# this week

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ALEX HANNAM/EMPICS/PA

## Staff vaccine uptake varies with ethnicity

**The Leicester hospital trust said it was surveying staff to find out why they hadn't taken up the vaccine**

A hospital trust in the Midlands has said it is working to understand why some of its staff remain unvaccinated against covid-19, after preliminary findings from a study showed that uptake was especially low among doctors and ethnic minority staff.

The analysis, published as a preprint, looked at 19 044 staff at the University Hospitals of Leicester NHS Trust who had all been offered a vaccination since 12 December. As of 3 February, 65% (12 278) had received at least one dose.

However, this masked much variation, with 71% (8147 of 11 485) of white staff receiving the vaccine but only 59% (2843 of 4863) of South Asian staff and 37% (499 of 1357) of black staff. Overall, 36% of the trust's staff are from ethnic minority backgrounds.

Across staff groups, uptake was lowest among doctors (57%, 1721 of 3001) and highest among administrative and executive staff (73%, 2537 of 3465) and healthcare scientists (73%, 634 of 871).

The authors noted that doctors were the only staff group at the trust where ethnic minorities formed the majority and were younger than other staff groups so might perceive themselves as being at lower risk.

Study lead Kamlesh Khunti, professor of primary care diabetes and vascular medicine at Leicester University and a SAGE member, told *The BMJ* the trust had done a "fantastic" job of promoting vaccination to staff through social media and emails and by providing access seven days a week but added that building trust required time.

"Minority populations have been disproportionately affected by covid-19, they feel they haven't been engaged in the decision making, in the vaccination rollout, and some also feel that ethnic minority populations may not have been tested in the randomised control trials, which isn't true," he said. "I've experienced this with my own staff where there was vaccine resistance.

"We've spent quite a while talking to them about why this is important and gone over some of the misinformation that has been created, and eventually they have taken the vaccine. They just needed more information, and we need to be supportive of that and not stigmatise people."

The Leicester trust said that uptake had risen since the data were collected and it was also surveying staff who hadn't accepted the vaccine to find out why and what would help persuade them to take it.

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2021;372:n460

### LATEST ONLINE

- Mesh removal: skills accreditation planned for surgeons who work in new centres
- Cap on public sector exit payments lifted after BMA's legal challenge
- Report highlights "devastating impacts" of Trump on every aspect of US health

# SEVEN DAYS IN

## Covid study: Children less likely to report fever, persistent cough, or appetite loss

JORDI BOIXAREU/ZUMA/PA

**The latest findings from the ongoing React-1 study, which involves swab testing more than 150 000 randomly selected people in England each month, found that young people aged 5-17 with covid-19 were less likely than adults to report fever, persistent cough, or appetite loss than adults.**

**The researchers, looking at swab tests and questionnaires from June 2020 to January 2021, found children aged 5-17 were more likely to report headaches, while muscle aches were more common in people aged 18-54. They also found that around 60% of infected people did not report any symptoms in the week up to their positive test. Previously the UK Biobank SARS-CoV-2 serology study found that around a quarter of people with evidence of past infection had no symptoms, while 40% did not have one of the three symptoms used to determine whether someone needs testing: fever, persistent dry cough, or loss of sense of taste or smell.**

**The preprint authors concluded that more covid-19 cases in the community could be detected if additional symptoms such as chills, headache, appetite loss, and muscle aches were added to the UK testing criteria.**

Elisabeth Mahase, *The BMJ* **Cite this as: *BMJ* 2021;372:n408**

## Covid-19

### WHO: Lab escape theory is "extremely unlikely"

A team of scientists sent to Wuhan, China, by the World Health Organization to investigate the origins of the covid-19 pandemic effectively ruled out the hypothesis of a viral escape from the nearby Wuhan Institute of Virology. It was "extremely unlikely" that the laboratory's work was behind the outbreak that struck the city at the end of 2019, said Peter Ben Embarek, a Danish food safety and animal

disease specialist who chaired the investigation team. He added, "It isn't a hypothesis we suggest implies further study."

### WHO recommends Oxford vaccine to include over 65s

The World Health Organization recommended the use of the Oxford-AstraZeneca SARS-CoV-2 vaccine even in countries tackling new variants. WHO said that the vaccine could be used in people aged over 65, although some countries, including Germany, have advised against this. It added that spacing out the two doses of the vaccine, as the UK has done, made the vaccine more effective. The interim recommendations, from WHO's Strategic Advisory Group of Experts on Immunization, said that the Oxford-AstraZeneca vaccine's overall effectiveness was 63% (95% confidence interval 51.81% to 71.73%).

## Staff wellbeing

### BMA: staff are not properly protected from covid

Many thousands of doctors still do not feel fully protected from covid-19 in their place of work, a BMA survey found. In its latest poll of 8153 doctors and medical students, conducted on 3-5 February, just 2005 said that they felt fully protected from the virus in their place of work. The BMA called for better access to more protective face masks, for covid secure rest facilities, and for doctors to be able to take the leave they have not been able to take so far.

### Staff "need time to recuperate" from pandemic

The NHS must have a realistic and steady approach to resuming services disrupted by the pandemic, explicitly recognising the need for "exhausted" staff to recover, leaders said. In a letter to the prime minister the NHS Confederation noted that over 5000 more patients were in UK hospitals with covid-19 right now than at the peak of the first wave. The leaders called for sustained local mental health support for the NHS workforce beyond the end of March and for a long term, fully funded plan to increase staffing numbers.

### Anaesthetists report poor mental health

More than a third (34%) of the Royal College of Anaesthetists' members who responded to a college poll reported poor or very poor mental health caused by the pandemic, and almost a fifth (18%) were considering leaving medicine altogether. Since March 2020 nearly half of the college's members said that they had been redeployed to work in intensive care units throughout the NHS, including 60% of anaesthetists in training. Respondents said that they were exhausted and burnt out, some experiencing extreme stress.

## Long covid

### WHO calls on countries to offer more rehab

WHO urged countries to prioritise rehabilitation for medium and long term consequences of covid-19 and to gather information on "long covid" more systematically. It has produced a standardised form to report clinical data from individual patients after hospital discharge or after acute illness. It has also set up technical working groups to build a consensus on the clinical description of the "post-covid-19 condition" and to define research priorities.

## Oral contraception

### Desogestrel could be made available over the counter

The MHRA launched a public consultation on the proposed reclassification of two progestogen-only contraceptive pills containing desogestrel: Lovima and Hana 75 µg film coated tablets. Both are oral contraceptives for continuous use to prevent pregnancy in childbearing age. The consultation asks whether the products should become available over the counter without a medical prescription, in addition to being available on prescription from GPs and sexual health clinics.

# MEDICINE

## Fossil fuels

**Related deaths worldwide "were 8.7m" in 2018**

Air pollution linked to fossil fuels is responsible for around one in five deaths, more than double the number previously thought, a study published in the journal *Environmental Research* found. Researchers estimated that 8.7 million people worldwide died in 2018 as a result of breathing air containing particles from burning fuels such as coal, petrol, and diesel, which aggravate respiratory conditions, including asthma, and can lead to lung cancer, coronary heart disease, strokes, and early death.

**Liverpool School divests from fossil fuels**

The Liverpool School of Tropical Medicine became the latest UK institution to announce that it is dropping all fossil fuel investments from its portfolio. The campaign organisation People & Planet estimated the value of the investments at around £2.6m. David Lalloo, the school's director, said, "We could not ignore any longer the strong moral and global health arguments for completing this move when we can already see the impact of climate change on disease patterns in endemic countries."

## Drug approvals

**Scotland approves MS drug rejected by NICE**

A drug that can reduce the number of relapses in people with multiple sclerosis was approved for use in Scotland, despite a provisional decision by the National Institute for Health and Care Excellence to reject it in England and Wales. Ozanimod (Zeposia) is a daily tablet that has been shown in a two year clinical trial to reduce relapses by around 38% when compared with an existing treatment, injectable interferon beta (Avonex). It provides an option for people who find injectable treatments difficult to administer and avoids the need for patients to visit clinics, which would be advantageous in the current pandemic.


**Protesters in London demonstrate against fossil fuel companies**

**EC approves expanded use of esketamine**

Esketamine nasal spray, sold under the name Spravato, was approved by the European Commission as a short term treatment for adults with a moderate to severe episode of major depressive disorder. The spray, which must be given alongside an oral antidepressant, has been approved for use in situations deemed a psychiatric emergency, to reduce depressive symptoms rapidly. The treatment was initially approved by the EC in December 2019 but only in combination with a selective serotonin reuptake inhibitor or a serotonin and noradrenaline reuptake inhibitor, for adults living with treatment resistant major depressive disorder.

Cite this as: *BMJ* 2021;372:n444

## COVID DEATHS

People with a disability made up six in 10 (59.5%) of all deaths involving covid-19 up to 20 November 2020, accounting for 30 296 of 50 888 deaths

*[Office for National Statistics]*

## SIXTY SECONDS ON . . . HOTEL QUARANTINE

**IS THIS A NEW COVID THEMED HOTEL?**

You could put it like that. Since 15 February UK residents returning to England having visited a "red list" country in the previous 10 days have had to quarantine in a hotel for 10 days.

