this week

DENGUE FEVER page 423 • **DELTA VARIANT** page 424 • **HANCOCK HEARING** page 426

OLI SCARFF/GETTYIMAGES

"Significant" US concerns over rapid tests

The US Food and Drug Agency has raised concerns about the safety and marketing of rapid lateral flow covid tests, the cornerstone of the UK's mass testing programme.

On 10 June the FDA warned the public to stop using Innova's SARS-CoV-2 antigen rapid qualitative test for detecting infection. The FDA published a class 1 recall after an investigation in March and April uncovered "significant concerns that the performance of the test has not been adequately established, presenting a risk to health."

In addition, the agency said "labelling distributed with certain configurations of the test includes performance claims that did not accurately reflect the performance estimates observed during clinical studies" and the test "has not been authorised, cleared, or approved by the FDA for commercial distribution or use in the US."

In a letter to Innova the agency also noted that the clinical study data submitted in the request for emergency use authorisation were "identical to data previously provided by other manufacturers" in separate requests. "The data reliability and accuracy problems noted herein raise significant concerns that the performance of the SARS-CoV-2 antigen rapid qualitative test has not been adequately established."

In a statement Innova said it had "worked diligently and proactively to tackle the FDA findings," adding that "none of the inspectional observations concern the performance of the test." It said, "We have voluntarily recalled the products. We are confident that we are on the pathway to fully comply with FDA requirements."

The FDA's notice came just days after the Royal Statistical Society called for new standards for diagnostic tests in the UK in response to regulatory gaps identified during the pandemic. Jon Deeks, professor of biostatistics at Birmingham University, who co-chaired the society's working group, said, "There have been many problems with transparency in the evidence to support the government's policies for use of this test. Given the more serious concerns identified by the FDA, it is essential full explanations and data are provided to explain decisions made about its continued use, if that is the decision made."

England's Department of Health said it had confidence in lateral flow tests after "the UK's rigorous Porton Down assessment process." The MHRA said it would review the implications of the FDA's findings.

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2021;373:n1514

The FDA has issued a class 1 recall of the Innova rapid lateral flow tests that are the cornerstone of the UK's mass testing programme

LATEST ONLINE

- GMC and NHS trust face legal action over case of doctor who took his own life
- Covid-19 vaccine doses expire in US as uptake falls by 68%
- Juul: less than half of e-cigarette trial outcomes were properly reported or declared, study finds

SEVEN DAYS IN

GPs are urged to see all children with respiratory symptoms in person

CHRISTOPHER FURLONG/GETTYIMAGES

GPs should consider seeing all children under 5 years with respiratory symptoms in person, NHS England has advised in its latest primary bulletin. The guidance comes amid concern that respiratory viruses that have been suppressed by social distancing and masks in the past year will rise as covid-19 restrictions are eased.

Government guidance continues to state that children with respiratory symptoms should be tested for covid if they have a high temperature or a new, continuous cough and to stay at home until they receive their result. But "this should not take precedence over clinical assessment," the bulletin said.

NHS England said it had given the advice in the context of a "remarkable reduction" in viral respiratory infections other than covid-19 in the past year, meaning "an increasing number of young children who have never been exposed to these common viruses." It emphasised that "prolonged illness or severe symptoms should not be attributed to covid-19 and should be evaluated as usual." It added, "We are asking that all children under 5 with respiratory symptoms are considered for face-to-face consultations and referred to secondary care as appropriate."

Gareth Iacobucci, *The BMJ* Cite this as: *BMJ* 2021;373:n1487

Drug approval

Experts resign after FDA approves Alzheimer's drug

Three members of a US Food and Drug Administration advisory committee, which advised against authorising the Alzheimer's disease drug aducanumab because of a lack of efficacy, resigned after the FDA went ahead and approved it. The committee concluded that, although the drug cleared amyloid plaques and reduced tau deposits in the brain, it did not improve cognition. One of the members who resigned, the Harvard professor of medicine Aaron Kesselheim, said that it was "probably the worst drug approval decision in recent US history."

Covid-19

WHO: act with caution to avoid pandemic resurgence

WHO's Regional Office for Europe launched a campaign with Unicef to encourage people to be cautious over the summer. Hans Kluge, WHO regional director for Europe, called for responsible travel, frequent handwashing, distancing, choosing open settings to meet, and wearing a mask. He said, "If we are to avoid another resurgence after the summer, we have to take last year's lessons on board: act fast on signals of increasing cases—expand testing and sequencing; step up contact tracing; and rapidly attain very high vaccine uptake in the most vulnerable populations."

Vaccine trial volunteers will be certified

People who have taken part in approved covid vaccine trials in the UK would not be disadvantaged in terms of any future domestic vaccine certification in comparison with people who received their vaccines under the standard NHS programme, said Jonathan Van-Tam (below), deputy chief medical officer for England. Volunteers who had a vaccine that will not be licensed or took a placebo will remain certified during a grace period, to allow them to have the NHS standard vaccines if these are recommended.

UK government kept modelling secret

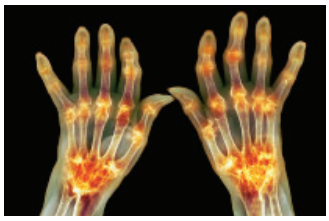
Public Health England said national security would be damaged by the release of reports on 11 pandemic and epidemic preparedness exercises, apart from one on influenza, as it admitted to the existence of the files after pressure from an NHS consultant haematologist, Moosa Qureshi. The exercises, carried out from 2015 to 2019, included one that tested the country's readiness to cope with Middle East respiratory syndrome, which is caused by a coronavirus. David Matthews, a reader in virology at Bristol University, told the *Guardian* that the MERS exercise "would have been completely relevant" to the government's response to covid-19.

Petition questions vaccinating children

More than 54 000 people have signed a petition urging the government not to vaccinate children until phase III trials are completed and more safety data have been collected. The petition—set up by Ros Jones, a retired paediatrician and member of the Health Advisory and Recovery Team, which researches and reviews covid-19 policy and studies—said that giving the vaccine to healthy children to protect adults would be "unethical and unjustifiable." However, others have said that there is a very strong argument to vaccinate children, as the delta variant could be more transmissible among them.

Rheumatoid arthritis

NICE expands treatments for moderate disease



Doctors can now prescribe the biological treatments adalimumab, etanercept, and infliximab to patients with moderate rheumatoid arthritis who have not responded to conventional treatments, in line with updated guidance from NICE. Biological treatments were previously recommended only for patients with severe rheumatoid arthritis. The companies that produce the drugs have each agreed a confidential price reduction with the NHS, making them a cost effective use of resources, said NICE.

MEDICINE

The minimum age to buy cigarettes should be 21, says parliamentary group

Smoking

MPs and peers urge end to tobacco epidemic by 2030

Raising the minimum age for buying cigarettes from 18 to 21 and securing a "polluter pay" amendment to the Health and Social Care Bill, which would make manufacturers pay to deliver the end of smoking, were among the recommendations in a report from the All Party Parliamentary Group on Smoking and Health. Its chair, Bob Blackman, said, "Our report sets out measures which will put us on track to achieve the government's ambition to end smoking by 2030, but they can't be delivered without funding. The manufacturers have the money: they should be made to pay to end the epidemic."

NHS backlog

Hospital waiting list surpasses five million

The number of people waiting for hospital treatment in England topped five million for the first time, as NHS leaders warned of unrelenting pressure on staff and services. Monthly performance data showed the waiting list rose by 171 720 in April to reach 5.1 million. At the end of April only 65% of patients waiting to start treatment were treated within 18 weeks, missing the 92% target.

Assisted dying

Campaigner removes ventilator at age 71

Noel Conway, who had motor neurone disease diagnosed in 2014 and challenged the blanket ban on assisted dying in the UK, died at home in Shropshire on 9 June at age 71. He died after deciding to have the ventilator he had become dependent on removed to hasten his death. In a statement that he asked to be released after his death, Conway said he was glad parliament was continuing to discuss assisted dying, adding, "It can only be a question of time before assisted dying will be approved in the UK."

Regulation

Leicestershire hospital enters special measures

The Care Quality Commission rated Priory Group's Burton Park Hospital as inadequate and placed it in special measures, after finding poor leadership had compromised patient safety. The 50 bed hospital in Leicestershire, which cares for people who need neurobehavioral rehabilitation, has now received three warning notices. Inspectors found leaders were detached and defensive and failed to treat staff with respect, impairing the quality and safety of care that patients received.

