# this week

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GUY BELL/SHUTTERSTOCK

## BMA welcomes U turn on mandatory vaccine

The government has made a last minute U turn on its plan to make covid vaccination mandatory for NHS staff in England.

Medical bodies welcomed the reversal of the plan which they had warned would exacerbate chronic workforce shortages by causing thousands of staff to lose their jobs.

Announcing the decision on 31 January, England's health secretary, Sajid Javid, said the balance of opportunities and risks of the policy had shifted with the dominance of the omicron variant, with the population as a whole better protected against the need for hospital admission, and with omicron being "intrinsically less severe" than delta.

"While vaccination remains our very best line of defence, I believe it is no longer proportionate to require vaccination as a condition of deployment," Javid told MPs.

The decision came just three days before the deadline given to patient-facing staff to have had their first vaccine dose or risk losing their job. The government said more than 127 000 NHS staff had had a vaccine since it first consulted on the issue in September. But on 16 January 80 092 (5.4% of the total) were still unvaccinated.

Javid said the regulations would now be revoked, subject to public consultation and parliamentary approval. He will also remove vaccination as a condition of working in care homes, a policy that had been in place since last year and was estimated to have resulted in 40 000 staff leaving their posts.

Chaand Nagpaul, BMA council chair, said, "It is now clear that the impact of mandatory vaccination on NHS staffing levels at a time of acute workforce shortages and record waiting lists would have put the continuity of services at risk and therefore compromised patient care and safety. Therefore, the decision is the right one."

In a joint statement the chief executives of the NHS Confederation, Matthew Taylor, and NHS Providers, Chris Hopson, said, "NHS leaders are frustrated to have such a significant change in policy at the 11th hour, given all the hard and complex work that has gone into meeting the deadline. They recognise the reasons . . . but there will be concern at what this means for wider messaging about the importance of vaccination for the population as a whole." Rachel Harrison of the GMB union said, "The U turn comes too late in the day for thousands of workers in our care homes who have already lost their jobs because of an unrealistic vaccination policy."

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2022;376:o269

**NHS staff protesting on 22 January against the now abandoned policy of mandatory vaccination**

**LATEST ONLINE**

- Man whose genetic condition went undiagnosed for 36 years is awarded £2.5m
- We need to talk about shielders: five minutes with Lucy Watson
- Pandemic waste threatens human and environmental health, says WHO

# SEVEN DAYS IN

## Former pupils seek legal redress for treatment with contaminated plasma

**Survivors of treatment with infected blood plasma and relatives of other people who died have asked the High Court to approve a group legal action against a school where the treatment was given to pupils with haemophilia.**

**The 36 claimants allege that Treloar School in Hampshire breached its duty of care in treating boys with pooled plasma in the 1970s and 1980s without the informed consent of pupils or parents. The boarding school catered for children with haemophilia and had a specialist NHS centre. Pupils were given contaminated factor VIII made from plasma from as many as 60 000 donors, much of it imported from US commercial companies, which was not heat treated.**

**More than 72 pupils have since died after being infected with hepatitis or HIV. Thousands of patients with haemophilia and others around the UK were also infected.**

**The lead claimant, Gary Webster (second right), said, "Why didn't our headmaster want to know what was being injected into pupils in their care? It beggars belief."**

**A spokeswoman said the school was unable to comment but was cooperating with the public inquiry.**

Clare Dyer, *The BMJ* **Cite this as:** ***BMJ*** **2022;376:o217**

## Covid-19

### Second antiviral for people most at risk

People with the highest risk of serious illness from SARS-CoV-2 infection who test positive for the virus—such as people who are immunocompromised or have cancer—will have access to Pfizer's antiviral drug Paxlovid from 10 February, as the government has procured 2.75 million courses. Pfizer has reported that Paxlovid, given within three days of symptoms starting, reduced the risk of covid related hospital admission or death from any cause by 89% compared with placebo. Nearly 10 000 high risk patients in the UK have already been treated with the antiviral molnupiravir and the monoclonal antibody sotrovimab.

### Government eases social care restrictions

The limit on the number of visitors allowed into care homes in England was dropped on 31 January, and self-isolation periods were cut from 14 days to 10, with further reductions if people test negative on a lateral flow test on days 5 and 6. Care homes will have to follow outbreak management rules for only 14 days rather than 28. By 16 February care workers will be asked to use lateral flow tests before shifts, replacing weekly PCR tests.

### Daily dashboard will include reinfections

Since 31 January the UK Health Security Agency has included data on possible reinfection episodes—defined as a positive test at least 90 days after a first infection—in its covid dashboard. New data published on 1 February show that reinfection rates averaged around 1.4% of cases until 16 November 2021, when a spike in infections took place after the emergence of the omicron variant, leading to a rise in reinfections that now represent around 10% of episodes each day.

### Booster doses "effective against omicron"

Two weeks after a booster vaccine, protection against dying with the omicron variant rises to 95% in over 50s, up from 60% six months after two doses of any vaccine, showed data from the UK Health Security Agency. Protection against hospital admission was 90-95% nine weeks after a Moderna booster and was around 75% 10-14 weeks after a Pfizer booster. For preventing symptomatic infection, a booster dose increased vaccine effectiveness to 63% against omicron and 70% against BA.2, the omicron variant sub-lineage—compared with only 9% and 13% protection 25 weeks after double vaccination.

### Call to allow countries to make own vaccines

More than 320 scientists and public health experts called for the UK government to put public health before the commercial interests of the drug industry "to prevent another year of uncertainty and tragedy," by allowing low and middle income countries to manufacture covid vaccines, tests, and treatments for themselves. They said that around 100 manufacturers in Africa, Asia, and Latin America were capable of manufacturing mRNA vaccines if intellectual property rules were suspended and drug companies shared their manufacturing details. More than three billion people have yet to receive their first dose of a covid vaccine.

## Clinical trials

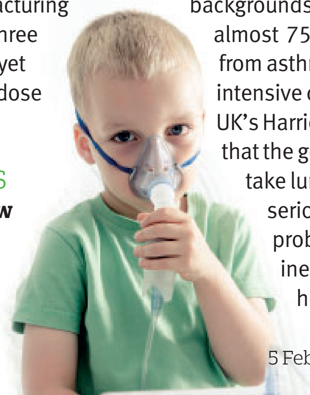
### EU launches new trial system

The EU Clinical Trials Regulation, which launched on 31 January, will include a streamlined system for trial sponsors and regulators, the European Medicines Agency announced. The Clinical Trials Information System will mean trial applications will not need to be submitted to 30 national authorities and ethics committees. It will provide a single place where results can be published and will have a searchable database. The regulation will require sponsors to make the results of trials public.

## Paediatrics

### Poorer children are worst hit by asthma

Children under 15 from poorer areas in the UK make up almost 60% of emergency hospital admissions for asthma and have almost double the risk of needing ventilation, a study in *Scientific Reports* found. It also showed that children from poorer backgrounds accounted for almost 75% of deaths from asthma in paediatric intensive care units. Asthma UK's Harriet Edwards said that the government "must take lung conditions seriously and tackle the problem of childhood inequalities head on."



