Call for alcohol price control in England

Further evidence of the success of minimum unit pricing of alcohol in reducing consumption has led to renewed calls for the policy to be introduced in England.

Scotland was the first country in the EU to introduce a minimum price of 50p per unit of alcohol in 2018, and Wales followed in March 2020. Research led by Newcastle University has found that alcohol sales in both Scotland and Wales have fallen since the introduction of higher prices, compared with neighbouring areas of England.

The researchers analysed 1.24 million separate alcohol purchases using sales information supplied by the global data company Kantar. This showed that, compared with the English regions, alcohol purchases fell by 7.7% in Scotland in the first half of 2020 and in Wales by 8.6%. This maintains the positive impact of the policy in Scotland, which was reported by the same researchers in September 2019 in The BMJ.

The latest study, published in Lancet Public Health, also found that the falls were concentrated in households that bought the most alcohol, although the highest purchasing households in the very lowest income bracket were not found to have reduced the amount they bought. Households that bought small amounts of alcohol, and most of those on low incomes, did not spend more on alcohol after the price rise. The greatest falls overall were seen in the purchase of ciders and spirits.

“This is powerful real world evidence of the success of minimum unit pricing as a harm reduction policy,” said Ian Gilmore, chair of the Alcohol Health Alliance.

“Westminster has said time and time again that it is waiting for evidence from Scotland and Wales on minimum unit pricing, meanwhile 80 people a day are dying from an alcohol related cause. The evidence is here—it’s time to introduce minimum unit pricing in England to save lives, cut crime, and reduce pressure on our NHS and emergency services.”

Eileen Kaner, professor of public health and primary care research who co-authored the study, said, “If we can reduce alcohol consumption, especially in the heaviest drinkers, we can reduce the alcohol attributable health burden. Overall, minimum unit pricing is an effective policy that could be easily implemented, and this evidence suggests it is a powerful, highly targeted option to reduce alcohol purchases and, hopefully, levels of consumption.”

Bryan Christie, Edinburgh
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Covid-19
Pfizer vaccine “likely” led to some deaths
The Pfizer-BioNTech covid-19 vaccine is “likely” to have been responsible for at least 10 deaths of frail elderly people in nursing homes in Norway, an expert review commissioned by the Norwegian Medicines Agency concluded. The expert group was established at the end of February to look into the cause of the first 100 reported deaths of nursing home residents who had received the vaccine. At the time, around 30 000 residents had been vaccinated.

Biden escalates efforts to identify virus origins
President Joe Biden (below) instructed the US’s intelligence community to intensify its efforts to study the origins of covid. “I have asked the intelligence community to redouble their efforts to collect and analyse information that could bring us closer to a definitive conclusion, and to report back to me in 90 days,” he said on 26 May. “As part of that report, I have asked for areas of further inquiry that may be required, including specific questions for China.”

UK approves Janssen single dose vaccine
The Medicines and Healthcare Products Regulatory Agency announced that it had approved a single dose covid-19 vaccine made by Janssen, a subsidiary of Johnson & Johnson. Trials of the vaccine, which will be the fourth to be used in the UK to protect against covid-19, found it to be 85% effective in preventing severe illness, and it can be given to over 18s. The UK has ordered 20 million doses, expected to arrive later this year.

Clinical guidance
Transvaginal laser therapy “needs more research”
NICE called for more evidence to be gathered on the safety and efficacy of transvaginal laser therapy (above) for stress urinary incontinence, as well as transvaginal laser therapy for urogenital atrophy, noting that the current evidence on their long term impact was inadequate. Kevin Harris, programme director and clinical adviser of NICE’s interventional procedures programme, said, “Carefully conducted research is required to properly understand the risks so that women are not harmed by these procedures and to ensure their long term safety and efficacy can be established.”

NICE advises inducing labour a week earlier
Pregnant women should be offered induction one week earlier than the current recommendations to help improve outcomes during birth, said draft guidance from the National Institute for Health and Care Excellence (NICE), issued after a review of the evidence. Women with uncomplicated singleton pregnancies should be offered induction at 41 weeks, to take place then or as soon as possible afterwards, the guidance said. The previous guideline in 2008 advised induction at 41 to 42 weeks and said that women who had chosen not to be induced should be monitored after 42 weeks.

Sierra Leone
Survivors of Ebola and civil war lack support
People in Sierra Leone are being failed by a lack of mental health services to cope with the devastating and lasting effects of the civil war and the Ebola epidemic. Amnesty International warned. Its report included 55 interviews with health professionals, government officials, and 25 people who had experienced violence during the civil war or had contracted the Ebola virus from 2014 to 2016, when more than 14 000 cases and nearly 4000 deaths occurred.

Northern Ireland
Doctors oppose plans for duty of candour failures
Proposals that could lead to criminal sanctions for doctors in Northern Ireland who fail to be honest with patients when things go wrong would create a hostile environment, said Tom Black, chair of the BMA’s Northern Ireland Council. The changes would also apply to doctors who witnessed a colleague making a mistake and did not report it.

CQC’s plans to rethink inspection ratings don’t go far enough, says BMA
Doctors’ leaders have urged the Care Quality Commission to rethink “crude” inspection ratings after it published a new strategy for regulating health and care in England.

The BMA said the regulator’s plans were “moving in the right direction,” but it criticised “unfairly judgmental” inspections as a poor measure of quality and a drain on resources. It said these inspections failed to acknowledge how workload pressures or staff shortages affected performance and could be “counterproductive.”

Chaad Nagpaul (left), BMA council chair, said, “Instead of instilling fear or blame in staff who are doing their best, the CQC should identify specific areas of improvement and facilitate support for positive change.”

The CQC said it was moving away from relying on scheduled inspections and that other methods, tools, and techniques would be used. Ratings would “evolve” to reflect how people experienced care so they were “focused on things that matter to them.” It added that services will be inspected “when there’s a clear need,” such as responding to risk.

Decisions would be backed by use of innovative analysis, artificial intelligence, and data science techniques, allowing it to respond quickly to changes in quality, it said.

