2019.

In response to *The BMJ*'s findings a Department of Health and Social Care for England spokesperson said, “Deliberate violence or abuse directed at NHS staff, who continue to work tirelessly to provide care, is unacceptable. All staff, including GPs and their teams, deserve to work in a safe and secure environment.

“The NHS violence reduction programme aims to protect the workforce and ensure offenders are punished quickly and effectively, and the government has taken action to support this—including by passing legislation to double the maximum sentence for assaults on emergency workers. Security measures including CCTV, panic buttons, and screens at reception have also been rolled out across GP surgeries.”

NHS England recently updated its *Primary Medical Care Policy and Guidance Manual* for service commissioners to add a chapter on managing inappropriate and unacceptable patient behaviour. A spokesperson said, “The NHS will not tolerate abuse or violence towards its staff and, despite the despicable actions of a minority, is grateful for the overwhelming sense of national support NHS workers have received over the last two years as they stepped up to fight covid.”

Gareth Iacobucci, *The BMJ*
Cite this as: *BMJ* 2022;377:o1333

“HE SAID WAS GOING TO HURT SOMEBODY”



Alan Stout, a GP in east Belfast and chair of the Northern Ireland General Practitioners Committee

THE INDIVIDUAL THEN APPEARED, KICKED THE LOCKED FRONT DOOR DOWN AND STORMED IN

Alan Stout, a GP in east Belfast and chair of the Northern Ireland General Practitioners Committee, told *The BMJ* how a recent incident of violence at the hands of a patient in March had affected GPs and staff:

“It began with a phone consultation—a patient was looking for additional medication. He got progressively more aggressive throughout the course of the conversation, and it culminated in him saying that he was coming down to the practice there and then and he was going to hurt somebody. So we locked the front door. The staff were in the reception and office area; there was only one doctor on [duty] at the time, and he was in his consulting room.

“The individual then appeared, kicked the locked front door down and stormed in, and then started attacking the door and the window to the reception where the reception staff were. At this point the doctor then had to lock themselves in their room. The police were contacted and subsequently arrived, and he was then arrested.

“We are getting increasing aggression and abuse on phones and then also on occasion in person at the practice as well. It absolutely has an effect on our practice and staff. We now keep the door to reception locked at all times. Also, quite frustratingly, we’ve ended up closing for an hour over lunchtime, predominantly to protect our staff. We had tried very hard to remain open at all times throughout the day, but by doing that we were reducing the number who were there [at lunchtime], and they were in a very exposed position.”

“WE EXPERIENCE TARGETED ABUSE OF INDIVIDUALS ON SOCIAL MEDIA”

IF PATIENTS COULD GET THE HEALTHCARE THEY NEEDED QUICKLY AND EASILY, EVERY TIME, I’VE NO DOUBT THAT ABUSE WOULD DECREASE

Richard Fairclough, a GP partner at Riverside Medical Practice in East Lothian, said his practice frequently experienced various types of abuse:

“This might be our call handlers being verbally abused over the phone or at the front desk, but also, increasingly, targeted abuse of individuals on social media. We recently needed to take the hard decision to remove the names and photos of our staff from our website, because some of them had been targeted by an anonymous Twitter user. We didn’t like doing that, but we need to protect our team.

“Thankfully, we haven’t seen the extreme, horrifying abuse that some staff at some other surgeries have experienced, but nonetheless there has been a very real impact on our team, which does then have a knock-on impact on the care we can give to our other patients. On a day-to-day basis we’ve seen members of our call team being very upset, and we think that abuse by patients—tied with unprecedented demand as we exited the first lockdown—did contribute to us losing a substantial number of team members from our call team back in late 2020.

“There’s a very real mismatch between patient demand and capacity in health services right across the country, and that’s what this is about, ultimately. If patients could get the healthcare they needed quickly and easily, every time, I’ve no doubt that abuse would decrease.”

“I’VE HAD A PERSON THREATEN TO COME DOWN AND STAB ME”



Adam Janjua, a GP in Fleetwood, Lancashire

Adam Janjua, a GP in Fleetwood, Lancashire, said, “In the past 2-3 years we’ve seen a huge rise in incidents. I’ve never seen it like this. The most recent time that we had to call the police was in a row over a person not wearing a mask. They shoved me in the chest. I’m quite a big guy, but if it had been someone else he could have done some real damage.

“I’ve had a person threaten to come down and stab me when I least expect it. We’ve had to update our zero tolerance signs to add ‘intimidation.’ Staff feel very mentally drained each day. We have a lot of abuse over the phone, people saying things like, ‘You don’t actually do anything.’ Most GPs don’t report these types of incidents to the police, as they don’t want to get tied up in red tape and it can take a long time.”

THE MOST RECENT TIME THAT WE HAD TO CALL THE POLICE WAS IN A ROW OVER A PERSON NOT WEARING A MASK. THEY SHOVED ME IN THE CHEST

SEVEN DAYS IN

Review calls for overhaul of child protection services after deaths of two children



An independent review into the deaths of two children has called for a fundamental reform of child protection services with dedicated teams and stronger multi-agency working.

Many relatives of Arthur Labinjo-Hughes, 6, and 16 month old Star Hobson had raised concerns with police and social workers, often in some cases, but their concerns were dismissed without enough investigation, and there was too easy an acceptance of the parents' version of events, said the independent national safeguarding practice review panel.

The report identified serious shortcomings in local practices but added this reflected wider national weaknesses. In a foreword the panel's chair, Annie Hudson, said, "There is too much inconsistency and ambiguity in child protection practice in England." The review calls for a multi-agency child protection unit to be established in every local authority and for a national Child Protection Board to be set up to bring together all relevant central government departments, local government, the police, and education and health representatives.

England's education secretary, Nadhim Zahawi (left), said, "I will be setting out a bold implementation plan later this year to bring about a fundamental shift in how we support better outcomes for our most vulnerable children and families."

Jacqui Wise, Kent [Cite this as: BMJ 2022;377:o1349](#)

Depression

"More research is needed" into nasal spray treatment

NICE said that it was not recommending esketamine (Spravato) nasal spray for treatment resistant depression, as further research was needed. The appraisal committee acknowledged an unmet need among people with treatment resistant depression but said that it was concerned about the manufacturer's economic model and the long term outcomes in people who used the treatment. The final draft guidance, which is subject to appeal, has a deadline of 14 June.