Patient safety

Warning letter for women taking sodium valproate

Women and girls aged 12-55 in England who take sodium valproate will be sent a letter reminding them of the risks associated with the epilepsy drug during pregnancy. The reminder is part of the NHS's response to the Independent Medicines and Medical Devices Safety Review, also known as the Cumberlege review, which was published last year.

Cite this as: *BMJ* 2021;373:n1519

CANCER

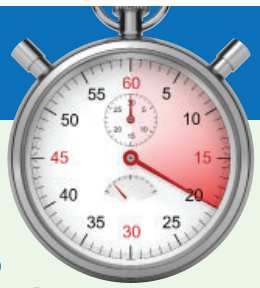
38 000

fewer people started treatment for cancer between April 2020 and March 2021 than in the previous year, including

10 600

fewer breast cancer patients

[Cancer Research UK]



SIXTY SECONDS ON . . . DENGUE

NOT ANOTHER EPIDEMIC?

This is good news. A three year randomised controlled trial, published in the *New England Journal of Medicine*, showed that releasing mosquitoes infected with *Wolbachia* reduced the incidence of dengue fever by 77% and hospital admissions by 86%.

WOLBACHIA, WHAT'S THAT?

It's a genus of bacteria that occurs naturally in 60% of insect species but not in the *Aedes aegypti* mosquito, the main vector of dengue. Researchers worked out how to introduce the bacteria into the mosquito, where they compete for resources with the dengue virus. This makes it harder for the virus to replicate and so reduces its spread.

WHERE DID THIS HAPPEN?

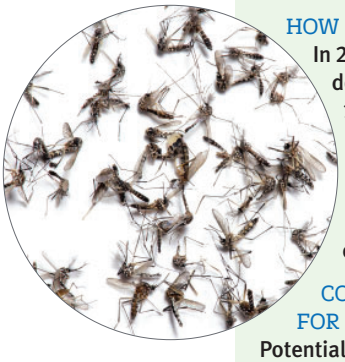
After pilot studies in Australia suggested the approach would work, the latest trial took place in Yogyakarta in Indonesia—a hot spot for dengue. Five million mosquito eggs infected with *Wolbachia* were placed in containers of water and fish food in backyards around the city.

AND WHEN THE MOSQUITOES DIED?

The approach is self-sustaining. As adult mosquitoes carrying *Wolbachia* emerged from the containers, they bred with the wild type until almost all the *A aegypti* in the intervention areas carried the bacteria.

COULD DENGUE BE ELIMINATED?

It looks promising. Efficacy was equivalent for all four serotypes of dengue in the trial. Mosquitoes infected with *Wolbachia* have now been released across the entire city and into neighbouring urban areas. One of the study leaders, Adi Utarini, from the Gadjah Mada University, said, "We think there is a possible future where residents of Indonesian cities can live free of dengue."



HOW BIG A PROBLEM IS DENGUE?

In 2019 the World Health Organization designated it as one of the top 10 global health threats. There are an estimated 100-400 million infections each year, and it is endemic in more than 100 countries. The threat of an outbreak now exists in Europe.

COULD THE STRATEGY WORK FOR OTHER DISEASES?

Potentially, yes. Laboratory studies indicate it could work for diseases such as chikungunya, yellow fever, and Zika.

Jacqui Wise, Kent

Cite this as: *BMJ* 2021;373:n1500

G7 global vaccine pledges fail to meet scale of challenge, say critics

G7 leaders have committed to provide one billion covid-19 vaccine doses for low and low-middle income countries over the next year, but the World Health Organization and campaigners said this is 10 billion short of what is needed.

The Carbis Bay declaration, signed on 13 June, also set out steps to prepare better for any future pandemic by improving early warning systems and increasing and coordinating global manufacturing capacity. And the *100 Days Mission to Respond to Future Pandemic Threats* report, prepared by the pandemic preparedness partnership formed to advise the G7, set out recommendations to shorten the cycle for the development of vaccines, treatments, and tests from 300 to 100 days.

> WHO said 47 of Africa's 54 countries—nearly 90%—are set to miss the World Health Assembly September target of vaccinating 10% of their population unless Africa receives 225 million more doses now

Of the billion vaccine doses pledged, at least 870 million will be shared directly by donating surplus supplies, with the aim to deliver at least half by the end of 2021, mainly through the UN led Covax scheme. The UK said it will donate five million doses by October, with a further 95 million doses within the next 12 months. The US has already committed 500 million doses.

While welcoming the vaccine pledge, WHO's director general, Tedros Adhanom Ghebreyesus, said, "Many other countries are facing a surge in cases, and they are facing it without vaccines. We are in the race of our lives, but it's not a fair race, and most countries have barely left the starting line."

WHO warned that numbers of cases had risen for the third week running in Africa and that vaccines were increasingly scarce. It said 47 of Africa's 54 countries—nearly 90%—are set to miss the World Health Assembly target of vaccinating 10% of their population by September unless the continent receives 225 million more doses now.

The summit made no progress on the demand from poorer countries for a temporary patent waiver on vaccines. The G7 agreed only to support manufacturing in low income countries and "will engage constructively with discussions at the World Trade Organization on the role of intellectual property."

Max Lawson of the charity Oxfam, said, "Never in the history of the G7 has there been a bigger gap between their actions and the needs of the world. By holding vaccine recipes hostage, the virus will continue raging out of control in developing countries and put millions of lives at risk."

Jacqui Wise, Kent Cite this as: *BMJ* 2021;373:n1520

Delta variant: **Latest on transmission, hospital admissions, and restrictions**

The UK has administered more than 71 million doses of vaccine, and in many areas lockdown has eased. But, asks **Elisabeth Mahase**, is another wave on the horizon?

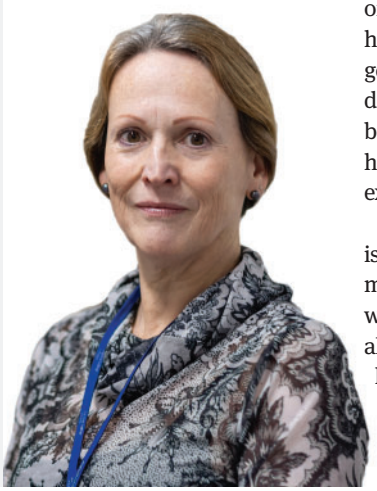
? Are covid admissions increasing?
Yes. The number of new cases has been rising in the UK for the past few weeks, and admissions are following suit. As of 9 June the number of people in hospital each day with covid exceeded 1000, after having fallen to the hundreds in the middle of May after the previous wave.

? Is this due to the delta variant?
Cases were expected to rise a little as restrictions eased, but the delta variant seems to have complicated matters. Public Health England figures show the variant now accounts for 90% of UK cases, with the number exceeding 42 000. Research indicates delta is associated with an estimated 60% higher risk of household transmission than the alpha variant, which was already much more transmissible than the original version of the virus. There are also suggestions that delta could carry a much higher risk of hospital admission.

Speaking to the BBC on 13 June, Andrew Hayward, an adviser to the government's Scientific Advisory Group for Emergencies (Sage) and professor of infectious disease epidemiology at University College London, said, "I think it's now very clear we will have a substantial third wave of covid infections. The really big question is how much that wave of infections is going to translate into hospitalisations. The fact that we've got 55% of the adult population double vaccinated means that this will be substantially less bad than it could have been, but we still don't know exactly how bad it could be.

"Sixty per cent more infectious is extremely worrying—that's the main thing that will drive the speed with which the next wave comes along. And the fact that the level of hospitalisations from this infection

Any delays, just from a purely scientific basis, will help, as they will allow more time for people to get the second dose of vaccine
Wendy Barclay



appears to be maybe up to double those of the previous infection is of course also extremely concerning."

Another concern is that the vaccines seem to be less effective against delta, especially after one dose. A PHE preprint found that the Pfizer-BioNTech vaccine was 88% effective and the Oxford-AstraZeneca 60% effective against the delta variant two weeks after the second dose, but both vaccines were only 33% effective against symptomatic disease from delta three weeks after the first dose. However, the most recent PHE analysis of 14 019 delta cases (14 June) indicates that two doses of either vaccine are still highly effective against hospital admission: 96% for Pfizer-BioNTech and 92% for Oxford-AstraZeneca.

