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Inside C2

Wednesday, December 15 2021

Pfizer shot less effective in South Africa after Omicron emerges, study shows



Vials labelled "VAC-CINE Coronavirus COVID-19" and a syringe are seen in front of a displayed Pfizer logo in this illustration taken December 11,

JOHANNESBURG, Dec 14 (Reuters) - Pfizer-BioNTech's COVID-19 vaccine has been less effective in South Africa at keeping people infected with the virus out of hospital since the Omicron variant emerged last month, a real-world study published on Tuesday showed.

Between Nov. 15 and Dec. 7, people who had received two doses of the shot had a 70% chance of avoiding hospitalisation, down from 93% during the previous wave of Delta infections, the study showed. When it came to avoiding infection altogether, the study by South Africa's largest private health insurance administrator, Discovery Health, showed that protection against catching COVID-19 had slumped to 33% from 80% previously.

The findings from the real-world analysis are some of the first about the protection vaccines offer against Omicron outside of laboratory studies, which have so far shown a reduced ability to neutralise the virus.

The study results were based on an analysis by Discovery's (DSYJ.J)

clinical research and actuarial teams in collaboration with the South African Medical Research Council (SAMRC).

South Africa alerted the world to Omicron in November, triggering alarm that it could cause another surge in global infections and leading to travel curbs on southern Africa. South Africa's daily infections have since risen to more than 20,000, with 35% of tests coming back positive in figures reported on Tuesday, and a further 600 hospital admissions and 24 deaths.

The South African study was based on more than 211,000 COVID-19 test results of which 78,000 were attributed to Omicron, the variant labelled "of concern" by the World Health Organization and reported in more than 60 countries.

The 78,000 cases were attributed to Omicron based on the relative prevalence of the variant within the country over the study period, but because they have not been confirmed as being the new variant the study cannot offer conclusive findings.

South African scientists sent 630 positive COVID-19 tests for genome sequencing in November to see if they were Omicron and another 61 so far in December. Last month, 78% were confirmed as Omicron and all 61 this month were the new

'CONFOUNDING FACTOR'

Discovery cautioned that the study's findings should be considered preliminary. Michael Head, senior research fellow in global health at the University of Southampton, also said there was a large degree of uncertainty for now about Omicron

"It is important to avoid inferring too much right now from any national scenario. For example, the narrative around South Africa is that Omicron may be much milder, whereas reports out of Denmark broadly suggests the opposite,"

South Africa is using the Pfizer-BioN-Tech (PFE.N), and Johnson & Johnson (JNJ.N) vaccines in its immunisation campaign, with more than 20 million Pfizer doses administered so far.

J&J and the SAMRC are conducting a large real-world study of J&J's vaccine and recent analysis has shown no deaths from Omicron, SAMRC President Glenda Gray said.

Vials labelled "VACCINE Coronavirus COVID-19" and a syringe are seen in front of a displayed Pfizer logo in this illustration taken December 11, 2021. REUTERS/Dado Ruvic/Illustration

A healthcare worker administers the Pfizer coronavirus disease (COVID-19) vaccine to a man, amidst the spread of the SARS-CoV-2 variant Omicron, in Johannesburg, South Africa, December 9, 2021. REUTERS/Sumaya Hisham/ File Photo

Vials labelled "VACCINE Coronavirus COVID-19" and a syringe are seen in front of a displayed Pfizer logo in this illustration taken December 11, 2021. REUTERS/Dado Ruvic/Illustration A healthcare worker administers the Pfizer coronavirus disease (COVID-19) vaccine to a man, amidst the spread of the SARS-CoV-2 variant Omicron, in Johannesburg, South Africa, December 9, 2021. REUTERS/Sumaya Hisham/ File Photo

"So that's the good news, it shows again that the vaccine is effective against severe disease and death," she said.

With at least 70% of the South African population estimated to have been exposed to COVID-19 over the past 18 months, high estimated levels of existing antibodies might skew the data.

