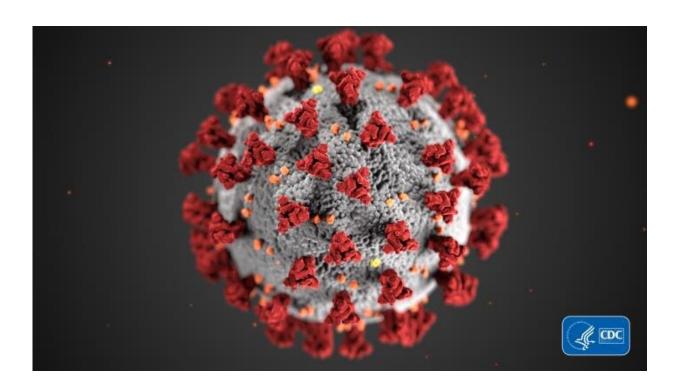


CoronaVac COVID-19 vaccine effective against new variant in Brazil

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Credit: CDC/NIAID

New research demonstrates that vaccination with CoronaVac, designed in China, is 50% effective at preventing COVID-19 within Manaus, Brazil.

The study includes a mixture of participants who had received either one or two doses of CoronaVac, which specifies a two-dose regimen for



optimal efficacy. Further results are expected in the coming month that will include follow-up of participants who have since received their second dose.

Still, these preliminary findings are encouraging because the city has been ravaged by P.1—which is widely known as the Brazilian variant of SARS-CoV-2. Manaus's experience became a global warning regarding the wildcard factor that new variants pose to COVID-19 vaccination and mitigation campaigns.

In the new work, researchers from Brazil, the University of Florida, Yale University and Stanford University performed an <u>observational study</u> among nearly 70,000 health care workers in Manaus from January to March. With 2.2 million residents, Manaus is the country's seventhlargest city. It lies at the juncture of the Amazon and Negro rivers in the center of the world's largest rainforest.

This is the first study to evaluate the effectiveness of CoronaVac, developed by Sinovac Biotech, in a population where P.1 is widespread. Data on the <u>vaccine</u>'s effectiveness will continue to be collected over the next few weeks to determine if there are differences in effectiveness between receiving only one or both doses of the two-dose vaccine regimen.

The study is publicly available on the pre-print server medRxiv and has been submitted for scientific peer review.

"These results are very encouraging," says first author Matt Hitchings, a postdoctoral fellow at the University of Florida in the College of Liberal Arts and Sciences Department of Biology. "We found that vaccination with CoronaVac is effective at reducing symptomatic COVID-19 disease in a setting where there is a lot of transmission of the P.1 variant."



While the 50% vaccine effectiveness is not as high as other vaccines in other settings, the finding of a protective effect is important given the circulation of the variant.

"The majority of people in the study had only received their first vaccine dose. Overall effectiveness may turn out to be higher as more people receive their second dose," says lead investigator, Julio Croda, who is a senior researcher at the Oswaldo Cruz Foundation, the Brazilian Ministry of Health, and is an adjunct professor at the Yale School of Public Health. "This is a critically important finding for it tells us that ramping up vaccination will turn the tide against the devastating resurgence we are experiencing in Brazil due to the spread of the P.1 variant."

UF biology professor Derek Cummings, who was hired under the university's preeminence program, also contributed to the study. Both Hitchings and Cummings are affiliated with UF's Emerging Pathogens Institute.

"It has been suggested that these new variants might be able to evade immunity generated by other vaccines," Cummings says. "We need to understand how well CoronaVac will work where P.1 is the dominant virus in circulation."

The rise of P.1

The P.1 variant was first identified in several travelers from Brazil, who were tested during routine screening at Haneda airport outside Tokyo, Japan, according to the US Centers for Disease Control and Prevention. It emerged in Manaus in late 2020 and has since spread throughout Brazil and into neighboring countries. In late January 2021, it was detected in the United States.



P.1 is characterized by 17 unique mutations, including three in the receptor-binding domain of the spike protein, that make it more transmissible and potentially more dangerous.

Brazil has been particularly hard hit by the pandemic and variants of the virus. The country's overall death toll from the disease is close to 337,000, which is second only to the United States. Recently, Brazil recorded more than 4,000 COVID-19-related deaths in a single day. Prior to its current surge, Manaus experienced a massive outbreak where researchers estimate that up to three-quarters of the city's residents were infected, though not all were symptomatic.

Study details

The study was designed to observe outcomes in people who chose whether to receive the CoronaVac vaccine. Called a test-negative case-control study, it is a widely used design for infectious diseases where it would be unethical for researchers to randomly assign certain participants to not receive a potentially life-saving vaccine.

"Even though this design controls for a lot of the bias by only picking people who chose to be tested, there is still a lot of potential for bias," Hitchings says. For example, older people may be more likely to get vaccinated than younger people, people with symptoms are more likely to get tested than those without symptoms, and where someone lives can be a proxy for access to healthcare and vaccines.

The researchers used a technique called matching to overcome some of these biases. People who received PCR testing for SARS-CoV-2 were selected, and those who tested positive were categorized as cases whereas those who tested negative were categorized as controls. Every case was then matched to a control of the same age, who lived nearby, and who got tested at the same time. (Anyone who had received a



COVID-19 vaccine other than the CoronaVac was excluded.)

"If a vaccine is working, we expect to find that more of the controls are vaccinated than the cases," Hitchings says. "Conversely, we would expect to see lower vaccination rates among the cases, because they are the ones falling ill. And that's what we found in Manaus."

The researchers then compared the vaccination coverage between cases and controls, which provided the estimation of CoronaVac's 50% effectiveness.

"We've seen in every randomized trial that the vaccines are very effective against more severe COVID-19 outcomes," Hitchings says. "And this seems to hold true here as well."

Cummings agreed: "This shows things are headed in the right direction," he says. "Fifty percent is actually pretty good and very encouraging for the situation in Manaus."

Future work is forthcoming that will refine the vaccine's effectiveness as more healthcare workers involved in the study receive their second CoronaVac doses and are followed over time. The study authors also plan to evaluate the effectiveness of CoronaVac and the AstraZeneca/Oxford vaccine among elderly people in the Brazilian cities of Manaus, Campo Grande and São Paulo.

More information: Matt D.T. Hitchings et al. Effectiveness of CoronaVac in the setting of high SARS-CoV-2 P.1 variant transmission in Brazil: A test-negative case-control study, *medRxiv* (2021). DOI: 10.1101/2021.04.07.21255081



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