Speaking at a briefing on 9 June, Neil Ferguson, director of the Medical Research Council's Centre for Global Infections at Imperial College London, said, "There's still quite a lot of uncertainty about what the vaccine efficacy against the delta will be for those more severe forms of disease. It's well within the possibility that we could see another third wave, at least comparable in terms of hospitalisations, maybe not as severe as the second wave.

"Almost certainly I think deaths probably will be lower. The vaccines are having a highly protective effect, and cases in hospital are milder, but still it could be quite worrying. There is a lot of uncertainty."

What is different about delta?

In some ways the delta variant is an "improved" version of alpha, making it more easily transmissible and more of a concern.

Speaking at the briefing, Wendy Barclay, professor of virology and head of infectious disease at Imperial College London, explained, "The delta variant has got two important mutations in its spike protein, or sets of mutations. One is at the furin cleavage site, which we think is quite important for the fitness of the virus in the airway. The virus that emerged in Wuhan was suboptimal in that respect, so it transmitted but perhaps not as well as it might. The alpha variant took one step towards improving that with a certain mutation, and the delta variant has built on that and taken a second step now, a bigger step, towards improving that feature."

Why is delta able to transmit more easily?

Barclay said the current data indicated the virus was "fitter in human airway cells," meaning an increased amount of the virus in the infected person, and so people may expel more virus out into the air to pass on to the next person. This is supported by the testing data, which show that the CT value (cycle threshold)—the number of amplification cycles needed for the virus to be detected—seems to be lower in samples from delta infected people, meaning they contain more virus.

Another suggestion is that if this variant is better at infecting human airway cells, people may become infected after a lower exposure.

Does delaying the easing of covid restrictions make a difference?

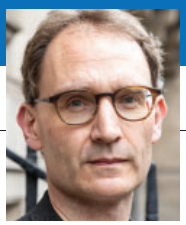
Yes, because it allows more people to receive two doses of the vaccine. Barclay said, "Any delays, just from a purely scientific basis, will help, because they will allow more time for people to get the second dose. And also just having the second dose is not quite enough. You need to get around seven days after the second dose for the vaccine to really boost the immune response up to the levels that you'd like it to be."

The final stage of easing in England, which had been expected on 21 June, has now been delayed to 19 July.

Could the NHS be overwhelmed?

Absolutely. Rising hospital admission rates would increase pressure on the already exhausted health system and could overwhelm it. Writing in BMJ Opinion, the chief executive of NHS Providers, Chris Hopson, said, "Given current NHS pressures, any increase in covid-19 admissions will set back progress on tackling the care backlog. Are we ready to accept this trade off?"

This message has been echoed by other health leaders, including Danny Mortimer, NHS Confederation deputy chief executive, who told the media the situation was "extremely precarious."



The vaccines are having a highly protective effect, and cases in hospital are milder, but still it could be quite worrying
Neil Ferguson

He said, "Health leaders are all too aware that rising infections, and especially at such a rapid rate, can easily lead to major rises in hospital admissions. Even a slight increase in admissions will affect capacity and could put recovery efforts at risk. Covid-19 hospital admissions are already going up, and that will put capacity under strain, especially as the latest figures showed 5.1 million people are waiting to start treatment."

Are more children becoming ill?

There are no official figures on this, although child health leaders have denied suggestions made by members of the Scottish government that children were more at risk and many had been admitted to hospital.

Steve Turner, Royal College of Paediatrics and Child Health registrar and consultant paediatrician at Royal Aberdeen Children's hospital, said, "As it stands there are very few children in hospital across the whole of the UK due to covid. We're not seeing any evidence of an increase in paediatric admissions with covid. A very small number of admissions who test positive for covid is what we'd expect.

"Our experience over the last 15 months is that many children who test positive have come into hospital for something else, like broken bones. At the moment the situation in the UK is stable. The number of children in hospital with covid remains very low."

Elisabeth Mahase, *The BMJ*

Cite this as: *BMJ* 2021;373:n1513

RESEARCH indicates that delta is associated with an estimated 60% higher risk of household transmission than the alpha variant

NEWS ANALYSIS

How did Hancock respond to Cummings's allegations?

Gareth Iacobucci reports on the health secretary's evidence session to MPs' inquiry into lessons learnt from the covid-19 pandemic

In a four hour session in front of the health and social care and science and technology select committees on 10 June, England's health secretary responded in detail to the allegations made against him and the government by Dominic Cummings, the prime minister's former chief aide. Cummings told the committees on 26 May he believed Hancock "should have been fired for at least 15 to 20 things, including lying to everybody on multiple occasions."

Care homes

The allegation

"Hancock told us in the cabinet room that people [in hospital] were going to be tested before they went back to care homes," said Cummings, referring to March 2020. He added, "The rhetoric was, 'We put a shield around care homes,' and it was complete nonsense. Quite the opposite . . . we sent people with covid back to care homes."

The response

"We set out a policy that people would be tested when tests were available, and then I set about building the testing capacity to deliver on that," Hancock told MPs. "Throughout we followed the clinical advice."

He went on to say that, at the time, the clinical advice had three parts. First, because it took about four days for tests to come back, anyone staying in hospital waiting for results could have tested negative but had contracted SARS-CoV-2 after the test. "That's obviously bad for that individual, but it's also bad because then they'd be going back to a care home with a negative result but having covid-19," said Hancock.

Second, clinical advice at the time was that if you didn't have symptoms you were likely to get a negative test result, he said. "That clinical advice stayed all the way through this period and then was changed later."

Third, ensuring care homes had infection prevention and control measures in place was essential, he said. "The data published since has shown that the best estimate from Public Health England is that 1.6% of the transmission into care homes came through [people being discharged]. What that tells you is that, sadly, the biggest route of covid-19 into care homes is through people who work in care homes. And so the most important thing for protecting care homes was staff testing, which we introduced as soon as we had the testing capacity," said Hancock.

The reality

After the data were released experts said the PHE analysis probably significantly underestimated the impact of the discharge policy on numbers of deaths in care homes.

Availability of PPE

The allegation

According to Cummings, Hancock told the cabinet in April 2020 that "everything is fine on PPE, we've got it all covered." But when Cummings came back from sick leave after having had covid-19 he said "almost the first meeting I had in the cabinet room was about the disaster over PPE, and how . . . hospitals all over the country were running out." Cummings alleged Hancock blamed NHS chief executive Simon Stevens and the chancellor of the exchequer, saying, "It's not my fault, they've blocked approvals of all sorts of things." The cabinet secretary investigated and told Cummings and Boris Johnson, "It's completely untrue. I have lost confidence in the secretary of state's honesty in these meetings,'" Cummings reported.

The most important thing for protecting care homes was staff testing, which we introduced as soon as we had the testing capacity
Matt Hancock

The response

Hancock called Cummings's description of events unfair. "I can't recall [the cabinet secretary investigating his claims], but what I can recall is that there was a cap on the price paid for PPE because the global price had shot up—we had to remove that cap, I requested its removal, it was removed. As the National Audit Office has shown, there was never a point at which NHS providers couldn't get access to PPE. But there were huge challenges."

Hancock referred to bureaucratic hurdles that required Treasury action. "Despite local challenges—and I don't deny at all there were challenges in individual areas—there was never a national shortage of PPE because of the actions that we took. I take, took, and have taken full responsibility for all of the areas that I'm responsible for. The chancellor played his part in resolving those blockages, and Simon Stevens has worked incredibly hard throughout this crisis."

The reality

In April 2020 *The BMJ* campaigned for #properPPE, backed by the BMA, after doctors reported a lack of protection.

Access to treatment

The allegation

Cummings maintained that Hancock lied when he said in the summer that everybody who needed it was being treated. "He knew that that was a lie because he had been briefed by the chief scientific adviser and the chief medical officer about the first peak, and we were told explicitly people did not get the treatment they deserved, many people were left to die in horrific circumstances," he said.

The response

Hancock acknowledged he had said "everybody got the covid treatment they needed, and I'm very proud of the fact that, with the NHS, we delivered on that, because it was critical."

He added, "There was no point at which I was advised (and I've taken the trouble to check) . . . that people were not getting the treatment they needed. On the contrary, one of the things we succeeded doing has been to protect the NHS so people have always had access to treatment for covid."

The reality

Difficult to verify, but a public inquiry may help to determine the facts.

100 000 tests a day target

The allegation

Cummings said Hancock interfered with the building of the test and trace system, to maximise his chances of "hitting his stupid target." He said, "We accused Hancock of telling half the government to 'down tools on this, do this, hold tests back so I can hit my target,' and [he] should have been fired. It was criminal, disgraceful behaviour that caused serious harm."