Legal news

GP is jailed for sexually abusing patients

A GP who was found guilty of 54 sex offences against female patients over a three and a half decade period has been jailed for 12 years. Krishna Singh, a GP in North Lanarkshire, was convicted of offences against 47 women and girls, including a victim of rape, teenagers, and pregnant women. He became the senior partner at the Coatbridge Health Centre, with his wife serving as practice manager, and women thought that they would not be heard if they complained, the jury was told.

Access to medicines

Pfizer makes pledge to low income countries

The drug company Pfizer said that it would provide all of its current patent protected medicines and vaccines that are available in the US and EU to 1.2 billion people in lower income countries on a not-for-profit basis. The company announced its "Accord for a



Healthier World" at the World Economic Forum in Davos, Switzerland, but it met criticism for being

"too little too late." Pfizer said that it would provide 23 medicines and vaccines for treating infectious diseases, some cancers, and rare and inflammatory diseases to 45 lower income countries.

Maternity

Ockenden will head up Nottingham review

Donna Ockenden (below), who led an inquiry into maternity care failings at Shropshire and Telford Hospital NHS Trust earlier this year, has been appointed as the chair of a new independent review into maternity services at Nottingham University Hospitals NHS Trust. A review currently under way, commissioned by the local

clinical commissioning group along with NHS England and NHS Improvement, has been criticised by families and campaigners over its remit and independence. Ockenden will lead a new team with new terms of reference.

General practice

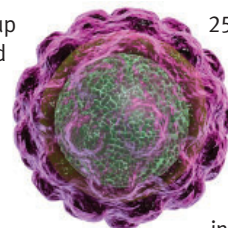
Workforce crisis must be tackled, says BMA

The BMA said that GP workforce and appointment data for England showed that the clock was ticking on tackling the workforce crisis. The number of GPs leaving the profession is in steady but sustained decline: the NHS lost the equivalent of 26 full time, fully qualified GPs from March to April. Although the number of GP appointments dipped slightly, the number of face-to-face consultations increased, and 45% of appointments in April took place on the same day they were booked.

Hepatitis

UK identifies 25 more cases in children

A further 25 confirmed cases of sudden onset hepatitis (above) in children aged 10 and under were identified in the UK as of



25 May, bringing the total to 222. Of the confirmed cases, 158 were resident in England, 31 in Scotland, 17 in Wales, and 16 in Northern Ireland.

The UK Health Security Agency is investigating but said it had found no evidence of any link to the covid vaccine. The majority of cases are in children aged under 5 and too young to have received the vaccine. The investigation still suggests a strong association with adenovirus, said the agency.

Cost of living

Chancellor's intervention is "not enough"

Matthew Taylor, chief executive of the NHS Confederation, said that while the measures contained in the chancellor's cost of living statement would offer some desperately needed help, health leaders were very concerned that these were "yet another sticking plaster that fails to significantly address the extreme challenges faced by people living on the lowest incomes." Taylor also called on the government to urgently consider increasing the pay rates of NHS and other public sector workers to support the staff who needed it most.



MEDICINE

Emergency medicine

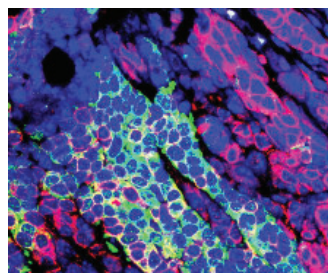
Burnout in healthcare workers is high

Emergency medicine healthcare workers experienced high levels of burnout after two years of the covid pandemic, said a survey carried out by the European Society of Emergency Medicine. The online survey of 1925 emergency medicine doctors, nurses, and paramedics in 89 countries found that 62% had at least one symptom of burnout syndrome, and 31% had two. Females reported a higher proportion of burnout than males, and nurses were more likely than physicians to report burnout. Only 41% of responders reported having access to psychological support.

Immunotherapy

Advanced triple negative breast cancer care allowed

NICE has now ruled that pembrolizumab (Keytruda) plus chemotherapy should be available as a treatment option for a limited group of patients with advanced triple negative breast cancer. Earlier this year NICE had said that



it was not a cost effective use of resources. This will provide another treatment option for people with triple negative breast cancer who cannot have the current standard of care—atezolizumab with chemotherapy.

Hospital IT

Faults disrupt services in Greater Manchester

Northern Care Alliance NHS Trust declared a critical incident at three hospitals—the Royal Oldham Hospital, Fairfield General Hospital



Almost two thirds of European emergency healthcare workers reported burnout symptoms after the pandemic

in Bury, and Rochdale Infirmary—where staff were unable to access clinical information or diagnostic tests online. The IT crashes have caused significant disruption to hospital workflows and have delayed patient services. North Manchester General Hospital, which is run by Manchester University NHS Foundation Trust, has also been affected, as have diagnostic and pharmacy services across all sites and at Salford Royal Hospital.

Menopause

NICE sets out scope of guideline update

The National Institute for Health and Care Excellence has outlined what aspects of menopause care will be updated in upcoming guidance, including areas where more research is needed. Cognitive behavioural therapy to manage menopausal symptoms and interventions to manage genitourinary symptoms associated with menopause will be included in the updated guideline, as will the effects of hormone replacement therapy on overall health outcomes. It has called for further research into whether testosterone helps to manage menopausal symptoms beyond altered sexual function.

Cite this as: *BMJ* 2022;377:o1363

CONFLICT

In 2021, **1335** health workers were attacked or arrested across **49** countries and territories in conflict. In total, **188** healthcare facilities were destroyed or damaged

(*Safeguarding Health in Conflict Coalition*)



SIXTY SECONDS ON... COVID REBOUND



ARE WE DISCUSSING BOUNCING BACK FROM COVID?

Yes and no. Some patients seem to be getting better and even testing negative for SARS-CoV-2 before then experiencing a recurrence of symptoms and retesting positive two to eight days later. The phenomenon has been termed “covid rebound.”

IS THIS PAXLOVID REBOUND?

Yes, although the US Centers for Disease Control and Prevention (CDC) has said that while many of the reports are of people taking a five day course of the antiviral paxlovid—which is used to prevent severe illness in newly infected at-risk patients—rebound has also been seen in those not taking the drug and seems to affect both those who are unvaccinated and vaccinated.

DO PEOPLE GET BETTER AGAIN?

So far there have been no reports of severe illness in those who have experienced rebound, and most people seem to recover and stop testing positive around three days later without needing extra covid treatment.

DID THE PAXLOVID TRIAL CATCH THIS?

