MEDICAL INTERNET NEWS

A Panel Backs Pfizer's COVID Booster for 65 and Older, Those at High Risk

Goodman, MA
ber 17, 2021

note: Find the latest COVID-19 news and guidance in Medscape's Coronavirus Resource Center.

ood and Drug Administration (FDA) advisory panel voted unanimously today to recommend a booster dose of Pfizer's mRNA COVID-19 vaccine for th
er, and for those at high risk of severe outcomes from the disease, including healthcare workers.
llowed an earlier 16-2 vote by the FDA's Vaccines and Related Biological Products Advisory Committee rejecting a booster dose for American age 16 an
nitially wanted the FDA to amend the Biologics License Application (BLA) for its Comirnaty vaccine to allow all Americans over the age of 16 get a boo
least 6 months after their second dose.
emental BLA is the typical way boosters are authorized in the US, but it requires a higher bar of evidence and more regulatory scrutiny than the agency h
le to give since Pfizer filed for the change just days after it was granted full approval for its COVID vaccine.
mmittee's actions were also a rebuff to the Biden administration, which had prematurely announced that boosters would be rolled out to the general public
ber 20. The announcement triggered the resignations of two of the agency's top vaccine reviewers, who both participated in Friday's meeting.
Gruber, PhD, director of the FDA's Office of Vaccines acknowledged that today's meeting would be her last, and she thanked the American public.
been a privilege to serve you. All of my actions and decisions over my 32-year career have been grounded in science, with you in mind, and in the best in
health and safety. And I will continue to hold fast to these principles moving forward," she said.
itially voting against Pfizer's request to change its BLA, the committee then worked on the fly with FDA officials to craft a strategy that would allow thi
be offered under an Emergency Use Authorization (EUA).
A requires a lower standard of evidence and is more specific. It will restrict third doses to a more defined population than a change to the license would. I
uire Pfizer to continue to monitor the safety of third doses as they begin to be administered.
hould demonstrate to the public that the members of this committee are independent of the FDA and that we do, in fact, bring our voices to the table whe
ed to serve on this committee," said Archana Chattergee, MD, PhD, a pediatric infections disease specialist who is dean of the Chicago Medical School at
d Franklin University in Illinois.
A doesn't have to follow the committee's recommendation, but it typically does, while retaining the right to make changes.

e not bound at FDA by your vote, we can tweak this," said Peter Marks, MD, PhD, director of the Center for Biologics Evaluation and Research at the F
participated in the meeting and helped to draft the revised proposal.
he FDA issues the anticipated EUA, a council of independent advisors to the Centers for Disease Control and Prevention (CDC) will meet to make speci
mendations about how the third doses should be given. After the CDC director weighs in, third doses will begin rolling out to the public.
na submitted data to the FDA on September 1 in support of adding a booster dose to its regimen. The agency has not yet scheduled a public review of tha

den administration is prepared to administer shots as soon as they get the green light, Surgeon General Vivek Murthy, MD, said at a Friday White House
g.
rocess is consistent with what we outlined in August where our goals were to stay ahead of the virus," Murthy said. "Our goal then and now is to protect
and well-being of the public. As soon as the FDA and CDC complete their evaluations, we will be ready to move forward accordingly."
used this time since our August announcement to communicate and coordinate with pharmacy partners, nursing homes, states and localities," he said.
House COVID-19 Response Coordinator Jeff Zients said vaccine supply is "in good shape for all Americans to get boosters as recommended."

g Cues From Israel

sidering Pfizer's original request, the committee overwhelmingly felt that they didn't have enough information to say that the benefits of an additional do
e in 16 and 17-year-olds would outweigh their risk.
cents have the highest risk of a rare side effect of myocarditis after vaccination. It is not known how the vaccines are causing this heart swelling. Most te
ave been diagnosed with the condition have recovered, though some have needed hospital care.
didn't include 16 and 17-year-olds in its studies of boosters, which included about 300 people between the ages of 18 and 55. The company acknowledge
its data but pointed to FDA guidance that said evidence from adults could be extrapolated to teens.
on't know that much about risks," said committee member Eric Rubin, MD, PhD, who is editor-in-chief of the *New England Journal of Medicine*.