**PLENTY OF ROOM?**

That's what the government is saying. It has struck deals with 16 hotels so far, providing 4963 rooms, with a further 58 000 on standby.

**WHAT'S THE COST?**

The charge for a single adult is £1750 for 10 days and 11 nights, £650 for an additional adult, and £325 for a child. They will get three meals a day, fruit, tea and coffee, soft drinks, and water, and two covid-19 tests.

**AND ACCESS TO THE SPA?**

Ah, no. Most people won't be allowed out of their rooms. Only in exceptional circumstances will they be allowed outside to exercise and then will be escorted and have to wear a face covering. Families with children and people with specific medical needs will be prioritised. Let's hope the wifi is good.

**WHICH ARE THE RED LIST COUNTRIES?**


Brazil, South Africa, United Arab Emirates, Uruguay, Venezuela, and Zimbabwe are among the current 33 countries on the list.

**WHAT RECEPTION HAS THE PLAN HAD?**

One potential flaw in the plan is that most other countries, including Scotland, with such hotel quarantine rules include all international travellers, not just those from a small number of countries. There are concerns that people could travel via another country and stay there for 10 days before re-entering the UK, to avoid the large fee.

**THIS COULD BE HEAVEN OR THIS COULD BE HELL**

Even highly regarded systems have had their problems. In Australia, a recent cluster of 13 cases of covid-19 have been linked to a quarantine hotel in Melbourne, which led to a five day lockdown being imposed in the state of Victoria. But overall the consensus seems to be that quarantine restrictions are generally effective at preventing transmission.

Elisabeth Mahase, *The BMJ*

Cite this as: *BMJ* 2021;372:n446

# NHS reform must not be rushed during pandemic, say leaders

The government's proposed reorganisation of the NHS in England must not be rushed through while "physically and emotionally exhausted" staff are dealing with covid-19, the BMA has warned.

Its chair of council, Chaand Nagpaul, said the NHS was facing the greatest backlog of care ever, on top of covid-19. Dealing with this would require "significant new resources and an immediate action plan," and investment must not be diverted to the reorganisation, he said.

### White paper

The government's draft white paper setting out proposals for reorganising the NHS included plans to reverse major parts of former health secretary Andrew Lansley's Health and Social Care Act 2012, including formally abolishing requirements to do with competition and competitive tendering in the NHS, and shifting control and decision making power back to Whitehall.

**Investment needed for backlog mustn't be diverted to reorganisation**
Chaand Nagpaul

The government also plans to replace CCGs with the new larger statutory "integrated care systems" (ICSs) that will manage local health systems. Substantial power will be shifted away from NHS England back to the health secretary, who will be given direct control over each local ICS, NHS England, and NHS foundation trusts.

### Social care "left behind"

Nagpaul also warned that the end of rules on competition must not lead to contracts being handed to suppliers without scrutiny, citing the "devastating impact" of this happening during the pandemic in the case of PPE and test and trace services. "This is an opportunity to roll back on the expensive and inefficient use of the private sector, not increase it," he said.

Rehana Azam (below), national secretary of the GMB, which represents health and social care workers, said social care was still being left behind. "The prime minister promised 18 months ago to 'fix' social care within 12 months of being in government. We still have nothing from them other than a flimsy pledge to set out these reforms 'this year,'" she said. The government said it would put forward proposals on social care reform later this year.


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Elisabeth Mahase, *The BMJ*
Cite this as: *BMJ* 2021;372:n431

# NHS trusts deny restricting staff access to PPE

**EXCLUSIVE**: A BMJ investigation shows a lack of transparency in how trusts protect staff in the pandemic

NHS trusts have denied issuing instructions to staff to restrict their use of personal protective equipment during the pandemic, despite hundreds of reports from doctors that trusts did so last year.

Trusts also denied that they had issued warnings to staff who raised concerns about PPE supplies being inadequate, despite doctors reporting this had happened, the *BMJ* investigation found.

Many trusts said that they had reminded staff periodically of the need to adhere to locally adopted national guidelines from national organisations such as Public Health England (PHE) over PPE specification and to use PPE wisely or appropriately.

The UK parliamentary public spending watchdog reported this week that the government had wasted hundreds of millions of pounds on poor quality and unusable PPE that left frontline staff insufficiently protected.

Only one trust admitted that deaths from covid-19 among its staff were being investigated by the Health and Safety Executive (HSE). Yet over 600 NHS staff have died from covid-19, and the HSE has said that it holds data on closed or open investigations at an undisclosed number of trusts.

### Freedom of information requests

*The BMJ* sent freedom of information requests to 130 NHS trusts in England asking about their policies on covid-19 PPE in 2020. Of the 66 trusts that replied, 60 denied issuing instructions to restrict PPE use, five refused to respond to the freedom of information request, and one said it did not hold the information requested.

Of the trusts that responded, one—Guy's and St Thomas' NHS Foundation Trust—confirmed it had issued an informal warning to one staff member over PPE use, and one—Chelsea and Westminster Hospital NHS Foundation Trust—said it had warned a staff member over PPE related comments made on social media.

Last year, however, the Doctors' Association UK, a not for profit medical membership organisation, logged over 1500 reports from members around the country highlighting inadequate access to PPE, together with a further 220 reports about frontline doctors being warned, threatened, disciplined, or made to feel bullied or unsupported for raising issues about PPE.

# People with mild asthma won't get early vaccination, charity claims

People with mild asthma won't be included in the sixth priority group for covid-19 vaccination, it has emerged.

Those left out of early vaccination plans include people with well controlled asthma who take regular inhaled steroids, and who would normally receive a request to come forward for flu vaccination each year. But others, including people who have been admitted to hospital as a result of their asthma symptoms, will be included.

Asthma experts told *The BMJ* there was no evidence to indicate that people with mild asthma were at a greatly increased risk of hospital admission or death because of covid-19. But the news has sparked confusion and anxiety among patients, given that NHS guidance has described people with a non-severe form of asthma as "clinically vulnerable," and Public Health England stated in January that people who

*The BMJ* sent a separate freedom of information request to NHS England asking if it had issued any communication to trusts from 1 March to 30 September 2020 about whether or how to discuss PPE specification, qualities, supplies, or availability in mainstream or social media and whether it had vetted, vetoed, or approved any communications from NHS trusts on these issues. "NHS England did not issue any communications to trusts regarding their own communication on PPE," it responded.

But senior NHS sources, who did not wish to be named, questioned this, telling *The BMJ* that NHS England had vetted and vetoed covid related communications from trusts during the pandemic.

### Investigating staff deaths

In response to *The BMJ*'s inquiry, only one trust, Pennine Acute Hospitals NHS Trust, admitted being under investigation by the HSE for covid-19 deaths among staff.

The trust said that it reported fewer than 10 staff deaths to the HSE from 1 May to 30 November 2020. "The HSE received the trust's investigation report and to date have taken no further action," the trust said.

The HSE admitted in response to a separate freedom of information request from *The BMJ* that it held information relating to investigations at an undisclosed number of trusts over staff covid deaths and sickness. But it would not disclose the total number of trusts investigated, would not say whether those investigations were closed or open under the freedom of information cost exemption, and was not prepared to name the trusts involved.

Katie Sanderson, spokesperson for the Doctors' Association UK, said that the process of investigating staff deaths had lacked consistency. "We know that the appalling death toll of 882 frontline health and social care workers will continue to rise if no action is taken," she said. "The investigation of these deaths has been piecemeal and inconsistent.

"We owe it to those who have lost their lives to learn from the circumstances surrounding their deaths, and we should be aiming for a situation where no healthcare workers contract covid-19 at work."

### Adhering to guidelines

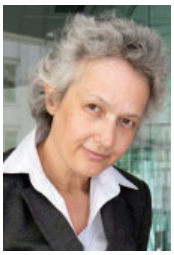
Chris Hopson, chief executive of NHS Providers, said that trusts were led on PPE use by experts at PHE. He said, "We know that the national guidance is based on careful, and full, expert consideration of all the most up-to-date scientific evidence and is reviewed in light of any changing circumstances.

"Trust leaders are deeply aware of staff concerns around PPE and will always do everything they can to listen carefully to, and meet, those concerns, including reassigning staff [who are] at high risk or uncomfortable with national guidance wherever they can."

But, in response to *The BMJ*'s findings, Jenny Vaughan, Doctors' Association vice chair and NHS consultant, said, "We do not feel that the PPE currently mandated by PHE offers healthcare workers an acceptable level of protection, and we are calling for the guidance to be urgently revised to ensure that all staff exposed to covid-19 have access to high level respiratory protection.

"There is also a clear lottery among hospital trusts: some are defying Public Health England rules to give their staff the protection they deserve due to concerns about hospital spread of the virus."