Matthew Limb London Cite this as: BMJ 2021;373:n1390
Child health

NHS calls for ban on magnetic ball toys
The NHS called for a ban on tiny magnetic balls sold as toys that can easily be swallowed, in response to “a potentially life threatening” trend on the video site TikTok that has seen them used as fake facial piercings by teenagers. The NHS issued a patient safety alert after at least 65 children were admitted to hospital for urgent surgery in the past three years after swallowing magnets. It warned that ingesting more than one can be life threatening and can cause significant damage within hours.

Type 2 diabetes

Remission diet found to “lower blood pressure”
A weight management programme developed by researchers at the universities of Glasgow and Newcastle for the Diabetes UK funded Diabetes Remission Clinical Trial (Direct) is effective at lowering blood pressure and reducing the need for anti-hypertensive medicines, as well as bringing remission of type 2 diabetes, a study published in the journal *Diabetologia* found. Roy Taylor of Newcastle University said, “We’ve shown that when substantial weight loss is achieved and maintained, patients can effectively manage both their blood pressure and type 2 diabetes without drugs.”

Surgery

College calls for new deal to tackle backlog
The Royal College of Surgeons of England called on the government to commit to a “new deal” for surgery, to include an extra £1bn every year for the next five years to reduce the “colossal elective surgery backlog.” Its report also called for every integrated care system in England to identify at least one “surgical hub” where planned surgery can continue safely if the country is hit again by covid-19, a new variant, or severe winter pressures.

Northern Ireland's waiting lists need urgent action
Surgical services in Northern Ireland must be restored to tackle the patient harm arising from the UK’s worst waiting lists, a report from the Royal College of Surgeons of England urged. It warned of unprecedented pressures on hospitals, as many patients now need emergency care because their conditions had deteriorated while waiting. It said that the risk of harm from long waiting lists was “already being observed in all surgical specialties.”

Emergency care

Four hour A&E target to be replaced in England
NHS England is set to replace the four hour waiting time target for seeing and treating patients in emergency departments, after a consultation found 78% of professionals supported switching to a package of metrics, including measuring the average waiting time of all patients rather than the percentage treated within a specific time frame.

NHS has warned of the dangers of a TikTok trend to use magnetic balls as fake facial piercings

Drug markets

The global medicine market is expected to reach about $1.6tn (£1.13tn) in total market size in 2025. This figure excludes spending on covid vaccines, where total cumulative spending is projected to be $157bn by 2025.

Free parking for NHS staff

Put the brakes on
These passes were available through NHS trusts and allowed staff to park for free in local authority owned off-street car parks and on-street bays during the emergency.

Why the gear change?
The government has decided that as part of its roadmap for lifting restrictions the passes will be withdrawn by 21 June. It will be down to local authorities to decide whether they want to continue to offer free parking.

Are doctors in a tailspin over it?
Yes, BMA consultants committee deputy co-chair Phil de Warren-Penny has described the decision as “absolutely appalling.” He said, “This has been done without warning or consultation and is a further blow to staff who have been pushed far beyond their limits, who have been calling for a pay increase and are already feeling undervalued and underpaid.”

So, back to hospital parking then?
Yes, but that is free. It has been since March 2020, when the health secretary announced the government would cover the costs of parking for NHS staff working in hospitals in England during the pandemic. There’s no sign of a U turn on this position yet.

Won’t that cost the NHS?
It might do. In 2019-20, the last year for which we have data, NHS trusts earned more than £90m from charging staff to park. These fees are used for patient care, but they are also used to pay for maintenance costs, private contractors, and alternative transport options such as park and ride.
“Complete nonsense” to say government shielded care homes

The assertion that a protective shield was placed around care homes in the first wave of the covid is “complete nonsense,” Dominic Cummings told MPs.

He said he was shocked in April 2020 to find that residents who were being discharged from hospital were not being tested before being sent back to care homes.

Cummings said the health secretary had assured him and the prime minister that residents would be tested before being discharged but “subsequently found out that that hadn’t happened.”

He said, “The government rhetoric was, ‘We put a shield around care homes’ and ‘Blah, blah, blah’—it was complete nonsense. Quite the opposite.”

In England and Wales more than 42,000 people in care homes have died within 28 days of a positive covid test.

At a press conference on 27 May, Matt Hancock denied Cummings’s version of events, insisting he had committed to testing everyone returning to a care home from hospitals but that it “took time” to build the testing capacity. “My recollection is that I committed to delivering that testing when we could do it,” he said. “I then went away and built the testing capacity . . . and then delivered on the commitment that I made.”

Gareth Iacobucci, The BMJ
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“Thousands died needlessly from UK pandemic response”

The government and senior officials fell “disastrously short” in their response to the covid-19 pandemic, the prime minister’s former chief aide has said.

In an evidence session to the parliamentary health and science select committees’ inquiry into lessons learnt from the pandemic on 26 May, Dominic Cummings acknowledged that thousands of people died needlessly as a result of the government’s mistakes.

He told MPs that the government had been too slow to get onto a “war footing” in January and February 2020, had no initial plan beyond herd immunity, and had been too slow to impose lockdowns in March and again in the autumn. “The truth is that senior ministers, senior officials, senior advisers like me fell disastrously short of the standards that the public has a right to expect of its government in a crisis like this,” Cummings said.

The former aide, who quit in November, was highly critical of the prime minister, calling him “unfit for the job.” He claimed that Boris Johnson initially dismissed covid-19 as a “scare story” and was later reluctant to lock down again in September 2020 despite the clear evidence from the first wave.

“There’s this great misunderstanding people have that because it [covid] nearly killed him therefore he must have taken it seriously,” said Cummings. “But in fact, after the first lockdown, he was cross with me and others with what he regarded as basically pushing him into the first lockdown.”

Cummings called for the public inquiry into the handling of the pandemic to start as soon as possible, because “a lot of the reasons for why [thousands of people died] are still in place.”

Cummings said that Johnson was fixated on reopening the economy, regretted the first lockdown, and ignored advice from him, the chief scientific officer, and the chief medical officer to impose a “circuit breaker” lockdown last September when covid cases were surging.