of the data on the potential benefits and risks of third Pfizer doses come from Israel, which first began rolling out boosters to older adults in July.
ghly anticipated presentation, Sharon Alroy-Preis, Israel's director of public health services, joined the meeting to describe the nation's experience with
rs.
began to see a third surge of COVID cases in December.
was after having two waves and two lockdowns," Alroy-Preis said. By the third surge, she said, Israelis were tired.
ecided on a lockdown, but the compliance of the public wasn't as it was in the previous two waves," she said.

e vaccine arrived. Israel started vaccinating soon after the FDA approved it in the US, and they quickly vaccinated a high percentage of their population,
months faster than the rest of the world.
inations are reported and tracked by the Ministry of Health, so the country is able to keep close tabs on how well the shots are working.
ines rolled out, cases fell dramatically. The pandemic seemed to be behind them. Then Delta arrived in March. By June, Israel's cases were doubling ever
spite about 80% of their most vulnerable adults being fully vaccinated, Alroy-Preis said.
ncerning was that about 60% of severe cases were breakthrough cases in fully vaccinated individuals.
l to stop and figure out, was this a Delta issue," she said. "Or was this a waning immunity issue.… We had some clue that it might not be the Delta varian
alone."
who had originally been first in line for the vaccines, seniors and healthcare workers, were having the highest rates of breakthrough infections since they
ther away from their second dose.
reis said that if they had not started booster doses in July, their hospitals would have been overwhelmed. They had projected that they would have 2000 c
ospital each day.
s have helped to flatten the curve, though they are still seeing a significant numbers of infections.
m Israel presented at the meeting show boosters are largely safe and effective at reducing severe outcomes in seniors. Israeli experience also showed that
ses, which generate very high levels of neutralizing antibodies -- the first and fastest line of the body's immune defense -- may also slow transmission of

fferences in the US

efit of slowing down explosive spread of a highly contagious virus was tantalizing, but many panel members noted that circumstances in Israel are very
t than in the US.
ent into its current Delta surge already having high levels of vaccination in their population. They also relied on the Pfizer vaccine almost exclusively for
mpaign.
used a different mix of vaccines and doesn't have the same high level of vaccination coverage of its population.
S, transmission is mainly being driven by unvaccinated people, Rubin noted.
ally means the primary benefit is going to be in reducing disease," he said, "And we know the people who are going to benefit from that … and those are
people the FDA has already approved a third dose for," he said, referring to an August authorization for immunocompromised people.
el only began vaccinating younger people a few weeks ago. Most are still within a window where rare risks like myocarditis could appear, Rubin said.
other members of the committee said they wished they had more information about the safety of third doses in younger adults.
n't have that right now, and I don't think I would be comfortable giving it to a 16 year old," Rubin said.

e same time, the primary benefit for third doses would be in preventing severe disease, and overall, data from t
nd other countries show that two doses of the vaccines remain highly effective at preventing hospitalization an
.

d why Israel began to see more severe cases in fully vaccinated people, the CDC's Sara Oliver, MD, said it wa
ably due to a mix of factors including the fact that Israel defines severe cases a little differently.

e US, a severe case is generally a person who has to be hospitalized or who has died from their infection. In Isr
son with a severe case is someone who has an elevated respiratory rate and someone who has a blood oxygen l
han 94%. In the US, that kind of patient wouldn't necessarily be hospitalized.

e end, one of the two committee members who wanted full approval for Pfizer's third doses said he was satisfie
the outcome.

Sawyer, MD, a professor of pediatrics and infectious disease at the University of California at San Diego said
yes on the first question because he thought full approval was the best way to give physicians the flexibility t
ribe the shots to vulnerable individuals.

really glad we authorized a vaccine for a third dose, and I plan to go out and get my vaccine this afternoon,"
er said, noting that he was at high risk as a healthcare provider.

ba Starts Vaccinating Kids as Young as 2

llis
ber 17, 2021

note: Find the latest COVID-19 news and guidance in Medscape's Coronavirus Resource Center.