# MEDICINE

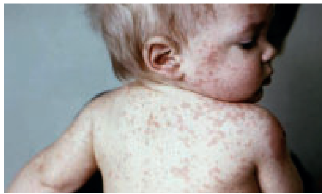
## Vaccinations

**Cuba seeks approval for covid vaccine**

Cuban health officials said they would apply for WHO approval of one of the country's homegrown covid vaccines, Abdala. Cuba's health regulator has approved the use of three of its homegrown vaccines: Abdala, Soberana 2, and the booster vaccine Soberana Plus. Non-peer-reviewed studies have found Abdala to be 92.3% effective against symptomatic infection after three doses, while Soberana 2 was 92.4% effective after two doses and an additional dose of Soberana Plus.

**Cuba wants WHO to approve Abdala, its locally developed covid vaccine**

**MMR uptake in UK is lowest in a decade**



Parents are being asked to ensure their children are up to date with the measles, mumps, and rubella vaccine after figures showed just 85.5% of 5 year olds in England had had two doses, well below the World Health Organization's 95% target needed to eliminate measles. A UK Health Security Agency survey of 2000 parents found that almost half (48%) were not aware that measles could lead to pneumonia and brain inflammation, and only 38% were aware that measles could be fatal.

## Polygenic risk scores

**Public warned against "unethical" embryo test**

Geneticists warned the public against buying polygenic risk score analyses, which some private fertility clinics claim can help in selecting embryos that carry the least risk of future disease. No evidence has shown these tests can predict the likelihood of an unborn child being liable to a specific disease, wrote European Society of Human Genetics representatives in the *European Journal of Human Genetics*. Markus Perola of Helsinki University, an author of the paper, said that selling the tests for this purpose was "like selling snake oil."

## AMR

**New agency will establish global networks**

The US Centers for Disease Control and Prevention has awarded $22m (£16.4m) to be disseminated through two new organisations. The Global Action in Healthcare Network will build an international collective of countries and organisations to reduce infections that are due to antimicrobial resistance, and the Global AR Laboratory and Response Network will work in 38 countries to improve detection of drug resistant microbes and the factors that drive their spread.

## Assisted dying

**New bid to secure parliamentary debate**

An amendment to the health and care bill, which would require the government to present a draft assisted dying bill to parliament within a year, has been tabled by a senior Conservative peer, Michael Forsyth. The amendment was deferred to the report stage of the bill, now at committee stage, after a debate on 26 January. Forsyth recently said he had changed his mind on assisted dying after his father, when dying of bladder cancer in 2020, criticised him for opposing previous bills that would have allowed him the option.

Cite this as: *BMJ* 2022;376:o264

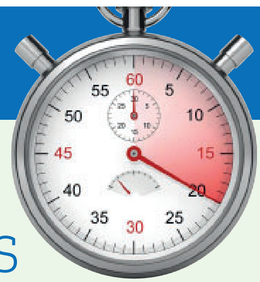
## FGM

The healthcare costs of female genital mutilation are set to almost double worldwide to an annual $2.1 bn by 2047, when it will affect an estimated

**205.8** million women a year in 27 countries studied, up from

**119.4** million in 2018

*[BMJ Global Health]*




# SIXTY SECONDS ON . . . SHIGELLA

### WHY IS IT IN THE NEWS?

The UK Health Security Agency has issued a warning over "extremely antibiotic resistant" *Shigella sonnei* infections after it detected a rise in cases. Between 1 September 2021 and 10 January 47 cases were reported; in the previous 17 months there were just 16. Officials have been following this strain of the species since 2018, but recent cases show antibiotic resistance is increasing.

### THAT DOESN'T SOUND GOOD

Indeed. Although in most cases symptoms will subside within a week, some people need to be admitted to hospital for intravenous antibiotic treatment. The UKHSA warns that effective antibiotic treatments are limited for this extremely resistant strain.

### REMIND ME OF THE SYMPTOMS

*Shigella* causes diarrhoea—sometimes mixed with blood—stomach cramps, and fever. Symptoms usually occur one to four days after the infection is picked up and are often mistaken for food poisoning.

### AND HOW IS IT TRANSMITTED?

The bacteria are found in faeces and are very infectious. Sex that may involve anal contact or contact with faeces is one way that the infection can spread. The recent cases have been detected mainly among men who have sex with men.

### WHAT CAN BE DONE?

Gauri Godbole, a consultant medical microbiologist at the UKHSA, advises practising good hygiene after sex, including avoiding oral sex immediately after anal sex, changing condoms between anal or oral sex, and washing hands with soap after sexual contact. He said it was important that men who have sex with men do not dismiss their symptoms and should speak to a GP or sexual health clinic if they are unwell.

### ANY MORE TIPS?

Anyone with a *Shigella* diagnosis should keep hydrated and get lots of rest. They should not have sex until a week after symptoms stop. Spas, swimming, hot tubs, and sharing towels as well as preparing food for other people should also be avoided. Men with *Shigella* infection may have been exposed to other sexually transmitted infections, including HIV, so a sexual health screen is recommended too.

Jacqui Wise, Kent

Cite this as: *BMJ* 2022;376:o253

# Health secretary wants more GPs to be employed by trusts, newspaper reveals

**It's clear the separation of general practice from the wider system comes with considerable drawbacks** Sajid Javid

England's health secretary is reportedly considering a radical shake-up of the NHS that would encourage GPs to be directly employed by hospitals rather than running their own practices as independent contractors.

The *Times* reported that Sajid Javid outlined the proposal in a letter to the prime minister as a way to keep more patients out of hospital. In the letter, seen by the newspaper, Javid wrote, "Whilst there are some strengths to the system of primary care, it's also clear that the historic separation of general practice from the wider healthcare system as created in 1948 comes with considerable drawbacks including an underinvestment in prevention."

His letter said the idea would be considered in an "independent review of the future of primary care" set up to examine "workforce, business models and how GPs work with the other parts of the NHS such as hospitals," the *Times* reported.

Sources told the newspaper there would be "no forcible state takeover" of general practices but that GPs would be offered incentives to be employed by hospital trusts. This would be similar to arrangements that already exist in a small number of areas, such as Wolverhampton.

The news followed recent reports of the government also considering establishing academy-style NHS hospitals in England to tackle variation in performance and give well run hospital trusts more freedom in how they operate.

When *The BMJ* asked the Department of Health and Social Care to provide details of the primary care review a spokesperson said, "We have no plans to nationalise general practice. We are incredibly grateful

WE ARE incredibly grateful for the phenomenal work that GPs do for their patients and have invested £520m to improve access and expand GP capacity during the pandemic DHSC spokesperson

# More consultants to receive lower value excellence awards

More consultants will be eligible for bonus payments under a shake-up of the National Clinical Excellence Awards, but the value of individual awards will be almost halved, the government has announced.