**There is a clear lottery among hospital trusts: some are defying PHE rules**
Jenny Vaughan



A spokesperson for the Department of Health and Social Care said, "As the NAO recognised, during the pandemic all of the NHS providers audited were always able to get what they needed in time."

David Oliver, Reading

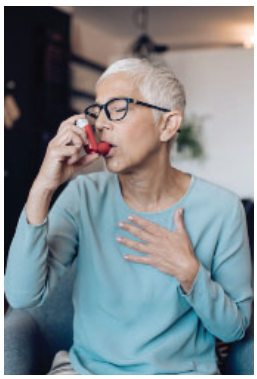
DAVID OLIVER, p 277

Cite this as: *BMJ* 2021;372:n442

**LAST YEAR** the Doctors' Association UK . . . logged over **1500** reports from members around the country highlighting inadequate access to PPE

have asthma and who use a steroid inhaler would be offered the vaccine.

In December the charity Asthma UK tweeted that it understood that people aged 16 to 64 with asthma would be invited for covid-19 vaccination in the UK as part of priority group 6 if they had previously been prescribed steroid inhalers. But in an update published last week the charity said people with well controlled asthma would not, in fact, be considered eligible. Group 6 vaccination will begin as early as March.



**The lack of information is confusing for many people with asthma**
Sarah Woolnough

In a statement Sarah Woolnough, chief executive of Asthma UK and the British Lung Foundation, said greater clarity was urgently needed. "The information we previously shared about group 6 was based on communication with the Department of Health and Social Care, who advised that the people included in group 6 would be those who are offered an annual free flu vaccine.

"The lack of information is causing confusion for many people with asthma and needs to be clarified urgently," she said.

The covid-19 "green book" published by Public Health England in November defines who is eligible for vaccination. It states that only those people with asthma who require regular systemic steroids (oral, non-inhaled steroids) or who have a history of hospital admission would be considered eligible for group 6 vaccination but says these definitions are "not exhaustive."

Asthma UK said greater clarity was needed on which people would be considered part of this group, in terms of how many courses of steroids or how many hospital admissions would make someone eligible.

Chris Baraniuk, Belfast

Cite this as: *BMJ* 2021;372:n430

NEWS ANALYSIS

# Covid-19: Are cloth masks still effective?

In light of new, more transmissible variants of SARS-CoV-2, **Elisabeth Mahase** examines what kinds of mask the public should be wearing, and where they should be worn

### Are cloth masks still recommended?

Early in the pandemic, major problems in the global supply of medical grade masks meant the public was asked to avoid using these so that stock could be used to protect healthcare workers. At this point, it was recommended that the public wear cloth masks and even to make them out of household items such as T shirts.

Many people are still wearing cloth masks, but as the worldwide supply of medical grade face masks has expanded, it has been argued that some members of the public should wear more protective masks such as surgical masks. This argument has been strengthened by the emergence of more transmissible variants of SARS-CoV-2, in response to which some countries have tightened guidance on what types of masks are allowed.

In France, homemade masks and some shop bought cloth masks have now been banned, after the president of the government's scientific committee, Jean-François Delfraissy, said that the new variants had "completely changed the game." Only three types of masks will be recommended in France: surgical (which filter 95% of 3 µm particles), FFP2 (which filter 94% of 0.6 µm particles), and fabric masks made to category 1 standards (those that filter 90% of particles).

Austria has gone a step further, making FFP2 masks mandatory in indoor public spaces and sending out free packs of these masks to all residents aged over 65 and to low income households. Like the UK, the country is currently in its third national lockdown.

Germany has made medical masks mandatory in supermarkets and on public transport. London mayor Sadiq Khan wants to introduce a similar requirement on the capital's public transport. Former health secretary Jeremy Hunt has also called for FFP2 respirator masks to be made compulsory on public transport and in shops.

On 1 December WHO updated its advice to recommend medical masks for people at risk of serious covid-19 illness and for people aged over 60. But this was made before it became clear how the new variants affected transmission. Commenting on the types of cloth mask the public should wear, a WHO spokesperson told *The BMJ*, "A reusable three layer fabric mask is advised. The filtration, breathability, and fit of the mask are important. If the mask is produced at home, WHO advises an inner absorbent material such as cotton, a non-absorbent fabric such as polyester outside, and a middle filter layer, such as non-woven spunbond polypropylene."

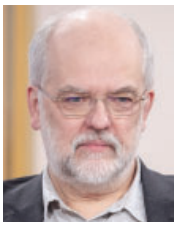
The spokesperson added that respirators and medical masks "continue to be in short supply for health workers."

### Are two masks better than one?

Anthony Fauci, chief medical adviser to US president Joe Biden, told the US *Today* television programme that "if you have a physical covering with one layer, you put another layer on it, it just makes common sense that it would be likely to be more effective."

New research from the CDC supports this. It has reported that transmission can be reduced by up to 96.5% if both an infected person and an uninfected person wear tightly fitted surgical masks or a cloth mask together with a surgical mask.

**If you have one layer, and you put another layer on it, it is just common sense that it would be likely to be more effective**
Anthony Fauci



**I think we would've done a lot better last year if we had actually paid more attention to WHO guidance than if we tried to make it up ourselves**
Paul Hunter

But a WHO spokesperson, commenting in the hours before the new CDC guidance emerged, told *The BMJ* that it was not currently recommending double masking. "Based on the currently available information on the spread of variants of concern, WHO is maintaining its advice on the use of masks. We will continue to review evidence as it becomes available."

### Should the public be wearing masks outdoors?

The UK Scientific Advisory Group for Emergencies (SAGE) said, in light of the UK variant B.1.1.7, that "using face coverings in a wider range of settings where people could be asymptomatic and may be in close proximity (less than 2 m)" should now be considered.

Its paper said, "Transmission in outdoor settings where people are distanced is likely to still be very low risk. However, it remains the case that if people are in close proximity for extended periods in an outdoor setting, there is a potential risk of transmission from the higher concentrations of respiratory particles near to an infected person. It is possible that this close range risk is greater with the B.1.1.7 variant (low confidence)."

The Department of Health and Social Care did not respond when *The BMJ* asked it whether the UK government was considering recommending masks outdoors.

Paul Hunter, professor in medicine at Norwich Medical School and one of the reviewers for the WHO mask

guidance, said the advice may depend on the situation. "If you're outside in a big queue, and people aren't socially distancing around you, I would put a mask on. But if I'm just walking on a not overly busy high street [or] going for a walk around a village I wouldn't wear a mask," he said.

Hunter added that people should be careful not to get their mask wet, especially if they are then going to go indoors wearing the same mask. He explained, "If that material gets wet, you can't breathe through the material, and the mask then loses much of its effectiveness. So if it rains and you've got a mask on, it becomes pointless because you can't breathe through it. If it's cold outside and your breath wets the mask, as it will do, it becomes much less useful."

WHO has recommended that masks be worn outdoors when there is "known or suspected community or cluster transmission" and when physical distancing cannot be maintained.

### Does the UK's mask policy need updating?

Despite the changes in other countries and calls from within the UK to update policy, a spokesperson for the Department of Health and Social Care—which does not consider cloth masks to be personal protective equipment (PPE)—told *The BMJ*, "We have no plans to make it mandatory for the public to wear PPE. The most important and effective actions members of the public can take for protection is to wear a face covering where necessary, staying at home unless leaving is absolutely necessary, and maintaining a 2 m social distance when in public.

"We are clear that PPE should be reserved for frontline health and social care workers and is not recommended for use in retail and hospitality settings or by the public."

But Hunter said the government should be reviewing its policy. He told *The BMJ*, "I would disagree with that. I think we would have done a lot better last year if we had actually paid more attention to WHO guidance than if we tried to make it up ourselves."

Many medical bodies, including the BMA and the Doctors' Association UK, have also been calling for PPE guidance for healthcare workers to be reviewed .

A WHO spokesperson told *The BMJ*, "Based on evidence gathered from scientists, public health professionals, and national health authorities to date, the variants appear to be more transmissible, but there does not appear to be a change in the way that they are transmitted.

"This is why our advice at the moment is to stress the importance of adherence to a combination of measures that are known to prevent the spread of SARS-CoV-2: practising physical distancing, wearing a mask, practising respiratory hygiene, performing hand hygiene, avoiding crowded spaces, and ensuring adequate ventilation."

### Is there any new evidence on mask wearing by the public?

US researchers recently looked at the impact of state-wide mask requirements on new cases per 100 000 population per day from 1 January 2020 to 24 October 2020. They reported that, after adjusting for interstate differences, states that adopted mask requirements early saw the strongest effects on numbers of new cases when compared with those that did not adopt such measures. The effect was smaller but still "clearly protective" when comparing early adopter states to late adopters.

Meanwhile, a preprint study tested the effectiveness of different face masks and compared this with the perceptions of protection among 710 US residents. The researchers reported that fabric face masks "blocked between 62.6% and 87.1% of fine particles, whereas surgical masks protected against an average of 78.2%. N95 masks blocked 99.6%."