s begun vaccinating children as young as 2 against COVID-19 because of a sharp increase in pediatric infections and deaths caused by the virus, The Miami reported.
ld vaccinations started this week, making Cuba one of the first countries in the world to vaccinate children so young.
rald said 12 children have died of COVID this year, including three 2-month-old babies, after no pediatric COVID deaths in 2020.
rald, citing the Cuban health ministry, said 117,500 minors have been diagnosed with COVID throughout the pandemic, with 7,660 of them being breastfeeding infan
ny other nations, Cuba saw an increase in pediatric COVID cases in recent months because of the Delta variant. On Monday and Tuesday, the health ministry said th
727 new cases, including 236 infants and 16 newborns, The Herald reported.
vaccinating its population, including the children, with the Soberana vaccine produced by the Havana-based Finlay Institute, a scientific organization created in 199
ve children dying, getting severe disease," Vicente Verez Bencomo, MD, director of the Finlay Institute, said in a video conference organized by Harvard's David
eller Center for Latin American Studies. "We are vaccinating children so we are moving closer to the point there is community immunity established."
ED, Cuba's regulating agency, gave an emergency use authorization last week for kids 2 to 18 years old to be given two doses of the Soberana 2 vaccine followed by
Soberana Plus booster.
ED based its vaccine authorization on a small clinical trial of 350 children between 3 and 18.
lay Institute said 99.3% of clinical trial participants aged 3-11 and 92.9% of participants aged 12-18 had had an antibody response that was four times the pre-vaccin

results show that the SOBERANA02 vaccine is safe for its administration in children and adolescents; and that the global security pattern is similar to adults," the Fi
said.
ults have not been published in peer-reviewed publications.
nited States, the Pfizer vaccine was authorized in May for children 12 and up, while the Moderna and Johnson & Johnson vaccines are for people 18 and up.

:
Herald. "Cuba starts vaccinating 2-year-olds, as COVID cases spike among children on the island"
ED. "CECMED approves the authorization for the emergency use of the Cuban vaccine Soberana® 02 in the pediatric population"
nstitute. "Summary of the results of the SOBERANA-PEDIATRÍA Clinical Trial

ng-Haul COVID in Kids Typically Ends Within 3 Months: Study

Y, Sept. 17, 2021 (HealthDay News)

and **teens**, symptoms of long COVID rarely last more than 12 weeks, a new international study reports.

earchers also found that exposure to the highly **contagious** Delta variant did not result in more serious disease in children compared to earlier variants, a

st cases of **COVID-19** were asymptomatic or mild.

those reassurances, the study did include a troubling finding: Young people with pre-existing conditions — such as **obesity**, chronic **kidney disease**, **hea**

or immune disorders — are 25 times more likely to get severe **COVID-19** than kids without pre-existing conditions. A recent review found that

COVID-19 occurred in 5% of those with pre-existing conditions and less than 1% of others, the researchers said.

lata is needed to describe the burden of COVID-19 in children and adolescents following the emergence of the highly transmissible Delta variant and bec

ave been prioritized for **vaccines**," said Andrew Steer from the Murdoch Children's Research Institute (MCRI), in Melbourne, Australia.

g COVID symptoms were hard to separate from indirect effects of the disease on kids, such as school closures and being unable to spend time with frien

s or hobbies, said Dr. Petra Zimmermann of the University of Fribourg, in Switzerland.

ghlights why it's critical that future studies involve more rigorous control groups, including children with other infections and those admitted to hospital

e care for other reasons," she said in an MCRI news release.

y co-author Nigel Curtis of the MCRI said that although kids with COVID-19 are usually asymptomatic or have mild disease with low rates of
talization, the risk and features of long COVID have not been well understood.

his study, the researchers reviewed 14 published studies that included more than 19,400 children and teens. The investigators found that the mo
non symptoms of long-haul COVID over four to 12 weeks were **headache**, **fatigue**, **sleep** disturbance, **difficulty concentrating** and **abdomin**

s said it was reassuring that there was little evidence that symptoms lasted more than 12 weeks, suggesting long COVID might be less of a pro
ung people than in adults.

low risk posed by acute disease means that one of the key benefits of COVID vaccination of children and adolescents might be to protect them
long COVID," Curtis said. "An accurate determination of the risk of long COVID in this age group is therefore crucial in the debate about the
enefits of vaccination."

added that, as pandemic restrictions ease and other respiratory **viruses** circulate, researchers need to learn whether co-infection with such viru
piratory syncytial virus or **influenza** increases COVID-19 severity in young people.

indings were published online Sept. 16 in the *Pediatric Infectious Disease Journal*.