The government argued the changes make the awards more inclusive and accessible to "help level the playing field," but the BMA warned the changes "are not positive ones for consultants" and could prompt many of the country's best consultants to leave the NHS.

The awards have existed since the inception of the NHS in 1948 and have been running in their current form since 2004. They are paid to consultants and senior academic GPs in England and Wales who perform above the standard expected of their role. They will be renamed National Clinical Impact Awards as part of the shake-up from April 2022.

In England the awards are currently worth £36 192, £47 582, £59 477, or £77 320 a year for five years. In contrast, the new scheme will pay just three awards, worth at least £20 000, £30 000, or £40 000 a year for five years.

An estimated 6% of consultants are expected to receive one. When the new awards open this April there will be 330, 200, and 70, respectively, on offer this year. The awards will no longer be pensionable, bringing them in line with the Local Clinical Excellence Awards scheme.

Wales will adopt the proposed reforms but with some differences, including retaining four awards, because, unlike in England, there is no additional local awards scheme.

The health minister Edward Argar said, "We're increasing the number of people who will be recognised and making the awards more accessible for under-represented groups, including women and younger consultants."

Vishal Sharma, chair of the BMA Consultants Committee, said the association would support a more equitable scheme that helped reduce the gender pay gap but that these changes failed to do that. He added, "These changes are not positive ones for consultants, and the loss of value of the awards risks the very highest performing consultants leaving the NHS, which, along with the changes to the pensionability of the awards, will leave others with little option but to take early retirement."

Ingrid Torjesen, London

Cite this as: *BMJ* 2022;376:o252

for the phenomenal work that GPs do for their patients and have invested £520m to improve access and expand GP capacity during the pandemic."

But the report prompted concern among GP leaders. Farah Jameel, chair of the BMA's General Practitioners Committee for England, described reading about the future of general practice in a newspaper as a "kick in the teeth."

"Now is the time to invest in general practice, not to try and reinvent the wheel through a wholesale change to the model," she said.

Martin Marshall, chair of the RCGP, said that looking for new ways for primary and secondary care to work better together was a "necessary exercise" but that the current model of general practice "delivers exceptional benefits."

He added, "We are open to exploring new ideas about the future of general practice, but there has to be a very good reason for changing a model that works well for patients, for the NHS, and for the taxpayer. Ultimately, no model of general practice will be sustainable without sufficient numbers of GPs and other practice staff."

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2022;376:o267

COMMENT p 190, 191, 192

# Covid patients treated in hospital have "high risk of adverse outcomes"

MARK THOMAS

Patients who leave hospital after being treated for covid are far more likely to be readmitted or to die than the general population, shows a UK study. The researchers said the findings emphasised that such patients were likely to pose a "substantial extra burden on healthcare."

The findings support those of a study published in *The BMJ* in March 2021 that found that patients of all ages discharged after hospital treatment for covid had higher than expected rates of multiorgan dysfunction.

In the new study, researchers used linked primary care and hospital data in England to evaluate the risks of hospital admission and death among 24 673 patients who were treated in hospital for covid between February and December 2020 and compared them with 123 362 matched controls and 16 058 people who had been discharged after hospital treatment for influenza between 2017 and 2019.

The findings, reported in *PLoS Medicine*, showed that during a follow-up period of up to 315 days the covid patients were more than twice as likely to need readmission or to die as the general population (fully adjusted hazard ratio 2.22 (95% confidence interval 2.14 to 2.30)) but slightly less likely than the patients who had been admitted to hospital for flu (HR 0.95 (0.91 to 0.98)).

A total of 7439 of the 24 673 patients admitted for covid died during follow-up, and were four times as likely (HR 4.82 (4.48 to 5.19)) as the general population controls and also more likely than the flu patients (HR 1.74 (1.61 to 1.88)) to die from any cause. Risks for all disease specific admissions and deaths were greater among former covid patients than the control group but similar to or lower than those among flu patients, except for respiratory and mental health outcomes.

Compared with flu patients, those with covid were more likely to be readmitted or to die because of their initial infection or other lower respiratory tract infections and more likely to experience a mental health or cognitive related admission or death. Former covid patients with pre-existing dementia had more than double the risk of hospital readmission for dementia or of death than the former flu patients.

"These findings suggest a need for services to support and closely monitor people following discharge from hospital with covid—for example, through more active follow-up in primary care in the weeks and months following a hospitalisation," concluded the researchers.

Ingrid Torjesen, *The BMJ*

Cite this as: *BMJ* 2022;376:o265

# Omicron BA.2 may have "substantial growth advantage"

More than 1000 cases of BA.2, a sub-lineage of the covid variant omicron, have been identified in England, the UK Health Security Agency has reported.

It warned that BA.2 had an "increased growth rate" when compared with the original omicron (BA.1) in all regions of England with enough cases to assess. It added that although growth rates can be overestimated, "the apparent growth advantage is currently substantial."

Contact tracing data found that people infected with BA.2 were more likely to infect their household, with 13.4% (64 of 476) of contacts testing positive, compared with 10.3% (10 444 of 101 773) of BA.1 contacts (27 December to 11 January). The agency also noted that early investigations found no evidence of less vaccine effectiveness against symptomatic disease for BA.2 than with BA.1.

Susan Hopkins, UKHSA chief medical adviser, said, "Although hospital admissions and deaths remain low, cases are still high in some areas and some age groups, so it's important that we continue to act cautiously as restrictions are lifted."

**BA.2**

At least 25 weeks after two doses, vaccine effectiveness against symptomatic infection was reported as **9%** and **13%** respectively for BA.1 and BA.2, which increased to **63%** for BA.1 and **70%** for BA.2 at two weeks after a third dose. No data on BA.2 severity are yet available.

John Edmunds, from the London School of Hygiene and Tropical Medicine, said BA.2 could become dominant in the UK in the next few weeks, as it had done in Denmark. He added, "It is difficult to say what the implications of this will be. It may well extend this wave of infection or even lead to another peak. The good news is that at present there is no evidence to suggest it is more severe than omicron and the vaccines appear to be as effective against it as they are against BA.1."

Latest hospital data show that, where variant information was available, most of the intensive care unit admissions from 24 November to 19 January were delta infections. However, admissions with omicron rose from 9% in the week beginning 15 December to 50% in the week beginning 12 January.

Elisabeth Mahase, *The BMJ*

Cite this as: *BMJ* 2022;376:o263

# Ethnic minority death rate is linked to lower uptake of vaccine

Death rates from covid remain higher in most UK ethnic minority groups than among people identifying as white British, and some of that disparity is because of their lower uptake of vaccines, show data from the Office for National Statistics.

Vahé Nafilyan, ONS senior statistician, said, "As already highlighted in our analyses of earlier periods, these differences in mortality are largely explained by sociodemographic and economic factors and health. For the first time, we show that the lower vaccination coverage in some ethnic groups also contributes to the elevated risk of covid-19 death, particularly in the black African and black Caribbean groups."

