



Nations are making plans for how to allocate coronavirus vaccines once they're ready.

WHO GETS A COVID VACCINE FIRST? ACCESS PLANS ARE TAKING SHAPE

Advisory groups around the world release guidance to prioritize health-care and front-line workers.

By Nidhi Subbaraman

Whether it takes weeks, as US President Donald Trump has hinted, or months, as most health-care experts expect, an approved vaccine against the coronavirus is coming, and it's hotly anticipated. Still, it will initially be in short supply while manufacturers scale up production. As the pandemic continues to put millions at risk daily, including health-care workers, older people and those with pre-existing diseases, who should get vaccinated first?

This week, a strategic advisory group at the World Health Organization (WHO) weighed in with preliminary guidance for global vaccine allocation, identifying groups that should be prioritized. These recommendations join a draft plan from a panel assembled by the US National Academies of Sciences, Engineering, and Medicine (NASEM), released earlier this month.

Experts praise both plans for addressing the historic scale and unique epidemiology of the coronavirus pandemic. And they commend the NASEM for including in their guidance minority racial and ethnic groups – which COVID-19 has hit hard – by addressing the

socio-economic factors that put them at risk. The WHO plan, on the other hand, will need more detail before its recommendations can become actionable, others say.

"It's important to have different groups thinking through the problem," says Eric Toner, an emergency-medicine physician and pandemics expert who has done similar planning at Johns Hopkins Center for Health Security in Baltimore, Maryland. And although the plans differ somewhat, Toner says he sees a lot of agreement. "It's great that there's a consensus of opinion on these issues."

Head of the queue

The WHO's guidance at this point lists only which groups of people should have priority access to vaccines. The NASEM guidance goes a step further by ranking priority groups in order of who should get a vaccine first.

After health-care workers, medically vulnerable groups should be among the first to receive a vaccine, according to the NASEM draft plan. These include older people living in crowded settings, and individuals with multiple existing conditions, such as serious heart disease or diabetes, that put them at risk of more serious COVID-19 infection.

The plan also prioritizes workers in essential

industries, such as public transport, because their jobs place them in contact with many people. Similarly, people who live in certain crowded settings – homeless shelters and prisons, for example – are called out as deserving early access.

Many nations already have general vaccine-allocation plans, but they are tailored for an influenza pandemic rather than the new coronavirus. They typically prioritize children and pregnant women; the COVID-19 plans do not, however, because most vaccine trials currently do not include pregnant women, and the coronavirus seems to be less deadly to children than is flu.

Unlike the NASEM guidance, the WHO plan notes that government leaders should have early access, but cautions that people prioritized in this way should be "narrowly interpreted to include a very small number of individuals".

"We were very concerned about the possibility that this group could serve as a loophole through which a truckload of people who identify as important could then push themselves to the front of the line," says Ruth Faden, a bioethicist at the Johns Hopkins Berman Institute of Bioethics in Baltimore, who was part of the group that drafted the WHO guidance.

Hard-hit groups

Access for disadvantaged groups is addressed in both the plans. Looking to past failures, the WHO guidance urges richer countries to ensure that poorer countries receive vaccines in the earliest days of allocation. During the 2009 H1N1 flu pandemic, "by the time the world had gotten around to figuring out how to get vaccines to some low- and middle-income countries, the pandemic was over", says Faden.

But the WHO proposal does not yet suggest how nations might resolve the tension between allocating vaccines in a country and allocating them between countries, says Angus Dawson, a bioethicist at the University of Sydney in Australia, who published a review of national pandemic allocation ethics earlier this year (J. H. Williams and A. Dawson *BMC Med. Ethics* 21, 40; 2020). In other words, should harder-hit nations receive a bigger allocation of an early vaccine before other nations have a chance to dose their high-priority groups?

The NASEM was asked to develop its allocation plan by both the US Centers for Disease Control and Prevention (CDC), which will set the US government's COVID-19 vaccination plan, and the US National Institutes of Health, which is coordinating vaccine and treatment trials. When tapping the NASEM to create the proposal, leaders from both agencies requested that the report address how to give vaccine priority to "populations at high risk", including "racial and ethnic groups" that have been affected by COVID-19 and have died in

NATALIA KOLESNIKOVA/AFP/GETTY

disproportionately higher numbers than have other groups in the United States. The panel determined that these groups are vulnerable chiefly for socio-economic reasons tied to systemic racism – for example, they have high-risk jobs and live in high-risk areas – and therefore addressed the request through this lens, without singling out the groups because of their identities.

“We really are trying to make sure that people of colour, who have been disproportionately impacted, will also have priority – but for the factors that put them at risk, not highlighting just their racial and ethnic make-up,” says Helene Gayle, president and chief executive of the Chicago Community Trust in Illinois and a co-chair of the NASEM committee that drafted the proposal.