information

ore on COVID-19, head to the **U.S. Centers for Disease Control and Prevention.**

RCE: Murdoch Children's Research Institute, news release, Sept. 16, 2021

n Reinberg

nstrual changes after covid-19 vaccination

doi.org/10.1136/bmj.n2211 (Published 16 September 2021)

s as: BMJ 2021;374:n2211

n side effects of covid-19 vaccination listed by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) include a sore arm, fever, fati
algia.[1] Changes to periods and unexpected vaginal bleeding are not listed, but primary care clinicians and those working in reproductive health are
ngly approached by people who have experienced these events shortly after vaccination. More than 30 000 reports of these events had been made to MH
card surveillance scheme for adverse drug reactions by 2 September 2021, across all covid-19 vaccines currently offered.[1]

eople who report a change to their period after vaccination find that it returns to normal the following cycle and, importantly, there is no evidence that co
tion adversely affects fertility. In clinical trials, unintended pregnancies occurred at similar rates in vaccinated and unvaccinated groups.[2] In assisted
ction clinics, fertility measures and pregnancy rates are similar in vaccinated and unvaccinated patients.[3456]

states that evaluation of yellow card reports does not support a link between changes to menstrual periods and covid-19 vaccines since the number of rep
elative to both the number of people vaccinated and the prevalence of menstrual disorders generally.[7] However, the way in which yellow card data are
d makes firm conclusions difficult. Approaches better equipped to compare rates of menstrual variation in vaccinated versus unvaccinated populations ar
and the US National Institutes of Health has made $1.67m (£1.2m; €1.4m) available to encourage this important research.[8]

ual changes have been reported after both mRNA and adenovirus vectored covid-19 vaccines,[1] suggesting that, if there is a connection, it is likely to be a
mmune response to vaccination rather than a specific vaccine component. Vaccination against human papillomavirus (HPV) has also been associated wit
al changes.[9] Indeed, the menstrual cycle can be affected by immune activation in response to various stimuli, including viral infection: in one study of
ating women, around a quarter of those infected with SARS-CoV-2 experienced menstrual disruption.[10]

cally plausible mechanisms linking immune stimulation with menstrual changes include immunological influences on the hormones driving the menstrua
or effects mediated by immune cells in the lining of the uterus, which are involved in the cyclical build-up and breakdown of this tissue.[12] Research
g a possible association between covid-19 vaccines and menstrual changes may also help understand the mechanism.

h reported changes to the menstrual cycle after vaccination are short lived, robust research into this possible adverse reaction remains critical to the c
of the vaccination programme. Vaccine hesitancy among young women is largely driven by false

that covid-19 vaccines could harm their chances of future pregnancy.[13] Failing to thoroughly investigate reports of menstrual changes after ation is likely to fuel these fears. If a link between vaccination and menstrual changes is confirmed, this information will allow people to plan ally altered cycles. Clear and trusted information is particularly important for those who rely on being able to predict their menstrual cycles to achieve or avoid pregnancy.

still awaiting definitive evidence, but in the interim how should clinicians counsel those who have experienced these effects? Initially, they s ouraged to report any changes to periods or unexpected vaginal bleeding to the MHRA's yellow card scheme. This will provide more complet itate research into any link and signal to patients that their concerns about vaccine safety are taken seriously, building trust. In terms of ement, the Royal College of Obstetricians and Gynaecologists and the MHRA recommend that anyone reporting a change in periods persistin everal cycles, or new vaginal bleeding after the menopause, should be managed according to the usual clinical guidelines for these conditions.

portant lesson is that the effects of medical interventions on menstruation should not be an afterthought in future research. Clinical trials prov al setting in which to differentiate between menstrual changes caused by interventions from those that occur anyway, but participants are unli rt changes to periods unless specifically asked. Information about menstrual cycles and other vaginal bleeding should be actively solicited in l trials, including trials of covid-19 vaccines.