"This could be a confounding factor for these hospital admission and severity indicators during this Omicron wave," Ryan Noach, chief executive of Discovery Health, said in a briefing on the

The analysis showed protection against hospital admission was maintained across all ages, from 18 to 79 years, with slightly lower levels of protection for the

Protection against admission was also consistent across a range of chronic illnesses including diabetes, hypertension, hypercholesterolemia and other cardiovascular diseases.

REINFECTION RISK

The study concluded there was a higher risk of reinfection during the fourth wave than during previous waves and the risk of hospitalisation among adults diagnosed with COVID-19 was still 29% lower than during the country's first wave last year.





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VEALEE'S GLOBAL NOTES

12/14/2021

Nanjing Massacre Scars Of History



The Nanjing Massacre was an episode of mass murder and rape committed by Japanese imperial troops against the residents of Nanjing which at that time was

Over a period of six weeks Japanese army forces brutally murdered hundreds of thousands of people. About 80,000 women were sexually assaulted. An estimate of over 300,000 Chinese were killed.

The event remains as a continuous political issue between the two countries. Nanjing, the capital of China, was left in ruins. It took decades to rebuild the city.

On December 13, 1937, the first troops of Japan's Central China Front Army entered the city having "killing contests." Chinese soldiers were hunted down and killed by the thousands and left in mass graves. Entire families were massacred. Even the elderly and infants were targeted for execution.

Today when we look

back at history, how horrified we are of the war.

We need to memorialize these scars of history. We urge all politicians to learn how to avoid war.

We see that the world is now in chaos. We are having trouble in the Taiwan Straits and in the Ukraine. These political hotspots could be leading to war.







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the capital of China.















Editor's Choice



Braelyn Todd, 8, holds her dog Abner, a Yorkshire Terrier, as her parents help a family member clear debris from their destroyed home in the aftermath of a tornado in Mayfield, Kentucky. REUTERS/Adrees Latif



Laura Croft searches through debris near the location where her mother and aunt were found deceased after tornadoes ripped through several U.S. states in downtown Dawson Springs, Kentucky. REUTERS/Jon Cherry



Divers work aboard the Danish cargo ship Karin Hoej which collided with the British cargo ship Scot Carrier between Ystad and Bornholm, on the Baltic Sea. Johan Nilsson/TT News Agency



A water tower for the town is seen destroyed in the aftermath of a tornado at sunrise in Mayfield, Kentucky. REUTERS/ Adrees Latif



Miss Universe winner Miss India Harnaaz Sandhu reacts as the Miss Universe crown is placed on her head by Outgoing Miss Universe Andrea Meza of Mexico, at the Red Sea resort of Eilat, Israel. REUTERS/Ronen Zvulun



James Strickland, 42, a houseless man, walks through the wreckage of his friend's home where he has been staying and guarding following a tornado in Mayfield, Kentucky. "I have only been able to take bits and pieces of it in," said James, "It hurts so much to see what was once a thriving beautiful town." REUTERS/Cheney Orr



Trials Of The New COVID-19 Pill Reduced Hospitalizations And Deaths By 50% In People **Recently Infected With The Coronavirus**

Merck COVID-19 Pill Seen As 'Huge **Advance' Raises Hope Of Preventing COVID-19 Deaths By 50 Percent**

Compiled And Edited By John T. Robbins, Southern Daily Editor



Merck & Co. shows their new antiviral medication. Pharmaceutical company Merck & Co. announced Friday, that its experimental COVID-19 pill reduced hospitalizations and deaths by half in people recently infected with the coronavirus and that it would soon ask health officials in the U.S. and around the world to authorize its use. Merck & Co. /AP

KEY POINTS

Merck says trials of its new COVID-19 pill reduced hospitalizations and deaths by 50% in people recently infected with the coronavirus. Merck will seek U.S. approval for pill as soon as possible. If approved, would be 1st oral antiviral COVID-19 drug Merck shares rally, some vaccine makers fall U.S. government to buy 1.7 mln courses at \$700 each

WASHINGTON — Merck & Co. said Friday that its experimental COVID-19 pill reduced hospitalizations and deaths by half in people recently infected with the coronavirus and that it would soon ask health officials in the U.S. and around the world to authorize its use.