The trial did see a small number of participants test positive again shortly after a negative test and some who had a rise in the amount of the virus detected by polymerase chain reaction test after completing their treatment course. Interestingly, however, this rebound effect was seen in the paxlovid and placebo groups. “A brief return of symptoms may be part of the natural history of SARS-CoV-2 infection in some people, independent of treatment with paxlovid and regardless of vaccination status,” the CDC said.

COULD THEY BE REINFECTION CASES?

Based on the current evidence, the CDC said it appears not. It noted, however, that during the rebound period it’s possible that people are infectious. As such, patients have been advised to re-isolate for at least five days if they experience a return of symptoms or test positive again.

THAT CAN’T BE WELCOME NEWS

The instruction to re-isolate certainly has some doctors and patients reconsidering the antiviral, but the guidance has not changed and paxlovid continues to be recommended in the US for early treatment of mild to moderate covid-19 among people at risk.

Elisabeth Mahase, *The BMJ*

Cite this as: *BMJ* 2022;377:o1365

GMC to review Manjula Arora's case after backlash from doctors over her suspension



It is absolutely right that our decisions are open to scrutiny

Charlie Massey

The GMC is to review the Manjula Arora case to see if there are “lessons to be learnt for future cases” after doctors and medical leaders expressed outrage over the decision to suspend the GP.

Arora, who trained in India before moving to the UK in the early 1990s, has been suspended for a month after it was ruled she exaggerated what she had been told by a senior doctor when making a request for a laptop. The hearing concluded that Arora had not set out to be dishonest or to mislead but that her use of the word “promised” when speaking to the IT department amounted to dishonesty.

The case centred around incidents that took place in late 2019 and

2020 while Arora was working for Mastercall, which provided a clinical assessment service for the North West Ambulance Service. It led to a nine day medical practitioners tribunal hearing that ended on 12 May 2022.

The case sparked fury among doctors who argued that the action was “wildly disproportionate” and questioned why this issue had not been resolved locally. Many also said the case showed that the disciplinary process was biased against doctors who trained overseas.

Compared with white doctors, those from ethnic minorities are twice as likely to be referred to the GMC by their employers for fitness to practise concerns. And the referral rate for doctors qualifying outside the UK is three times that for UK doctors.

In response to the backlash, Charlie Massey, chief executive of the GMC, said, “I hear the strong views being expressed about this case, and it is absolutely right that our decisions are open to scrutiny. As a regulator, we are not complacent and always believe

COMPARED with white doctors, those from ethnic minorities are **twice as likely** to be referred to the GMC by their employers for fitness to practise concerns

Javid pledges more research for ME/CFS after relative's diagnosis

Patients with myalgic encephalomyelitis (ME) can expect to see more research and support for the condition, which “has been neglected for far too long,” England’s health and social care secretary has said.

Speaking at the launch of a report by the All Party Parliamentary Group on ME on 25 May, Sajid Javid revealed that a relative had had her life severely affected by ME, and he pledged to tackle the lack of research on the condition. He will co-chair a round table of international experts next month to help set this research strategy.

A lack of understanding about the condition and the absence of a proper diagnosis test meant patients, including his relative, had been let down by the NHS, he said. Within weeks his relative had gone from being an active 12 year old—interested in

sports, captain of her school netball team, and doing well academically—to one who struggled with fatigue and low energy. Doctors were unable to explain her illness or offer any treatment and had diagnosed ME.

“I just felt like the clinicians weren’t doing their job—well, certainly not well enough—because it felt like it was the default option,” said Javid. “When you just can’t really find out what the true cause is, let’s just call it ME/CFS [chronic fatigue syndrome]—

that’s a sort of convenient bucket—and let’s just leave that child in that bucket.”

Although he told patients at the launch he could not “promise miracles,” he pledged a cross government approach, encompassing health, education, work and pensions, and local government.

The all party parliamentary group’s report, Rethinking ME, says the research focus on long covid provides an opportunity to develop a better understanding of

causes and treatments for other conditions that may develop post-virally, including ME.

Collaborative research projects could “finally put an end to the narrative that these conditions are psychological in nature,” it says, adding that long covid studies funded by the National Institute for Health Research should include patients with ME as comparators.

The report also highlights last year’s NICE clinical guideline that “sets the precedent for a medical shift away from a problematic behavioural or psychological understanding of ME and towards a more holistic biomedical or physiological understanding.” Its primary recommendation is “to ensure the new guideline is swiftly implemented in full by relevant health services.”

When you can't find out what the true cause is, let's just call it ME/CFS—a sort of convenient bucket—and let's just leave that child in that bucket

Sajid Javid



Shoes left outside the Department of Health in 2016 as part of the #MillionsMissing protest day demanding more ME/CFS research

MARK KERRISON/ALAMY

Ingrid Torjesen, *The BMJ*
Cite this as: *BMJ* 2022;377:e01341



that there is room to improve the way that we carry out our duties.

“Accordingly, I have asked for a review of this case to understand whether there are lessons to learn and apply to future cases. I know too that it has prompted discussion about our work to eliminate disproportionate referrals and to ensure fairness in our own processes. I am wholeheartedly committed to tackling discrimination in medicine and ensuring that we constantly seek ways to improve our own processes.”

But writing in *The BMJ*,

Chaand Nagpaul, the BMA’s chair of council, said that the GMC’s response did not go far enough, and said “a root-and-branch, independent review with radical reform of the entire pathway” was required. “This entire case demonstrates how the current system is structurally disproportionate, lacks timeliness, with insufficient checks and balances, and is manifestly unjust,” Nagpaul wrote.

Elisabeth Mahase, *The BMJ*
Cite this as: *BMJ* 2022;377:o1350

COMMENT, p 357-9

WHAT HAPPENED AT THE HEARING?

Arora had emailed her medical director (referred to as Dr B) to ask about getting a new laptop for work and had been told that, although no laptops were currently available, “I will note your interest when the next roll out happens.” Arora later told the IT department over the phone that she had been “promised” a laptop by Dr B.

Arora’s Medical Defence Union representative Alan Jenkins argued that “no one could read the telephone call, in its entirety, as an attempt to mislead.” Additionally, it was noted that Arora had told the IT staff that they could speak to Dr B directly about the laptop request.

But Carl Hargan, representative for the GMC—which chose to pursue the case—said that the wording of Dr B’s email was

“NO ONE COULD READ THE TELEPHONE CALL, IN ITS ENTIRETY, AS AN ATTEMPT TO MISLEAD”

“entirely unambiguous” and that Arora’s words in the phone call to IT were “clear.” Hargan argued that Arora had “brought the medical profession into disrepute.”