Speaking at prime minister’s questions in response to Cummings’s claims, Johnson told MPs, “The handling of this pandemic has been one of the most difficult things this country has had to do for a very long time, and none of the decisions have been easy.

CUMMINGS claimed Boris Johnson initially dismissed covid-19 as a “scare story” and was later reluctant to lock down in September despite the clear evidence from the first wave

Hancock “should have been fired at least 15 to 20 times”

Cummings launched an incendiary attack on the health secretary for England’s handling of the pandemic, accusing Matt Hancock of “lying to everybody on multiple occasions.”

He claimed that Hancock, under pressure to explain the shortage of personal protective equipment last April, falsely accused NHS England chief Simon Stevens and the Treasury of blocking orders. Cummings said an investigation by the now former cabinet secretary Mark Sedwill found this to be false, prompting both Cummings and Sedwill to urge the prime minister to fire Hancock.

“Lying to everybody”

Cummings said, “The secretary of state for health should have been fired for at least 15 to 20 things, including lying to everybody on multiple occasions in meeting after meeting in the cabinet room and publicly.” He added, “I said repeatedly to the prime minister he should be fired, so did the cabinet secretary. So did many other senior people.”

Cummings said there were “numerous” other examples of Hancock lying, including last summer when he said that everybody who needed treatment got the treatment they required during the pandemic.

“He knew that was a lie because he’d been briefed by the chief scientific adviser and chief medical officer about the first peak. We were told explicitly that people didn’t get the treatment they deserve. Many people were left to die in horrific circumstances.”

Cummings added, “There are many senior people who, during the pandemic, fell disastrously
What did we learn from the former No 10 aide’s select committee hearing?

Besides shedding light on what happened at critical moments during the pandemic, the former aide’s evidence to the House of Commons committee last week also provided some lessons for learning. Most important were the governance problems he described, which taken together portrayed a system that is not fit for purpose and go some way to explaining why the UK’s response was so poor.

The first relates to transparency. Cummings described a bizarre paradoxical situation. In theory, key decisions should be made at Cobra meetings, which are supposed to be top secret but “leaked like a sieve,” said Cummings, with the media hearing about what was discussed almost in real time. As a consequence, the meetings were, it seems, dysfunctional, consisting mainly of anodyne PowerPoint presentations.

Scientific advice

Conversely, the scientific advice to the government, channelled mainly through SAGE, and which should be transparent, was at the start of the pandemic a closely guarded secret, as were the names of the experts giving the advice. Cummings’s account suggests this was a big mistake. There was groupthink. Cummings described how he sought advice from two leading mathematicians who challenged these views, and SAGE was eventually opened up to scrutiny.

A second lesson relates to government capacity. Cummings related many accounts of junior staff doing remarkable things in record time but also examples of monumental incompetence. He confirmed there was no plan for the pandemic or for disposing of the bodies of those who might die, nor any for emergency procurement.

One quote from his evidence stands out: “The political system is not set up to deal with a secretary of state who repeatedly lies.” But maybe this raises wider questions about all ministers.

However, the chances of doing anything about it seem remote. As Cummings said, “The British state is set up almost by design to create a dysfunctional system.”

Martin McKee is professor of European public health at the London School of Hygiene and Tropical Medicine.

THE GOVERNANCE PROBLEMS HE DESCRIBED PORTRAYED A SYSTEM NOT FIT FOR PURPOSE.
England is set to remove all legal limits on social contact from 21 June and allow nightclubs to reopen, although masks may still be required in some public spaces and the test and trace system will continue.

However, the emergence of the Delta (B.1.617.2) variant, first detected in India, has led to concerns that further easing may need to be delayed. As cases of this variant spread across the country, The BMJ looks at what we know.

What do the data on cases and admissions show?
Latest data from Public Health England (PHE) show that cases of the B.1.617.2 variant have risen by 3535 from 12 May to 19 May, totalling 6959. While Bolton, Bedford, and Blackburn with Darwen still have the highest prevalence, most parts of the country now have cases of the variant. The report says that B.1.617.2 is likely more transmissible than the Alpha (B.1.1.7) variant, first identified in the UK.

“In some affected areas, hospitalisations are rising,” said PHE. “Hospital attendances and admissions are predominantly in unvaccinated individuals, highlighting how crucial it is that people in these areas come forward to receive vaccination.”

Around England 201 people with the B.1.617.2 variant had attended emergency departments and 43 had been admitted, as of 25 May.

Chris Hopson, chief executive of NHS Providers, told Times Radio on 26 May, “Trust leaders are telling us that covid-19 hospital cases are increasing steadily in areas most affected by the variant first identified in India but not at an alarming rate. Hospitalisations clearly seem to be focused among those patients who haven’t been vaccinated yet. “The proportion of those requiring critical care is lower than in previous waves, which trust leaders are putting down to the lower age range of patients than in previous waves.”

However, Neil Ferguson, an epidemiologist at Imperial College London, has said that the B.1.617.2 has now overtaken the B.1.1.7 to become the dominant variant. He told BBC Radio 4’s Today programme on 27 May, “It’s now in well over the majority of local authority areas in the country and is now the dominant strain. The majority of new cases are of the variant: that is obviously concerning.”

On the same day, England’s health secretary, Matt Hancock, said as many as three quarters of all new covid cases in the UK involved the B.1.617.2 variant.

What do the latest national mortality data show?
The Office for National Statistics’ latest data release reported 151 deaths mentioning covid-19 (1.5% of all deaths) in the week ending 14 May. This was an increase on 129 deaths the previous week, but the ONS warned that the difference should be “interpreted with caution” because of the early May bank holiday. Most of the covid-19 related deaths were in people aged over 75.

Danny Mortimer, chief executive of the NHS Confederation, said, “Any rise in the number of deaths involving covid-19 is cause for concern, and with reports of rising hospitalisations as the variant first identified in India continues to spread, the government must think extremely carefully about its next steps. “If this increase continues, it must be ready to adjust or reverse the timetable for easing lockdown. Given the warnings on the increased transmissibility of the variant, it is also vital that the government goes further to overcome financial barriers to self-isolation in our poorest communities.”