While in the pandemic's first wave the risk of death from covid was highest among people in the black African group, the latest data show that between the start of the vaccination programme and the end of the second wave (8 December 2020 to 12 June 2021) death rates were highest in the Bangladeshi group (5 times greater for males and 4.5 for females), followed by the Pakistani group (3.1 and 2.6), and the black African group (2.4 and 1.7). Only Chinese people and women identifying as "white other" had similar levels of mortality to white British people.

DIFFERENCES ARE MOSTLY EXPLAINED BY HEATH AND SOCIAL AND ECONOMIC FACTORS

Adjustment for factors such as geography, disadvantage, occupation, accommodation, and pre-existing health conditions substantially reduced excess covid mortality risk in most ethnic groups, and after adjusting for vaccination status there was no evidence of a greater risk of death in the black Caribbean group or in black African females.

Provisional data for the third wave of the pandemic (13 June to 1 December 2021) indicated that the risk of death remained highest in the Bangladeshi group (4.4 times greater for males and 5.2 times greater for females than in the white British group), followed by Pakistani (3.5 and 4.3), black Caribbean (2.3 and 3), and black African (1.6 and 2.4) groups. Again, people from black Caribbean and black African ethnic groups remained at higher risk of death than white British people after adjustment for demographic and socio-economic factors and pre-existing health conditions but not after adjustment for vaccination status.

Ingrid Torjesen, *The BMJ* **Cite this as: *BMJ* 2022;376:o233**

# Omicron, hospital admissions, and deaths: unravelling the mystery

Covid fatalities in the UK are at their highest since last February despite omicron being less severe than previous variants. **Gareth Iacobucci** investigates why

Confidence is growing among experts and ministers in the UK that omicron is milder than previous variants of SARS-CoV-2, and politicians and scientists alike are increasingly bullish that the worst of the covid-19 pandemic is behind us. At the same time, the number of people dying from covid in the UK is higher than it has been since February 2021.

**How high are the current figures?**

Daily deaths (within 28 days of a positive test by date of death) have regularly exceeded 250 in recent weeks. This is some way short of the UK's worst daily death toll, which peaked at 1359 on 19 January 2021. But this year's peak of 276 deaths, on 17 January, was the highest daily total since 23 February 2021, when 288 deaths were recorded.

The media often use figures of deaths by date reported. But David Spiegelhalter, chair of the Winton Centre for Risk and Evidence Communication at the University of Cambridge, told *The BMJ* that using the date of death was more accurate because data were not returned at weekends, creating a reporting lag.

**Are covid deaths being overestimated?**

One theory put forward by sceptics throughout the pandemic is that, because the government's covid death figures are based on total deaths from any cause within 28 days of a positive covid test, the number of people dying from covid has been overestimated. But the numbers don't back this up, as highlighted by David Oliver (*BMJ* 2021;372:n352) and Spiegelhalter, among others. If anything, the government data have underestimated the true number of deaths since the start of the pandemic.

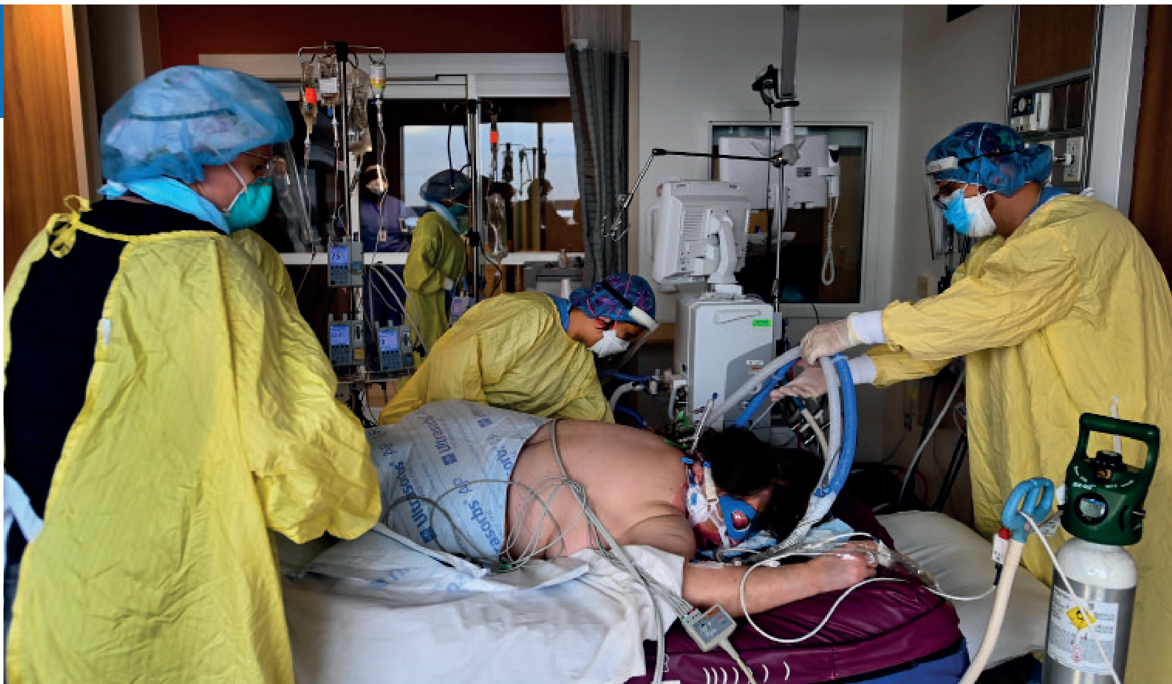
Using the government's way of counting covid deaths shows that a total of 155 040 people died from covid up to 27 January 2022. In contrast, according to data from the Office for National Statistics—which are based on cases where covid is mentioned on death certificates and so are considered to be more reliable—176 813 people have died from covid.

In the latest week for which data are available, whether we look at government or ONS data, the trends in mortality are broadly similar and show that deaths are higher than they have been for some time.

ONS data show that in the week ending 14 January 2022, with omicron now the dominant variant, 1382 deaths were registered in England and Wales, up 50% on the previous week. This is slightly lower than the government figure (1621 deaths in the week to 14 January) but is still the highest weekly figure from ONS since the week ending 12 March 2021, when 1501 covid deaths were registered.

**THE DATA**

Daily deaths (within 28 days of a positive test by date of death) have regularly exceeded 250 in recent weeks. This is some way short of the UK's worst daily death toll, which peaked at 1359 on 19 January 2021. But this year's peak of 276 deaths, on 17 January, was the highest daily total since 23 February 2021, when 288 deaths were recorded



**When there are a lot of infected people out there, there will be a lot of infected people coming into hospital**
Kevin McConway

### ? Could high case numbers be behind the high death rates?

Despite the high proportion of the population already vaccinated and omicron seeming to be less severe than previous variants, one potential reason why deaths are currently so high is the infectiousness of omicron, which has driven high case rates over the past few months. While the virus itself might be less severe, the sheer volume of infections has meant that many people are being admitted to hospital, including those not admitted primarily for covid.