100% French nasal vaccine against SARS-CoV-2 to move into the clinical phas 2022

*wed by [Emily Henderson, B.Sc.](#)*Sep 18 2021

ntrast to intramuscular vaccines, only nasal vaccines are able to block the virus in the nose by inducing local immunity in the nasal mucosa, i.e. the portal of entry and plication of the virus. The vaccine candidate, developed by the BioMAP team, would take position as the eighth nasal vaccine currently starting clinical testing in the , and the only one based on viral proteins in France.

technology for nasal vaccine has already proven to be an efficient barrier against toxoplasmosis infection in primates

SARS-CoV-2 protein vaccine candidate builds on the BioMap team's expertise in mucosal vaccine design. In partnership with the biotech company Vaxinano, the tea y successfully developed an effective candidate vaccine to protect monkeys from toxoplasmosis. This stable, non-toxic and adjuvant-free nasal vaccine is based on a n extract from *Toxoplasma gondii* the infectious agent being produced by the team and further encapsulated in starch and lipid-based nanoparticles (Vaxinano techno ARS-CoV-2 nasal vaccine candidate is based on similar technology.

milar strategy, the SARS-CoV-2 vaccine protein component was designed and produced by the team, and then encapsulated by Vaxinano. The vaccine, consisting of ike protein with other viral proteins that are not prone to mutations, would protect vaccinated individuals regardless of the mutated circulating coronavirus variant st

vaccine was first tested *in vivo* in a pre-clinical mouse model. Two nasal applications, three weeks apart, induced a strong humoral immune response - in particular of sal compartment with neutralising Immunoglobulin A (IgAs), which are polyspecific, i.e. more permissive against variation of the Sars-CoV-2 - along with a cellular nse in the nasal cavities and lungs. The protective efficacy of the vaccine was also assessed in terms of survival and absence of clinical signs after infection on vaccin ls, 100% of individuals survived with no clinical signs (respiratory distress, weight loss, etc.) unlike the unvaccinated control group. Second, the candidate vaccine w for contagiousness in the established Syrian hamster model, which mimics the human pathophysiology of COVID-19, again providing striking results with no viral ion in the lungs and nose of vaccinated/infected animals while unvaccinated/infected animals showed a high levels of viral RNA in both lungs and nasal cavities. Th s, highly predictive of the effectiveness of a vaccine in humans, allow us to predict that contagiousness between individuals is completely abolished.

inistered, non-invasive, vaccine as a first dose or a booster

e vaccine will be administered by means of a small adapter placed at the end of a needle-less syringe, allowing an ideal diffusion within the nasal cavity. Currently, a device developed for this vacci
being evaluated in collaboration with the Recipharm/Resyca group. Non-invasive and with minimal logistics requirement, this basic vaccination system would allow for a wider distribution to Europ
over, the vaccine is highly stable at room temperature and even longer at 4°C and thus would not imply the required restraining logistics mandatory to maintain cold chain integrity, unavailable in mo

would therefore target unvaccinated populations to protect against severe and moderate forms of COVID-19 and could moreover be a booster for already vaccinated populations to prevent transmissi

ch research and development consortium

e results, the research team will rely on the skills of companies based in France, which have already been identified, to develop its vaccine for future clinical trials:

sed in Lille,

, a CDM,(Contract Development and Manufacturing Organisation) based near Toulouse,

a, a CRO, based in Saint Malo,

manufacturer based in Monts, near Tours.

to the clinical phase, supported by the ANRS/ Maladies infectieuses émergentes, is scheduled for the second half of 2022, with the perspective to bringing the vaccine to market in 2023.

by the financial support of the ANR and the Centre-Val de Loire Regional Council, as well as by the commitment of all the partners mentioned, this project still involves a number of stages to be co
brought to market. It is set to provide a major improvement in the protection of populations, in terms of prevention, contagiousness, effectiveness on current and future variants, and increasing the pe
ted and thus collective protection.

ousands of vulnerable hospital patients set to benefit from new COVID-19 atment

ed by Emily Henderson, B.Sc. Sep 18 2021

ands of vulnerable NHS patients in hospital due to COVID-19 are set to benefit from a ground-breaking new antibody treatment, the government has ann (17 September 2021).

reve, a combination of two monoclonal antibodies, will be targeted initially at those in hospital who have not mounted an antibody response against COV

cludes people who are immunocompromised, for example those with certain cancers or autoimmune diseases, and therefore have difficulty building up a dy response to the virus, either through being exposed to COVID-19 or from vaccination.

overnment has taken action to secure supply of the new therapeutic for NHS patients across the four nations, buying enough to treat eligible patients in ho ext week. Guidance will shortly be going out to clinicians so they can begin prescribing the treatment as soon as possible.