If cleared, Merck's drug would be the first pill shown to treat COVID-19, a potentially major advance in efforts to fight the pandemic. All COVID-19 therapies now authorized in the U.S. require an IV or injection.

Merck and its partner Ridgeback Biotherapeutics said early results showed patients who received the drug, called molnupiravir, within five days of COVID-19 symptoms had about half the rate of

hospitalization and death as patients who received a dummy pill. The study tracked 775 adults with mild-to-moderate COVID-19 who were considered higher risk for severe disease due to health problems such as obesity, diabetes or heart disease. Among patients taking molnupiravir, 7.3% were either hospitalized or died at the end of 30 days, compared with 14.1% of those getting the dummy pill. There were no deaths in the drug group after that time period compared with eight deaths in the placebo group, according to Merck. The results were released by the company and have not been peer reviewed. Merck said it plans to present them at a future medical meeting.



The Merck logo is seen at a gate to the Merck & Co campus in Rahway, New Jersey, U.S., July 12, 2018. (Photo/REUTERS/Brendan McDermid) An independent group of medical experts mon-

itoring the trial recommended stopping it early because the interim results were so strong. Company executives said they are in discussions with the Food and Drug Administration and plan submit the data for review in coming days. "An oral antiviral that can impact hospitalization

risk to such a degree would be game-changing," said Amesh Adalja, senior scholar at the Johns Hopkins Center for Health Security.

Current treatment options include Gilead Sciences Inc's (GILDO) infused antiviral remdesivir and generic steroid dexamethasone, both of which are generally only given once a patient has already been hospitalized.

"This is going to change the dialogue around how to manage COVID-19," Merck Chief Executive Robert Davis told Reuters.

Existing treatments are "cumbersome and logistically challenging to administer. A simple oral pill would be the opposite of that," Adalja added.

The results from the Phase III trial, which sent Merck shares up more than 9%, were so strong that the study is being stopped early at the recommen-

BUSINESS dation of outside monitors. Shares of Atea Phar-

2021年12月15日

maceuticals Inc (AVIR.O), which is developing a similar COVID-19 treatment, were up more than 21% on the news. Shares of COVID-19 vaccine makers Moderna Inc (MRNA.O) were off more than 10%, while Pfizer (PFE.N) was down less than 1%.. Jefferies analyst Michael Yee said investors believe "people will be less afraid of COVID and less inclined to get vaccines if there is a simple pill that can treat COVID."

Pfizer and Swiss drugmaker Roche Holding AG (ROG.S) are also racing to develop an easy-to-administer antiviral pill for COVID-19. For now, only antibody cocktails that have to be given intravenously are approved for non-hospitalized

White House COVID-19 response coordinator Jeff Zients said on Friday that molnupiravir is "a potential additional tool... to protect people from the worst outcomes of COVID," but added that vaccination "remains far and away, our best tool against COVID-19."

"It exceeded what I thought the drug might be able to do in this clinical trial," said Dr. Dean Li, vice president of Merck research. "When you see a 50% reduction in hospitalization or death that's a substantial clinical impact."

Side effects were reported by both groups in the Merck trial, but they were slightly more common among the group that received a dummy pill. The company did not specify the problems. Earlier study results showed the drug did not benefit patients who were already hospitalized with severe disease



molcalled nupiravir being developed Merck & Co Inc and Ridgeback Biotherapeu-

tics LP, is seen in this undated handout photo released by Merck & Co Inc and obtained by Reuters May 17, 2021. Merck & Co Inc/Handout via REUTERS

A planned interim analysis of 775 patients in Merck's study looked at hospitalizations or deaths among people at risk for severe disease. It found that 7.3% of those given molnupiravir twice a day for five days were hospitalized and none had died by 29 days after treatment. That compared with a hospitalization rate of 14.1% for placebo patients. There were also eight deaths in the placebo group. "Antiviral treatments that can be taken at home to keep people with COVID-19 out of the hospital are critically needed," Wendy Holman, Ridgeback's CEO, said in a statement.