Spiegelhalter said that omicron was "both milder and more prevalent," producing "some novel trends."

"First, of registered deaths that involve covid, the share that covid is 'contributing to,' rather than being a direct cause, has risen," he said. "Usually, this share falls when there is a lot of virus around, but we are seeing the opposite pattern here, presumably because the variant is milder.

"Second, we know that nearly half those in hospital are 'incidental' cases in which covid is not the main diagnosis, and so presumably there will be more deaths of people who just happen to have tested positive, and so covid should not appear on the death certificate."

Spiegelhalter explained the impact of this change on the data being collected regarding covid deaths. "This would probably lead to a divergence between the dashboard count of deaths within 28 days of a positive test and the ONS's count of deaths involving covid," he said. "These two counts have been rather well matched for some time, but there are early signs that the daily reports may be overcounting due to including incidental deaths."

### ? What about deaths not from covid?

The ONS data illustrate Spiegelhalter's point that the proportion of people dying with covid is rising. These figures show that in the week ending 14 January 2022 covid was not the primary cause of death in 23% (312) of the 1382 deaths recorded, even though it may have been a contributory factor. In contrast, this proportion was only 16% in November 2021, when omicron had only just emerged. And it was lower still, at around 10%, in January 2021 when alpha was dominant.

### ? Do hospital data shed any light on this?

Data on covid patients in hospital show a similar picture to the figures on covid deaths. Of the 14 588 beds occupied by patients with confirmed covid-19 on 18 January, 52% (7605) were being treated primarily for covid, a noticeable drop from the 74% (4148 of 5585 patients) on 1 December.

However, Kevin McConway, emeritus professor of applied statistics at the Open University, said that, although the dominance of omicron coincided with a fall in the proportion of beds occupied by patients who were being treated primarily for covid, we need to be careful when interpreting the data.

He also highlighted that the current level of almost a quarter of covid related deaths not being primarily due to covid had occurred before and had fluctuated depending on the overall level of covid deaths at the time.

"It could have nothing to do with omicron, except indirectly because of the infectivity of omicron causing infections to rise a great deal," he told *The BMJ*. "When there are a lot of infected people out there, there will be a lot of infected people coming into hospital for non-covid reasons, but they will be reported as covid patients.

"Also, if there are a lot of patients in the hospital with covid—even if not being primarily treated for it—there are going to be more nosocomial infections.

"All of this is likely to worsen in winter simply because there will be more patients being admitted for other reasons."

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2022;376:o254

**WE KNOW** that nearly **50%** of those in hospital are "incidental" cases in which covid is not the main diagnosis
David Spiegelhalter

THE BIG PICTURE

# Candles for "abortion law death"

**A shrine in Krakow, Poland, set up by women's rights activists, honours Agnieszka Torbus, who died from sepsis, her family says, after doctors refused to remove the dead fetus of one of the twins she was carrying.**

**It is alleged that doctors at Blessed Virgin Mary Provincial Hospital in Częstochowa cited the country's strict anti-abortion law and said the surviving twin could be saved and therefore they could not intervene. The second twin died two weeks later, on 29 December.**

**Torbus, 37, who was in her first trimester, died on 25 January after being transferred to Blachownia Hospital, leaving three children and a husband.**

For the full story see *BMJ* 2022;376:o250

Owen Dyer, Montreal

OMAR MARQUES/GETTYIMAGES

EDITORIAL

# Menstruation and covid-19 vaccination

## Latest evidence is limited but reassuring

Vaccination against covid-19 provides protection against the potentially serious consequences of SARS-CoV2 infection, but as the vaccines were rolled out into younger age groups, clinicians were increasingly approached by patients worried that the vaccine had caused a change to their periods.

More than 36 000 reports of menstrual changes or unexpected vaginal bleeding following covid-19 vaccination have so far been made to the yellow card surveillance scheme run by the UK Medicines and Healthcare Products Regulatory Agency (MHRA).[1] But as cycles vary naturally and the MHRA does not collect comparison data from unvaccinated people, these data cannot be used to establish whether menstrual changes increase after vaccination. A similar signal appeared in the US vaccine adverse event reporting system (VAERS), and as a result the National Institutes of Health allocated $1.67m (£1.2m) for research into a possible connection.[2]

ANDY BUCHANAN/AFP/GETTYIMAGES

### Existing dataset

The first of these studies has now reported.[3] The authors took advantage of an existing dataset from a menstrual cycle tracking app: 3959 Americans logged at least six consecutive cycles; 2403 of them were vaccinated and the remainder acted as a control group. In adjusted models, the first dose of vaccine had no effect on timing of the subsequent period, while the second dose was associated with a delay of 0.45 days (98.75% confidence interval 0.06 to 0.84).

Most affected were the 358 individuals who received both doses of the vaccine in the same cycle, experiencing a 2.32 day (98.75% CI 1.59 to 3.04) delay to their next period. Among this group, 10.6% experienced a change in cycle length of more than 8 days, which is considered clinically significant,[4] compared with 4.3% in the unvaccinated cohort (P<0.001). In all groups, cycle lengths returned to normal by two cycles after vaccination.

**Much of the public concern around this issue arises from misinformation**

A study from the Norwegian Institute of Public Health asked a pre-existing cohort of 5688 Norwegians whether they had experienced specific menstrual changes (such as unexpected breakthrough bleeding or worse than normal period pain) in the cycles before and after each vaccine dose.[5] The high level of variation in normal cycles is underlined by the finding that 37.8% of participants reported at least one change from normal even in pre-vaccination cycles. The study identified heavier than normal bleeding as the change most associated with vaccination (first dose: relative risk 1.9, 95% confidence interval 1.69 to 2.13; second dose:1.84, 1.66 to 2.03).

The findings from both these studies are reassuring: changes to the menstrual cycle do occur following vaccination, but they are small compared with natural variation and quickly reverse.

Taking advantage of pre-existing datasets and cohorts means we have been able to make progress on these questions in a short time, but there is still much to learn. Scientifically, it will be important to characterise the mechanism by which post-vaccination menstrual changes occur. Medically, we must also determine whether any group is particularly vulnerable—for example, those with pre-existing gynaecological conditions—so they can be counselled appropriately. There is already evidence that covid infection can alter periods,[6,7] but better defining the extent and persistence of these changes will also be important in counselling women on the risks and benefits of vaccination.

Much of the public concern around this issue arises from misinformation that covid-19 vaccines cause female infertility.[8] Although we already have evidence that this is not the case, it comes from the clinical trials, in which pregnancy rates were extremely low because participants were using contraception,[9,10] and fertility clinics, where users do not necessarily reflect the broader population.[11-14]

### Sperm count

Studies of pregnancy rates in couples trying to conceive through intercourse are needed, and they should also include analyses of the effects of having covid-19, because evidence suggests that infection may reduce sperm count and quality.[15] A deeper understanding of the effects of both infection and vaccination on fertility will enable better counselling of patients for whom this is of particular concern.