The tribunal concluded that, although “Arora had not set out to be dishonest, and that she had not set out to mislead [IT] . . . she had exaggerated the position in her use of one inappropriate word.” As such, in the specific use of “promised,” she had been dishonest.

In the same hearing Arora was cleared of a second charge of having referrals from the North West Ambulance Service call centre suspended without authority.

All areas need “single, urgent care teams with same day access”

Proposals for primary care networks to evolve into more collaborative “integrated neighbourhood teams” to improve access to care have been broadly welcomed.

A “stocktake” report commissioned by NHS England, published on 26 May, called for urgent same day appointments to be dealt with by “single, urgent care teams” for every neighbourhood with greater use of a range of health and social care professionals.

Doctors’ leaders welcomed many of the recommendations but emphasised they could only work if the government resourced primary care practices better and tackled workforce shortages.

The report, written by Claire Fuller, a GP and chief executive of Surrey Heartlands Integrated Care System, said that a single system-wide approach to managing integrated urgent care should be developed to guarantee same day care for

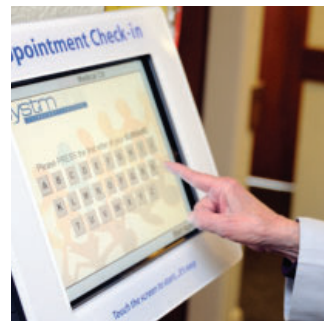
patients and a more sustainable model for practices. This would require a change in national policy towards NHS 111, because currently that could result in duplication of efforts for patients and clinicians.

“This should be for all patients clinically assessed as requiring urgent care, where continuity from the same team is not a priority,” the report said. “Same day access for urgent care would involve care from the most clinically appropriate local service and professional and the most appropriate modality, whether a remote consultation or face to face.”

Ideally, primary care networks, wider primary care providers, secondary care and social care teams, and domiciliary and care staff

These bold suggestions will ultimately be determined by the willingness to properly resource GP practices

Farah Jameel



would work together to share resources and information by forming multidisciplinary teams dedicated to improving health and wellbeing of patients and tackling health inequalities, the report said.

Fuller added, “Inadequate access to urgent care is having a direct impact on GPs’ ability to provide continuity of care to those patients who need it most.”

In addition, the report called for innovative employment models to be developed, such as joint appointments and rotational models that promote collaboration

rather than competition between employers.

Fuller acknowledged the current pressures on primary care, saying, “Teams are stretched beyond capacity, with staff morale at a record low. Left as it is, primary care as we know it will become unsustainable in a relatively short period of time. Addressing the shortfall in GPs is essential and urgent.”

Farah Jameel, chair of the BMA’s GP committee in England, said, “This report presents some bold suggestions . . . but it will ultimately be determined by the government’s willingness to properly resource practices, while addressing recruitment and retention.”

Martin Marshall, chair of the Royal College of General Practitioners, described the report as “appropriately ambitious given the scale of the crisis in general practice.”

Adrian O’Dowd, London
Cite this as: *BMJ* 2022;377:o1342

THE BIG PICTURE

Helping nature ease pain of mental health

Among the 39 gardens that graced the RHS Chelsea Flower Show this year was the Mind Garden (right). Designed by the eight time gold medal winner Andy Sturgeon (below) for the mental health charity, Mind, it is a place created to allow people to connect, share experiences and find comfort together.

At its highest point, a circular seating area creates a sanctuary for conversation. Set within curved, clay rendered walls, it's a place to sit side by side, surrounded by meadow-like spaces and calming birch trees. A gravel path then leads down to a lower level, bringing people together before the garden opens out before them.

After the show the garden is to be transported to Mind in Furness, Cumbria, to enable people to support each other for many years to come.

Alison Shepherd, *The BMJ*

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MARK THOMAS

Investigating the monkeypox outbreak

Here's what we know, and what we need to know

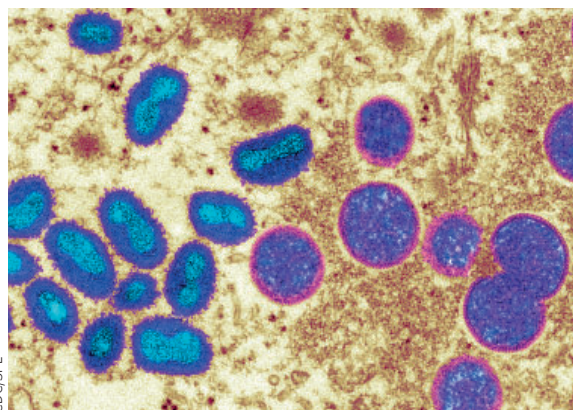
Between 4 and 30 May, 478 confirmed (by reverse transcriptase PCR) and 134 suspected cases of monkeypox have been reported from 35 countries outside Africa including 22 in Europe.¹ New cases are being reported daily; more can be expected and in more locations. Why the extraordinary surge now? What do we need to know to stop it?

Almost all patients so far are male (three are female) and presented with symptoms typical of monkeypox, including fever, vesicular rash, skin lesions and ulcers, and swollen lymph nodes.² The first case in this outbreak was a man who visited Nigeria from the UK.³ He developed a rash on 29 April before leaving Nigeria, arriving back in the UK on 4 May. He was immediately isolated at a London hospital on the same day. His contacts on the flight to the UK, together with others in the community plus healthcare staff, were followed for 21 days, considered the upper limit of the incubation period for monkeypox.⁴ None of these contacts are reported to have developed symptoms.

Another 105 confirmed cases have been reported in the UK (all four nations), in multiple different groups. There is evidently person-to-person transmission within groups but no known links between groups or with the first case in England.

Informed response

At least six lines of investigation will help to develop national and global responses in the coming days and weeks. The first is to find out whether the exceptionally large number of exported infections is linked to the increased frequency of travel to and from endemic areas of Africa now that covid restrictions have been lifted. If it is, published travel schedules between countries will help to specify and then mitigate risk around the world.