The response

Hancock said his target helped "galvanise the system." "We needed diagnostics companies to come to the table, we needed the NHS labs to . . . expand, and it said to everybody, 'We are going for it big time,' and it worked," he said. He added that Cummings's charge had surprised him. "The prime minister was four square behind me and gave me his full wholehearted support," he said.

The reality

While Hancock reached his target, the ability of NHS Test and Trace to control the virus's spread has been described as "marginal" by SAGE and others.

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2021;373:n1505

COMMENT

Science is the fall guy in blame game

Matt Hancock blamed "scientific consensus" for key government failings, as he came out fighting against his critics this week.

Giving evidence to MPs, Hancock defended his and the government's record and rebutted claims made by the PM's former chief aide, Dominic Cummings, made in front of the same committees two weeks earlier.

The health secretary seemed emboldened on learning that Cummings had failed to supply the committee with documentary evidence for the numerous allegations of incompetence and misconduct he had levelled at the government and, most pointedly, at Hancock himself.

He started confidently and was as enthusiastic as ever, responding to a list of Cummings's key allegations with the air of a man who had turned up well prepared for an exam.

"I take, took, and have taken full responsibility for all of the areas that I'm responsible for," he said, sounding more like a contestant from *The Apprentice* rather than the secretary of state for health.

"I can be quite forceful when I'm trying to get something through that needs to happen," he added, sounding increasingly like one of Alan Sugar's hopefuls in the TV boardroom. "You can't respond to a pandemic just by pointing fingers," Hancock pointed out, before, in true *Apprentice* contestant style, pointing fingers.

Mistakes were largely brushed off or put down to his naively following the advice of others. In a sadly predictable development a wriggling Hancock blamed "clinical advice" for several major government failings.

He said he "bitterly" regretted accepting what be described as early scientific consensus that asymptomatic transmission of covid-19 was unlikely—before health committee chair Jeremy Hunt gently pointed out to him that there was no consensus on this

There were several important things that the health secretary couldn't recollect

and that the government's Scientific Advisory Group for Emergencies had said in January 2020 that asymptomatic transmission could occur.

Hancock also insisted that backing a lockdown earlier in 2020 would have meant "over-ruling scientific consensus," a claim Stephen Reicher, a member of the government's Independent Scientific Pandemic Insights Group on Behaviours (SPI-B), dismissed in a subsequent statement as "quite simply untrue."

There were several important things that the health secretary couldn't recollect, most notably whether or not his department had leaned on Public Health England to soften discharge testing advice, because of a lack of testing capacity, and whether the cabinet secretary had investigated the veracity of Hancock's claims about NHS staff access to personal protective equipment.

But one thing he could recall was his delight at hitting his target to reach 100 000 covid-19 tests a day last year, a target that was savaged by Cummings during his recent testimony.

"Sometimes you have to put yourself in jeopardy, put yourself on the line," Hancock said, switching from Apprentice Matt to Action Hero Matt in the blink of an eye.

Hancock became more defensive as the session progressed, showing flashes of irritation as some MPs turned up the heat and pressed him for detail on some of his answers. But by closely aligning himself with the prime minister—who he said had given him "wholesale support"—and casting Cummings as an untrustworthy outsider that the government was better off without, Hancock may well have done enough to avoid hearing the dreaded words "you're fired," despite his unconvincing performance.

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2021;373:n1504

Matt Hancock (left) and Dominic Cummings give evidence to the joint select committee hearings on 10 June and 26 May, respectively

THE BIG PICTURE

Trying out nature's cure

GPs in Salford have joined forces with the Royal Horticultural Society to take social prescribing to a new level by offering patients gardening sessions at Bridgewater Garden in Worsley (left), which is due to open next year.

In a year long pilot, 75 people with mental and physical healthcare needs will be referred by their GP to tend plants under the supervision of therapeutic gardener Ozichi Brewster (below), in the grounds of the 62 hectare site.

The RHS Bridgewater team has funded 15 community green space projects in collaboration with Salford Clinical Commissioning Group to promote health and wellbeing, including a brand new garden at Veterans' Garage, a social hub for former armed forces personnel to alleviate social isolation.

The benefits of the scheme on patients' physical and mental health will be analysed by researchers from Salford University.

Alison Shepherd, *The BMJ*

Cite this as: *BMJ* 2021;373:n1521

MARK WAUGH/RHS

EDITORIAL

Intellectual property rights and covid vaccines

Waivers are essential for global vaccine equity

The US caught the world by surprise on 5 May when it announced its intention to support a World Trade Organization proposal that would temporarily waive intellectual property rights on covid-19 vaccines. While this move is encouraging, the Biden administration's support is the first step of many required.[1]

Waiving intellectual property rights is essential to tackle serious inequity in the global distribution of covid-19 vaccines, whereby wealthy countries currently control the lion's share of existing supplies. By the end of April, over 1.3 billion doses had been administered worldwide, but only 0.2% of vaccines had been given in low income countries.[2]

More than one year into the pandemic, the situation is at a low point globally. The average number of weekly deaths in April was over 36 000 in just India and Brazil,[3] and variants are proliferating. Experts fear a devastating second wave across Asia and Africa.[4]

Voluntary action has not worked. It's time for mandatory rules and legal commitments that can help put an end to this pandemic.

The proposed intellectual property waiver is appropriate as vaccine manufacturers have relied heavily on publicly funded research into coronaviruses.[5] Together, companies holding intellectual property rights are estimated to have benefited from government funding of around €93bn (£80bn).[6] The Moderna vaccine was funded almost exclusively by the US government.[7]

A successfully negotiated intellectual property waiver would ensure manufacturers cannot block production or access to raw materials and finished products for covid-19 technologies worldwide. A waiver would also prevent companies from charging unaffordable prices while insulated from competition.

RON ADAR/SOPA /ZUMA/ALAMY

It's time for mandatory rules and legal commitments

Priti Krishtel, co-executive director, Initiative for Medicines, Access, and Knowledge (I-MAK), Oakland, California
priti@i-mak.org

Rohit Malpani, global health consultant, Paris

Lack of competition in the vaccines market has a long history. Previously, the two companies with a duopoly for the human papillomavirus (HPV) vaccine[8] held patents that prevented competition.

Similarly, Pfizer successfully enforced secondary patents on its pneumococcal vaccine through legal proceedings in India[10] and South Korea,[11] which delayed competition.

Inadequate access to essential vaccines is predictable in a system that prioritises monopolies—and this will repeat itself in the absence of an intellectual property waiver for covid-19 vaccines.

Key features

A successfully negotiated waiver would meet four important criteria. The waiver's primary aim should be to save as many lives as possible. The Biden administration wants the waiver to focus on vaccines. This constraint should be removed. The original proposal applies to all medical technologies related to covid-19, including diagnostics, medicines, and ventilators. Many people are likely to become sick even if vaccination rates improve worldwide.

Second, negotiations should be completed quickly. Governments should have made substantial progress ahead of the WTO meeting on 8 June. Third, any waiver should be straightforward, unambiguous, for a reasonable duration, and limit manufacturers' ability to file legal challenges that impede access.

Finally, negotiating texts should be fully disclosed, with negotiations transparent to ensure all countries negotiate as equals. In the past, powerful nations have used their leverage to extract concessions from less powerful countries behind closed doors.[14]

Opponents of a waiver question whether manufacturers in lower income countries have the required capabilities. This argument was also made in the 1980s when Merck and GSK dominated the market for complex recombinant hepatitis B vaccines. It was discredited in 1997, when Indian manufacturer Shantha Biotechnics launched a vaccine that reduced the cost of a dose from up to $23 to just $1. Many millions of people worldwide have since been successfully immunised.[15] Manufacturers in low and middle income countries are already critical to overall immunisation efforts worldwide: in 2018, they provided over half of the 2.4 billion vaccine doses procured by Unicef.[16]

Suppliers worldwide are gearing up to meet this moment. New mRNA vaccines are under development in India[17] and China,[18] and several companies in middle income countries are already manufacturing covid-19 vaccines.[19 20] WHO is establishing a technology transfer hub to support local production of mRNA vaccines.[21] Although follow-on manufacturers can produce complex vaccines without support from holders of technology, sharing knowledge would save time and lives. The ability to respond swiftly to global crises cannot be left to a handful of private companies in a few wealthy countries. We need a more cooperative global response to this and future public health emergencies.