The work that has been done represents a step in the right direction, but the fact that it has taken us so long to get here reflects the low priority with which menstrual and reproductive health is often treated in medical research. The widespread interest in this topic highlights how pressing a concern this is for the public. It's time we started listening to them.

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EDITORIAL

# List of covid-19 symptoms must be updated

Failure to list new variant symptoms is a threat to pandemic control in the UK

With the omicron variant of SARS-CoV-2 now dominant across the UK, and the World Health Organization warning that half of Europe will have been infected within the next six to eight weeks,[1] we must respond and adapt our approaches to meet the challenges it poses. Although studies have found that omicron is less likely to cause severe illness than the delta variant,[2] this highly infectious strain of SARS-CoV-2 has driven covid-19 rates to the highest yet seen in the UK. The NHS remains stretched to breaking point, with several hospitals declaring critical incidents[4] because of rising pressures and staff absences.

Alongside boosting vaccination uptake, our test, trace, and isolate system remains our most important tool in tackling the spread of covid-19 and protecting the NHS. However, these measures can deliver successfully only if built on a foundation of proper messaging and public trust—and it is here that the government is continuing to fail with its lack of clear public health messaging.

That omicron infection produces milder symptoms and causes less severe illness is certainly a good thing, but this also means that it is much harder to detect, making an effective testing programme more crucial than ever. Given that we now know from research such as the ZOE study that the primary symptoms of the omicron variant include runny nose, headache, fatigue, sneezing, and sore throat,[5] it is profoundly unhelpful that the government has not updated its official—and now outdated—list of symptoms, which highlights high temperature, a new continuous cough, or a loss or change to sense of smell or taste.

Maggie Rae, president, Faculty of Public Health, London
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**Primary symptoms of the omicron variant include runny nose, headache, fatigue, sneezing, and sore throat**

Across the world, government agencies, including WHO and the US Centers for Disease Control and Prevention, have updated their case definition of covid-19 to include more diverse symptoms, thus greatly reducing the threshold for people to test and isolate when appropriate. Unless the UK follows the clear evidence on the symptoms caused by the omicron variant and updates its guidance in step with global partners, we will see the effectiveness of our response programme compromised by an unfit case definition.

### Keeping up with covid-19

Similar to improving domestic and international vaccine uptake, the importance of a well functioning testing regime cannot be overemphasised in our efforts to tackle covid-19. The Scientific Advisory Group for Emergencies recommends that we prioritise the rapid testing of symptomatic people over testing asymptomatic people in outbreak areas to have the greatest effect on identifying cases and reducing transmission.[6] With the government's definition of covid-19 symptoms not reflecting the evidence on omicron, infected people are not testing or isolating and are continuing to spread this highly infectious virus.

Of course, if government listens to evidence and expands the case definition for covid-19, the number of people testing and isolating will increase. This likely increase in demand must be matched with increased capacity within the testing system. Providers have warned that pharmacies across the UK have faced shortages of lateral flow tests in recent weeks,[7] and in the run-up to the Christmas holidays people in England were often unable to order home test kits, an unacceptable and dangerous situation. To support and help the public in taking every action possible to prevent the spread of covid-19, the government must urgently remedy these procurement and distribution problems.

As well as a well functioning testing system, there must be better support for those required to isolate as a result of a positive test result. Throughout the pandemic we have seen the clear consequences of health inequalities play out, with the communities most at risk of serious illness from covid-19 also the least likely to come forward for testing and vaccination.[8] Although some financial support is available for those who need it to self- isolate, these packages do not go far enough, or move fast enough, to offer the safety net needed by individuals and families in our most disadvantaged communities.

Our mission to control and prevent the spread of covid-19 to save lives and protect the NHS remains unchanged, and boosting vaccine uptake alongside our test, trace, and isolate system remain our most important tools in achieving this aim. But if these systems are to continue to deliver results, they must be supported by timely and accurate public health messaging. Not following clear evidence and updating the case definition for covid-19 is a failure of government that threatens the effectiveness of the measures we have put in place to control the spread of the disease.

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DATA BRIEFING

# Planning for the healthcare workforce: how many GPs do we need?

How many doctors would be sufficient to provide sustainable primary care services to patients? **John Appleby** considers the challenges involved in making accurate calculations

Workers are the most vital of healthcare inputs, and most informed observers and commentators would argue that the NHS needs more staff. But how many more?

Part of the problem with planning how many more members of staff the NHS needs is the word "need." Wants, demands, and needs are often, wrongly, used interchangeably. And, in healthcare, demand and supply are not independent—demand can be influenced by supply, and whatever is demanded might not be what people want or what they need.

### Opportunity cost

With that confusion in mind, how many general practitioners do we need? The economist's approach to this question requires a couple more ideas to produce an answer. One is the concept of opportunity cost and scarcity. Given a fixed budget, how much should the NHS spend on GPs rather than intensive