The U.S. has approved one antiviral drug, remdesivir, specifically for COVID-19, and allowed emergency use of three antibody therapies that help the immune system fight the virus. But all the drugs have to be given by IV or injection at hospitals or medical clinics, and supplies have been stretched by the latest surge of the delta variant. Health experts including the top U.S. infectious disease expert Dr. Anthony Fauci have long called for a convenient pill that patients could take when COVID-19 symptoms first appear, much the way the decades-old flu medication Tamiflu helps fight influenza. Such medications are seen as key to controlling future waves of infection and reducing the impact of the pandemic. Merck's pill works by interfering with an enzyme the coronavirus uses to copy its genetic code and reproduce itself. It has shown similar activity against other viruses.

The U.S. government has committed to purchase 1.7 million doses of the drug if it is authorized by the FDA. Merck has said it can produce 10 million doses by the end of the year and has contracts with governments worldwide. The company has not announced prices. Several other companies, including Pfizer and Roche, are studying similar drugs that could report results in the coming weeks and months.

Merck had planned to enroll more than 1,500 patients in its late-stage trial before the independent board stopped it early. The results reported Friday included patients enrolled across Latin America, Europe and Africa Executives estimated about 10% of patients studied were from the U.S. (Courtesy npr.com)

'A HUGE ADVANCE'

Scientists welcomed the potential new treatment to help prevent serious illness from the virus, which has killed almost 5 million people around the world, 700,000 of them in the United States.



"A safe affordable and effective oral antiviral would be a huge advance in the fight against COVID." said Peter Horby, a professor of emerging infectious diseases at the University of Oxford. The study enrolled patients with laboratory-confirmed mild-to-moderate COVID-19, who had symptoms for no more than five days. All patients had at least one risk factor associated with poor disease outcome, such as obesity or older age. Drugs in the same class as molnupiravir have been linked to birth defects in animal studies. Merck has said similar studies of molnupiravir – for longer and at higher doses than used in humans - indicate that the drug does not affect mammalian DNA.

Merck said viral sequencing done so far shows molnupiravir is effective against all variants of the coronavirus including the highly transmissible Delta, which has driven the recent worldwide surge in hospitalizations and deaths. It said rates of

adverse events were similar for both molnupiravir and placebo patients, but did not give details. Merck has said data shows molnupiravir is not capable of inducing genetic changes in human cells. but men enrolled in its trials had to abstain from heterosexual intercourse or agree to use contraception. Women of child-bearing age in the study could not be pregnant and also had to use birth control. The U.S. drugmaker said it expects to produce 10 million courses of the treatment by the end of 2021.

Merck and partner Ridgeback Biotherapeutics said they plan to seek U.S. emergency use authorization for the pill as soon as possible and to make regulatory applications worldwide. The results from the Phase III trial, which sent Merck shares up more than 9%, were so strong that the study is being stopped early at the recommendation of outside monitors.

A planned interim analysis of 775 patients in Merck's study looked at hospitalizations or deaths among people at risk for severe disease. It found that 7.3% of those given molnupiravir twice a day for five days were hospitalized and none had died by 29 days after treatment. That compared with a hospitalization rate of 14.1% for placebo patients. There were also eight deaths in the placebo group.



"Antiviral treatments that can be taken at home to keep people with COVID-19 out of the hospital are critically needed," Wendy Holman, Ridgeback's CEO, said in a statement.

The company has a U.S. government contract to supply 1.7 million courses of molnupiravir at a price of \$700 per course.

