

TGIF 😊

Today under Covid-19 News I discuss the recent FDA and ACIP meetings on boosters. Next, I review the plan to rollout vaccine for children ages 5-11 when approved which is expected in the next 2 weeks under EUA.

Under Journal Review I start with an important report from the NAM on communication strategies for Covid-19 vaccines. The next two articles report on the Pfizer VE in adolescents. The last article reports on VE in preventing deaths with both Pfizer and AZ vaccines.

I hope everyone has a wonderful weekend.

Ed

COVID-19 News

FDA and CDC Meetings

The FDA announced on Wednesday, that they will make boosters available to most adults who have been fully vaccinated and have passed the recommended waiting period. Any adult who got a J&J vaccine may get a booster from Pfizer, Moderna or J&J at least two months after the single dose shot. People who were initially vaccinated with a Pfizer or Moderna vaccine can get any booster at least six months after their second dose so long as they are seniors or at high risk because of underlying medical conditions or their workplace. Recent research reported in the Briefing October 15th, indicates people who mix and match, especially if they got the J&J vaccine first followed by an mRNA vaccine, may get more protection. The chart below summarizes the current recommendations. The FDA delayed clearing the Moderna vaccine in adolescents while it assesses the risk of myocarditis. (See below)

The ACIP recommended Thursday afternoon by a vote of 15-0 that everyone over age 18 who are at least 2 months past their J&J vaccine should get a booster and approved a booster at least 6 months after their last Moderna shot for the same groups who can get a Pfizer booster. They are: (1) anyone over age 65; (2) those over age 18 with an underlying health condition that puts them at risk of severe COVID-19; (3) those over age 18 who may be at higher risk of a COVID-19 infection because they live or work in a risky setting. Some committee members expressed discomfort in broadly recommending boosters, stressing that there is very little evidence supporting the need for boosters in people younger than age 50. The Moderna booster, regardless of what vaccine a person received first, is half the dose that was given in the first two shots (50 µg).

Safety updates were presented. The data confirm that serious adverse events after vaccination are extremely rare, but in some cases, they may rise above the risk for those problems generally seen in the general population. GBS and the platelet disorder thrombosis with thrombocytopenia (TTS) are more common with the J&J vaccine. Out of 15.3 million doses of the vaccine given to date, there have been 47 cases of TTS and five deaths. These events are more common in younger women. The mRNA vaccines, can cause myocarditis or pericarditis. This side effect is more common in men 18 to 24 years old. The reported rate of myocarditis after vaccination is 39 cases for every 1 million doses. The risk of TTS and myocarditis/pericarditis is much more common with natural infection.

Immunity Boost

The FDA came out with new recommendations for Covid-19 vaccines, allowing for boosters for all three main vaccines for at least some people in the 18-64 age group.

AUTHORIZED FOR: ✓ Everyone

✓ People who are immunocompromised, have underlying conditions, are in high-risk occupations or live in high-risk areas

	PFIZER-BIONTECH		MODERNA		JOHNSON & JOHNSON	
	First doses	Additional/booster	First doses	Additional/booster	First dose	Additional/booster
Under age 11	✗	✗	✗	✗	✗	✗
Ages 12 to 17	✓	✗	✗	✗	✗	✗
Ages 18 to 64	✓	✓	✓	✓	✓	✓
Age 65 and older	✓	✓	✓	✓	✓	✓

Number of people in the U.S. who have received a booster dose by vaccine type

Pfizer-BioNTech

9.6 million

Moderna

1.7 million

Johnson & Johnson

11,397

Unknown

5,186

Vaccination doses administered*

800 million

600

400

200

Jan. 2021



*Does not include nearly 900,000 doses administered where the maker is unknown

Sources: Food and Drug Administration; Centers for Disease Control and Prevention; Our World in Data (percentage who received a booster)

Comment: Now every Covid-19 vaccine authorized in the U.S. also has a booster. And people who took one company's shot to get vaccinated could choose to get a booster dose made by a different company. The FDA has already begun reviewing whether to expand the booster authorizations to anyone 40 years and older. The CDC's ACIP panel unanimously approved that certain people who received Moderna and all who got J&J vaccines should receive a booster dose, and in general, people should stick with the original vaccine they initially received. Concerning the dose-mixing recommendation, ACIP's recommendation was a bit more limiting than the FDA's decision Wednesday that opened the door to

people getting any of the three vaccines as a booster, however late Thursday Dr. Walensky, CDC director approved mix or matching.