But they said that survey respondents tended to "underestimate the effectiveness of masks, especially fabric masks." The results indicated that "fabric masks may be a useful tool in the battle against the covid-19 pandemic and that increasing public awareness of the effectiveness of fabric masks may help in this endeavour," the authors concluded.

Elisabeth Mahase, *The BMJ*

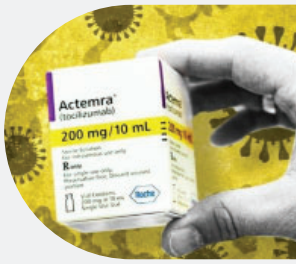
Cite this as: *BMJ* 2021;372:n432

# Arthritis drug cuts death rate in hospital patients with covid

The anti-inflammatory drug tocilizumab improves survival of patients who have been admitted to hospital with covid-19, shortens their time to discharge, and reduces the need for a mechanical ventilator, results from the Recovery trial show.

For every 25 patients treated with tocilizumab, one additional life would be saved, said the researchers from Oxford University.The benefits were in addition to those seen with the steroid dexamethasone, which is now standard care as a result of earlier positive results from the Recovery trial.

Results in November showed that tocilizumab improved outcomes in critically ill patients in intensive care. These latest results show that the drug can also benefit patients who are less severely ill on general wards.




THE BENEFITS WERE IN ADDITION TO THOSE SEEN WITH DEXAMETHASONE, WHICH IS NOW STANDARD CARE

The study, published as a preprint, compared 2022 patients randomised to receive tocilizumab and 2094 patients who had usual care. All the patients had evidence of inflammation and required oxygen with a simple face mask, non-invasive ventilation, or mechanical ventilation. Most (82%) were also taking a systemic steroid such as dexamethasone.

The researchers said treatment with a combination of dexamethasone and tocilizumab reduced mortality by about one third among patients who needed simple oxygen and nearly one half among those needing mechanical ventilation. Tocilizumab also increased the probability of discharge within 28 days, from 47% to 54% (rate ratio 1.23 (95% confidence interval 1.12 to 1.34)) and reduced hospital stay by five days.

Martin Landray, professor of medicine and epidemiology at the University of Oxford and joint chief investigator, told a Science Media Centre briefing that when his team started the Recovery trial they thought it unlikely that one drug alone would make a difference. He explained that a combination approach can have a big effect.

The evidence on tocilizumab from previous trials has been inconclusive. But the Recovery trial is four times as large as all the other trials combined and as a result the benefits were now clear cut, Landray said.

Jacqui Wise, London

Cite this as: *BMJ* 2021;372:n433

**THE RECOVERY TRIAL RESULTS SHOWED**

**596 (29%) of the patients in the tocilizumab group and 694 (33%) in the usual care group died within 28 days, giving a 14% reduction in relative mortality (rate ratio 0.86 (95% confidence interval 0.77 to 0.96)).**

THE BIG PICTURE

# Bruises detail abuse directed at healthcare staff

Artist Nathan Wyburn (pictured) has used examples of verbal abuse directed at NHS staff to create this image of a health worker whose face appears bruised from wearing personal protective equipment.

He made the piece from a series of stamps embossed with the actual words and phrases used in abuse messages directed at NHS workers on social media during the pandemic, including "lazy," "ignorance," "don't care," "Shipman," "shill," and "lies."

Wyburn said, "These select phrases are just a tiny amount of the words used, given to me by healthcare professionals."

The work, entitled *Words Bruise*, is now on display at the Wales Millennium Centre and was created in partnership with Cardiff & Vale Health Charity, the NHS charity of the Cardiff and Vale University Health Board.

Tom Moberly, *The BMJ*

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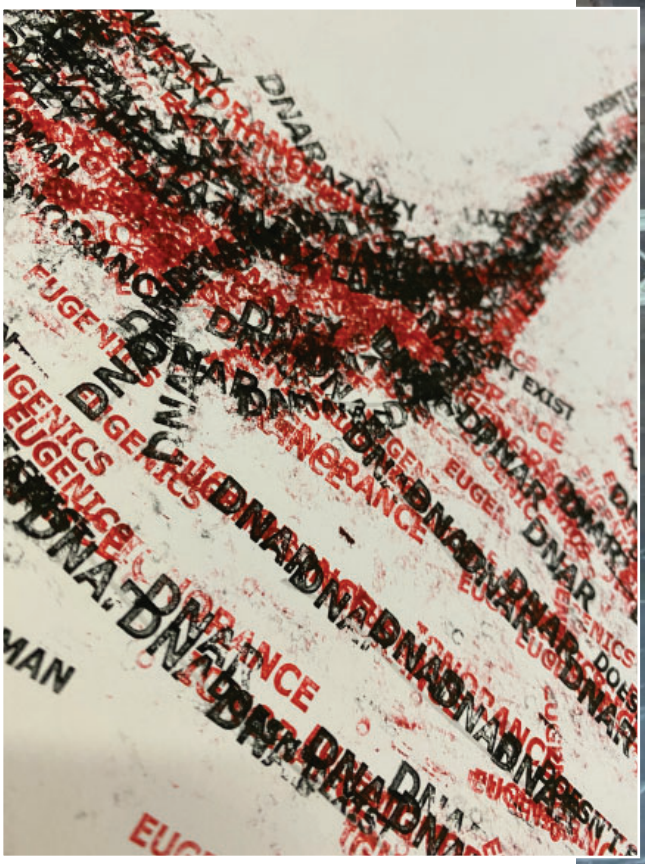


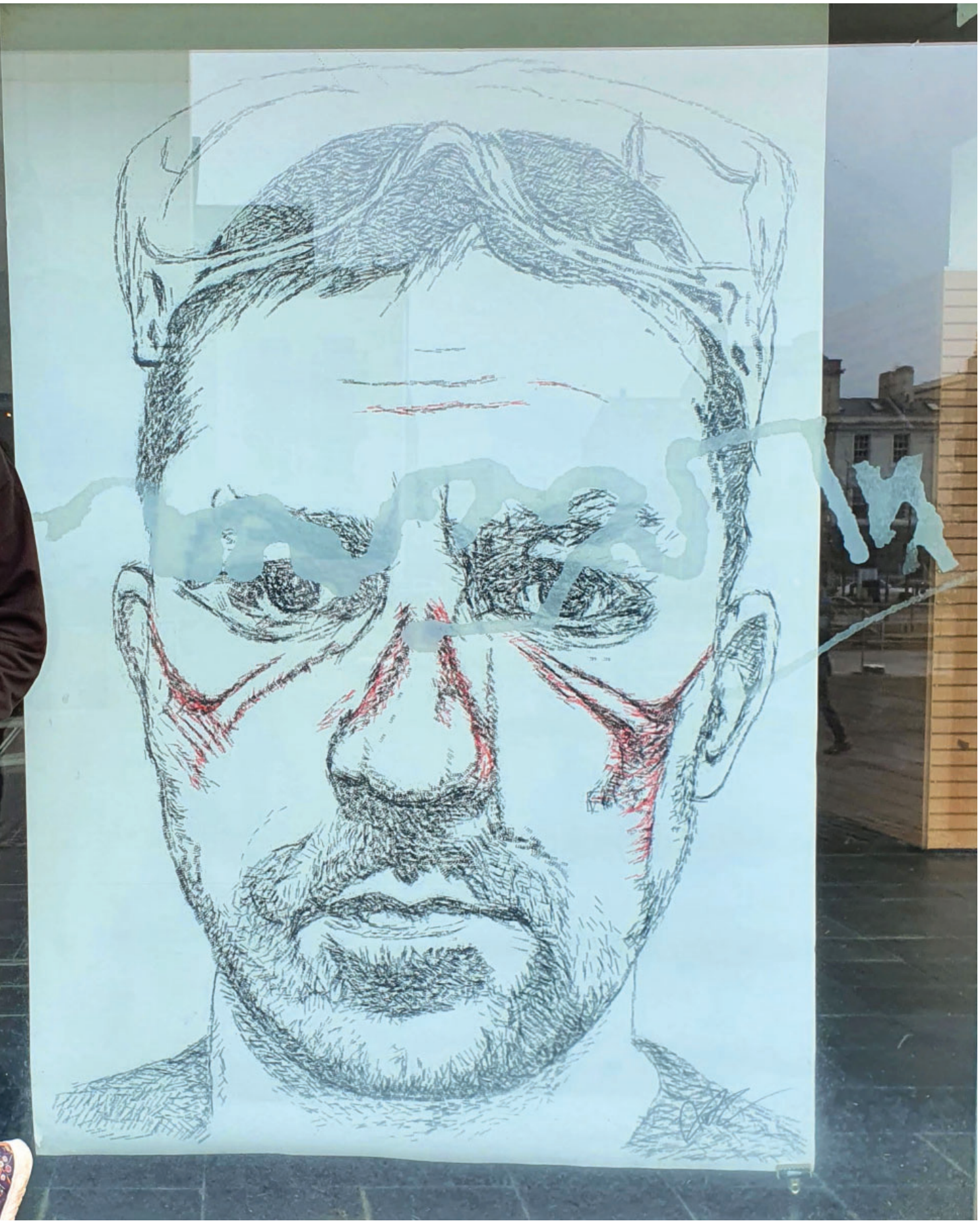

EDITORIAL

# Cervical cancer screening in older women

Should women over 65 be offered a catch-up HPV test?