Is surge testing making any difference to the data?
Surge testing has been rolled out in areas considered to have high levels of the B.1.617.2 variant. In these areas, residents and people who are in the area for work or education are encouraged to take a PCR (polymerase chain reaction) test, even if they are not showing symptoms. Additionally, second covid-19 vaccine appointments have been brought forward from three months to eight weeks for people in the nine priority groups.

However, while this is not the first time that surge testing has been rolled out for a variant of concern, no evidence has yet been made public to show whether it’s effective.

What about surge vaccinations?
Surge vaccinations—where younger and unvaccinated adults are preferentially targeted for vaccination in areas with high prevalence or rapidly growing outbreaks—have been rolled out in a number of areas in England including Bedford, Bolton, Burnley, Kirklees, Leicester, London, and North Tyneside.

The Scientific Advisory Group for Emergencies (Sage) reviewed surge vaccinations and said that although it could be “operationally challenging” and might slow vaccinations in other parts of the country, the benefit in areas of high variants of concern growth was “many times higher.” Sage specified that, because of...
the lag between vaccination and protection, surge vaccinations must be started as soon as possible while the number of variant cases remains relatively low. They should also be targeted at a wider geographical area than where the variant is prevalent, said Sage, and should be accompanied by “short term non-pharmaceutical interventions covering the area in question, to allow for the surge vaccination to have time to take effect.”

How effective are the vaccines against the B.1.617.2 variant?
A preprint paper released by PHE on 22 May found that, two weeks after the second dose, the Pfizer-BioNTech vaccine was 88% effective against the B.1.617.2 variant, and the Oxford-AstraZeneca vaccine was 60% effective. However, both vaccines were only 33% effective against symptomatic disease from B.1.617.2, three weeks after the first dose. This led to calls for the vaccination programme to be speeded up and for the next stage of restriction easing to be delayed.

PHE reported on 27 May that its updated analysis of nearly 3000 symptomatic cases of the B.1.617.2 variant reinforced the message that two doses of either vaccine were “highly effective against the variant first identified in India.”

Generally, covid-19 vaccines have so far prevented nearly 40,000 hospital admissions and more than 13,000 deaths in people aged over 60 in England as of 13 May, PHE has estimated.

What do the data on school transmission show?
This is exactly what many teachers, unions, and scientists would like to know. The government announced on 10 May that secondary school students would no longer be advised to wear masks in classrooms or communal school spaces from 17 May, but many people have urged them to publish the evidence behind this decision.

In its announcement the

We believe that step four of the roadmap should be delayed until a much higher proportion of the population has been fully vaccinated

Independent Sage report

Department for Education said, “Transmission of the virus in schools continues to decrease in line with wider community transmission, with the latest statistics showing a significant drop in the number of teachers and staff testing positive. The decision has taken into consideration the latest scientific evidence, medical advice, and stakeholder feedback on the impacts of wearing face coverings in schools and colleges.”

However, the published version of the PHE report, which looked at the spread of the B.1.617.2 variant, did not include a page of data on the variant’s spread in schools that the Observer said it had seen. This led to accusations that this had been removed after pressure from Downing Street.

Eight unions have since written to the government and PHE demanding that they publish the “missing” data. The letter said, “There are growing concerns around the variant B.1.617.2 and reports from areas such as Bolton that cases are growing fastest among school age children, with cases in Bolton higher now than at any point during the pandemic.

“Education unions have repeatedly requested this data since early May. It should have been released in advance of the change in guidance on face coverings, which came into effect on 17 May.”

Should the final restrictions be eased on 21 June?
Not according to Independent Sage, which has advised that the next phase of easing should be delayed because only 43% of adults (30% of the whole population) have received two doses of the vaccine, and one dose does not offer enough protection.

Its report said, “Unless the risk assessment for B.1.617.2 is downgraded in the coming weeks as more evidence emerges, we believe that step four of the roadmap should be delayed until a much higher proportion of the population has been fully vaccinated or until new evidence of reduced risk emerges.

“Allowing cases to continue to rise will result in a greater burden of long covid, risks the Sage modelling predictions becoming true and risks new variants evolving with higher levels of vaccine escape and/or higher transmissibility. The risk of simply waiting and watching is too high.”

Sage previously said that if the variant was found to be more transmissible than the B.1.1.7 variant, which was previously dominant, “it is a realistic possibility that progressing with all roadmap steps would lead to a substantial resurgence of hospitalisations.”

Some people have highlighted Israel—where lockdown was eased once 70% of the population had received two doses—as an example to follow. In the UK, 36% of the population has had two shots.

Speaking to the Today programme on 28 May, the Independent Sage member Christina Pagel, a mathematician from University College London, said, “If we can just delay international travel, delay stage four of the roadmap until we have a much higher proportion of people vaccinated with two doses, we’re in a much, much better position.”

Elisabeth Mahase, The BMJ
Cite this as: BMJ 2021;373:n1399

BOTH VACCINES were only 33% effective against symptomatic disease from B.1.617.2, three weeks after the first dose
THE BIG PICTURE

Call for UK to back covid vaccine waiver

Campaigners demanding an intellectual property waiver on covid-19 vaccines and treatments stage a protest at the Department for International Trade, in London, at the start of the two day virtual meeting of G7 trade ministers last week.

Protesters from Global Justice Now and STOPAIDS called for trade ministers from G7 nations, including the UK’s Liz Truss, to support a waiver of the vaccine manufacturers’ trade related intellectual property rights (TRIPS) agreement.

As a petition calling for G7 leaders and pharmaceutical chief executives to suspend patents passed two million signatures, Heidi Chow, senior campaigns and policy manager at Global Justice Now, said, “Liz Truss and her G7 counterparts have a choice to make. “They can protect big pharma profits and prolong this pandemic. Or they can follow the United States, India, South Africa, and the majority of the world’s nations and clear away the intellectual property barriers that are restricting global vaccine production.”