Vaccine Rollout for Children Ages 5-11

The White House on Wednesday announced its plan for vaccinating children ages 5-11 against COVID-19, so that the vaccines can be quickly distributed and made equitably available upon FDA authorization and a CDC recommendation. Below are a few highlights.

1. The FDA's vaccine advisory panel, the Vaccines and Related Biological Products Advisory Committee, has scheduled a meeting Oct. 26 to review Pfizer's emergency authorization request for use of its COVID-19 vaccine in children ages 5-11.
2. The CDC's ACIP has scheduled meetings on Nov. 2 and Nov. 3 to discuss pediatric COVID-19 vaccines.
3. The White House is holding operational readiness calls with every state, encouraging them to help increase enrollment of pediatric providers. The US will provide resources to support outreach and public education.
4. The White House has secured enough of Pfizer's reformulated COVID-19 vaccine for children to inoculate the country's 28 million children ages 5-11. The vaccines will be packaged in 10-dose vials in cartons of 10 vials each. They can be stored for up to 10 weeks at standard refrigeration temperatures and six months at ultralow temperatures.
5. The US will continue to use funds from the American Rescue Plan to fully reimburse states for vaccinations and outreach.
6. The US. will make vaccinations available at more than 25,000 pediatricians' offices and other primary care sites, more than 100 children's hospitals and health systems, tens of thousands of pharmacies, hundreds of school and community-based clinics and hundreds of community health centers and rural health clinics.
7. HHS will launch a national campaign to educate parents and guardians about COVID-19 vaccinations and how they can protect children and the community. The campaign will involve trusted community messengers, schools, health departments, faith leaders and community organizations.

See National Academy Report below.

Journal Review

Communication Strategies for Building Confidence in COVID-19 Vaccines: Addressing Variants and Childhood Vaccinations (2021)

published by The National Academies Press October 2021

<https://doi.org/10.17226/26361>.

In the executive summary it starts: "The fourth wave of the COVID-19 pandemic in the United States has been fueled by the delta variant, which is more contagious than earlier variants, and a slowing down in new vaccinations. Most hospitalizations and deaths in the United States are occurring among people who are not vaccinated. This context affirms the importance of tackling vaccine hesitancy and communicating with parents of children who are eligible to be vaccinated and those for whom future eligibility is anticipated."

The authors suggest communication strategies that they believe will be useful in discussing with people who are vaccine hesitant, and for building confidence among parents and guardians of children. Below are key communication strategies they believe will be helpful.

Communicating with People Who Are Not Vaccinated

- Using new, personally relevant, and salient information to influence change: Highlight new events or evidence to urge a change in vaccination status without derogating people's previous decision to avoid vaccination.
- Identifying and targeting people's reference groups: Use the fact that people are influenced by those they relate to in providing information about vaccination.
- Using trend information: Show data from three or more points in time to highlight changes in vaccination rates among people's reference groups.
- Using trusted messengers: Use the fact that people are more likely to respond if someone they trust delivers a message about vaccination.
- Tackling misinformation and disinformation: Target false "information" to help build vaccine confidence.

Communicating with Parents

- Emphasizing safety and efficacy: To alleviate parents' concerns, emphasize the rigorous clinical process of safety, efficacy, and continued monitoring of the approved vaccines that are available for children.
- Encouraging parent-provider communication and primary care provider recommendations: Most children, especially young children, visit primary care providers on a regular basis, and these health care providers are a highly trusted group; messages from primary care providers about vaccines' safety and efficacy may be important for parents.
- Leveraging social networks to influence parents' vaccination decisions: Parents are influenced by their broad trusted social network connections; targeting members of those networks, especially the most influential ones, can help encourage parents to vaccinate their children.

Comment: The recommendations are common sense steps we should all review and try to speak with one voice.