CDC/SPFL

Vigilance and open minded investigation are needed worldwide

The second is to investigate whether and how the spread of monkeypox is being driven by a rise in case numbers at source in west and central Africa. The number of monkeypox cases increased in Africa between 1970-79 and 2010-19.^{6,7} This rise has included major outbreaks, the largest of which affected 17 states of Nigeria in 2017-18.^{8,9}

Thirdly, the main routes of transmission need to be re-examined. The 2017-18 Nigerian epidemic was caused by multiple introductions from animals (most likely rodents) to humans, plus limited and perhaps non-sustaining chains of transmission between people.⁸⁻¹¹ Now, however, waning immunity to smallpox and smallpox (vaccinia) vaccine could have magnified the risk of sustained transmission between people, within and beyond Africa.^{12,13} The relative importance of different transmission routes could also have changed. Close contact is normally needed to acquire infection from skin lesions, body fluids, exhaled droplets, or contaminated clothing and bedding. The discovery of cases among gay and bisexual men, notably in Canada, Spain, and the UK, points to sex as one among other forms of close contact, although monkeypox is not primarily a sexually transmitted disease.

Fourthly, we need to reassess what proportion of infections cause severe or fatal disease.

Historically, two different genomic clades of monkeypox virus have been described in west and central Africa.⁷ All cases so far genotyped in Europe during the current outbreak are more closely related to the west African clade and to viruses exported from Nigeria to Israel, Singapore, and the UK in 2018 and 2019.^{14,15} The west African clade has been associated with milder illness and a lower case fatality rate (roughly 4%) than the central African clade (roughly 10%).⁷ If some infections are asymptomatic, as previously described,¹¹ these estimates of case fatality could be too high. Asymptomatic cases might also be missing links in transmission chains. Case fatality, and the risk of severe disease, can be reduced with some antivirals effective against poxviruses, but there is undoubtedly more to be learnt about supportive and therapeutic clinical care.¹⁶

The fifth line of investigation is to determine whether monkeypox could evolve, or has recently evolved, to become more pathogenic or more transmissible, or transmissible in a different way.

Lastly, the effectiveness of vaccination in protecting individuals and populations should be further evaluated. Pre-exposure inoculation with vaccinia vaccine is efficacious (about 85%) against monkeypox disease and probably also reduces onward transmission.¹⁹ Post-exposure inoculation gives less protection, so vaccine effectiveness in practice will depend on what proportion of people at risk can be immunised before rather than after acquiring infection.

On present evidence, monkeypox is unlikely to become a global health emergency. Nevertheless, vigilance and open minded investigation are needed worldwide.

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Clinicians caring for migrants need more support

A harsh immigration environment brings unique challenges

Recent political events, including the conflict in Ukraine, the Taliban takeover in Afghanistan, and the passing of the Nationality and Borders Bill,¹ are set to worsen the effect of the UK's immigration system on asylum seekers and other migrants with irregular immigration status. The bill includes provision for sending asylum seekers to Rwanda to have their claims processed rather than in the UK asylum system. These developments widen the gulf between asylum seekers' needs and what clinicians are allowed to do for them.

The UK remains the only European country with no upper time limit on immigration detention. Professional groups have raised serious concerns about healthcare within immigration detention centres and the mental health consequences of such detention.²⁻⁴ Recently, asylum seekers have been housed in institutional and restrictive "quasi-detention" settings such as former army barracks. An all-party parliamentary group inquiry into quasi-detention in December 2021 reported considerable risks to the mental health and wellbeing of migrants housed in these settings as well as risks to public health because of inadequate prevention and detection of covid-19.⁵ Proposed community alternatives to detention have not been taken up, despite evidence of effectiveness.^{6,7}

As well as "offshore" processing, which has been tried in Australia with disastrous consequences,⁸ the Nationality and Borders Bill proposes the development of accommodation centres (despite the unsuccessful barracks pilot⁹) and a two tier system for asylum seekers based on mode of UK entry and promptness of application rather than need for protection.



SPINKE/JOHNSON/DOITW

Clinicians working in the detention estate may struggle to meet detainees' complex health needs

Effect on clinicians

Austerity policies and the pandemic have further exacerbated pressure on already overburdened healthcare staff, including those providing care to detained people with irregular immigration status. Concerns have been raised about the risks of moral injury, institutionalisation, and vicarious traumatisation for clinicians working in immigration detention and quasi-detention settings.¹⁰

Clinicians working in the detention estate may struggle to meet detainees' complex health needs. Treatment cannot be fully evidence based since there is little published research to underpin health interventions in detention. Bureaucratic barriers obstruct high quality research.¹⁰ Detained people's mistrust of authority can erode the therapeutic relationship,¹⁰ and clinicians may not be supported when raising concerns about patients to custodial staff, creating professional dilemmas.

Working in isolated environments can be detrimental to clinicians' individual professional development and could jeopardise patient safety and quality of care.¹² Furthermore, clinicians in detention settings encounter complex practical and ethical challenges unusual in everyday NHS practice.¹²

Asylum seekers are dispersed all over the UK, often after detention or quasi-detention, so clinicians working outside immigration may

also encounter asylum seekers in their clinical practice. They may feel unsupported in managing the complex needs of this population, especially patients who have experienced detention.

Nationally agreed standards should be developed, co-produced by clinicians and experts by experience, to address the needs of healthcare staff and provide best clinical care for migrants. Trauma informed practice, recognising the broad effect of trauma on mental health and on emotional, psychological, and social wellbeing, is essential.¹⁴ Such practice also approaches care through collaboration and partnership and thereby fosters the development of social networks. Professional medical bodies must support the introduction and monitoring of trauma informed practice in all settings housing migrants.

Despite ongoing time pressures, clinicians working with such patients need regular space for thoughtful discussion about clinical and ethical issues.¹⁵ Professional initiatives such as online clinical networks can also be helpful.

Training in migrants' health needs through trauma informed practice is necessary for all clinicians, not just those working within the immigration estate. Training should include awareness of the effects of detention and quasi-detention and other adverse experiences on migrants' health, along with the moral dilemmas arising from treating patients subject to restrictive conditions. Professional bodies and individual clinicians should press for more ethical and socially just migration policies.¹⁶ Health leaders should also call for better support and supervision for clinicians working with migrants, both in the community and in detention settings.

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The black market for covid-19 antivirals

Unequal global distribution means patients are buying pills online that may not be safe when taken without medical supervision. **Gabriel Plata** reports

A worldwide black market in molnupiravir (Lagevrio) has developed, despite lacklustre trial results for the oral antiviral drug for SARS-CoV-2. Though experts now question whether its approval was premature, and some doctors eschew its use, patients are paying high prices for generic versions online. These drugs are then taken without medical supervision and may not be safe. In the UK the MHRA has said that molnupiravir, which is given to people infected with SARS-CoV-2 to prevent severe disease, should be prescribed only by a doctor or as part of a clinical trial.