Davis said Merck has similar agreements with other governments, and is in talks with more. Merck said it plans a tiered pricing approach based on country income criteria

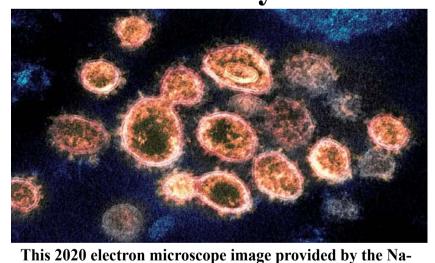
The U.S. government has the option to purchase up to an additional 3.5 million treatment courses if needed, a U.S. health official told Reuters. The official asked to remain anonymous because they were not authorized to comment publicly on the contract. Merck has also agreed to license the drug to several India-based generic drugmakers, which would be able to supply the treatment to low- and middle-income countries.

'Molnupiravir is also being studied in a Phase III trial for preventing infection in people exposed to the coronavirus.

Merck officials said it is unclear how long the FDA review will take, although Dean Li, head of Merck's research labs, said, "they are going to try to work with alacrity on this." (Courtesy reuters.com)



The 'Original' COVID-19 Is Essentially Gone



tional Institute of Allergy and Infectious Diseases – Rocky Mountain Laboratories shows SARS-CoV-2 virus particles which cause COVID-19, isolated from a patient in the U.S., emerging from the surface of cells cultured in a lab. Viruses are constantly mutating, with coronavirus variants circulating around the globe. (Photo/NIAID-RML via AP)

Key Point

One infectious disease expert says the coronavirus that kicked off the pandemic has been 'elbowed out of the way by the newer, more competitive strains'

Compiled And Edited By John T. Robbins, Southern Daily Editor

beta and delta (in Prince-like fashion, the strains," said Andrew Novmer, an epidevirus previously known as B.1.617.2). But do you know delta AY? And epsi- who studies infectious diseases.

lon, gamma, iota, lambda, mu and theta? These variants of SARS-CoV-2 have all been logged in Southern California, and dozens more versions of the virus are circulating across the globe, battling for world domination like tiny Dr. Evils in an Austin Powers movie.

So, what happened to the "original" virus? The very first one that jumped from bats or labs — or wherever — into human beings who were immunologically pow- The nocturnal intermediate horseerless against it, eventually leading to shoe bat (Rhinolophus affinis), lives the deaths of nearly 5 million people and in caves and collect many diseases. grinding world economies to a near halt? Chinese researchers said they have Gone the "way of the dinosaurs, at least found a batch of new coronavirusin humans," said Dr. George Rutherford, es in bats including one that may be professor of epidemiology and biostatis- the second-closest yet, genetically, to tics at UC San Francisco.

"It has been displaced. Elbowed out of (Shutterstock)

We all know the virus strains of alpha, the way by the newer, more competitive miologist and demographer at UC Irvine



the virus that causes Covid-19 virus.

COMMUNITY

it's gone, however, Noymer said. And Rutherford adds this caution:

"God knows what's going on in bats." Welcome to this friendly tutorial on viral mutation and why your life may depend

The SARS-CoV-2 that surfaced in Wuhan, China, in 2019 was likely not the original one, researchers say. And the version that swept through the United States in fall 2020 was already a mutation of the Wuhan version. And the one that steamrolled through the United States this summer was different still.

Scientists have logged scores of versions of the virus that causes COVID-19 across the globe, and thanks to genetic sequencing, they can pinpoint which are circulating where. Sometimes, those genetic changes are of little consequence. Sometimes, they make the virus much better at infecting humans or evading treatments, and thus more dangerous.

The U.S. Centers for Disease Control and Prevention lists just the highly contagious delta B.1.617.2 and AY lineages as "variants of concern" here in the U.S., while the World Health Organization also includes alpha, beta and gamma on its "variants of concern" list.

Up and coming mutants to watch? The WHO is keeping its eye on lambda and



Bats, rats and snakes were still being sold at an Indonesian market known for its 'extreme' wildlife offerings in February 2020, despite calls to take them off the menu over fears of COVID-19 coronavirus link. (Photo by RONNY ADOLOF BUOL/AFP via **Getty Images**)

Once upon a viral time Scientists saw this coming.

