

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



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Vision: To be the **Healthiest State** in the Nation

Guidance for COVID-19 Boosters

September 13, 2023

As the federal government makes new boosters for COVID-19 available, the Florida Department of Health (Department) reminds health care providers of their obligation to remain up to date with the current literature related to the mRNA COVID-19 vaccines.

A new mRNA COVID-19 booster was approved on September 11, 2023, by the federal government. While the initial mRNA COVID-19 vaccines were authorized by the United States Food and Drug Administration (FDA) utilizing human clinical trial data, the most recent booster approval was granted in the absence of any meaningful booster-specific clinical trial data performed in humans. In both cases the federal government has failed to provide sufficient data to support the safety and efficacy of the COVID-19 vaccines. Health care providers are expected to include the information in this guidance in discussions with patients regarding the mRNA COVID-19 vaccines.

Based on the high rate of global immunity and currently available data, the State Surgeon General recommends against the COVID-19 booster for individuals under 65. Individuals 65 and older should discuss this information with their health care provider, including potential concerns outlined in this guidance.

Providers and patients should be aware of outstanding safety and efficacy concerns:

- Throughout the pandemic, studies across geographic regions have found that the mRNA COVID-19 vaccines are associated with [negative effectiveness](#) after 4 to 6 months. As efficacy waned, studies showed that COVID-19 vaccinated individuals developed an [increased risk for infection](#). This is not found in other vaccines, including the [flu vaccine](#).
- The mRNA COVID-19 vaccines present a risk of [subclinical](#) and clinical [myocarditis](#) and other [cardiovascular conditions](#) among otherwise healthy individuals.
- There is unknown risk of potential adverse impacts with each additional dose of the mRNA COVID-19 vaccine; currently individuals may have received five to seven doses (and counting) of this vaccine over a 3-year period.
- Elevated levels of [spike protein](#) from the mRNA COVID-19 vaccine [persist](#) among some individuals for an indefinite period of time, which may carry [health risks](#).

Improving habits and overall health help manage and reduce the risk of serious health problems such as heart disease, type 2 diabetes, and obesity. The State Surgeon General and the Department continue to encourage Floridians to prioritize their overall health by:

- Staying physically active,
- Minimizing processed foods,
- Maximizing vegetables and healthy fats, and
- Spending time outside to support necessary vitamin D levels.

References

- Altarawneh, H. N., Chemaitelly, H., & Ayoub, H. H. (2022). *Effects of previous infection and vaccination on symptomatic omicron infections*. The New England Journal of Medicine. <https://www.nejm.org/doi/full/10.1056/NEJMoa2203965>
- Buerger, N., Lopez-Ayala, P., & Hirsiger, J. R. (2023). *Sex-specific differences in myocardial injury incidence after COVID-19 mRNA-1273 booster vaccination*. Wiley Online Library. <https://onlinelibrary.wiley.com/doi/10.1002/ejhf.2978>
- Brogna, C., Cristoni, S., Marino, G., Montano, L., Viduto, V., Fabrowski, M., Lettieri, G., & Piscopo, M. (2023). *Detection of recombinant Spike protein in the blood of individuals vaccinated against SARS-CoV-2: Possible molecular mechanisms*. Proteomics Clinical applications, e2300048. Advance online publication. <https://doi.org/10.1002/prca.202300048>
- Castelli, J. M., Rearte, A., Olszevicki, S., Voto, C., Del Valle Juarez, M., Pesce, M. et al. (2022). *Effectiveness of mRNA-1273, BNT162b2, and BBIBP-CorV vaccines against infection and mortality in children in Argentina, during predominance of delta and omicron covid-19 variants: test negative, case-control study*. BMJ. <https://www.bmj.com/content/379/bmj-2022-073070>
- Chemaitelly, H., Ayoub, H. H., AlMukdad, S., Coyle, P., Tang, P., Yassine, H. M., Al-Khatib, H. A., Smatti, M. K., Hasan, M. R., Al-Kanaani, Z., Al-Kuwari, E., Jeremijenko, A., Kaleeckal, A. H., Latif, A. N., Shaik, R. M., Abdul-Rahim, H. F., Nasrallah, G. K., Al-Kuwari, M. G., Butt, A. A. Abu-Raddad, L. J. (2022). *Duration of mRNA vaccine protection against SARS-COV-2 omicron ba.1 and BA.2 subvariants in Qatar*. Nature News. <https://www.nature.com/articles/s41467-022-30895-3>
- Demicheli, V., Jefferson T., Di Pietrantonì, C., Ferroni, E., Thorning, S., Thomas, RE., Rivetti, A. *Vaccines for preventing influenza in the elderly*. Cochrane Database of Systematic Reviews 2018, Issue 2. Art. No.: CD004876. DOI: 10.1002/14651858.
- Eythorsson, E. (2022). *Rate of SARS-COV-2 reinfection during an omicron wave in Iceland*. JAMA Network Open. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2794886>
- Lin, D.-Y., Gu, Y., & Xu, Y. (2022). *Effects of vaccination and previous infection on Omicron infections in children*. The New England Journal of Medicine. <https://www.nejm.org/doi/full/10.1056/NEJMc2209371>
- Mansanguan, S., Charunwatthana, P., Piyaphanee, W., Dechkhajorn, W., Poolcharoen, A., & Mansanguan, C. (2022). *Cardiovascular manifestation of the BNT162B2 mRNA covid-19 vaccine in adolescents*. MDPI. <https://www.mdpi.com/2414-6366/7/8/196>

- Nabin K Shrestha, Patrick C Burke, Amy S Nowacki, James F Simon, Amanda Hagen, Steven M Gordon, Effectiveness of the Coronavirus Disease 2019 Bivalent Vaccine, *Open Forum Infectious Diseases*, Volume 10, Issue 6, June 2023, ofad209, <https://doi.org/10.1093/ofid/ofad209>
- Nordstrom, P., Ballin, M., & Nordstrom, A. (2022). *Risk of infection, hospitalisation, and death up to 9 months after a second dose of COVID-19 vaccine: A retrospective, total population cohort study in Sweden*. The Lancet. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)00089-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00089-7/fulltext)
- Roltgen, K., Boyd, S. D., Nadeau, K. C., Pinsky, B. A., Oscar, S., & Nielsen, S. C. A. (2022). *Immune imprinting, breadth of variant recognition, and germinal center response in human SARS-CoV-2 infection and vaccination*. Cell. [https://www.cell.com/cell/fulltext/S0092-8674\(22\)00076-9](https://www.cell.com/cell/fulltext/S0092-8674(22)00076-9)
- Trougakos, I. P., Terpos, E., Alexopoulos, H., Politou, M., Paraskevis, D., Scorilas, A., Kastiris, E., Andreacos, E., & Dimopoulos, M. A. (2022). *Adverse effects of COVID-19 mRNA vaccines: The Spike hypothesis*. Trends in molecular medicine. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9021367/>
- Yonker, L. M., Swank, Z., Bartsch, Y., Burns, M. D., Kane, A., Boribong, B., Davis, J. P., Loiselle, M., Novak, T., Senussi, Y., Cheng, C.-A., Burgess, E., Edlow, A. G., Chou, J., & Dionne, A. (2023). *Circulating spike protein detected in post-COVID-19 mRNA vaccine myocarditis*. Circulation. <https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.122.061025>