The safety of Merck's molnupiravir and Pfizer's antiviral nirmatrelvir (Paxlovid) have not, for example, been established in pregnancy. In the US the FDA recommends that patients do not have unprotected sex for at least three months after taking molnupiravir.

In the UK women of childbearing age are told to use contraception while taking the drug and for four days afterwards.

"If molnupiravir is sold through the black market and used without medical supervision, there is a risk that patients will not understand these problems and take the drug without proper contraception," says Andrew Hill, a senior visiting research fellow in the pharmacology department at Liverpool University. "This could then increase the risk of birth defects."

Despite these risks, on the website buymolnupiravironline.com, apparently based in London, customers can buy a course for £124.99, seemingly without prescription or review by a doctor.

The BMJ contacted the MHRA about the website, and a spokesperson said, "Websites that offer to supply prescription only medicines without a prescription are not only in breach of UK legal requirements and likely to be committing a criminal offence but are putting patients' health in jeopardy." Buymolnupiravironline.com did not respond to *The BMJ*'s request for comment.

There is no guarantee that black market drugs have gone through adequate quality control, says Paul Little, professor of primary care research at the University of Southampton. Widespread, unregulated use of antivirals may also encourage viral resistance, he added. He called for "high level public campaigning" about the dangers of taking black market antivirals.

Disappointing results

Developed by Merck and Ridgeback Biotherapeutics, molnupiravir was the first oral antiviral brought to market and was sold to more than 30 countries. In interim results announced in a press release in October 2021, Merck said the drug reduced the risk of hospital admission or death by around 50% in people with mild to moderate covid-19, while a separate trial found nirmatrelvir showed a reduction of nearly 90%.

When Merck's final study was published it showed only a 30% reduction in risk. Further trials found molnupiravir "did not demonstrate clinical benefit" or showed a reduction only in hospital admissions in people over 60 years old. Researchers like Hill are calling for the MHRA to reconsider molnupiravir's approval once the results of Oxford University's UK-wide Panoramic



A variety of generic versions of molnupiravir are available on Indiamart

trial have been released. Panoramic included molnupiravir in its platform trial and represents the first independent study of the drug. "It is possible no significant improvement in hospital admission risk will be seen in Panoramic," Hill says.

But it may be too late. The company's interim data created a buzz around the drug that sparked demand in many countries. In November 2021 England's health secretary, Sajid Javid, called it a "gamechanger" after stockpiling 480 000 doses of the drug before it was authorised by the MHRA. In many countries, demand was met by black markets.

If the drugs haven't been tested for bioequivalence they may be substandard, meaning there is a risk of reduced efficacy

Unauthorised generics

Generic versions of molnupiravir are easy to buy online. *BMJ* reporters posted a request on the online market website Indiamart, asking to buy 100 boxes of the drug and have them sent to Mexico. Within hours, three sellers got in touch to make offers, even though the Mexican authorities have not permitted generic versions of the drug to be imported into the country.

One seller gave advice on how to avoid customs. “The customs in Mexico are crazy and the clearance process is not so easy,” wrote an account named Rakshit Jain from Bull Pharmachem. “Most of our Mexican customers prefer to have it shipped to the USA and then they carry it across. We regularly do this for a lot of Mexican clients,” he wrote, advising us to ship 10 boxes at a time. “Each country has their own set of rules for importation and none is easier than the USA. We ship to Chile, Peru, Colombia, and Brazil every day,” he added.

In Mexico molnupiravir was given emergency approval on 7 January 2022, as the country saw the most rapid increase of covid cases since the onset of the pandemic. The news prompted an all time high in Google searches for the drug and ways to buy it. Under the emergency declaration, it would be available only at federal and state hospitals, and no generic versions were authorised for importation.

Just a week later, on 14 January, COFEPRIS, the regulatory body in charge of drug approval, released an alert to warn the public of the illegal sale of two unauthorised generics of molnupiravir. Those generic unauthorised drugs—produced by Azista and Merit Organics—continue to be distributed online in Mexico, selling for around MXN\$14 000 (£562) for a pack of 40 pills.

Other versions of molnupiravir were offered for sale as early as 19 July 2021 on Facebook, more than three months before the first authorisation for the drug was granted in the UK or any results of the stage 3 trials had been released.

For consumers it is hard to distinguish between



Unregulated antiviral use may encourage viral resistance
Paul Little

authorised and unauthorised generics. To accelerate and expand global access to molnupiravir, Merck authorised the production of generics under a voluntary licence. This was initially to five Indian companies and later to the Medicines Patent Pool (MPP), the UN backed organisation working to increase access to drugs in low and middle income countries through negotiating licences and shared intellectual property, which further extended it to another 27 companies. Azista and Merit are not among those companies, and it is unlikely they have been tested for bioequivalence, says Andrea Taylor, assistant director of programmes at Duke University.

If the drugs have not been tested for bioequivalence they may be substandard, which means less of the drug gets into the bloodstream and there is a risk of reduced efficacy, says Paul Newton, head of the Medicine Quality Research Group at the Infectious Disease Data Observatory. *The BMJ* contacted Azista and Merit Organics with these allegations but did not receive a response.

Inequality in access

Mexico’s government was not the only one warning the public against unauthorised covid antivirals. In January 2022 the government of the Philippines warned about the spread of illicit molnupiravir there, advising people not to buy drugs from unauthorised sources. Articles online describe how people are using unauthorised molnupiravir in Japan and Vietnam.

“Inequality is a driving force in the distribution of substandard and falsified medical products,” says Pernelle Bourdillon-Esteve, WHO’s acting team lead for incidents and substandard and falsified medical products. “When people cannot access safe quality medical products, they might turn to unsafe sources.”

According to data from Duke University, most of the supply of molnupiravir has been purchased by high income countries, a trend that is predicted to continue in 2022. As of 4 April 2022, nearly 66% of all molnupiravir has been bought by these

countries. Merck said it has strategies in place to accelerate global access, including granting voluntary licenses to the MPP to allow generic versions to be produced for low and middle income countries, and an agreement with Unicef to distribute doses.

Social media marketplaces are one way substandard and falsified medical products are distributed, says Bourdillon-Esteve. “People often have the image of a dodgy pharmacy, and that’s certainly the case, but there are other online mechanisms, whether Facebook or Instagram, among many others.”

In Mexico, since molnupiravir is available only in certain federal and state hospitals, doctors working in private institutions said patients had bought unauthorised generic versions online. Benjamin Valente Acosta, a specialist in internal medicine at the ABC Medical Center, a private hospital in Mexico City, said some of his patients paid MXN\$15 000-30 000 for a five day course.