Most women in the UK aged over 65 years have never had a test for human papillomavirus (HPV). On present trends, about 5000 of these 6.5 million women will die from cervical cancer over the next 35 years.

The NHS cervical screening programme prevented an estimated 5000 deaths a year[1] by offering regular cytology up to age 65. HPV testing of cervical samples has now replaced cytology for primary screening in many countries, including the UK. In Australia this was accompanied by an increase in the upper age for screening to 74,[2] and in Denmark all women born before 1948 have been offered an HPV test.[3] But in England, where half of all cervical cancer deaths are now among women aged 65 years or over, screening is still stopped at age 65.

The NHS programme justifies not screening women beyond age 64 because "it is highly unlikely that women over 64 who have been regularly screened will go on to develop the disease."[4] The proportion who will develop cervical cancer at age 65-84 is about one in 1200 among women who have been regularly screened and 1 in 200 among inadequately screened women.[5] These are not negligible risks, and there is now evidence that more than half these cases and a larger proportion of deaths after age 65 might be prevented by one sensitive HPV test.

The long term cancer risk is much lower after a negative HPV result than after a negative cytology result.[7] Women currently being discharged from the screening programme with a negative HPV result will therefore be at extremely low risk of developing cervical cancer. However, lifelong risk will be substantially higher in women who were screened only with cytology and exited the programme before 2019 with normal cytology results.

**Half of all cervical cancer deaths are now among women aged 65 years or over**

## Strong case

There is a strong case for offering these women a "catch-up" HPV test to detect the small proportion who are HPV positive (4% of women aged 69 or over in the Danish catch-up programme[3]).

Most cervical cancers in older women are likely the result of infections acquired many years previously. A large proportion of older women who are HPV positive may already have subclinical precancerous cells.

The ability of a single HPV test to detect these latent precancerous cells depends on test sensitivity. In the Artistic trial, five of the samples taken at baseline from the 13 women who were later diagnosed with cancer gave negative results with the standard HPV Hybrid Capture 2 assay, but only one was negative when the samples were reanalysed with a PCR assay.[12]

The population benefit of a "catch-up" HPV test will depend on engaging and educating inadequately screened women,[13] whose response rate may be low.[8] The risk of cancer among women who have not been screened since age 50, many of whom have never been screened, is about six times higher than the risk among adequately screened women.[5] Conventional screening in primary care involves speculum examination which can be painful in older women. Vaginal self-sampling, which yields higher response rates[14] and has similar sensitivity for HPV detection, is likely to be the optimal testing strategy for women over 65.[15]

Women testing positive for HPV could either be referred straight to a gynaecologist or asked to provide a repeat self-sample 12 months later to identify those with persistent infection, the strongest predictor of underlying disease.[16 17]

Colposcopy and biopsy are difficult in older women as most do not have a fully visible transformation zone. Current NHS guidelines do not recommend cone biopsy or large loop excision in women with persistent HPV but no apparent abnormality indicated by cytology or colposcopy. This does not seem appropriate given the low sensitivity of cytology seen in two Swedish studies in older women.[14 18] A qualitative review by Danish researchers reported that older women with persistent HPV, for whom the associated increased risk of preterm birth is no longer relevant, preferred a diagnostic cone biopsy to continued surveillance even if this proved to be overtreatment.[19]

Half the cervical cancer deaths in England now occur in women aged over 65 years. Studies in women aged up to at least 80 should now be done to determine whether self-sampling is the easiest and most cost effective option for HPV testing.

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EDITORIAL

# Growing backlog of planned surgery

Millions of people are now waiting and worried

Covid-19 continues to have a severe effect on planned surgery in the UK, and dealing with the resulting backlog is a critical concern for the NHS. Data from NHS England show that the number of patients awaiting treatment hit a record high of 4.52 million in December 2020,[1] with the number of referrals well below 2019 levels. The same data suggest that roughly 2.3 million people are currently waiting for surgical care.

The number who have already waited more than a year for treatment has reached 162 235, a 170-fold increase from 953 in December 2019, and growth shows no sign of slowing. Trauma and orthopaedics, oral surgery, and plastic surgery seem particularly affected, but even cancer surgery has been delayed: the percentage of patients having cancer surgery within one month of the decision to treat dropped from 92% to 89% over the same period.[2]

Why have waiting times increased so much? Solid evidence is not yet available, but several contributors are likely. Operating theatres and outpatient clinics were closed as they became needed to treat patients with covid-19 during the first wave in 2020. Surgical staff, particularly junior surgical and nursing staff, were redeployed to provide cover for extra beds occupied by patients with covid-19 and for staff unable to work because they had covid-19 or were isolating.

The procedures put in place to protect patients and staff mean that seeing and treating patients in hospital takes much longer than it did before the pandemic.

The NHS has enjoyed substantial public, political, and media support during the pandemic. However, the historical lack of spare capacity has arguably resulted in poor resilience and weakened its ability to cope with a stressor such as covid-19.

MARK THOMAS

**Patients want information that is easy to find, transparent, consistent, timely, and understandable**


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James A Smith, postdoctoral scientist

Jenny Camaradou, patient representative

Daniel Prieto-Alhambra, professor of pharmaco and device epidemiology, Botnar Research Centre, Oxford


Although many patients have been understanding and are waiting patiently for the situation to improve, they have concerns about delays and the lack of information about expected new timelines.

### Better communication

Patients also want reassurance that they will be safe from covid-19 when they are admitted. Governments must develop communication strategies that identify patients' concerns and misconceptions about risk of infection and provide information that patients can trust. Individual differences in perception of risk are key to effective communication, as is open acknowledgment of uncertainty.

Patients want information that is easy to find, transparent, consistent, timely, and understandable so that they can make more informed decisions about their treatment and contingency plans.

Predictive modelling suggests that around 28 million operations were cancelled or postponed globally during the peak 12 weeks of the first wave[3]; this number will surely increase as the pandemic progresses. The ability to clear the resulting backlog will depend on the resources available in different countries, and will be a serious challenge for many. In the US, one study estimated that a backlog of at least one million orthopaedic surgical cases would remain two years after elective surgery stopped being deferred because of covid-19.[4]

As the huge task of clearing the backlogs begins, surgical teams must be provided with appropriate resources, facilities, and both professional and mental health support.[5,6] One promising route to increasing the volume of surgical care in the UK is so called "green pathways"—covid-free areas of hospitals where planned surgery can continue with substantially reduced risk to patients and staff.

New ways of working with remote consultations, community diagnostic hubs, increased use of the independent sector, and regional treatment hubs with ring fenced resources for planned care are already emerging in many areas.[7] One concern, however, is that extra capacity in the independent sector is concentrated in the south east and not where it is most needed.

Some regions are increasing activity by pooling waiting lists, prioritising cases, and removing patients from waiting lists who no longer need surgery. Many patients have had to accept compromises, including reduced choice about where and by whom they are treated. Clear and regular communication with patients regarding local plans and the likely timescale for their surgery remains critical.

Additional resources and greater capacity will not be enough. Profound changes to the way we work will be also be required, along with reform to create a leaner, more cost effective, and more flexible NHS able to make nimble decisions in response to crises such as covid-19.


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COVID-19

# How the UK vaccine rollout has delivered success, so far

**Chris Baraniuk** explains why the programme is a global front runner and describes obstacles ahead

It looks like a world beating performance—the UK has administered more covid-19 vaccine first doses per 100 people (19) than any other nation of comparable population size.

At the time of writing, 12 million people—roughly as many as the entire population of another front runner, Israel—have received their first dose of either the Pfizer-BioNTech or Oxford-AstraZeneca vaccine. Daily reports indicate that, on some days, more than half a million people have received a dose.

### Head start

The UK became the first country in the world to approve a covid-19 vaccine for emergency use in early December. But the groundwork was laid nearly a year earlier, when the Department of Health reportedly began planning a mass vaccination programme before confirmation of the first case in the UK.

Just five months later, in June, the UK signed a contract for 100 million doses of the Oxford-AstraZeneca vaccine. A separate deal securing access to 30 million doses of the Pfizer-BioNTech vaccine was announced the next month. This was increased to 40 million doses in October. "They got ahead on ordering vaccines and they've got [the doses in hand] to give," says Simon Clarke, associate professor in cellular microbiology at the University of Reading. "It's as simple as that."

Pascal Soriot, AstraZeneca's chief executive, has said the early orders were a reason why deliveries to the UK have not been held up in the same way as those to the EU. Batches of vaccine must be made up months in advance, and because cell cultures are used in the manufacturing procedure, the exact yield is unknown until each process is complete. The UK's deal was struck three months before the EU's, so its batches were set in motion earlier and separate to those for the EU, the yield of which turned out lower.