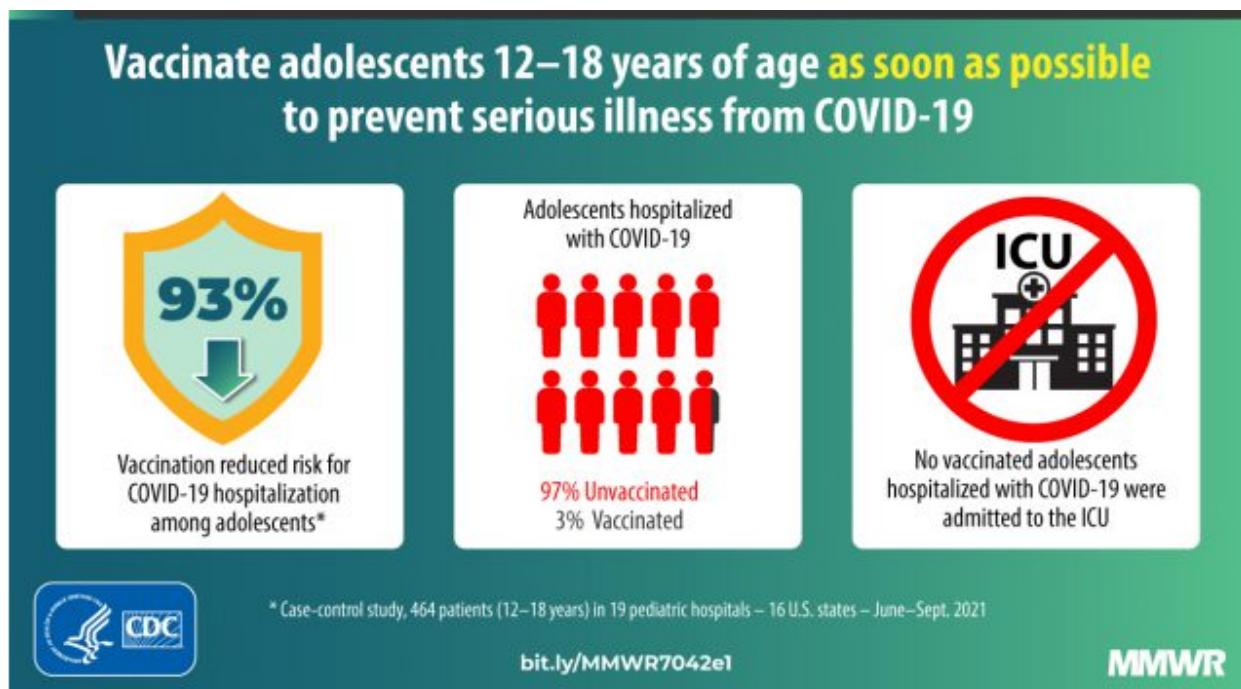
Effectiveness of Pfizer-BioNTech mRNA Vaccination Against COVID-19 Hospitalization Among Persons Aged 12-18 Years — United States, June-September 2021

MMWR October 19, 2021

This study used a test-negative design, similar to other post authorization VE evaluations, in which vaccine performance is assessed by comparing the odds of antecedent vaccination among laboratory-confirmed case-patients hospitalized with COVID-19 and hospitalized controls without COVID-19. Participants were aged 12-18 years and were admitted to 19 pediatric hospitals in the CDC-funded Overcoming COVID-19 Network during June 1-September 30, 2021. Case-patients were hospitalized with symptomatic COVID-19-like illness and a positive PCR or antigen test result. Because vaccination with Moderna or J&J vaccine were not authorized for persons aged <18 years at the time of this evaluation, only receipt of Pfizer vaccine was assessed in this analysis. The study included fully vaccinated persons aged 12-18 years with COVID-19 vaccination status categorized as 1) unvaccinated (no receipt of any COVID-19 vaccine before illness onset) or 2) fully vaccinated (receipt of 2 doses of Pfizer vaccine, with the second dose administered ≥14 days before illness onset). Patients who were partially vaccinated

(i.e., received only 1 dose or received a second dose <14 days before illness onset) were excluded from the analysis. The 464 patients in the final analysis comprised 179 case-patients and 285 controls.

Among case-patients and all controls, the median age was 15 years, 72% had at least one underlying condition, including obesity, and 68% attended in-person school. Among 179 COVID-19 case-patients, six (3%) were vaccinated and 173 (97%) were unvaccinated. VE against COVID-19 hospitalization was 93% (95% CI = 83%–97%), during the period when Delta was the predominant variant. No vaccinated adolescent with Covid-19 was admitted to the ICU.