MALCOLM WILLETT

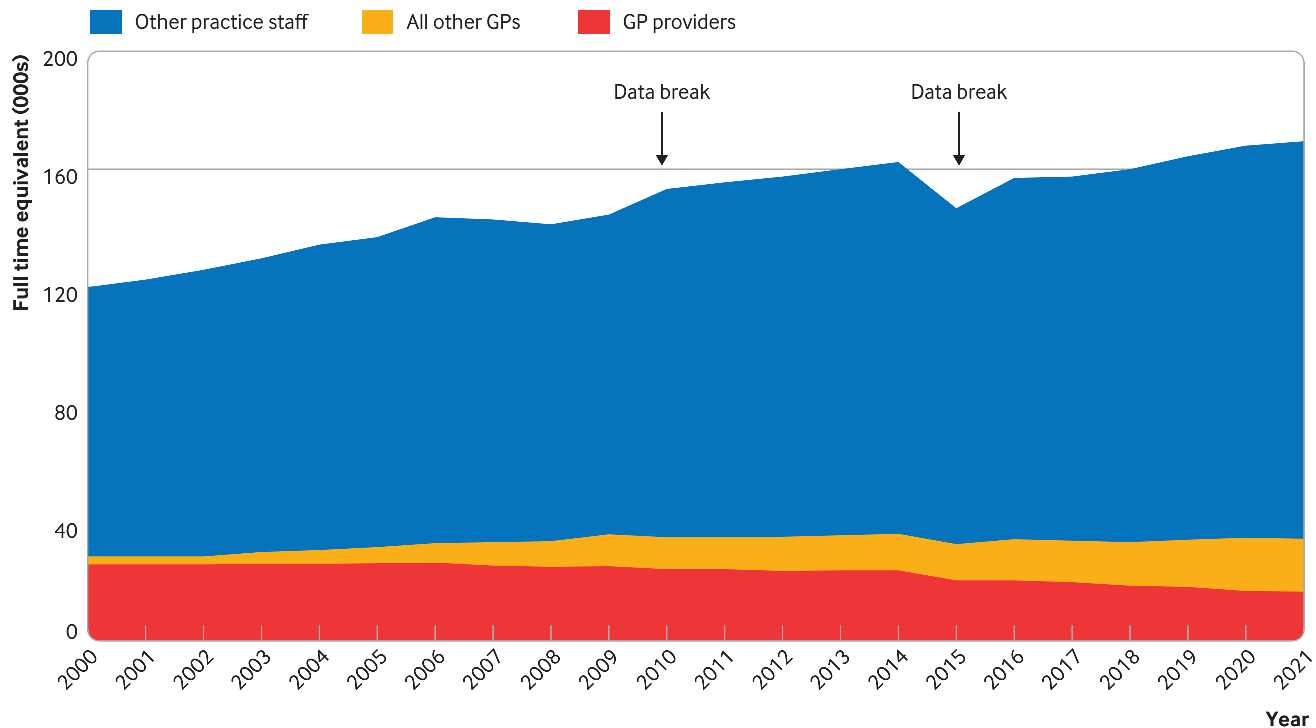


Fig 1 | GPs and other primary care practice staff: England 2000 to 2021.[3] In 2010 changes occurred in data collection for practice staff. Data for 2015 need to be treated with caution owing to under-reporting from a new data collection system. "All other GPs" includes GP registrars and other GPs. "GP providers" includes partners and singlehanded GPs

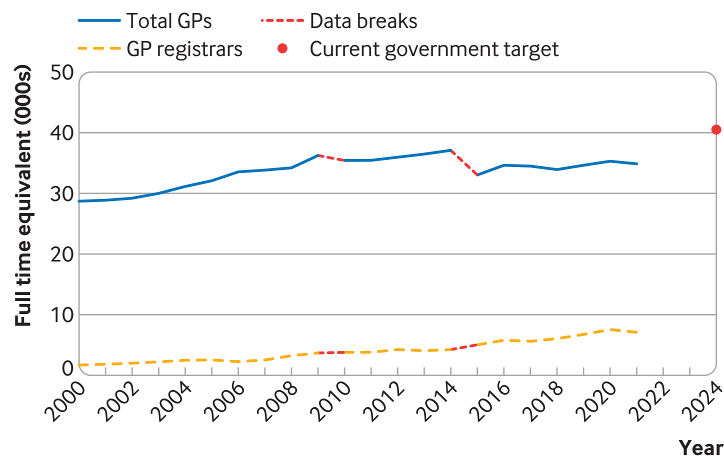


Fig 2 | GPs and GP registrars: England 2000-2021.[3] In 2010 changes occurred in data collection for practice staff. Data for 2015 need to be treated with caution owing to under-reporting from a new data collection system.

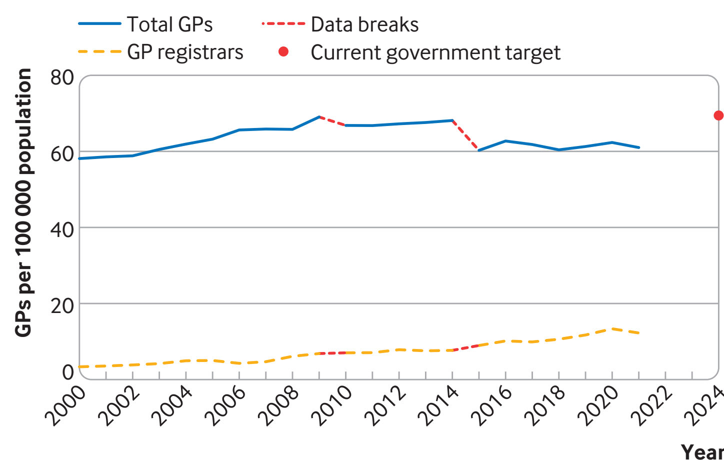


Fig 3 | GPs and GP registrars per 100 000 population: England 2000-2021.[3] In 2010 changes occurred in data collection for practice staff. Data for 2015 need to be treated with caution owing to under-reporting from a new data collection system.

care nurses, cancer drugs, or computed tomography scanners? The same choices and weighing of opportunity costs persist even if the budget increases.

In short, the theoretical answer is that the NHS should keep employing more GPs until the point at which employing one more GP would lead to less health benefit than spending the same amount of money on something else. To get a practical answer, however, we would need to know not only what health benefit an extra GP would produce but also every other possible use of the money that an extra GP costs the NHS (and to have those figures in comparable units).

This is essentially the problem that NICE faces in evaluating the cost effectiveness of health technologies. NICE uses quality adjusted life years (QALYs) as the common measure of benefit and gets around the prohibitive need to measure marginal benefits of all other uses of healthcare spend by using a single (if slightly blurred and to an extent arbitrary) opportunity cost threshold of £20 000 to £30 000 cost per QALY to reach a decision about the worth of a particular health technology.

In principle, a similar approach could be used to plan the number of GPs “needed.” But in reality, we don’t know how many QALYs a GP produces, we don’t know how this figure changes as the number of GPs increases, and we don’t know whether a NICE type single cost effectiveness threshold is appropriate for such a complex health technology as a GP.

**Even without the data needed to make economically efficient decisions, decisions still have to be made**

### Numbers are flat

But even without the data needed to make economically efficient workforce planning decisions, decisions still have to be made. Since 2015, the number of GPs has remained fairly flat, just keeping up with increases in the population (figs 1, 2, and 3), but the total number of primary care staff has risen.

The current government has promised an extra 6000 GPs by 2024, which equates to a rough cost of around £2.4bn to the NHS (with additional training costs of around £1bn of taxpayers’ money). This followed a 2015 pledge to increase the number of GPs by 5000 by 2020—a target that was missed by around . . . 5000.

More GPs would improve access, reduce waiting times for appointments, and possibly increase consultation times—all benefits to patients. All good. But, given all the competing claims on finite NHS money, whether an extra 6000 GPs is what we “need” remains an open question.


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FEATURE

# Long covid in Europe

Clinics, primary care and studies. **Chris Baraniuk** looks at the range of responses around Europe

Maarte Preller leads a Facebook group for patients with long covid in Austria. It has nearly 1500 members so far. In September, Preller, and others like her across Europe, established a new network of patient associations, formed partly through social media websites, called Long Covid Europe. The group is demanding better research and treatment for the tangle of ongoing symptoms that afflict many people who have had covid-19.

A patchwork of small studies has given some indication of what long covid on the continent is like. In a study of 130 cases, 40% of patients reported "persistent fatigue" 60 days after their first symptoms, while 30% reported breathlessness. Another, of 143 patients in Italy, revealed 55% had three or more symptoms 60 days after they were discharged from hospital.