Alison Shepherd, The BMJ
Cite this as: BMJ 2021;373:n1388
END VACCINE APARTHEID - SUPPORT TRIPS WAIVER NOW!
Preparation for the next pandemic
Independent panel’s recommendations fall short

"Make it the last pandemic," urges the report of the Independent Panel for Pandemic Preparedness and Response, convened by the World Health Organization to assess the handling of covid-19. The report highlights how governments and international organisations did too little to mitigate covid-19. It proposes a plan to end this pandemic and prevent another one.

The panel makes six recommendations. Governments must urgently provide oxygen, diagnostics, and vaccines equitably worldwide to halt the spread of SARS-CoV-2. All nations must strengthen their capacity to prevent, detect, and respond to pandemics. A high level global council on health threats should be established for political attention and allocation of pandemic funds. Countries should adopt a new, legally binding pandemic treaty. A global platform should be built for equitable development and distribution of drugs, vaccines, and medical supplies. And WHO should get more power and money.

These are good recommendations. But we need bigger reform. The problem is one of government compliance. States gave WHO the mandate to lead any response to emerging epidemics within the International Health Regulations (IHR). Yet many countries ignored WHO advice, focused on nationalistic approaches, and rejected norms of global solidarity.

Rich nations continue to reject such norms, hoarding covid-19 vaccines and blocking poorer nations from local production. Ironically, many of the same governments are pushing hardest for a pandemic treaty.

Under this treaty, governments would commit to legally enshrined solidarity to prevent and mitigate future outbreaks. Yet leaders have failed to comply with international legal obligations under IHR in the past 16 months, so any new treaty must include meaningful sanctions for non-compliance, or incentives such as financing tied to reporting outbreaks and sharing information.

### Mandatory funding commitments

The panel proposes a new international pandemic financing facility with contributions of $5bn-$10bn (£3.5bn-£7bn) annually, to finance ongoing preparedness and emergency response. Wealthier nations would pay the most. Yet governments have previously failed to fund preparedness voluntarily, so a mandatory mechanism is needed. Moreover, the distribution of such funds should be tied to reporting under IHR, incentivising compliance.

A threats council could be valuable, but it would need powers and governance more akin to the UN Security Council than current global health structures that are unable to curb powerful states. Without care, it could take remaining political power from WHO, further weakening the institution that the panel seeks to strengthen as the lead coordinator for global health emergencies.

The panel’s suggestion to assess preparedness through the powerful International Monetary Fund, which lacks health expertise and has policies that often undermine public health, would better be scrapped in favour of giving WHO more leverage.

The panel recommends that the Access to Covid-19 Tools Accelerator, launched 13 months ago to speed development and equitable access to tools for controlling covid-19, should be made permanent. But equitable access to vaccines and diagnostics has not been secured, with lower income countries locked out—by rich countries, and by private monopolies on knowledge and production.

Making the accelerator permanent is unlikely to solve these problems, which demand fundamentally different power and knowledge structures.

Global leaders should do even more while the window for change is open. “If not now, then when?” says the panel. We agree. Emergency funding should be tied to the declaration of a public health emergency of international concern—from mandatory contributions that are sufficient to enable rapid response.

The panel proposes an automatic waiver of World Trade Organization rules on intellectual property over covid-19 tools if companies do not volunteer to share know-how in three months from now—but why wait three months? This waiver could be made automatic in future international health emergencies. If a treaty is to be written, it must be enforceable—even if only through mandatory reporting. Giving global health governance and WHO sufficient political power and financing is the only way to end to the cycles of panic and neglect we continue to experience worldwide.

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**Editorial Staff**

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Find the full version with references at [http://dx.doi.org/10.1136/bmj.n1295](http://dx.doi.org/10.1136/bmj.n1295)
Rethinking sex-assigned-at-birth questions

Unhelpful, potentially harmful, and should be abandoned

Many scholars support the collection of data on sexual orientation and gender identity in clinical, research, and census records to improve collective knowledge of sexual and gender minority health. Organisations often recommend using two-step questions to record identity: typically an initial question about gender (“What is your gender identity?”) followed by one about sex assigned at birth (“What sex were you assigned at birth, on your original birth certificate?”). However, transgender people have concerns about sex-assigned-at-birth questions, and these questions may not be the best way to obtain the information that clinicians need.

The United Nations recommends that all countries maintain a population registry in which sex is a required personal detail. The rationale has been to uphold sex specific rights, duties, and policies such as those related to military service, pregnancy, and segregation in prisons and other facilities. Medicine also has a longstanding history of dividing the population by sex assignment for the purposes of identification, inpatient care, and policy enforcement.

Questions about sex assigned at birth were putatively added to questions about gender to identify more transgender people for research purposes, to increase clinicians’ knowledge about their patients, and to inform both preventive healthcare and differential diagnoses in acute care settings.

However, no evidence exists that clinicians with knowledge of assigned sex provide better care, and recent qualitative research suggests that most transgender people do not believe people should be asked about their sex assigned at birth. Clinicians assign sex according to the external genitalia of a baby. This determination may not fully characterise a person’s chromosomes, hormonal milieu, or external and internal anatomy. Up to 2% of participants in population based studies have bodies that do not fit dimorphic sex classification, and other people have chromosomal abnormalities that may make external appearance an incomplete characterisation of later hormonal milieu.

Changes to bodies over a lifetime—for example, through hysterectomy or orchietomy—may also render sex assignment an incomplete or obsolete assessment of anatomy and physiology. Questions about sex assigned at birth cannot serve as shorthand for anatomy (Do I need to add testicular torsion to my differential diagnosis?), hormones (Do I need to consider the role of oestrogen in this person’s thromboembolism?), or screening needs (Would cervical smear testing improve this person’s health outcomes?).

Who are they harming?

These questions have the potential to harm patients when they are used as a proxy for the more specific questions about anatomy and hormonal levels required to determine someone’s health needs. Furthermore, they do not inform clinicians about patients’ identities, names, or pronouns, all of which are important for truly inclusive clinical encounters. Instead, they may worsen rapport since sex assigned at birth is a construct that often clashes with the identity of transgender, intersex, and other people.