and Social Care Secretary Sajid Javid said:

e secured a brand new treatment for our most vulnerable patients in hospitals across the UK and I am thrilled it will be saving lives from as early as nex

K is leading the world in identifying and rolling out life-saving medicines, particularly for COVID-19, and we will continue our vital work to find the bes ents available to save lives and protect the NHS."

reve is the first neutralizing antibody medicine specifically designed to treat COVID-19 to be authorized by the Medicines and Healthcare products Regu y (MHRA) for use in the UK.

eat patients without antibodies to SARS CoV-2 who are either aged 50 and over, or are aged 12 to 49 and are considered to be immunocompromised.

ill first be used to determine whether patients are seronegative, meaning those who do not have an adequate existing antibody response, and will therefore receive the treatment. The treatment antibo
ill then be administered to patients through a drip and work by binding to the virus' spike protein, stopping it from being able to infect the body's cells.

nowned vaccination programme also continues to provide protection to tens of millions of people across the country, and has so far saved 112,300 lives, prevented 230,800 hospitalizations and stopp
nd alone.

g of the pandemic, the UK has proven itself to be a world-leader in identifying and rolling out effective treatments for COVID-19 - including the world's first treatment dexamethasone, which has sin
UK so far and an estimated million worldwide.

rolled out monoclonal immunomodulatory antibody treatments tocilizumab and sarilumab, following clinical trial results from the government-funded REMAP-CAP trial. The treatments were found
h by 24%, when administered to patients within 24 hours of entering intensive care.

e government also brought together a new Antivirals Taskforce to supercharge the search for new treatments for patients who are exposed to COVID-19 to stop the infection spreading and speed up

esearch infrastructure and life sciences sector makes it the ideal base for the brightest of global innovators to research and progress cutting-edge treatments for COVID-19 through the clinical trials p

OVID-19 Lead at Roche Products Ltd, said:

onths, our goal has been to do everything we can to minimize the impact of the pandemic on those affected and the brilliant people who work tirelessly to treat and care for them. Ronapreve is the fir
d for COVID-19 to receive marketing authorization from the MHRA, representing a significant milestone in how the NHS is able to fight this disease.

step in our journey to overcome COVID-19, and we will continue to collaborate with partners to identify and investigate multiple options that may help different groups of patients. Together with Re
laboration of the vaccine taskforce and NHS England in helping to bring this important antibody cocktail to treat and prevent acute COVID-19 across the UK."

rt inflammation more common among men following mRNA-based COVID-19 vaccination

Robertson, B.Sc. Sep 16 2021

hers in the UK have assessed data from around the world to better understand the frequency and risk factors for myocarditis and pericarditis following immunization er RNA (mRNA)-based vaccines designed to protect against coronavirus disease 2019 (COVID-19).

of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the sac surrounding the heart) following mRNA-based COVID-19 vaccination f in Israel in May 2021 and further cases have since been reported in numerous other countries.

mantha Lane and Saad Shakir from the Drug Safety Research Unit in Southampton and have used spontaneous reporting systems from the UK, the United States, an n Economic Area to estimate the frequency of these events following exposure to the mRNA-based COVID-19 vaccines developed by Pfizer-BioNTech and Modern

orting rates suggested that both events are very rare and that the typical clinical course is mild, with full recovery reached in most cases.

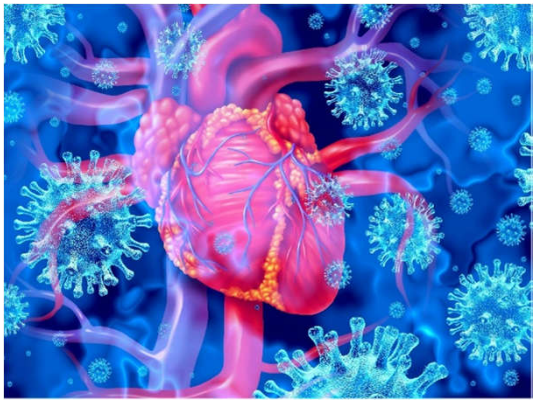
r, the reports also suggested that the events were more common amongst males, occurred more frequently following a second vaccine dose and mostly affected youn es.

a Lane and Saad Shakir say that the results were consistent across the three data sources used.