Cite this as: *BMJ* 2021;373:n1344

Find the full version with references at http://dx.doi.org/10.1136/bmj.n1344

EDITORIAL

Dying at home during the pandemic

Increase in home deaths could be because of preference or pressure

Data from the Office for National Statistics show that covid-19 was responsible for most of the 76 000 excess deaths during 2020 in England and Wales, with only around 2000 attributable to other causes.[1] The number of deaths from all causes in private homes increased by about one third to 167 000 in 2020, compared with an average of 125 000 between 2015 and 2019.

Around 41 000 more people died in private homes than in a normal year (which is more than half of the total number of excess deaths) but only a small number (just over 3000 or 7%) were recorded as being due to covid-19.[1] Most of these deaths at home were from underlying causes seen every year: dementias (which increased by 65%), heart and lung diseases, cancers, and neurological diseases.[2] Some covid-19 deaths that occurred at home may have been wrongly attributed to these conditions, especially early in the pandemic when symptoms were poorly understood and testing scarce. Nevertheless, this is still likely to represent a significant shift of people dying of causes other than covid-19 from hospital to home.

Many people prefer home over hospital for their end-of-life care,[3] and, although some people do not have preferences regarding place of care,[4] the mismatch between preferences and reality is well documented.

Preferences are influenced by trade-offs between competing priorities, expected outcomes, levels of engagement, and abilities to form and express preferences.[6] Was the increase in home deaths during 2020 evidence of improved achievement of peoples' preferences or the result of pandemic related displacement from healthcare facilities?

Hospitals and community services worked hard to free up beds for increasing numbers of covid-19 admissions. This may have facilitated discharge of patients at the end of life, helping some to achieve their preference for home care. Alternatively, the pandemic may have influenced peoples' preferences outside hospitals—through concerns about restricted visiting, fear of infection, and motivation to reduce pressure on stretched hospital services.

LUCAS BARIOULET/AFP/GETTY IMAGES

Patients should receive high quality end-of-life care in the place of their choosing

Unfortunately, we have no systematic evidence about the quality of home care given to people towards the end of life during the pandemic. Such information is vital if we are to understand whether the increase in deaths in private homes is a reflection of preference or of poor quality alternatives because of pressured hospital services.

Care at home can be of high quality,[7] particularly when home services are available at all times, symptoms are well controlled, and communication is timely and skilful.[8] Rapid innovations to anticipatory prescribing by general practitioners observed during the pandemic may have aided symptom management for patients at home.[9] However, the Marie Curie report on dying during the pandemic and other research present a mixed picture.[10 11] For people needing palliative care during the pandemic, research is urgently needed to find out how well symptoms were controlled; how families, preferences, and priorities were supported; and how easily services were accessed, including by remote consultation.

Sustaining the shift

Any shift towards more deaths at home needs to consider the size of the community palliative care workforce. During 2020, pressure on community palliative and end-of-life care surged, reaching levels of need not expected until 2040. Combined with existing gaps in the workforce, this suggests an urgent need to grow and train community clinicians skilled in palliative care.

Help from family members and informal carers is a critical and often overlooked component of care at home. The furlough scheme and increase in working from home may have made it easier for some people to provide the flexible care needed to support those important to them at the end of life. In research done before the pandemic, for example, support from family members significantly increased the odds (range 1.78 to 7.85) of patients with cancer dying at home.[13] For others, however, pandemic restrictions such as shielding and travel bans may have prevented them from providing support.

A detailed plan for better palliative care, *You matter because you are you*, recently published by Cicely Saunders International, gives a comprehensive approach to filling the gaps in palliative and end-of-life care.[14] Providing expertise in places where people are cared for, joining up care, empowering patients to access palliative care, and increasing community support, training, and research are all essential to ensure that patients receive high quality end-of-life care in the place of their choosing—often at home.[14]

Irene J Higginson, professor of palliative care and policy, King's College London
irene.higginson@kcl.ac.uk

David Brooks, Macmillan consultant in palliative medicine, Chesterfield Royal Hospital

Stephen Barclay, general practitioner, Primary Care Unit, University of Cambridge

Cite this as: *BMJ* 2021;373:n1437

Find the full version with references at http://dx.doi.org/10.1136/bmj.n1437

ESSAY

Industry-funded medical education is always promotion

Although awareness of individual conflicts of interest and ethical problems with physician-industry relationships has increased, few people realise just how much continuing education is used for advertising products, writes **Adriane Fugh-Berman**

Many countries require doctors to complete a certain number of hours of continuing medical education (CME, known as continuing professional development in the UK) to maintain a medical licence.[1] But CME is heavily funded and influenced by drug and medical device manufacturers. And because CME is considered education rather than advertising, no country regulates it as product promotion.

Studies analysing content have shown consistent messaging in industry-funded CME that favours sponsoring companies' drugs and disadvantages competing products.[2-9] The messages work: commercial CME affects prescribing choices. A sudden tripling in prescribing of an antipsychotic—an increase lasting at least three months—at the Minneapolis Veteran's Affairs Medical Center was traced to a grand rounds presentation by a speaker paid by the manufacturer.[10] A 1992 study found that after an all-expenses-paid CME symposium held at a tropical resort, prescription rates for the CME sponsor's drugs more than doubled.[11]

Although every study designed to detect commercial bias in CME has been positive, doctors cannot detect bias. Studies that have asked doctors whether commercial bias existed in specific commercially funded CME activities have found that most detect none.[12-15] Other studies have found that most doctors do not believe that commercially sponsored CME is biased in general.[16-18] Only one study, which surveyed Chinese doctors attending a nephrology conference partially funded by industry, found that most respondents thought that industry supported courses were biased.[19]

That most doctors cannot detect covert commercial bias is unsurprising given the depth to which industry messaging has become ingrained in medicine's definition of diseases, as well as perceptions of treatments.

CME was used to cast normal ageing as a disease in both men and women to sell hormonal formulations

Creating a market

Creating diseases, or expanding the market for existing diseases, is key to marketing. Industry-funded CME is designed to increase awareness of what industry calls "disease states;" to encourage off-label use; to emphasise benefits and minimise perceived risks of targeted drugs; and to exaggerate harms of competing treatments.[2] "Condition branding" is when a company creates, adopts, or redefines a disease state and then links that specific condition to a targeted treatment.[2]

CME was used to cast normal ageing as a disease in both men[3] and women[4] to sell hormonal formulations, for example. Gastroesophageal reflux disorder (formerly heartburn) was created to increase sales for omeprazole and esomeprazole.[2]

Examples of converting symptoms or risk factors into diseases tailormade for new drugs include premenstrual dysphoric disorder, created to extend patent protection for fluoxetine, and social anxiety disorder, created to establish a marketing niche for paroxetine, an antidepressant that entered the market too late to carve out much market share for depression.[2]

Industry-funded CME encourages clinicians to diagnose and treat mild symptoms or conditions for which the harms of treatments overwhelm putative benefits. Hypoactive sexual desire disorder was created by manufacturers of the testosterone patch.[2] The diagnosis was revived by the manufacturer of flibanserin, another purported libido boosting drug. There is no scientific norm for sexual desire, and lack of interest in sex is profoundly influenced by life stresses, relationship problems, illness, and drugs. Nonetheless, commercial CME activities have increased the percentage of primary care clinicians who indicated that they would screen for this "disease."[2]

Promoting "emerging" (off-label, unproved, or disproved) uses of drugs is another way that CME is used for marketing. This gets around laws that prohibit off-label promotion, because CME is not regulated as advertising.[6] CME has been used to promote many drugs[5] including

BIOGRAPHY

Adriane Fugh-Berman is a professor in the Department of Pharmacology and Physiology and the Department of Family Medicine at Georgetown University Medical Center. She directs PharmedOut, a Georgetown University Medical Center project that advances evidence based prescribing and educates healthcare professionals and students about drug and medical device marketing practices. She is a paid expert witness at the request of plaintiffs in litigation regarding drug and medical device marketing practices. Additionally, she serves on the executive board of Physicians for Responsible Opioid Prescribing.

BELLE MELLOR

CME gets around laws that prohibit off-label promotion because it is not regulated as advertising

Neurontin (gabapentin), an antiepileptic that was promoted for migraine, chronic pain, psychiatric disorders, and other off-label uses.[7] CME activities on binge eating disorder subtly promoted lisdexamfetamine as a weight loss agent, an off-label claim.[8] Most off-label uses of drugs and devices are unproved. It is impossible to assess a risk-benefit ratio without knowing whether benefits exist and when risks are misrepresented.