Given that sex assigned at birth does not accurately characterise gender identity, anatomy, or the health needs of individuals we recommend that questions about sex assigned at birth are abandoned. When specific information about anatomy, physiology, hormonal medication, and history are required in clinical settings, individually tailored questions are more likely to provide the answers required for safe and efficacious patient-centred care.

In both clinical and research settings, questions that allow patients to self-identify as transgender are critically important to identify and quantify health disparities and to develop effective interventions to reduce them. Questions about transgender identity should be developed by transgender people and vary according to setting, such as research, clinical practice, and census records. Questions regarding gender, transgender, and other relevant identities should be asked in research settings; in clinical settings, questions about pronouns and anatomy may be more relevant. These questions should be rigorously evaluated in the setting for which they were developed.

Recognising and respecting the gender of another person provides an opportunity to connect in a non-hierarchical manner. More broadly, recognising gender without reference to flawed constructs around sex assigned at birth allows us all greater personal autonomy and is key to eliminating transphobia in medicine and beyond.
The road to Recovery: the world’s biggest covid treatment trial

CLINICAL RESEARCH

With the largest study of covid therapeutics finding dexamethasone saves lives, the UK leads global research. Chris Stokel-Walker looks at the 40000 patient programme, and why studies elsewhere have faltered.

Hatched on a London bus ride on 9 March 2020, Recovery quickly became—and remains—the largest covid-19 treatment trial in the world, with nearly 40000 patients enrolled at 181 sites globally, helping to shape the treatment of patients worldwide during a live and ever-changing pandemic.

“We realised—on the now famous bus trip—that we had to get a treatment trial up and running into routine clinical pathways within hospitals in advance of the pandemic really hitting hard,” says Martin Landray, deputy chief investigator of Recovery. “We were fighting a deluge of admissions to hospital,” says Ian Hall, director of the Nottingham Biomedical Research Centre and a principal investigator in Recovery, of the early days of the pandemic.

“Everybody was under enormous pressure back then,” says Landray, adding that they realised, “You’ve got to do something. We can’t wait another two months to get a result. People are dying today.”

Funding bodies

The UK has historically made significant investments in infrastructure—largely through the National Institute for Health Research (NIHR)—that enable it “rapidly to roll out clinical studies across many centres if there’s a need to do so,” says Hall.

“We really have got it right here in the UK,” says Emmanuelle Denis of Oxford University, who is supporting Recovery as it expands internationally. “And, partly, it’s the integration of the NIHR with the NHS.”

Both the NIHR and UK Research and Innovation, which acts as a non-departmental government funding body, provided significant funding for coronavirus trials, as have independent non-profit organisations like the Wellcome Trust, which co-funds Recovery.

At the same time, the Medicines and Healthcare Products Regulatory Authority (MHRA), which regulates clinical trials, cut the amount of time to approve covid-19 studies 10 fold, down from around 60-90 days to just 6-10 days.

The MHRA’s streamlined approach enabled Recovery to enter the field within nine days. This required a rethink away from the overly cautious, risk averse approach that has pervaded medicine, says Landray.

“Very often trials are seen as being risky, and not to do trials is fine as a sort of unjustified faith in the quality of the evidence base that goes behind routine care,” he told The BMJ. Yet, in reality, much of medicine isn’t based on evidence from formal clinical trials but on physicians’ intuition, supported by prior cases. Landray points to cardiology, where he estimates just 15% of clinical guidelines are based on robust evidence from randomised trials—“and cardiology is probably at the top of the evidence based tree,” he says.

Every hospital across the country was set the challenge of enrolling one in 10 of its covid-19 patients into the trial, a target it succeeded in achieving. Some hospitals, led by individual doctors, managed to recruit at an astonishing rate.

It also eliminated some of the political egos that can clog up clinical trial approval, Hall adds. “Many clinical academics or centres feel somewhat competitive about the way they work and think they know how to do it—and that their colleagues down the road don’t do it as well. But any differences that might have existed were largely put to one side.”

Red tape cut

Landray says, “The really important thing was stripping away everything else that doesn’t matter.” For example, a recent analysis of four vaccine trials’ consent documents found that their average length was 8333 words, requiring participants to read for 35 minutes to provide consent.

Among the most lauded features of Recovery is its clear endpoint: does the drug reduce mortality? “If one in four people who go into hospital are dying, then the thing we need to know is: ‘Does drug X reduce the risk of dying?’ And if it does, will almost everything else be by the by?” says Landray.

We already know, for instance, that steroids increase blood glucose, and the risk of infection, “We didn’t need to know that all over again by running it in the trial.” Likewise, the use of pre-existing primary care data enabled
Go global

Over a year since Recovery first started, the UK remains the leader in covid-19 treatment trials, running more than anywhere else. That seems remarkable given the pandemic’s continuing grip around the world. Even the US, with the world’s biggest economy and the heaviest covid toll, has just one major therapeutics trial—Activ-3 run by the National Institutes of Health and with 10000 participants. “I don’t think that’s down to a lack of will within the US,” says Hall, “it just seems to be more difficult. They haven’t—I don’t think—invested in the underpinning infrastructure in quite the same way.”

The second largest covid-19 therapeutics trial—the World Health Organization’s Solidarity—reported interim results for four drug treatments from 405 hospitals in more than 30 countries in October 2020, just six months after launching. None of the four showed an improvement in patient outcomes. After a seven month pause, on 7 May, WHO announced a second phase focused on inflammation. Why it took over half a year to start the next phase is uncertain: WHO did not respond to requests to comment for this story. Sources The BMJ spoke to were cagey about commenting on the delay, but attributed it to high levels of bureaucracy and the challenges of coordinating many countries.

Strub-Wourgaft helps oversee the Anticov trial, conducted across 13 African countries by 26 partners. “You duplicate the questions by 13 when you have 13 countries,” Strub-Wourgaft says. All the problems that Recovery could quickly expedite—including political sensitivities—become more difficult when dealing with so many countries who want to manage things according to their own culture, she says.

When she proposed the terms of the Anticov trial to the countries participating, she received more than 300 questions. Some were duplicated across countries, but many weren’t. “They have to do it right, and to do it right, they need to take time,” Strub-Wourgaft says.