The UK's hefty orders were made in part thanks to the 2011 film *Contagion*. Health secretary Matt Hancock was spooked by the film's ending, in which countries ravaged by a respiratory disease fight for a limited number of vaccine doses. He insisted on ordering 100 million Oxford-AstraZeneca doses despite receiving advice to order 30 million.

The UK government's vaccines taskforce, set up by chief scientific adviser Patrick Vallance and led by venture capitalist Kate Bingham, was established to help accelerate the acquisition and distribution of doses. Bingham's appointment attracted scrutiny but she has a track record in the biotech industry and long running business connections to the likes of BioNTech.

**UK vaccine orders**

| Manufacturer | Doses ordered (millions) | Status |
|---|---|---|
| Pfizer-BioNTech | 40 | Delivery started |
| Oxford-AstraZeneca | 100 | Delivery started |
| Moderna | 17 | Approved for use. Deliveries due spring 2021 |
| Novavax | 60 | Clinical trials ongoing |
| Janssen (Johnson & Johnson) | 30 | Deliveries due second half 2021, pending MHRA approval |
| Sanofi Pasteur-GSK | 60 | Clinical trials ongoing |
| Valneva | 100 | Clinical trials ongoing. Deliveries potentially across 2021 and 2022 |
| CureVac | 50 | Phase III trials |

Since May 2020 the taskforce, experts in science, technology, and logistics, has secured orders from seven vaccine manufacturers—a total of 400 million doses or enough to vaccinate the UK population three times over. In an interview with *La Repubblica* Bingham said her team placed emphasis on sourcing vaccines that could be used as early as 2020. "We weren't choosing vaccines on the basis of being cheap [but on] being effective and available quickly," she said, adding that they favoured Pfizer-BioNTech over Moderna because of the supply chain to European countries, knowing that initial stocks would be limited. Still, it was a gamble at a time when no vaccine had been found to be effective against the virus.

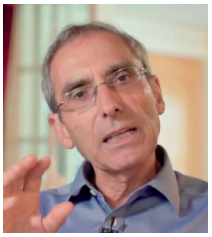
"Our upfront cost was £900m. We were willing to write off that money, which was largely for manufacturing, if those vaccines failed," Bingham, who has stepped down from the taskforce, told the Italian newspaper.

By the autumn, clinical trial data indicated that both the Pfizer and AstraZeneca vaccines were highly effective at preventing symptomatic disease. Moderna also reported positive results, prompting the UK to increase its order from five million to 17 million doses.

### Rollout

From sports halls to cathedrals, buildings around the UK have been converted into vaccination sites, alongside hospitals and general practices. Eventually, hundreds of high street pharmacies will join the effort. Large and small vaccination sites are needed, says George Kassianos, national immunisation lead at the Royal College of General Practitioners. "As long as the vaccine supply flows freely to the centres, we will vaccinate even more than the prime minister promised," he says.

According to the government, everyone in England now lives within 10 miles of a vaccination centre. A small number of people living in remote areas have access to mobile units. In total, there are more than



**Everybody has come together to deliver**
George Kassianos

**Private couriers distribute the UK doses**
Martin Sawer

**They got ahead on ordering vaccines**
Simon Clarke

1400 sites in England, 1100 in Scotland, 295 in Wales, and 328 in Northern Ireland.

Different parts of the UK are approaching the priority group cohorts in roughly the same way, with GPs focusing on older patients and hospitals acting as hubs for the vaccination of health workers. But there are some regional differences. Northern Ireland, for example, launched a twin track approach in January, where seven regional vaccination centres (a mix of hospitals and leisure centres) have offered appointments, bookable online or by telephone, to 65-69 year olds. Some people have received their first dose within 24 hours of booking, though many have reported technical glitches with the online system. Meanwhile, GPs continue to offer jabs to older and clinically extremely vulnerable people.

The twin track scheme was unveiled suddenly and has confused some patients. Louise Douglas, a GP in Belfast, says, "People have been phoning us saying, 'We can't get an appointment' or, 'We don't want to go to the vaccination centre, we want to come to you.'" *The BMJ* has also heard reports of patients in England left confused after they received invitations from both their local GP practice and the separate mass vaccination team.

There are also disparities in the density of vaccine doses administered so far. Officials have sought to smooth things out, redirecting doses from Yorkshire and the north east of England because those areas had vaccinated a higher proportion of their over 80 cohort than parts of southern England.

Ollie Hart, a GP in Sheffield, says it is "normal" to see disparities in the rate of vaccination between different parts of the country. "This obsession with keeping everybody absolutely level does seem a little bit strange," he adds. The first delivery of vaccine doses his practice received was double the number expected—nearly 400. "It was literally the day before we found out," he says, adding that they could, in principle, routinely administer hundreds more per week than at present, were the supplies available and delivery clearly communicated in advance. An NHS spokesperson told *The BMJ*, "Vaccines delivered to the NHS are sent out as soon as possible to vaccination sites, with as much notice given of delivery dates as possible, as supplies come online and are made available to the NHS."

## Production

When asked by *The BMJ*, Pfizer declined to give the latest figure of shipments made. AstraZeneca did not respond to requests for comment on its delivery progress.

AstraZeneca's facilities in the UK are producing doses for the country, and the *Telegraph* reported in January that a new factory in Oxfordshire, opening later this year, will be capable of making 70 million doses in 4-5 months. Construction of the Vaccines Manufacturing and Innovation Centre was already underway with a planned 2022 opening, but the government invested an extra £131m to bring the completion forward.

Doses arriving from production facilities in Europe have continued to move smoothly despite Brexit. Martin Sawer, executive director of the Healthcare Distribution Association, told *The BMJ* that after vaccine batches are tested by the MHRA—generally taking two days—they are then taken from central storage hubs to vaccination sites by private couriers. Only a small number of companies are handling the Pfizer-BioNTech vaccine, as it requires cold storage at around −80°C. The number of staff involved in deliveries currently number a few hundred. Sawer says that delivery staff in Northern Ireland have been offered vaccines, but not yet those working elsewhere in the UK.

## New challenges

Even if the government met its mid-February target, there will still be tens of millions of people waiting for their first dose. And the challenge will become more complex as vaccinators are tasked with administering millions of second doses on schedule.

The UK's much debated decision to delay administrating the second dose from 3 weeks to up to 12 weeks will help stretch vaccine stocks over a larger proportion of the population, with preliminary data for the Oxford-AstraZeneca vaccine indicating that the tactic should allow people to achieve a degree of immunity against the virus while also potentially cutting transmission. Clarke argues, however, that there are insufficient data to support delayed dosing of the Pfizer-BioNTech vaccine.

And then there is the threat of new variants that could evade immunity, potentially requiring the production and rollout of a new generation of vaccines or boosters. Scientists are already working on this, with Oxford University saying that a tweaked version of its vaccine could be available by the autumn. The vaccine taskforce has also struck a deal with German company CureVac to develop vaccines against emerging variants, agreeing to purchase 50 million doses should they prove effective, and to convert an animal vaccine plant to bring human mRNA vaccine production to the UK. To date, the UK has had to rely on overseas production.

The government is already planning for a third round of booster shots in the autumn. And Bingham has spoken of the need for alternative delivery methods to injections, such as nasal sprays or patches, to allow vaccination in pharmacies or even self-administration at home. This could reduce the pressure on hospitals, vaccination centres, and GPs. As we learn to live with the virus and its variants, covid-19 vaccination might become an annual event like flu jobs.

There is much uncertainty ahead. But the mass vaccination programme has buoyed a country in its third national lockdown and that has recorded its 100 000th covid-19 death. "Everybody has come together to deliver," says Kassianos. "That, actually, is our NHS."

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# yes

Deliberate intent to spread malicious disinformation should be considered criminal

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Vaccination is the proposed way out of covid-19. But not everyone agrees. Some people spread vaccine disinformation—false information with malicious intent—or misleading misinformation, based on incorrect beliefs.

Both can increase vaccine hesitancy, which the World Health Organization has listed as one of the top 10 health threats. And the consequences can be real. Although measles vaccinations saved 23 million lives, misinformation was linked to the disease's resurgence.

### The many faces of false information

False information about vaccines is heterogeneous, spread by groups ranging from anti-vaccine libertarians protecting civil liberties to concerned parents and health conscious people.

Simple, emotive, and compelling disinformation can sow doubt and distrust by exploiting perceived U turns in scientific knowledge or by presenting government or public health decisions as establishment failures. "Merchandising doubt" is effective, from denying a link between cigarettes and cancer to questioning climate change or national election results. Doubt destabilises, polarises, and erodes trust.

We are also facing an "infodemic"—an overabundance of information, both factual and false. In uncertain conditions people struggle to sort through complex, evolving information: 25% of Americans report having unwittingly shared fake news stories. A majority (70-83%) of Americans and Europeans use the internet to find health information, often on social media. Over 65% of YouTube's content about vaccines seems to be about discouraging their use—focusing on autism, adverse reactions, or mercury content. And search algorithms promote content similar to what users have previously watched, leading people into increasingly narrow echo chambers of disinformation. A recent UK study found that users who relied on social media for their information, particularly YouTube, were significantly less willing to be vaccinated.