A preprint posted last month of an ongoing study of 70 000 Norwegian patients listed altered smell or taste, poor memory, fatigue, and shortness of breath as common symptoms in the country's first wave (in early 2021), while those infected from autumn 2021 onwards tended to mention muscle and joint pain more. The data suggest that symptoms were experienced for 11-12 months after infection in the first wave and for one to two months in the second.

**The waiting list for day clinics is incredibly high**
Danilo Buonsenso

**We are establishing the first post-covid healthcare unit in Spain**
César Fernández-de-las-Peñas

A World Health Organization policy brief published earlier this year found that surveillance of long covid was not happening routinely in European countries. There are few specialist clinics for the condition—access to such a service largely depends on where you live—and in many countries action seems to be limited to guidance and monitoring.

### WHO DEFINITION

WHO set a clinical case definition in October 2020 and added "post covid-19 condition" to the International Classification of Diseases codes used to "document or flag conditions that occur in the context of covid-19. In particular, the need for disambiguation between acute disease, late effects, or lengthy course led to the neutral formulation 'post-covid.'"[7]

"Post covid-19 condition occurs in people with a history of probable or confirmed SARS-CoV-2 infection, usually three months from the onset of covid-19 with symptoms that last for at least two months that cannot be explained by an alternative diagnosis. Common symptoms include fatigue, shortness of breath, and cognitive dysfunction, but also others, and generally have an impact on everyday functioning. Symptoms may be new onset following initial recovery from an acute covid-19 episode or persist from the initial illness. Symptoms may also fluctuate or relapse over time."

## The many faces of action

In the UK, there are more than 80 NHS run long covid clinics. Long covid services were highlighted as part of £6.6bn in new funding announced in March 2021 for the ongoing NHS response to the pandemic. Separately, the Scottish government has announced £10m in funding for local health boards to help patients who have long term symptoms.

In the European Union, specialist long covid clinics are reported to be operating in Belgium, France, Germany, and Spain, among others, but these rarely cater for more than a small part of the population.

In Italy, no government funded clinics for long covid have yet been established, according to Danilo Buonsenso at Gemelli University Hospital in Rome, although some hospitals have day clinics for following up patients who had been admitted to hospital during the acute stage of covid-19. A few of the day clinics include patients who have no history of hospital admission for covid-19, however, "the waiting list is incredibly high," Buonsenso adds.

In May 2021, the Italian government allocated around €28m for 2021 and €24m for 2022, to the "respiratory care" of covid-19 patients who had been admitted to hospital. In July, Italy's National Institute of Health (ISS) published a report on interim indications on long covid management, which refers to the need for specialist "post-covid clinics" as well as facilities linked to general practice and hospitals.

The French National Authority for Health (HAS) published official guidelines for the follow-up of long covid patients in February 2021, stating that most can be followed up through primary care.

This echoes an initiative in Belgium. Ann Li, Long Covid Europe's representative for Belgium,

CLAUDIA BENTLEY

told *The BMJ* in late 2021 that there was a primary care initiative from Belgium's National Institute for Health and Disability Insurance, ordered by the minister of health. "Some specialists, assurance companies, and professional associations from [the primary healthcare sector] are part of the initiative. The tool should be ready by the end of this year and should make it easier for our primary care workers to plan rehabilitation for long haulers. It will include a financial compensation plan for patients who visit psychologists, dieticians, or physiotherapists." The tool is now expected to launch in the spring of 2022, Li added later.

In Spain, two doctors recently received a grant of €1.8m from the Spanish government to open a clinic for long covid patients. One of the pair, César Fernández-de-las-Peñas, a physical therapist at Rey Juan Carlos University, told *The BMJ* that the clinic would be "the first post-covid healthcare unit in Spain" when it opens, possibly as soon as March 2022. They also received €1m funding for long covid research.

In Norway last summer, the then health minister, Bent Høie, asked hospitals to establish outpatient clinics for people with long covid. There are now four in total, one for each health region in the country. A spokesman for Norway's health directorate told *The BMJ* that there is a "national action plan" focusing on providing information about the condition for patients. "We have also developed guidance for healthcare workers on how to detect and treat people having post-covid symptoms," the spokesman says. He added, however, that the actual treatment delivered will depend on the clinic in question and that it is down to individual doctors to recommend a plan for each patient.

In neighbouring Sweden, Judith Bruchfeld, physician at Karolinska University Hospital, who leads a research project on long covid, helped the National Board of Health and Welfare to implement guidelines for follow-up. But support for care or further research has been unforthcoming. "Long covid is new and complex, and resources are needed," says Bruchfeld, adding that only seven out of 21 regions were able to run a long covid clinic.

Estonia is also providing guidance to healthcare workers. Heidi Alasepp, deputy secretary general on health at Estonia's ministry of social affairs, says, "Guidance and training has been given to GPs and specialists to raise awareness and provide advice on how to deal with long covid." There's no plan for specialist clinics, but the ministry has launched a covid-19 patient follow-up study that will cover a 12 month period.

**We have 2-3 patient enquiries for every appointment available**
Carmen Scheibenbogen

**Only 7 out of 21 Swedish regions can run a long covid clinic**
Nina Langeland

**Long covid is new and complex, and resources are needed**
Judith Bruchfeld

## Research gap

Carmen Scheibenbogen, professor of immunology at Charité University in Berlin, says she currently has two or three patient inquiries for every appointment available at her clinic.

"We need to put more effort into research," she says. "In Germany, at least, we don't have much funding at the moment for these post-covid syndromes." The German Ministry of Education and Research has allocated €6.5m to 10 projects investigating the condition. The French government's budget for long covid research is €2.2m, according to France24. By contrast, the UK has allocated nearly £20m in funding to research the condition.

Dominique Salmon-Ceron, an infectious disease researcher at the Hôtel-Dieu Hospital in Paris, told France24 in June that she had applied for funding four times in the past year, only to be declined by the health ministry.

In May, the European Commission said it would accelerate research into long covid and seek to develop treatments as part of its covid-19 therapeutics plan. But no further detail or specific funding has been revealed. A spokeswoman for the European Medicines Agency told *The BMJ* that "none of the treatments that are currently under the EMA's evaluation are intended for long covid."

Long Covid Europe's representatives say they want to see more patient focused research, and longer term follow-up to ensure that clinics have had a positive impact on patients, among other things. There is also a need for improved services for children with long covid, they say.

Bigger and more coordinated treatment trials could, in theory, help to enable that. Mark Toshner, lecturer in translational respiratory research at Cambridge University, who is involved in a UK trial of long covid treatments, says Europe—and the rest of the world—will be missing a trick if experiments with existing drugs or therapies as treatments aren't wrapped into formalised, international trials. He points out that thousands of patients need to be enrolled in studies like this to achieve useful results.

As Nina Langeland, professor of infectious diseases at the University of Bergen in Norway, put it, when it comes to long covid, "we're all lagging behind, that's my worry."

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