For black market sellers, obtaining the drugs wholesale requires little effort. On websites such as Indiamart, a marketplace that has connected 550 million sellers and buyers in the past year, anyone can ask to buy molnupiravir, and dozens of sellers reach out with generics available to be sent to virtually any country. Among the generics on offer were the two produced by Azista and Merit that the Mexican government warned against. Indiamart told *The BMJ* that it is “a content platform with huge data aggregation and processing happening every second” and therefore “it is difficult to monitor content.”

It said it works with an array of national and international organisations monitoring counterfeit and substandard drugs and regulatory malpractices. These include the International Narcotics Control Bureau, India’s Narcotics Control Bureau, and React, a global anti-counterfeiting network.

An Indiamart spokesman said its users sign up to terms of use in which they agree not to violate any law, statute, ordinance, or regulation. “Our endeavour is to create a marketplace ecosystem for legitimate and lawful products,” he added.



The profit margins for black marketeers are large. The generics sold by Bull Pharmachem costs \$35 a box, plus \$50 for the shipment of 10 boxes. In Mexico, vendors can sell them for at least 18 times that price.

In a statement Bull Pharmachem told *The BMJ* it “categorically denies” its employee offered to ship molnupiravir to Mexico and other countries or gave advice on avoiding customs, and said an impostor was speaking under its company name. It added, “We have not exported a single bottle of molnupiravir to the US or Mexico, ever.”

However, *The BMJ* believes its reporters were speaking to a genuine member of the company. The Bull Pharmachem shop on Indiamart had a TrustSeal verification—where Indiamart has verified that a company is genuine. Companies pay around \$300 a year for verification, which involves physical verification and Indiamart confirming uniquely identifiable information on the company, such as its tax identification and export licence. That same verification is proudly displayed on Bull Pharmachem’s official website. The Bull Pharmachem Indiamart vendor gave out contact details matching those of the official company, rather than a fake phone number or email address, and gave another mobile phone number as a back up that matches that of Bull Pharmachem’s chief executive, Parag Jain.

The BMJ also asked Indiamart if it had received any complaints about the Bull Pharmachem vendor registered on Indiamart, which has been active for seven years. Indiamart said it had not received any complaints from sellers or from Bull Pharmachem itself.

Bourdillon-Esteve says, “Every region in the world is affected by the problem of substandard and falsified medical products. Because of constraint, access, poor governance, and weak technical capacity, however, some regions will be more vulnerable.”

“Patients taking molnupiravir, generic or patent, must have medical supervision. These drugs should not be accessible for everyone to buy without it,” Valente Acosta added.

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CORONAVIRUS

How vaccines are being adapted to meet the changing face of covid-19

Covid vaccine development was a miracle of modern science—but as SARS-CoV-2 adapts, how are manufacturers and researchers responding? **Chris Stokel-Walker** learns more

It seems like a lifetime, but the first clinically approved vaccine against SARS-CoV-2 was given to a patient just 17 months ago, on 8 December 2020. Since that first dose, developed by Pfizer, several vaccines have been developed. Ten are approved by WHO, and scores more are still undergoing trials.

However, just as vaccine development hasn’t stood still, neither has the virus itself. The changing face of the novel coronavirus has challenged scientists to modify existing vaccines to better tackle the changing characteristics of SARS-CoV-2. Yet, despite much talk of modified vaccines for variants, the world is still using largely the same original ones for initial rollouts and booster doses.

“It seems as if the dominant things I’m hearing about at the moment are updates to existing vaccines,” says Paul Bieniasz, virologist at the Rockefeller University, New York. Those updates modify how a vaccine works to make it better match the circulating strains of SARS-CoV-2 around the world, much like the existing system for vaccinating against influenza. National and international groups analyse which strains are circulating worldwide and then decide

which are the most likely to require updates to existing vaccines.

A key question at this phase of the covid pandemic is whether it’s better to continue playing catch-up with the virus and its variants or to try to develop multivalent vaccines, based on a mixture of strains that could prime the immune system against potential future variants.

“We haven’t yet got a consensus agreement on what strains manufacturers should put in their vaccines,” says Penny Ward, visiting professor in pharmaceutical medicine at King’s College London. “In part that’s because of the rather rapid emergence of novel strains of this virus and the fact we’re learning about the disease it causes as we’re going.”

What modified or updated covid vaccines are in development?

Many of the original main vaccines against SARS-CoV-2 are the subject of ongoing trials looking at the immune response to different variants, says Ward. Not many findings have been publicly released, but Moderna released a preprint in April looking at a modified vaccine variant raised against the spike protein of the beta variant. Reassuringly, says Ward, “it showed a superior immune response when they use the variant vaccine in an already immunised population.”

Some more experimental vaccines in development aim to invoke a broader immune response—not just to variants we’ve encountered so far or could see in the near future, says Bieniasz, but to sarbecoviruses, the group of viruses that gave rise to SARS-CoV-2 and the original SARS-CoV. One early trial, which began in September 2021, has reported promising initial results from a multivalent vaccine, albeit one that triggers the production of neutralising antibodies at a similar rate to approved mRNA vaccines.



Vaccines: “least expensive way” to protect people

The most widely used of these experimental approaches is based on nanoparticles that contain mixtures of parts of the spike protein from various sarbecoviruses. “It’s somewhat clear these vaccines can induce a broader antibody response that would give broader protection,” says Bieniasz. One such drug, developed by researchers at the University of Cambridge, entered clinical trials in December 2021.

How do these approaches compare with the adaptation of flu vaccines each year?

The first bivalent flu vaccine, which can neutralise the effects of influenza types A and B, has its 80th birthday this year. But the key difference with SARS-CoV-2 is time, says Ward. She explains, “We’re not in the same position we’re at with the flu vaccines, where there are two yearly updates of the vaccines: one for the southern hemisphere and one for the northern hemisphere seasons, based on the types that have been circulating the preceding seasons.”

Although flu also adapts and spreads significantly, SARS-CoV-2 does so while being a relatively unknown quantity. “With the omicron variant, within three months, pretty much everybody on the planet has had the infection, whether or not you’ve been vaccinated,” says Paul Hunter, professor of medicine at the University of East Anglia. “The value in developing new variant vaccines is always mitigated against the time taken to find a new variant, figure out if it’s an important one, [and then] develop, modify the vaccine, check it’s worked, and approve.”