### Criminalisation and knowledge voids

On ethical grounds, deliberate intent to spread malicious vaccine disinformation that could result in preventable deaths should be considered criminal. But criminalisation is not straightforward.

Laws against spreading fake news and health disinformation have been passed in France, Germany, Malaysia, Russia, and Singapore. As of 2018, Germany required social media platforms to remove hate speech or fake information within 24 hours, threatening maximum fines of €50m (£43.9m; $60.4m). The argument for such legislation is that it could force social media companies to self-regulate and to police content. Traditional media (newspaper, TV, radio) are considered "publishers," being subject to regulation. Social media platforms give the public a voice to exchange information, and the most common sources of vaccine information are often non-experts. But social media companies have argued that they are not publishers and have minimal responsibility to vet posts, although they have agreed to conduct some editorial decisions and fact checking.

Criminalisation, of course, has a cost. Early evaluation of the German law showed that social media companies were risk averse, curtailing freedom of expression and censoring legitimate material. In Russia, criminalisation has stifled criticism of the government.

Proposed alternatives to criminalisation include inoculating the public against false information by increasing media literacy. But countering emotional narratives that play to our deepest fears is not only about being media savvy. We need to decide whether social media companies are publishers, and we need legislation to guide them to adjust their algorithms and determine to what extent information should be balanced and fact checked, with users directed to accurate sources. For instance, certification systems could gauge content accuracy in terms of traceable sources, explicit conflicts of interest, ethical compliance, and revenue reporting.

But criminalising people who intentionally hurt others through false information should also be considered. The freedom to debate, and to allow the public to raise legitimate vaccine concerns to fill the knowledge void, should not extend to causing malicious harm.

## Should spreading antivaccine misinformation be criminalised?

The spread of false health information casts a shadow over required vaccine coverage. **Melinda Mills** says that we must, reluctantly, consider criminalising people who deliberately spread false information—but **Jonas Sivelä** argues that the definitions are too murky and that criminalisation may do more harm than good

# no

## Failing to consider or answer people's worries would only result in an increased lack of confidence in the long run


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In recent years concern has grown regarding the global spread of misinformation, disinformation, fake news, and conspiracy theories. They constitute a considerable risk for society in general and for many public health matters, particularly vaccination. There is no denying that the world would be a better place without misinformation or that it would be in the public interest for anti-vaccination misinformation not to exist. But should it be criminalised? No.

The strongest arguments against criminalisation relate to the notion of the rule of law and democracy, including freedom of speech and other civil liberties. But criminalising anti-vaccine misinformation could make it grow even stronger.

We should be cautious when we talk about misinformation and disinformation, as there is a difference: misinformation is defined as "incorrect or misleading information"; disinformation as false information deliberately spread with the purpose of influencing public opinion. The crucial difference is the intention to deceive.

### Murky waters

The Universal Declaration of Human Rights states that everyone should have the right to freedom of opinion and expression. Freedom of speech reinforces and legitimises all other human rights: without them we would have oppression, tyranny, and other extrajudicial practices. It is true that civil liberties, including freedom of speech, can and should be restricted in certain cases—for example, when it comes to inciting lawless activities and violence. But anti-vaccination misinformation is not such a case.

Vaccine hesitancy is a "delay in acceptance or refusal of vaccines despite availability of vaccination services." Contrary to how it often appears in the public debate, vaccine hesitancy is affected not only by anti-vaccination lobbying or misinformation but also by the convenience of vaccination services and public complacency. Criminalising anti-vaccine misinformation seems a strong response but does not deal with these issues.

Most importantly, attitudes and perception regarding vaccines and vaccination sit on a continuum including people who have no doubts and accept all vaccines on the one side, and those who vocally refuse all vaccines on the other—as well as a heterogeneous group between these two extremes that can be hesitant to different degrees, depending on the context.

We must also acknowledge legitimate concerns about vaccines that should be allowed to be voiced. It is understandable that vaccines and vaccination, like other public health measures, raise questions. If these are labelled as criminal there is a genuine risk of suppressing legitimate concerns and questions, expressed without the intent to deliberately spread false information.

Failing to consider or answer people's worries, and instead suffocating relevant discussion, would only result in an increased lack of confidence in the long run—and an increase in misinformation.

### More harm than good?

Anti-vaccine disinformation, conspiracy theories, and fake news can often be considered counternarratives—expressions of resistance. In such cases, they can be born from and fed by distrust in authorities and institutions, expressions of resistance to hegemonic ideologies and rules. Hegemonic legislation that could be seen as criminalising the right to express legitimate worries or pose questions would only trigger more misinformation.

Instead of criminalising communication, other technical solutions for tackling misinformation have proved successful, such as efforts by Facebook and Twitter to deal with false claims through fact checking and labelling misinformation.

Moreover, trust in authorities, governments, and the healthcare system is key when it comes to ensuring high vaccine acceptance. The only way to sustainably reduce misinformation about vaccination—and to strengthen vaccine confidence and acceptance in the long run—is to increase trust in these institutions and authorities in different countries.

Cite this as: *BMJ* 2021;372:n272

CORONAVIRUS

# Wearable technology: covid-19 and the rise of remote clinical monitoring

Interest is growing in the use of devices to track patients with covid-19 and chronic illness, writes **Jo Best**


In the age of covid-19, digital devices worn by patients are increasingly being piloted to monitor those who might need hospital admission or who have recently been discharged.

In a scheme in north west London, "wearables" collected the vital signs of people quarantining before or after travelling abroad and healthcare staff who couldn't isolate at home. Round-the-clock data were monitored by a trained team. If the team spotted signs of deterioration, people could be transferred to hospital when necessary. Reducing direct contact between people in quarantine and health workers could reduce transmission of SARS-CoV-2 and reduce the use of personal protective equipment.

In Northampton, wearables have been used to track patients with chronic illness or who are recovering from covid-19, with clinicians reviewing vital signs data regularly in virtual ward rounds and through remote consultations. By enabling clinicians to monitor patients from afar, it is hoped that fewer vulnerable patients will need to be admitted, freeing up beds and staff time.

In the context of covid-19 and more broadly, using wearables to monitor patients before or after admission "can give a level of reassurance when people are being treated remotely that they're not in danger," says Pritesh Mistry, digital fellow at the think tank the King's Fund.

### What are wearables?

Medical grade wearables can be as simple as a sensor that measures a single variable, such as a photoplethysmograph. Others are more complex pieces of hardware worn around the arm or as a patch on the chest, that gather a selection of vital signs, with information typically relayed to clinicians for monitoring or analysis. Wearables can measure data 24/7, and algorithms can alert clinicians if a threshold is breached, for example, if vital signs go too far outside the normal range.

Clinicians may get a better picture of a patient's health over a longer period, instead of an occasional snapshot during periodic hospital appointments, and they can observe patients' progress without having to call them into the clinic. Automatic data gathering may also free staff time by sparing them having to make manual observations.

Wearables are a way of "providing resources to the healthcare system and reducing clinical risk," said Mistry.

Consumer grade wearables, such as the Apple Watch and Fitbit bands, can also gather health data that can be shared with doctors. These devices are commonly used by the wearer to monitor trends in, for example, their exercise or sleep (box 1). Models of Apple Watch and Fitbit come with a single lead electrocardiograph that might identify some people at increased risk of atrial fibrillation.

Wearables are no more likely to present challenges for data privacy than other hospital systems or electronic health records. For medical grade devices, whether a nurse or a machine collects periodic data makes little difference to confidentiality. For consumer grade devices, it's up to consumers which data they agree to share with others, including companies or their doctor.

### Fledgling use in the NHS

The NHS Long Term Plan, published in 2019, envisioned a health service in which digital devices worn by patients played a useful role. Wearable technology could ultimately be used to help predict and prevent events leading to

**Box 1 | Consumer wearables find clinical use**

The most common way patients encounter wearables in a medical context is through fitness tracking devices. Clinicians are already finding them useful too. In one of the biggest health related deployments of wearables, thousands of people at risk of developing diabetes have been given fitness trackers to encourage them to increase their physical activity. The project, part of the digital diabetes prevention programme run by NHS England, Public Health England, and the charity Diabetes UK, includes peer support groups and apps with access to health coaches.

Wearable fitness trackers won't appeal to everyone, but they can help encourage exercise in the right context, says Neil Gibson, senior physical activity adviser at Diabetes UK. People "need appropriate follow-up support so that people know why they're being given wearable tech," he said. Such devices have been found to increase activity levels, particularly when additional support is provided.


CLAUDIA BENTLEY

**This kind of data can be viewed as patient-reported information to create a holistic picture** Theodoros Arvanitis, University of Warwick

### Box 2|Drowning in data

Information overload is a concern. Patients in a 2019 study of using wearables to collect vital signs in hospital feared being overwhelmed by seeing their markers in real time.

