



Florida Surgeon General Recommends Against mRNA COVID-19 Vaccines for Males Aged 18–39

Description

USA: Florida’s Surgeon General, Dr. Joseph A. Ladapo, announced new guidance on messenger RNA (mRNA) vaccines on Friday, specifically recommending against mRNA COVID-19 vaccines for males aged 18 to 39.

Messenger RNA is the technology utilized by both the Pfizer and Moderna COVID-19 vaccines, the most administered vaccines in the United States and a number of other countries.

The new guidance came after the Florida Department of Health carried out an analysis to evaluate vaccine safety, the department said in a [bulletin](#) on Friday.

The statewide analysis of vaccinated Florida residents aged 18 years or older ([pdf](#)) found an 84 percent increase in the relative incidence of cardiac-related deaths among males aged 18–39, within 28 days of mRNA vaccination.

“Non-mRNA vaccines were not found to have these increased risks,” the Florida Department of Health noted.

Given the high level of global immunity to COVID-19, the benefit of vaccination with mRNA vaccines “is likely outweighed by this abnormally high risk of cardiac-related death among men in this age group,” the department said.

“As such, the State Surgeon General recommends against males aged 18 to 39 from receiving mRNA COVID-19 vaccines,” it said. “Those with preexisting cardiac conditions, such as myocarditis and pericarditis, should take particular caution when making this decision.”

“Far less attention has been paid to safety and the concerns of many individuals have been dismissed—these are important findings that should be communicated to Floridians,” Ladapo said in a statement, referring to the analysis.

In the new guidance ([pdf](#)), Florida’s health department said it also “continues to stand by” its guidance for pediatric COVID-19 vaccines it issued in March. That guidance ([pdf](#)) recommends against COVID-

19 vaccination for healthy children and adolescents aged 5–17. It now also recommends against COVID-19 vaccination among infants and children under five years old.



A COVID-19 vaccine is prepared in a file image. (Stephen Zenner/Getty Images)

Statewide Analysis

The analysis from the Florida Health Department that informed Ladapo's latest recommendation had sought to "evaluate the risks of all-cause and cardiac-related mortality following COVID-19 vaccination."

Residents in Florida aged 18 years or older who died within 25 weeks of having received a COVID-19 vaccine, since the start of the vaccination roll-out in the state—Dec. 15, 2020—were included. The study end date was June 1, 2022.

People were excluded from the study if they had a documented COVID-19 infection, had a COVID-19 associated death, had received a COVID-19 vaccine booster, or had received their last COVID-19 vaccine after Dec. 8 2021. The last criterion was put in place to make sure that each person was followed up after 25 weeks.

The study found that COVID-19 vaccination "was not associated with an elevated risk for all-cause mortality," but "was associated with a modestly increased risk for cardiac-related mortality 28 days following vaccination."

“Results from the stratified analysis for cardiac-related death following vaccination suggests mRNA vaccination may be driving the increased risk in males, especially among males aged 18–39,” according to the analysis.

It also noted that the risk for both all-cause and cardiac-related deaths was “substantially higher 28 days following COVID-19 infection.”

As such, the study concluded that people should weigh the risk associated with mRNA vaccination with the risk associated with COVID-19 infection.

The analysis was a self-controlled case series (SCCS), which is a study design originally developed to evaluate vaccine safety, the department stated. The SCCS method uses individuals as their own control, such that comparisons are made within individuals.

The U.S. Food and Drug Administration’s authorization of the Pfizer-BioNTech and Moderna COVID-19 vaccines for emergency use in 2020 marked the first time it did so for vaccines that use mRNA technology.

[According to the FDA](#), the mRNA vaccine contains a small piece of the SARS-CoV-2 virus’s mRNA that instructs cells in the body to make the distinctive spike protein of the virus. When a person receives the vaccine, their body produces copies of the spike protein which “does not cause disease, but triggers the immune system to learn to react defensively, producing an immune response” against the virus, according to the agency.

The mRNA-based COVID-19 vaccines from Pfizer-BioNTech and from Moderna have both been linked with heart inflammation, including myocarditis and pericarditis, data from around the world have suggested. Younger populations, especially young men, have been observed to experience these conditions at much higher than expected rates, data from the Centers for Disease Control and Prevention (CDC) previously suggested. A small number of deaths from heart inflammation after COVID-19 vaccine have also been reported.

The primary regimens of the vaccines, which are two doses administered several weeks apart, were insufficient to protect against infection and showed waning efficacy in protecting against hospitalization amid newly-emerging variants. This prompted the governments of many countries to recommend boosters and subsequent boosters throughout the COVID-19 pandemic.

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