As a business plan unveiled in a legal case regarding off-label promotion states, "Medical education drives this market." Another internal drug company document describes a CME programme as a way to support "growth opportunity" in off-label prescribing.[7] More than half (54%) of 41 whistleblower complaints regarding off-label marketing of drugs involved CME events with speakers whom companies knew promoted off-label uses.[5]

Hiding harms

But perhaps the most damaging effect is the omission or minimisation of product harms. Opioid manufacturers have called doctors who are reluctant to prescribe opioids "opiophobic," and used CME to promote off-label use of transmucosal fentanyl products for migraines, sickle cell pain crises, injuries, and wound dressing changes.[9]

One study asked participants randomly assigned to read either a CME monograph sponsored by a fentanyl manufacturer or a clinical practice guideline on chronic non-cancer pain and to summarise the main messages.[9] Those who read the industry-funded article focused on the benefits of opioids and largely failed to mention addiction or other serious adverse effects. Those assigned to the non-industry-funded article noted, correctly, that evidence was lacking for the use of opioids in chronic non-cancer pain, and that opioids were linked to addiction and death.[9] Another study found that not one of 27 industry-funded CME modules on binge eating disorder mentioned that the amphetamines recommended for treatment can cause addiction, myocardial infarction, stroke, and death.[8]

Elsewhere, materials disclosed in litigation have shown that a CME journal supplement commissioned for a manufacturer of oestrogen drugs was specifically designed to "diminish the negative perceptions" regarding breast cancer caused by menopausal hormone therapy.[4] Marketing messages that exaggerate benefits and minimise harms of targeted therapies in CME activities have been found for hypoactive sexual desire disorder,[2] binge eating disorder,[8] chronic non-cancer pain,[9] and testosterone therapy.[3]

Influencers

Even if a CME activity is not directly funded by industry, faculty who are funded by industry convey marketing messages. A misapprehension among physicians is that doctors paid by industry are not salespeople because they do not push a specific product. But industry-funded CME activities are designed to persuade learners of industry friendly perspectives without setting off suspicion that the activities are marketing exercises.

Key opinion leaders are industry paid influencers vital to industry-biased "education." Key opinion leaders are usually academic physicians; medicine is apprenticeship based, and physicians trust their teachers. Companies identify—and also create—key opinion leaders, providing early career academic physicians with speaking engagements and other paid opportunities.[20] One study of 75 US industry-funded courses involving testosterone found that more than half of the speakers were directly paid by drug companies for speaking, consulting, or advising; 65 courses used at least one faculty member who had worked for a company that manufactured or marketed testosterone products.[3]

Selling a drug or medical device is never a key opinion leader's job. It is their job to sell the disease, preparing the terrain for marketing messages about targeted drugs to be planted. And it's not just doctors. In the US in 2018, continuing education interactions with nurses, pharmacists, and other healthcare providers increased by 61% over the previous year (some of the increase might have been due to increased reporting).[21]

"Free" education

Doctors cannot claim CME credit unless events are accredited by organisations that are supposed to ensure objectivity. In the US, the Accreditation Council for CME (ACCME) certifies providers, including universities and medical education and communications companies. The European Accreditation Council for CME (EACCME) does similar for events directly. Both have policies that prohibit mentioning brand names or emphasising specific drugs in CME. Although these policies supposedly

reduce industry influence, they align exactly with what industry wants—seemingly objective "education" riddled with marketing messages.

Both accreditation bodies depend on payments from entities that provide industry-sponsored education—a disincentive to effective actions against commercial bias. And although the ACCME claims that 90% of CME activities were not industry supported, it actually stopped counting "equipment, supplies, and facilities" and other "non-monetary resources provided by a commercial interest in support of a CME activity" as commercial support a decade ago. In other words, industry can pay for meeting space, hotel rooms, audiovisual costs, food, and other costs related to a CME event, but as long as the money is paid directly to a hotel, caterer, or other entity, none of the money is reported as "support."[24] The ACCME also doesn't count advertising and exhibit income as commercial support,[24] although industry is unlikely to purchase exhibition space at an event inconsistent with its marketing goals.

Medical education and communications companies are commonly used to hide industry funding of programmes. These companies provide meeting and event coordination, and sometimes writing services, to drug companies. In one example, to promote off-label use of Neurontin (gabapentin), a medical education company trained speakers to deliver grand rounds lectures on off-label use of anticonvulsants at 70 hospitals.[7]

Most CME is funded by drug companies, but funding by the medical device industry is also common, according to an international expert panel of 15 surgeons.[22] Industry sponsorship is only expected to grow, as academic medical centres and hospitals are expected to cease funding CME for attending surgeons by 2022.[22] The expert panel also noted that surgical residents favour free educational opportunities (which are more common with industry-funded education).

In June 2019, the European Federation of Pharmaceutical Industries and Associations affirmed that its industry members can organise and provide input to CME activities and fund independent CME activities.[23] An alliance between Mental Health Europe and organisations representing healthcare professionals and medical education stakeholders protested that "pharmaceutical companies must not be granted the right to influence the content of medical education."[23]

Activities with no commercial funding may still be commercially biased

Can bias be avoided?

Some CME accreditors might genuinely want to avoid commercial bias, but their staff are unequipped, unqualified, and unable to detect bias. Not only are they generally untrained in psychology, marketing, or content analysis, but looking for messages that emphasise a particular drug misses the bulk of marketing that doesn't mention the targeted drug at all. Marketing for a drug starts up to 10 years before a drug comes on the market, with messaging about disease states, mechanisms, and competing products. Because messages in CME foster specific diagnoses rather than specific drugs, they rarely raise suspicion.[25]

Three instruments have been developed to identify bias in CME activities. One, a nine item questionnaire, asks the audience to assess whether generic or brand names were used, whether patient care recommendations were made without citing evidence or which were inconsistent with the best evidence available, whether harms and benefits were discussed, whether strengths and weaknesses of studies were presented, and whether company logos were present.[14] Another assesses the presence of a company logo or product branding, use of trade versus generic names, off-label uses, presentation of evidence based medicine, cited sources, complete and balanced data presentation, whether one product is inappropriately championed over another, and whether the activity enhances medical knowledge.[26] The third assesses sponsorship type, percentage of commercial support, responsibility for course logistics, funds management, relationship of the course director to industry, and discussion of off-label uses.[27]

No existing tool, however, assesses subtle biases. They evaluate the use of brand names, logos, use of trade versus generic names, off-label uses, and overt off-label promotion—mistakes that no self-respecting drug company would make.

Restrict unrestricted grants

"Unrestricted educational grants"—given by industry to medical societies, universities, or medical education and communications companies—should be banned. Unrestricted grants are arguably even more effective as marketing than direct industry funding: having a middleman handle events implies impartiality.

Most of the popular CME providers accept industry support. My team's analysis of a 2020 ACCME list of accredited CME providers in the US found that 82% of the top 200 most prolific CME providers accept industry funding, and 76% receive funding for advertising and exhibits. The situation is similar in Canada, where 82% of 60 professional medical associations accepted industry sponsorship of CME.[29] In the US in 2018, commercial support constituted 26% of total CME funding, accounting for $748m (£528m) of $2.8bn spent on CME.[21] Institutional financial support covered only a median of 40% of Canada's and 30% of US total expenses.[28] (Some US academic medical centres refuse direct industry support for CME, which may explain a recent increase in industry support of medical education and communications companies.[21])

Activities with no commercial funding may still be commercially biased, especially when the course director or speakers receive funds from industry. CME managers understand that, if a sponsor is unhappy with a presentation, future business is at risk. Unrestricted educational grants are unrestricted only as long as the funder approves the content. (A personal anecdote: after a talk I gave on industry influence in medicine, the sponsoring drug company threatened to withdraw its "unrestricted" educational grant, and the hospital pleaded with the organiser to apologise to the company for inviting me. She refused.)

Sponsored CME is always related to the sponsor's business. Industry-funded CME is designed to create or expand markets for products that might be unnecessary, inferior, or overpriced. Allowing off-label promotion of drugs for untested, unproved benefits misleads clinicians about both the benefits and risks of targeted products. By affecting medical discourse, industry-funded CME distorts doctors' understanding of diseases and treatments, and ultimately harms patients.