As wearables are used more widely, standards will need to specify which data are shared with patients and how. Show too much, and patients may become anxious or self-medicate without clinical support. Show too little, and patients may miss potentially useful information or feel shut out from their own health data.

"As a doctor, you never share all the information you have unless it's helpful and relevant to the patient, and that varies from case to case," said Matt Wilkes, a former NHS Lothian anaesthetics registrar and now a covid-19 fellow in critical care and chief safety officer at Current Health, a remote monitoring wearable technology company. "Giving physicians, in the clinical context, some control over which [wearables] data are shared is just a pragmatic and helpful way for that doctor-patient interaction to proceed."

hospital admissions and monitor patients' physiology to help care for them at home. And use of wearables in medicine is growing.

Currently, most wearables deployed in the NHS are in small scale research or pilot projects for just a handful of uses: helping patients self manage their condition, monitoring chronic illnesses, or tracking vital signs to spot deterioration in patients in hospital or at risk of admission.

One recent pilot involving more than 400 patients is investigating wearables for patients in the community with chronic obstructive pulmonary disease. Doctors use patient reported and physiological data, including from wearables, to identify deterioration and intervene earlier to reduce hospital admission.

Wearable technology has been piloted to identify problems early among patients with dementia and epilepsy. Wearables are also being tested in orthopaedic settings to analyse patients' gait after surgery and to offer them tailored exercises to prevent future joint problems.

#### What patients and clinicians think

Research into the use of wearables in hospitals is scant, but several projects have been undertaken, including an as yet unpublished study by NHS Lothian in Edinburgh involving 250 patients. It aimed to shorten attendances by predicting deteriorations in emergency patients and intervening earlier using data gathered from wearables, such as temperature, blood oxygen saturation, and respiratory and heart rates.

A 2019 study on the use of wearables for gathering vital signs in hospital found that "continuous monitoring in the ward was not only well received by most patients and their relatives but also by their healthcare professionals."

Clinicians reported detecting deterioration earlier and intervening quicker. Nurses said that automatic gathering of vital signs freed time for patient care; they believed patients were disturbed less than with manual collection. Some patients reported feeling more secure knowing they were being continuously monitored. Others had concerns about information overload (box 2).

Negative consequences included false alarms, which increase instead of reduce clinicians' workload, and risk of "alarm fatigue," when staff become desensitised to frequent automated alerts.

Such problems show that successful clinical use depends on more than just deploying wearable technology. "Information flow is crucial: who does the alarm go to, and how are they going to act on it?" asked Matt Wilkes, former NHS Lothian anaesthetics registrar. Wilkes is now a covid-19 fellow in critical care and chief safety officer at Current Health, a company whose remote monitoring wearable technology is used in several NHS trusts, including in the NHS Lothian pilot.

"You have to close the loop of action—something has to happen when the monitor is triggered," he said.

#### Data as patient-reported information

The rise of consumer wearables is likely to be accompanied by a rise in patients asking for help interpreting the results. A 2019 review for the NHS by the US cardiologist Eric Topol predicted that by 2021 people would be able to consent to data uploaded from their consumer wearables and lifestyle apps being linked with health records (via the NHS app), enabling review by clinicians.

"This kind of data, which is probably not as accurate as from a clinical grade device, is very useful to show particular trends," said Theodoros Arvanitis, professor of digital health innovation and director of the Institute of Digital Healthcare at the University of Warwick.

"It can be viewed as patient-reported information to create a holistic picture of a patient, and especially in chronic disease management this could be useful," he added.

However, getting to the stage where physicians could review those data will require huge investment in infrastructure and skills, and device manufacturers will need to ensure compatibility with NHS software.

The King's Fund's Mistry said, "At a minimum, for wearables to be used within a healthcare system, you need to have the ability to interpret the data, the data need to be accessible, the devices need to be able to plug in and talk to each other—you need interoperability."

Questions remain about how to make sure data are presented in a way that clinicians can easily interrogate and interpret. "You've got so much information: for example, in a 10 minute GP consultation, there will be a lot of wearables information from the patient alongside everything else that needs to be considered," he said.

NHSX, which sets policy for technology, digital, and data in the NHS, didn't respond to *The BMJ*'s requests to confirm plans to connect wearables data to electronic health records through the NHS app. Nonetheless, wearables will almost certainly figure higher on all doctors' agendas in future, as consumer devices become more popular and manufacturers increasingly add medical-type features.

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# Why did a German paper insist the Oxford vaccine was ineffective for older people?


Reporting information from single anonymous sources that turns out to be false could erode confidence in the vaccines that are crucial to controlling the covid-19 pandemic. **Hristio Boytchev** reports

"AstraZeneca vaccine apparently hardly effective in seniors," reported the German economic newspaper *Handelsblatt* on 25 January. "Setback for vaccine" ran as its top story in print the next day, subtitled, "The AstraZeneca vaccine apparently has an effectiveness of only 8% in the elderly. The government's vaccination strategy is shaky."

*Handelsblatt* attributed news of 8% effectiveness among over 65s to an anonymous government source. The story does not explain the calculation. There was no comment from AstraZeneca, and the German health ministry declined to answer questions about effectiveness. With huge global public health implications, *Handelsblatt*'s story rapidly became international news—and was rapidly rebuffed. Calls for the underlying data filled social media. An AstraZeneca spokesperson described the reported figure as "completely incorrect."

The controversy came at a moment of intense finger pointing between the European Commission and AstraZeneca over unfulfilled vaccine shipments, and in the week that the European Medicines Agency was expected to decide whether to recommend authorisation.

## Baseless figure

By 29 January the EMA had given the vaccine conditional authorisation for use in all ages and on 10 February the World Health Organization recommended the vaccine for all adults. Although the EMA warned that data for over 55s were limited, it was now clear that the single digit effectiveness from *Handelsblatt*'s story was baseless.

Many EU countries including Germany have restricted the vaccine's use for older people. "It is not about critique of the vaccine, but of the lack of data," Thomas Mertens, head of the German Standing Committee on Vaccination (STIKO), told *The BMJ*. "When there is more and better data, STIKO will change its recommendation."

Thomas Mertens, head of the German Standing Committee on Vaccination (STIKO), told *The BMJ*. "When there is more and better data, STIKO will change its recommendation."

Earlier in the week, a column in US magazine *Politico* had compounded the confusion, quoting an anonymous British government source: "8% is the percentage of people over 65 in the study, but not the efficacy. Not sure if the reporter got mixed up."

The German health ministry repeated this speculation in an email to journalists: "At first sight, it seems that two things have been confused. About 8% of the subjects in the AstraZeneca efficacy trial were between 56 and 69 years of age" (974 out of 11 636).

But in a follow-up story *Handelsblatt* stood by the figure of 8%, quoting an anonymous health ministry bureaucrat: "Confusion is out of the question. According to the data available to us so far, effectiveness in people over 60 is less than 10%."

Two days later, however, the ministry's press office released draft recommendations to journalists from STIKO, marked confidential. "According to this, it is not possible to make a statement about the effectiveness of the AstraZeneca vaccine in people over 65 years," the email said.

The draft also recommended not using the vaccine in this age group. This news was covered widely without mentioning the recommendations' draft status. Mertens said he was "annoyed" that the draft had been given to the press, adding that the data were clearly confidential.

The draft included a calculation that might have led to *Handelsblatt*'s false claim. It states the AstraZeneca vaccine to be 6% effective in patients over 65—but with a confidence interval of −1405% to 94% this is meaningless. The final recommendations report "insufficient data for a robust statistical statement on effectiveness" for this age group.

## He says, she says

*Handelsblatt* "turned the matter into a 'he says, she says' story to absolve itself of responsibility for spreading stupid stuff," Markus Lehmkuhl, professor for science communication at the Karlsruhe Institute of Technology, told *The BMJ*. Avoiding "admission of its own error further unsettles the public and undermines confidence in the vaccine."

Lehmkuhl sees a fundamental problem: the desire to report precise numbers that suggest certainty. *Handelsblatt*'s reporting was a "beginner's mistake," he said. "Precise scientific information" was attributed to a single "unsuitable source, who, to make matters worse, did not want to be quoted by name," Lehmkuhl said. "The journalists should have realised that such low effectiveness is implausible" given the efficacy reported in other age groups.

Soon after the original story broke, journalists asked why a political story should be free from basic fact and plausibility checking. Gregor Waschinski, *Handelsblatt*'s political correspondent, tweeted, "I understand that some would like to see the story substantiated with actual data. However, this is not an academic preprint but a sourced piece of political reporting." Four days after publication, *Handelsblatt* changed the story online "to include current developments," changing the headline to "Discussion about efficacy of AstraZeneca vaccine in seniors."

*Handelsblatt* declined *The BMJ*'s request to comment on why it had not made a correction. Despite inquiries from *The BMJ*, the ministry did not comment on its allegation about the story or why it had released confidential draft recommendations to journalists.

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