Faden says the recommendations acknowledge the current focus on racial injustice in the United States. “I was reading to see: does this report speak to the cultural moment in the United States, does it speak to racism and other forms of structural inequality? And it does,” she says.

The WHO’s strategic advisory group will continue to update its guidance, first to assign rankings to its priority groups, and then to include real data from vaccine trials, such as

how effective a given vaccine is in older people. In the United States, the NASEM committee is due to issue a final plan in October. Ultimately, the CDC will consider these recommendations, among others, while developing its own vaccine-allocation plan for the country, expected later this year.

That will be the guidance that public-health departments, doctors and pharmacies throughout the United States should follow

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when handing out vaccines – assuming that one has been proved safe and people are willing to take it.

Trump has been rooting for a vaccine to be ready by November, in time for the US presidential election – but a perception that the vaccine has been rushed could erode trust in it, says Sandra Crouse Quinn, a behavioural scientist at the Center for Health Equity at the University of Maryland in College Park. This could make vaccine-allocation plans less effective.

in Samone, Italy. Bucci says that he noticed irregularities in the paper soon after it was published (D. Y. Logunov *et al. Lancet* <https://doi.org/gg96hq>; 2020). For example, in one figure, in which the authors report their measurements of markers of a type of immune cell in the blood, many members of two groups of nine volunteers tested with different formulations of the vaccine seem to have the same levels. “The odds of this arising by coincidence are extremely small,” Bucci says.

“To see such similar data patterns between unrelated measurements is really not likely,” says Konstantin Andreev, who studies viral respiratory infections at Northwestern University at Evanston, Illinois. “These discrepancies are not minor.” Andreev had been independently concerned about aspects of the clinical trial, and signed the open letter shortly after it was made public.

“We are not alleging scientific misconduct, but asking for clarification about how these apparently similar data points came about,” says Bucci. “When we read reports that Russia had started to inject the vaccine into people outside clinical trials, we felt we had to speak out immediately.” Late-phase clinical trials of the vaccine, which will involve tens of thousands of people, began on 26 August.

The paper’s underlying data should be made available, says epidemiologist Michael Favorov, president of DiaPrep Systems, a diagnostics company in Atlanta, Georgia. “We have a lot of questionable data – in terms of its presentation,” he says. “Maybe the data are good – we can’t judge.” He adds that the decision to publish the reports without the underlying data seems unusual. By contrast, when clinical studies involving a coronavirus vaccine that was developed by the pharmaceutical company AstraZeneca and the University of Oxford, UK, were published in the same journal, they were accompanied by a large amount of supplementary data that other researchers were able to scrutinize (P. M. Folegatti *et al. Lancet* 396, 467–478; 2020).

The Russian paper’s lead author, Denis Logunov at the Gamaleya National Research Centre for Epidemiology and Microbiology in Moscow, did not respond to requests for comment from *Nature*’s news team. But he told the Russian news outlet Meduza that he did not intend to respond to the open letter. He denied that there were errors in the publication, and stated that measured antibody levels were “exactly as they were presented” in the figures. He added that he was in contact with *The Lancet* and “was ready to clarify any issues”.

The Lancet declined to comment on its policy for providing data in support of clinical trials that it publishes, but said that it “has invited the authors of the Russian vaccine study to respond to the questions raised in the open letter by Enrico Bucci”, and that it would continue to follow the situation closely.

RESEARCHERS QUESTION RUSSIAN COVID VACCINE TRIAL RESULTS

Scientists flag trial findings that seem to be duplicated and call for access to the underlying data.

By Alison Abbott

A group of researchers have expressed concern about repetitive patterns of data in a paper describing early-phase clinical trials of Russia’s coronavirus vaccine – the first jab worldwide to be approved for widespread use.

In an open letter to the study authors, who published the trial results¹ this month, the researchers highlight values that seem to be duplicated, and warn that the paper presents its results only as box plots, without providing a detailed breakdown of the data on which they are based. “While the research described in this study is potentially significant, the presentation of the data raises several concerns which require access to the original data to fully investigate”, the letter says. It has been signed by almost 40 scientists (see go.nature.com/3kqvsqv).

The trials tested two slightly different

viral-vector vaccines – which use genetically engineered adenoviruses to produce coronavirus proteins in the body – on 76 volunteers. The results indicated that the vaccine produced a strong immune response, and that side effects were limited to mild, short-term effects, such as irritation at injection sites or headaches, in a few people. In August, the Russian authorities approved the vaccine, called Sputnik V, for widespread use, and have said that it could be available to the general public within months. This fast-track approval caused consternation among researchers, who argued that the decision to roll out the vaccine before larger safety and efficacy trials had been completed was dangerously rushed.

Possible duplications

The open letter was posted on a blog run by molecular biologist Enrico Bucci, who heads a science-integrity company called Resis