Michael Buchmeier, an infectious disease researcher at UCI who has been studying coronaviruses for decades, takes us back some 20 years, to the original strain that sparked the SARS-1 outbreak in 2002-03.

Back then, only 12 other animal or human coronaviruses were known. SARS-1 likely arose when two or more strains of bat coronaviruses combined

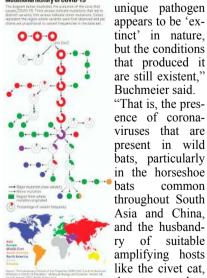
No one can say with 100% certainty that and jumped to palm civets, a masked currently circulating in bat populations." animal that resembles a raccoon and is widely sold in live animal markets throughout Asia, he said. There, the virus was amplified and adapted, and eventually infected humans. It spread widely in China, Hong Kong, Taiwan

and into Canada due to travel. The fatality rate was 10%; for those over

age 50, it was close to 50%. There's a key difference between SARS-1 and SARS-2, however: SARS-1 infections were essentially always symptomatic, making it far easier to spot and isolate outbreaks. SARS-2 can be spread by people with no symptoms, making it much harder to stop.

So, where is that virus now? "SARS-1 as a

Mutational history of COVID-19



tinct' in nature, but the conditions that produced it are still existent," Buchmeier said. "That is, the presence of coronaviruses that are present in wild bats, particularly in the horseshoe bats common

throughout South Asia and China, and the husbandof suitable amplifying hosts like the civet cat, the raccoon dog,

and now the pangolin and perhaps others capable of adapting the virus to more easily infect humans.

Hundreds of viruses have been isolated from bats in Asia and worldwide, many of them coronaviruses that can recombine into dangerous pathogens, he said. A paper in Clinical Microbiology Reviews, published in 2007, issued a warning: "Coronaviruses are well known to undergo genetic recombination, which may lead to new genotypes and outbreaks. The presence of a large reservoir of SARS-CoV-like viruses in horseshoe bats, together with the culture of eating exotic mammals in southern China, is a time bomb. The possibility of the reemergence of SARS and other novel viruses from animals or laboratories and therefore the need for preparedness should not be ignored." In 2015, another paper, in the journal Nature, warned of "a potential risk of SARS-CoV re-emergence from viruses And, so, here we are. The precise origin of the virus that sparked the COVID-19 pandemic is still an official mystery, and may always be one. In addition to the widely embraced bat/wet market theory, there are suspicions that the virus may have leaked from a lab in Wuhan. The WHO has appointed a new, 25-member Scientific Advisory Group for the Origins of Novel Pathogens, with scientists from all over the world, to try to figure that part out.



A team from Kasetsart University collect bats at the Khao Chong Pran

coronavirus research on September 12, 2020 in Ratchaburi, Thailand. (Photo by Lauren DeCicca/Getty Images)

Mutation nation

Each new infection is a new opportunity for the virus to mutate into something else. Maybe something less troublesome. Maybe something more trouble-

"What's worrying me about the upcoming winter wave is not so much the variants — it's that we need more people vaccinated," said UCI's Noymer. "Seventy-five percent is not good enough to protect some age groups.

Vaccination doesn't prevent infection, but it's very protective against severe disease, hospitalization and death, even with the highly contagious delta variant. "The clear message is that as long as vaccination of populations remains incomplete and clearly effective social distancing and masking are not observed, we're very likely to see more waves," Buchmeier said.

Will SARS-CoV-2 mutate into something more lethal still? Crystal balls are cloudy, but many experts don't expect that to happen. They do, however, expect it to remain in circulation as part of the "human virome" — the total collection of viruses in and on the human body

— for a very, very long time. Viral variants will continue to appear, and some may be more capable of spreading.

But even if we eventually make peace with this virus — as we have with the flu — threats loom. Buchmeier said that the precursors of SARS-CoV-1 and SARS-CoV-2 remain in bats, and may provide a reservoir for future cycles of human infection. (Courtesy ocregister.com)