COVID-19 vaccination: Altering doses? Data doesn’t back it

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What’s the news: Top leaders at the Food and Drug Administration (FDA) are pushing back against growing calls to alter the COVID-19 vaccine administration schedule that are accelerating amid a frustratingly slow vaccination rollout and documented U.S. community spread of a more transmissible coronavirus variant.

“We have been following the discussions and news reports about reducing the number of doses, extending the length of time between doses, changing the dose (half-dose), or mixing and matching vaccines in order to immunize more people against COVID-19,” says a statement issued by FDA Commissioner Stephen M. Hahn, MD, and FDA Center for Biologics Evaluation and Research Director Peter Marks MD, PhD.

Those are all reasonable questions, but they are ones that should be considered and evaluated in clinical trials, Drs. Hahn and Marks said.

“At this time, suggesting changes to the FDA-authorized dosing or schedules of these vaccines is premature and not rooted solidly in the available evidence. Without appropriate data supporting such changes in vaccine administration, we run a significant risk of placing public health at risk, undermining the historic vaccination efforts to protect the population from COVID-19.

“The available data,” they added, supports “the use of two specified doses of each authorized vaccine at specified intervals.”

There are 21 days between the first and second doses of the Pfizer-BioNTech COVID-19 vaccine, and a 28-day interval for dose administration of the Moderna vaccine. Stay updated with the AMA to get the latest information on COVID-19 vaccination.
Why it’s important: According to the Centers for Disease Control and Prevention’s COVID-19 vaccine data tracker, more than 17 million doses of the two vaccines have been distributed in the U.S., yet the total number of people getting their first dose is less than 6 million.

That gap between distribution and administration—along with documented cases of a more contagious SARS-CoV-2 variant in patients without recent history of travel outside the U.S.—have sparked calls for “first doses first” or other approaches to get more vaccine into the arms of the U.S. population more quickly.

“We were all hoping for more efficient distribution than what we’ve seen. It’s taken much longer to gear up distribution of the vaccines. … The states, the hospitals, have a way to go to really scale their distribution,” said AMA Chief Health and Science Officer Mira Irons, MD, during a recent episode of the “AMA COVID-19 Update.”

Despite those frustrating delays—exacerbated by the fact that hospitals and health systems already slammed by booming COVID-19 caseloads also are being asked to lead massive vaccine administration efforts—moving ahead of the scientific evidence is the wrong direction to pursue, Dr. Irons told AMA Chief Experience Officer Todd Unger.

“It’s very concerning,” she said, noting that British health officials announced recently that they will pursue different vaccine administration approaches with the aim of getting more people at least one dose more quickly.

“The thing we really have to remember is that there is no evidence to support that,” Dr. Irons said. “What we know of the efficacies of the Pfizer and Moderna vaccines is really based on two doses in a short period of time between that first dose and second dose. Moving to different immunization regimens without having the evidence to support that is really concerning, especially when you have the supplies available in the United states.” Among those opposed to adopting the British approach, she noted, is Anthony Fauci, MD.

The data from the Pfizer-BioNTech and Moderna clinical trials “is commonly being misinterpreted” by advocates of alternative administration approaches, Drs. Hahn and Marks noted in their statement.

“In the phase 3 trials, 98% of participants in the Pfizer-BioNTech trial and 92% of participants in the Moderna trial received two doses of the vaccine at either a three- or four-week interval, respectively. Those participants who did not receive two vaccine doses at either a three-or four-week interval were generally only followed for a short period of time, such that we cannot conclude anything definitive about the depth or duration of protection after a single dose of vaccine from the single dose percentages reported by the companies.”
Pursuing a single-dose or half-dose COVID-19 vaccination regimen without adequate data could have a big downside, Drs. Hahn and Marks said.

“If people do not truly know how protective a vaccine is, there is the potential for harm because they may assume that they are fully protected when they are not, and accordingly, alter their behavior to take unnecessary risks,” the FDA leaders said.

**Learn more:** The AMA has developed documents to answer frequently asked questions about COVID-19 vaccination: one is aimed at physicians, and other addresses patient queries.

Even as dissatisfaction with the slow pace of U.S. vaccine administration mounts, the other side of the coin is an alarming series of news reports of vaccine refusal or hesitancy, even among health professionals. A Jan. 19 AMA webinar will feature Marie Brown, MD, who will help physicians understand why vaccine hesitancy exists and how to communicate with storytelling and metaphors—not just numbers. Find out more and register now for the webinar, “Vaccinations: Roadmap for success.”