Adriane Fugh-Berman, professor, Georgetown University Medical Center ajf29@georgetown.edu

Cite this as: *BMJ* 2021;373:n1273

The seven year wait: Northern Ireland's disintegrating secondary care services

If the province were scaled to England's population, nearly eight million people would have been waiting over a year for hospital treatment and many for much longer. **Lisa Smyth** reports

Almost 450 000 patients in Northern Ireland are waiting for an inpatient or first outpatient appointment, show figures published on 27 May. The situation is so dire that many GPs routinely recommend their patients pay for private healthcare instead. Even the health minister has acknowledged that a two tier system now operates in the province.

The reasons are complex, including Northern Ireland's recent lack of government for three years, failures to reconfigure the health system by setting up more regional services, and the covid-19 pandemic. A government commissioned report by health experts in October 2016, *Systems, Not Structures—Changing Health and Social Care*, made grim predictions about the state of health and social care services in Northern Ireland.

The options were "either to resist change and see services deteriorate to the point of collapse over time, or to embrace transformation and work to create a modern, sustainable service that is properly equipped to help people stay as healthy as possible and to provide them with the right type of care when they need it," the report said. Among its recommendations were to concentrate specialised procedures on a smaller number of sites, aggressively scaling up good practice, and ringfencing funding for transformation.

Unusually for Northern Ireland, the report received support from across the political spectrum, prompting optimism that the changes required to revive the ailing health service could happen.

Waiting lists are causing untold harm to countless people who are suffering for years
Tom Black

Government suspended

Less than three months later, however, in January 2017, the Northern Ireland Assembly was suspended during a row over a green energy scheme, dissolving any hope that reform of the health service was imminent. At that time 246 198 people were waiting for a first outpatient appointment, 19% of whom had been waiting longer than a year. By the time the assembly was restored in January 2020 some 305 017 people were waiting for a first consultant led appointment, 111 963 (37%) for longer than a year.

The New Deal, New Approach agreement that restored government in the province contained commitments that offered fresh hope. No one who had been waiting over a year for a first outpatient appointment or inpatient treatment at the end of September 2019 would still be on a waiting list by March 2021, the public was told. Of course, the ravages of covid-19 put paid to that promise (box 1).

Ministerial targets state that 55% of patients should wait no longer than 13 weeks for inpatient or day case treatment, with no patient waiting longer than 52 weeks. No specialties met both the 13 week and the 52 week target.

Waiting up to seven years

With so many people on waiting lists, it's little wonder that patients can wait anything up to seven years for a first hospital appointment—but the figures tell only part of the story.

"Waiting lists in Northern Ireland are the worst they've ever been, and they're causing untold harm to countless people who are suffering for years," says Tom Black, chair of the BMA's Northern Ireland Council.

He told *The BMJ*, "Of course, there will be patients on those waiting lists who have cancer that hasn't been picked up. You can't tell a patient that they will have to wait three or four years living in chronic pain when there is a simple operation that will resolve the issue.

"The situation has become so bad that GPs are routinely telling their patients they should be going private."

Concerns are increasing that Northern Ireland now effectively operates a two tier health service, where people who can pay can access treatment while those who can't pay languish on seemingly endless waiting lists.

Speaking at the assembly recently, the health minister, Robin Swann, admitted that this was the case. "Our health service prides itself on being available to all, free at the point of access," he said. "We are in grave danger of undermining this essential feature of our health service.

"With ever growing waiting lists, I would question whether all of our citizens have adequate access to the health services they need."

Box 1 | Latest waiting times

Data released on 27 May have only increased alarm about patient safety (figs 1 and 2).

Northern Ireland's Department of Health says that 335 042 people were waiting for a first outpatient appointment on 31 March 2021, 189 753 of whom had been waiting for longer than a year.

Some 111 209 people were waiting for an inpatient appointment, of whom 68 309 were waiting longer than a year. Meanwhile, 51 259 of the 137 235 people referred for a diagnostic test had been waiting longer than 26 weeks at the end of March.

To put this in context, the latest official figures from England show that nearly 388 000 people have waited more than a year to start treatment. If Northern Ireland's figures were scaled up to match England's population, more than 7.7 million people would have been waiting longer than a year for an inpatient or outpatient appointment (fig 3).

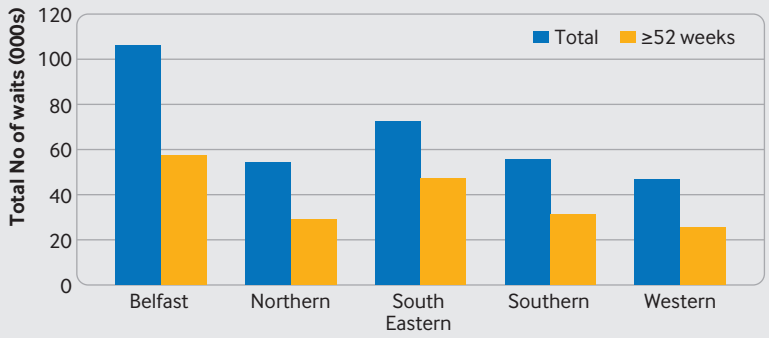


Fig 1 | Waiting lists at 31 March 2021 by health trust

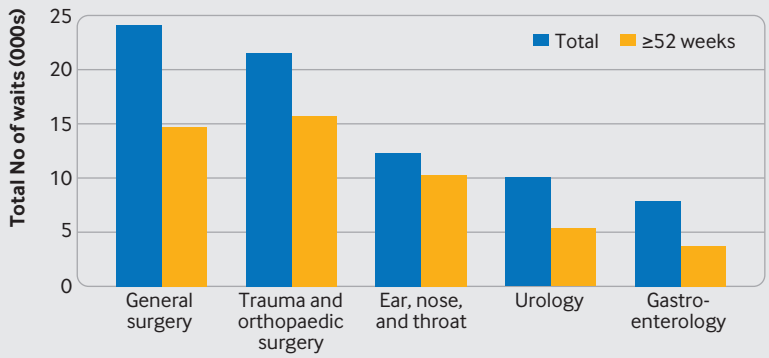


Fig 2 | Waiting lists at 31 March 2021 by specialty

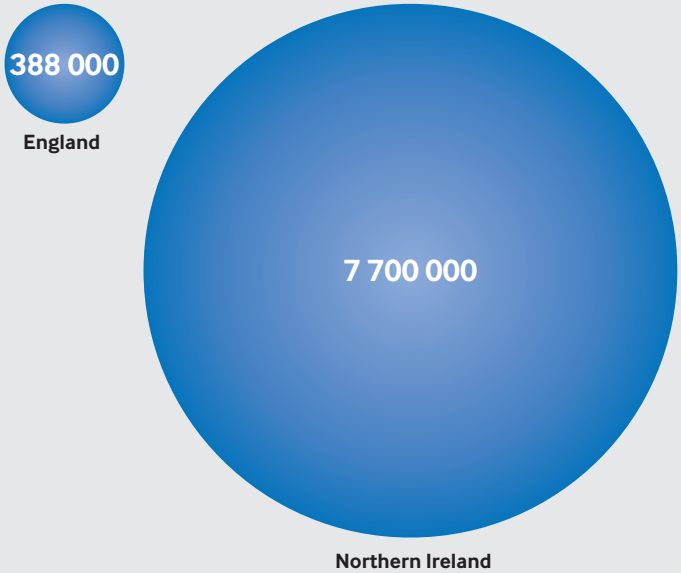


Fig 3 | People waiting more than a year to start treatment if Northern Ireland's population were scaled to match England's

Not a day goes past when I'm not speaking to people who are on a waiting list
Michael McKenna

Systemwide impacts

As well as real consequences for patients, spiralling waiting lists affect all areas of the health and social care system in Northern Ireland, creating additional stress for an already overstretched service.

Michael McKenna, a GP based in west Belfast, which has high levels of social deprivation, told *The BMJ*, "It's very difficult when you work in an area where most of the people can't afford the option of going private. There isn't a day that goes past when I'm not spending time speaking to people who are currently on a waiting list, who have been referred for issues and are coming back to have me deal with those issues.

"They're trying to get more medication or asking if there is anything else I can do to expedite their appointment. You feel completely impotent in terms of what you can do: it's hugely frustrating and demoralising, and you feel like you're banging your head up against a brick wall."

Frustrations in the medical profession are obvious on social media. Kathleen Cairns, another Belfast based GP, complained recently on Twitter that she was dealing with a growing number of phone calls from patients who have received a letter for a hospital appointment but can't remember why they were referred.