Anticov got going in November last year and started a new arm in April, recruiting participants to test a drug combination of nitazoxanide and ciclosporine to treat mild and moderate cases of covid-19.

Strub-Wourgaft freely admits to being jealous of Recovery’s fast track processes, prioritisation, and resources. “The problem in low and middle income countries is that you don’t have all those resources that are up and ready to be mobilised.”

In February, Recovery launched an international expansion to its trial, starting in Indonesia, Nepal, and Vietnam (Denis, who is liaising between them and the UK team, told The BMJ that there are also plans to launch an arm in Ghana). At the time of writing, there are 127 participants across four sites.

Recovery International aims to find alternative treatments and therapeutics that can be used in areas where medical and infrastructural resources are weaker than in the UK. It initially planned to test the efficacy of aspirin and colchicine against covid but has switched to more promising therapeutics: a high dose dexamethasone course of treatment, and the monoclonal antibody infliximab.

The teams took pains to reset expectations of speed from the off. “In the UK, the trial could be rolled out rapidly thanks to the joined-up nature of the NHS,” says Denis. “Where Recovery in the UK was able to streamline a lot, we’re finding that it may be more difficult to do that in other places.”

One way they hope to speed up approval is with the support of the MHRA, that has offered to talk to other countries’ regulatory authorities to “reassure them and share their experiences,” says Denis.

“I can’t tell you how exciting it is to be part of Recovery,” she says. “It’s going to be a game changer for academic led clinical research. It will show that you can strip away a lot of the extras that are expected to be done and take a really risk based approach.”

“When you look at it and see how many people have been helped, just by dexamethasone, it will help to persuade regulators in the long run of the benefits of taking a more pragmatic, streamlined approach in trials like this where you’re using known drugs.”

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How harm reduction advocates and the tobacco industry used the pandemic to promote nicotine

Scientific papers suggesting that smokers are less likely to fall severely ill with covid-19 are being discredited as researchers’ links to cigarette and e-cigarette manufacturers are revealed.

Stéphane Horel and Ties Keyzer report

In the early days of the pandemic, media outlets around the world reported that smokers seemed to be under-represented among patients seriously ill with covid-19 in China and France. The headlines asked, does nicotine protect against covid-19?

The origins of this hype were two preprints published in quick succession in April 2020 by a team at the Pitié-Salpêtrière Hospital in Paris, led by Zahir Amoura. The first found that only 5% of patients with covid-19 were smokers. Their second study hypothesised that nicotine might act on ACE2, the virus’s entry receptor. “Nicotine substitutes may provide an effective treatment for acute infections such as covid-19,” the authors argued.

The stories made headlines worldwide. They were also picked up by libertarian media outlets such as the British online magazine Spiked. “Smoke fags, save lives,” encouraged Christopher Snowdon, director of lifestyle economics at the Institute of Economic Affairs, an industry sponsored think tank supported by the tobacco industry.

The World Health Organization worried that decades of tobacco control could be undermined. “Smoking is responsible for eight million deaths each year from cardiovascular and lung diseases, cancer, diabetes, and hypertension,” WHO stated in response to the French studies, explaining that “available evidence suggests that smoking is associated with increased disease severity and mortality among hospitalised covid-19 patients.”

It has since been roundly disproved that smoking protects against covid-19. Among other studies, the OpenSafely dataset, based on the primary care records of 17.3 million adults in the UK, found that smoking, when adjusted for age and sex, was associated with a 14% increased chance of covid-19 related death.

The BMJ can today also report on undisclosed financial links between certain scientific authors and the tobacco and e-cigarette industry in a number of covid research papers. This follows the high profile retraction of one such paper in the European Respiratory Journal last month, after two authors failed to disclose conflicts of interest.

Early concern
Tobacco watchdogs first became concerned after the publication of one of the Paris preprints, which floated the hypothesis that nicotine might have a protective effect against covid-19. The name of one of the coauthors rang alarm bells.

A neuroscience celebrity and specialist in nicotine receptors, the retired Collège de France professor Jean-Pierre Changeux has a history of receiving funding from the most infamous tobacco industry front group, the Council for Tobacco Research, whose purpose was to fund research that would cast doubt on the dangers of smoking and focus on the positive effects of nicotine. From 1995 to 1998, tobacco industry documents show that Changeux’s laboratory received $220 000 (£155 000) from the Council for Tobacco Research.

This is a “sensitive issue [that] has unfortunately given rise to ‘fake news’ about me,” wrote Changeux in an email to the authors of this BMJ article. He has not received any funding linked “directly or indirectly with the tobacco industry” since the 1990s, he said.

Even before the Paris preprints a Greek researcher, Konstantinos Farsalinos, was the first to publish a preprint on this subject, noting “the relatively low prevalence of current smoking” in patients admitted to hospital with covid-19 and relating it to ACE2 receptors. In the absence of data on e-cigarettes he suggested that the potential protective effects of nicotine were “equally applicable” to them. Since then Farsalinos has championed the “nicotine...
hypothesis” in a dozen preprints and articles, as well as in tobacco industry circles such as the Global Tobacco and Nicotine Forum. In September 2020 he was a speaker in a panel on “the role of nicotine in the fight against covid-19” alongside the director of scientific research for British American Tobacco, which manufactures Lucky Strike cigarettes.

Farsalinos, a cardiologist affiliated to the universities of Patras and West Attica in Greece, is “one of the most prominent researchers in the field of electronic cigarettes,” his own blog states. “Dr F”, as he is known in the very active online vaping community, started publishing on e-cigarettes in 2011 and has published almost 100 scientific articles on the subject since.

Tobacco harm reduction
For almost a decade Farsalinos has also been at the heart of a small, seemingly hyperactive network of scientists and consultants who advocate for vaping and tobacco harm reduction (THR) through initiatives sometimes akin to lobbying.

Writing letters to WHO, the European Parliament, the European Commission, and national governments, these advocates urge policy makers to “embrace harm reduction.” Stemming from treatment for drug addiction, the THR approach recognises that some smokers are unable to quit and should rather switch to non-combustible nicotine delivery products, positioned as “reduced risk products.”