With SARS-CoV-2 the emergence and spread of new variants, globally and whatever the season, has been scarily fast.

Should we ignore variant specific vaccine development and aim for a pan-coronavirus vaccine?

A pan-coronavirus vaccine would certainly be ideal, says Bieniasz. But it’s easier said than done. Ward points out that we still have no pan-influenza vaccine, “and we’ve been at it for 80 years.”

In fact, no such pan-virus vaccine exists. “We don’t really have anything that has the breadth of protection we are envisaging for the current effort in pan-coronavirus vaccines,” says Bieniasz.

What we do have are extraordinarily effective vaccines against diseases such as measles, where we’ve been using the same vaccine for a long time. Yet for every success there are also big misses. HIV still has no effective vaccine.

“The difference there is the genetic diversity of the two viruses,” says Bieniasz. “Measles just doesn’t change very much, whereas with HIV there are more variants in a single individual at any given time point than that individual’s immune system can cope with.” The fear is that SARS-CoV-2 is closer to HIV’s continual series of variants.

One key issue is the brief immunity that seems to exist after SARS-CoV-2 infection. The fact that people are being reinfected with different variants suggests that it would be difficult to develop a vaccine with broad enough coverage and long enough lasting immunity to be effective at stopping viral infection and transmission.

“The sort of breadth that might be achievable with a pan-coronavirus perhaps won’t be as ‘pan’ as many people imagine,” warns Bieniasz. Pan-sarbecovirus vaccines may be possible, he says—his laboratory is one of those working on it—but coronaviruses in general, whether SARS, MERS, or others, are so different that catching them all under one net is a challenge.

Still, WHO’s chief scientific officer, Soumya Swaminathan, finds it “scientifically quite feasible” that such a vaccine may be developed within the next two years. She told *The BMJ* in April, “That’s partly because of the huge amount of research that’s gone into SARS-CoV-2 and also the understanding of immunology, as well as on the virus itself. So, we’re in a good position to be optimistic about a pan-coronavirus vaccine.”

What alternative preventive treatments are there?

“Not much, in terms of vaccinology, unfortunately,” says Ward. Monoclonal antibodies can be generated against less mutated parts of the viral genome that help prevent disease when given to patients who have contracted the novel coronavirus.

Antivirals are also being developed at pace, which is important but expensive. Ward says, “Generally speaking, we all believe that vaccines are the least expensive way of protecting a population.”

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Pretty much everybody has had omicron, whether vaccinated or not
Paul Hunter



The main things I’m hearing about are updates to existing vaccines
Paul Bieniasz



We’re in a good place to be optimistic about a pan-coronavirus vaccine
Soumya Swaminathan



We still have no pan-influenza vaccine, even after 80 years
Penny Ward

Diagnosing asymptomatic prostate cancer

Screening tests are not currently recommended and should be approached with caution

The pandemic has disrupted the diagnosis and treatment of cancer in health systems worldwide. In response, patients at risk of cancer have been encouraged to present to health services to support prompt diagnosis.¹ In England, this has included a collaboration between the NHS and Prostate Cancer UK to find the 14 000 men estimated to have not yet started treatment for prostate cancer because of the pandemic.²

The heterogeneous behaviour of prostate cancers, along with the poor performance of prostate specific antigen (PSA) testing in identifying clinically important disease, remain obstacles to implementing beneficial strategies for early diagnosis.^{3,4}

Multiparametric magnetic resonance imaging has the potential to ameliorate some of the harms of screening by reducing the proportion of patients with a raised PSA value who require biopsy and thereby limiting biopsy related complications.⁶ These developments, combined with advances in identifying those with a higher genetic risk, may in time tip the balance of benefits and harms in favour of screening.⁷ In the meantime, routine screening is not recommended by the UK's National Screening Committee or the US Preventive Services Task Force.^{8,9} In both countries, asymptomatic patients can opt for PSA testing after exploring the benefits and harms with a clinician.^{8,10}

The number of tests performed has increased markedly over the past two decades,^{11,12} contributing to a higher incidence of prostate cancer but with uncertain benefits since a large



If a risk checker tool is to be promoted as part of an early detection strategy, it must be evidence based and evaluated appropriately

proportion of screen detected cancers probably constitute overdiagnosis.¹³ Given these uncertainties, UK general practitioners are advised that PSA testing should not be offered to asymptomatic patients unless specifically requested.¹⁴

Risk checker

NHS England's bid to "find the 14 000 men" seems to depart from this cautious approach. The campaign encourages men to use a risk checker. This informs men older than 45 with particular risk factors (black or mixed black ethnicity, or a first degree relative who has had prostate cancer) and all men older than 50 that they may be at higher risk and suggests arranging a GP appointment to discuss this risk. Further prompts explain that the first step to finding early prostate cancer is a PSA test.¹⁵

Arguably, this messaging is consistent with the established principle of allowing patients to decide for themselves on PSA testing, and the risk checker does provide some valuable information. However, the apparent presumption of benefit in detecting asymptomatic disease could lead people to believe that the NHS is promoting screening.

For GPs, ensuring that patients understand the pros and cons of PSA testing and arrive at a decision that is consistent with their values and priorities is vital, but making shared decisions is complex and

time consuming.¹⁷ Particularly where patients have a firm expectation of having a PSA test at the outset, GPs may find it expedient to accede without fully exploring the possible consequences.¹⁸ Encouraging all asymptomatic men older than 50 to book a GP appointment to discuss their risk has resource implications.¹⁹

Repeat testing

If men choose screening, after what interval should they consider repeat testing? Should asymptomatic patients consider having digital rectal examination along with a PSA test? What resources should guide shared decision making, and is there a role for risk calculators?²⁰ Should GPs counsel men younger than 50 who have been flagged as higher risk by the risk checker that PSA is not supported by official guidance for their age group?¹⁰

Information for the public should emphasise that although PSA testing is available on request for men older than 50, it is not currently recommended, and why. If asymptomatic men over 45 in certain risk categories should be eligible for PSA testing, this needs to be stated in the national guidance, which has not been updated for over six years.¹⁰ GPs and patients need practical up-to-date guidance on PSA testing, including recommended evidence based tools and resources to support shared decision making. If a risk checker tool is to be promoted as part of an early detection strategy, the tool must be evidence based and evaluated appropriately. Meanwhile, efforts must continue to focus on ensuring prompt diagnosis of symptomatic patients and generating the evidence needed to satisfy the National Screening Committee of the clinical and cost effectiveness for any proposed screening programme.

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