an important finding, because as vaccination programs around the world progress, rates of myocarditis and pericarditis are likely to increase," they write. "Regulator ies

continue to monitor the effect that mRNA vaccination might have on the heart in the populations for which they are responsible."

rint version of the research paper is available on the *medRxiv* server* while the article undergoes peer review.



y: *Reports of myocarditis and pericarditis following mRNA COVID-19 vaccines: A review of spontaneously reported data from the UK, Europ and the US. Image Credit: Lightspring / Shutterstock*

e about the emerging reports of myocarditis and pericarditis

carditis and pericarditis have recently been recognized as very rare adverse events following vaccination with the COVID-19 vaccines develo fizer-BioNTech and Moderna.

gnal of these events following mRNA-based vaccination was first identified in Israel in May 2021, where 148 cases of myocarditis were repor n 30 days of immunization, usually following a second dose.

prompted the Israeli Ministry of Health to issue an investigation into any possible link between these cases of myocarditis and vaccination.

results pointed to a possible link between the second vaccine dose and the onset of myocarditis among young men aged 16 to 30, with a strong dentified among those aged 16 to 19.

ng the initial signal in Israel, further cases of myocarditis and pericarditis following mRNA-based vaccination were reported in numerous other countries.

duct information for both the Pfizer-BioNTech and Moderna vaccines was then updated to include myocarditis and pericarditis as an adverse event of unknown frequ
Europe, and the US.

*gh most cases appear to have mild severity, further follow-up of cases is ongoing to determine the long-term outcomes of myocarditis and pericarditis following mRN
," say the researchers. "Individual regulatory authorities continue to monitor the events of myocarditis and pericarditis in their own spontaneous reporting systems.*

ng spontaneous reports from around the world

d Shakir used spontaneous reporting outputs from the UK (Yellow Card scheme), the US (Vaccine Adverse Event Reporting System [VAERS]), and the European Ec
udraVigilance) to estimate the frequency of reported cases of myocarditis and pericarditis following immunization with either the Pfizer-BioNTech or Moderna vacci

lock points were August 6th, 2021, for VAERS and EudraVigilance, and August 4th, 2021, for the Yellow Card scheme.

ng to the reporting rates of spontaneous adverse reactions, myocarditis and pericarditis were very rare events across all three data sources.

for the UK

K, 7.93 cases of myocarditis and 6.73 cases of pericarditis occurred per million recipients of at least one dose of the Pfizer-BioNTech vaccine. For the Moderna prod
nding figures were 2.07 and 1.79 cases per million.

were available regarding the age or sex of those reporting the events, or on which vaccine dose either of the events occurred.

findings

S, 6.47 cases of myocarditis and 3.53 cases of pericarditis were reported per million individuals who had received two doses of the Pfizer-BioNTech vaccine. For the
product, the corresponding figures were 3.65 and 2.69 cases per million.

myocarditis events reported following Pfizer-BioNTech vaccination, 759 (78.4%) occurred in males. Reports of myocarditis were also more frequent in younger age
e of gender. Similarly, while pericarditis was more frequently reported among males, this pattern was less pronounced among those older than 40 years.

nds were observed for the Moderna vaccine.

e majority of both myocarditis and pericarditis events occurred following the second dose of either vaccine.

pean Economic Area

pean Economic Area, 4.23 cases of myocarditis and 2.87 cases of pericarditis were reported per million individuals who had received at least one dose of the Pfizer-
or the Moderna product, the corresponding figures were 6.15 cases and 3.84 cases per million.

RNA vaccines, 71.56% of the myocarditis events and 53.46% of the pericarditis events were reported to have affected males.

s must continue to monitor the effects on the heart

y adds to existing evidence that younger vaccinees more frequently report myocarditis and pericarditis following mRNA COVID-19 vaccines compared with older va
s are more frequent following the second dose," said the researchers.
rare events with a typically mild disease course occur more frequently among males, they add.

Shakir say that the consistencies in the reporting rates and the trends within the three data sources suggest that the results may be generalizable to other populations.

rtant that regulatory authorities continue to monitor the effects of mRNA vaccines on the heart, particularly as vaccine programs progress to include younger vaccin
of the world," they write.

tis and pericarditis following mRNA COVID-19 vaccines is an area which requires further research," concludes the team.