Comment: This is another publication supporting the value of vaccination. This article demonstrated that 2 doses of Pfizer vaccine were highly effective in preventing COVID-19 hospitalization among persons aged 12–18 years. This study reinforces the importance of vaccination to protect U.S. children against severe COVID-19 which in turn reduces transmission to vulnerable persons. The sample was too small to assess VE by underlying conditions or by other subgroups of interest, including against critical illness. Since vaccination of persons aged 12–15 years commenced only recently, evaluation of duration of protection was not possible. See next two articles.

Effectiveness of BNT162b2 Vaccine against Delta Variant in Adolescents

N Engl J Med published online October 20, 2021

DOI: 10.1056/NEJMc2114290

The investigators sought to estimate the vaccine effectiveness of Pfizer vaccine against the delta variant among vaccinated adolescents for whom an unvaccinated match was found. They used data from Clalit Health Services, the largest health care organization in Israel, to conduct an observational cohort study involving adolescents between the ages of 12 and 18 years who had no prior SARS-CoV-2 infection noted in their electronic medical record and who had been vaccinated between June 8 and September 14, 2021.

Of 184,905 vaccinated adolescents, 130,464 met the eligibility requirements, and 94,354 of these vaccine recipients were successfully matched with 94,354 unvaccinated controls. The eligible population was similar to the matched population with respect to several demographic and clinical characteristics. The estimated vaccine effectiveness against documented SARS-CoV-2 infection was 59% (95% confidence interval [CI], 52 to 65) on days 14 through 20 after the first dose, 66% (95% CI, 59 to 72) on days 21 to 27 after the first dose, and 90% (95% CI, 88 to 92) on days 7 to 21 after the second dose. The estimated vaccine effectiveness against symptomatic Covid-19 was 57% (95% CI, 39 to 71) on days 14 to 20 after the first dose, 82% (95% CI, 73 to 91) on days 21 to 27 after the first dose, and 93% (95% CI, 88 to 97) on days 7 to 21 after the second dose.

Comment: These results show that the Pfizer vaccine was highly effective after vaccination against both documented infection and symptomatic Covid-19 with the delta variant among adolescents between the ages of 12 and 18 years. Like other studies to achieve high VE, two doses are needed. This study found the exact VE as the CDC study above.

BNT162b2 and ChAdOx1 nCoV-19 Vaccine Effectiveness against Death from the Delta Variant

N Engl J Med published online October 20, 2021

DOI: 10.1056/NEJMc2113864

The authors conducted a cohort study and used Cox regression to estimate vaccine effectiveness against death from delta variant infection from April 1 to August 16, 2021, among adults 18 years of age or older, who were followed up to September 27, 2021, in Scotland. They used a Scotland-wide surveillance platform (Early Pandemic Evaluation and Enhanced Surveillance of COVID-19 [EAIVE II]) that includes individual-level linked data on vaccination, testing, viral sequencing, primary care, hospital admissions, and mortality among 5.4 million people (approximately 99% of the Scottish population).

A total of 1,563,818 adults underwent testing in the community. Our mortality analysis was based on 114,706 adults who tested positive for SARS-CoV-2. Sequencing data showed that 99.5% of S-positive infections were caused by the delta variant and that 98.8% of delta variant infections were S-positive. Among adults who tested positive, those who were unvaccinated tended to be much younger, to have fewer coexisting conditions, and to have a lower socioeconomic status and were more likely to be men than those who were vaccinated; these differences tended to be especially pronounced in comparison with those who received the AZ vaccine.

Among persons 16 to 39 years of age who had infections for which data on S gene status were available, no deaths occurred among those who were fully vaccinated, as compared with 17 deaths among those who were unvaccinated. Among those who were 40 to 59 years of age, VE against death from Covid-19 was 88% (95% confidence interval [CI], 76 to 93) for AZ vaccine and 95% (95% CI, 79 to 99) for Pfizer vaccine; VE was 90% (95% CI, 84 to 94) and 87% (95% CI, 77 to 93), respectively, among those 60 years of age or older. Overall, VE against death from the delta variant 14 or more days after the second vaccine dose was 90% (95% CI, 83 to 94) for Pfizer and 91% (95% CI, 86 to 94) for AZ vaccine.

Comment: This is another study that found that the Pfizer as well as AZ vaccines offered significant protection against death from Covid-19 caused by the delta variant including persons over age 60.