THR is a complex concept, advocated by individuals with ties to the tobacco industry or to e-cigarette manufacturers, as well as by public health experts and consumers who are convinced that it is a solution. In the UK, for example, the basic principle of harm reduction in tobacco control is accepted as having a place in smoking cessation by NICE and the Royal College of Physicians, among others.

Nick Hopkinson, reader in respiratory medicine at Imperial College and chair of Action on Smoking and Health, says, “There are staunchly anti-tobacco industry groups that acknowledge tobacco harm reduction among other approaches based on what we know about the safety [or] effectiveness of e-cigarettes.”

Ruth Malone, editor in chief of Tobacco Control, wrote in a recent editorial that “different countries already take very different approaches” to newer and novel nicotine and tobacco products (NNNTPs), which “keep popping up like Whack-A-Mole,” and that “it can be hard to find a place to stand together on shifting sands.” She added, “The proliferation of new NNNTPs creates much instability, with resources potentially diverted from work to advance basic tobacco control policies to studying, sorting, arguing about and addressing the wide range” of those products.

WHO, which does not endorse THR, warns policy makers that electronic devices also pose a health risk. It has said of e-cigarettes, “There is insufficient data to understand the full breadth of their impact on health, as devices have not been on the market long enough.”

However, tobacco companies redeployed THR as a marketing strategy to sell their new products: e-cigarettes and heated tobacco products. Philip Morris International, the largest cigarette manufacturer, began the staggered launches of IQOS, its stylishly designed heated tobacco product, in 2014. Smokeless products now account for nearly 19% of the company’s sales—nearly £5bn (£4.3bn) in 2019.

Although his preprint on the Qeios website had gone largely unnoticed, Farsalinos was the first to publish the “nicotine hypothesis” formally in a journal, in the form of an editorial in Toxicology Reports in late April 2020. The journal’s editor in chief, Aristidis Tsatsakis, whose name was
not present in the preprint, featured as a coauthor. Another coauthor, A Wallace Hayes, was a member of Philip Morris International’s scientific advisory board in 2013 and has served as a paid consultant to the tobacco company.

University conflicts
Another coauthor on the Toxicology Reports editorial on the nicotine hypothesis is Konstantinos Poulas, head of the Molecular Biology and Immunology Laboratory at the University of Patras, where Farsalinos is affiliated. The laboratory has received funding from Nobacco, the market leader in Greek e-cigarettes. Their partnership included the development of “nicotine e-liquids” through funding of up to €75 000 a year, Greek accounting documents show. Nobacco has been the exclusive distributor of British American Tobacco’s nicotine delivery systems since 2018.

Neither Farsalinos nor Poulas has ever declared this Nobacco funding in their published scientific articles. Both authors attended the press conference launching the Nobacco project in 2014.

Poulas has not responded to multiple requests for comment for this article. In an email response Farsalinos said that he was unaware of the relations between Nobacco and Patras University and was therefore unable to mention it. “I have never participated in any project funded by a commercial entity,” he added, accusing us of “witch hunting.” Nobacco took the webpage mentioning their collaboration offline shortly after being contacted.

Research funding
Farsalinos nonetheless received a fee from the American E-Liquid Manufacturing Standards Association, in connection with two studies and his presence as an expert at a meeting with US regulators in 2016. In declarations of interest through the years across journals, he also disclosed funding from the Tennessee Smoke Free Association, FlavourArt, and Nobacco for an earlier study in 2013.

Poulas, for his part, declared in a 2019 paper “a scoping grant by the Foundation for a Smoke Free World,” a non-profit established by Philip Morris International in 2017, with a funding commitment of $1bn over 12 years to promote “harm reduction science.” Four years later, Philip Morris International is still the foundation’s only funder. Claiming “to end smoking in this generation” and distributing grants worth millions, the foundation is in other respects similar to the many front groups that the tobacco industry has set up in the course of the last century to manufacture doubt about the harmful effects of smoking. In the days following its creation, WHO’s Framework Convention on Tobacco Control secretariat warned against what it considered “a clear attempt to breach the [Convention] by interfering in public policy.” More than 400 organisations, including 17 leading North American schools of public health, have since committed to refuse any funding from the Foundation for a Smoke Free World.

Two grants were in fact attributed in 2018 by the foundation to “Patras Science Park” for the “development of an Institute for Research and Innovation” on THR. Tax documents filed in the US show that the grants, whose amounts are not disclosed on the foundation’s website, came close to €83 000. The money went to NOSMOKE, a university start-up incubator headed by Poulas, which markets an “organic” vaping product.

Retraction
This March the European Respiratory Journal issued a retraction notice for a July 2020 publication cowritten by Poulas and Farsalinos, among others. “Two of the authors had failed to disclose potential conflicts of interest at the time of the manuscript’s submission,” the notice stated. Poulas did not declare his role at NOSMOKE (funded by the Foundation for a Smoke Free World); nor had José M Mier disclosed his activities as a harm reduction consultant to the tobacco industry. The retracted article had found that “current smoking was not associated with adverse outcome” in patients admitted to hospital with covid, and it claimed that smokers had a significantly lower risk of acquiring the virus.

The foundation has invested heavily in the covid-19/nicotine hypothesis. In June 2020 it set aside €900 000 for research “to better understand the associations between smoking and/or nicotine use, and covid-19 infection and outcome.” Its request stated that the pandemic offered “both an opportunity and a challenge for individuals to quit smoking or transition to reduced risk nicotine products.” In March 2021 the foundation named the US based consultancy BOTECA Analysis as the benefactor of the grant.

“If anyone is going to take away our business it should be us,” wrote a British American Tobacco executive as early as 1992, in a correspondence unearthed by Dorie Apollonio and Stanton Glantz, researchers at the University of California, San Francisco. In 2021, amid a global lung disease pandemic, tobacco industry figures are increasingly pushing the narrative of nicotine as the solution to an addiction that they themselves created, with the aim of persuading policy makers to give them ample room to market their “smoke-free” products. This makes studies on the hypothetical virtues of nicotine most welcome indeed.

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