Family doctors in Northern Ireland have also been criticised for prescribing rates of antidepressant and analgesic drugs despite

I would question whether all citizens have adequate access to health services
Robin Swann

The backdrop to these appalling waiting lists is long overdue structural reform
Deirdre Heenan

having few alternatives as they manage complex, painful, and debilitating conditions in primary care, including rheumatoid arthritis, slipped discs, and chronic headaches.

Emergency departments are seeing a knock-on effect as well, as units become snarled up with patients on hospital waiting lists as their conditions deteriorate to the point of emergency. This hinders efforts to tackle growing elective waiting lists because surgeons have to prioritise the emergency admissions. It's a vicious circle, and, as the most recent figures show, the situation is in steep decline.

What can be done?

The Royal College of Surgeons of England has produced a 10 point plan that it says will reduce waiting lists in Northern Ireland. This includes a call for more "covid-light surgical sites" to treat elective patients who don't have the virus, as well as protected surgical beds and expansion of the surgical workforce.

Ultimately, however, it will take a monumental and combined effort by health professionals, policy makers, politicians, and the public to get Northern Ireland's health service back on track, while some unpopular reconfiguration of services—to include closing some hospitals—is essential (box 2).

The BMA's Black has echoed Swann's calls for the health service to receive multiple year budgets. "It's very difficult to plan for changes, particularly around workforce, if you don't know what the financial situation will be in years to come," he says. "The executive needs to sort that out. How can the health minister plan any further than next year if he is only given a one year budget?"

It will take a monumental effort to get Northern Ireland's health service back on track

However, this argument has been challenged by Deirdre Heenan, director of the Health and Wellbeing Research Centre at Ulster University—particularly after Swann's newly elected party leader, Doug Beattie of the Ulster Unionist Party, called for greater taxation to fund initiatives to reduce waiting lists.

Who is in charge?

Heenan, who has been working with the health think tank the Nuffield Trust to produce a plan to tackle waiting times in Northern Ireland, says, "This is smoke and mirrors, and if it were true, we could simply plan for nothing. The real deficit is not financial, it's in bold decision making.

"The backdrop to these appalling waiting lists is long overdue structural reform: seven major reviews in the past two decades have highlighted the need to reconfigure the system, as it isn't fit for purpose. The system is crippled by fragmentation, duplication, poor forecasting, insufficient data, outdated systems, bureaucracy, and a lack of transparency, accountability, and transparency.

"Our appalling waiting lists are a damning indictment of our 'pass the parcel' attitude to health. Who is in charge? Sir Liam Donaldson posed this question in 2015. We still don't know."

Box 2 | Too many hospitals

Successive expert reports have called for service reconfiguration: put simply, there are too many acute hospitals in the region. These reports included a review of the health service in Northern Ireland by Liam Donaldson, former chief medical officer for England, published in 2015.

Donaldson said that elsewhere in the UK a population equal to Northern Ireland's would be served by four acute hospitals, not the 10 in operation at the time. "Some populations are just too small to warrant full blown general hospital facilities, yet they are kept in place because of public and political pressure," he said.

Some populations are just too small to warrant full blown general hospital facilities
Liam Donaldson

More than six years later, little progress has been made on this front because attempts to reconfigure services are met with protests from patient groups and politicians eager to be seen protecting local services, even when stopping reconfiguration is detrimental to their constituents.

Robin Swann, health minister, has warned his Stormont colleagues against such politically motivated campaigns in the run-up to May 2022's assembly elections, vowing that he is willing to make difficult decisions regardless of the impact at the ballot box.

Even with this commitment, however, he has warned that it will take as long as a decade and £1bn to solve the waiting list conundrum. Another major stumbling block, he has said, is the lack of recurrent funding his department receives.

Lisa Smyth, health correspondent, Belfast Telegraph, Belfast
l.smyth@belfasttelegraph.co.uk
Cite this as: *BMJ* 2021;373:n1479

BMJ OPINION Deepti Gurdasani, Hisham Ziauddeen, Stephen Reicher, and Martin McKee

Delta variant: we need an urgent focus on mitigations in schools

Action is needed now to protect children and staff

MATTHEW HORWOOD/GETTYIMAGES

On 17 May, the government removed the requirement for face coverings in secondary schools in England. Writing in *The BMJ* on 14 May, we argued that this was ill advised given the clear evidence of the role of children and schools in transmission of SARS-CoV-2 and the rise of the new delta variant, which was already implicated in school outbreaks at the time.

There has been a lack of transparency from Public Health England (PHE) around the spread of delta in schools. On 22 May, an article in the *Observer* reported that these data had been withheld by PHE at the request of the government. On 31 May, the Citizens, a group promoting accountability in public life, and the data rights firm AWO sent a pre-action letter warning they would seek judicial review unless PHE published the data, on the grounds it had acted "unlawfully" by withholding data and had "surrendered its independent judgement."

Concerningly, even now PHE has failed to release full data. In a detailed technical report released on 3 June, it provided only data on the number of "incidents" or outbreaks involving two or more pupils in schools. It did not provide numbers of delta cases linked to schools, which had been specifically requested by unions and scientists and specified in the pre-action letter. Despite including several complex analyses, the 66 page report had no breakdown of cases by age.

Even the limited data provided raise concerns, however. According to the report, 140 outbreaks of delta had been identified in educational settings up to 30 May, the largest number in any of the settings specified. The data on "common exposures" (defined as two or more infected children with sequenced virus) for the week ending 11 May, just prior to dropping recommendations for masks in schools, showed that there were more than 1000 common exposures in children infected with the delta variant in educational settings. Additionally, data from PHE and the Office for National Statistics (ONS) showed the highest overall infection rates were among secondary school age children.

PHE has continued to put out contradictory claims. Just a day after reporting that infection rates were highest in 10-19 year olds, it claimed cases among schoolchildren were low. This contradicted ONS data released the same day that showed rapid rises in prevalence in this age group, with this now being much higher than all other groups. A day later the health secretary Matt Hancock stated that a "huge proportion of latest cases are in children."

As with the government's many previous errors, there is no acknowledgment that it has not followed advice from its own advisers. The government has left children, staff, and communities exposed to the rapid spread of a new and more transmissible variant, and at risk of long covid. Yet, even as we see absenteeism related to covid rising in schools, with 31% of children absent from secondary schools in Bolton, the messaging remains focused on rapid tests. This is despite dropping uptake over time and clear evidence that tests alone have not been able to contain spread in schools. Even after acknowledging the risks of infection and transmission in children, there is still no emphasis on urgent mitigations, including masks and ventilation, which are vital if schools are to remain open.

Peak in July

While we welcome the health secretary's announcement that children may be eligible to be vaccinated in August, this does not help right now. According to SAGE modelling, the current wave is expected to peak in late July. By that time thousands of children and their family members will have been affected.

Data from Bolton and several other places where delta gained dominance suggested early on that infection spread first among schoolchildren, and then to other age groups. It is likely that lack of mitigations in schools played an important role in this highly transmissible, more virulent, variant gaining dominance rapidly across England. Spread of delta is likely to have played an important role in the exponential rises of cases in England and hospital admissions in the north west.

We must reintroduce masks both at primary and secondary levels, in classrooms and communal areas

The focus by the government and media on reopening detracts from actions that need to be taken immediately to pre-empt the potentially devastating impact of a third wave. There are several actions that must be taken to keep our children safe.

First, we must reintroduce masks both at primary and secondary levels, in classrooms and communal areas. Unions have called for an immediate reintroduction in secondary schools, and several local councils have reinstated these. This needs to be incorporated into Department for Education guidance as a recommendation for all schools.

Second, there needs to be investment in ventilation and air cleaning in schools. Risk can be reduced by moving learning outdoors where possible, including PE activities.

Third, there must be practical, financial, and remote learning support for families with children who are isolating.

And lastly, the government must provide adequate resources for children who have lost out on education over the past year.

In sum, schools are the place where infections are rising fastest. Yet schools are a place where the basic mitigations of face, space, and fresh air are not simply missing, but—in the case of masks—have been removed. This makes no sense. The government must act now to protect and support its children at this critical juncture.

Deepti Gurdasani, senior lecturer in machine learning, Queen Mary University of London

Hisham Ziauddeen, consultant psychiatrist, Cambridge and Peterborough NHS Foundation Trust

Stephen Reicher, professor, University of St Andrews. Member of Independent SAGE

Martin McKee, professor of European public health at the London School of Hygiene and Tropical Medicine. Member of Independent SAGE