



I GOT
MY COVID-19
VACCINE!



WE
CAN
DO
THIS



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DISCLAIMER

The information presented today is based on CDC's recent guidance and MAY change.

September 21, 2021

COVID-19 Vaccine Updates

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COVID-19 Vaccine Key Updates



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COVID-19 Vaccines BLA Status

(Biologics License Application)

- August 23, 2021, the Food and Drug Administration (FDA) approved the first COVID-19 vaccine for ages 16 years and older.
 - Marketed as Comirnaty™
 - Emergency use authorized for 12-15 years of age
 - Emergency use authorized for an additional dose in immunocompromised persons
 - Emergency use authorized for a booster dose in persons ≥ 65 years of age and those at severe risk of COVID-19?



COVID-19 Vaccines BLA Status

Full Approval (Biologics Licensure Application)

- Moderna has also submitted a biologics licensure application with the FDA.
 - However, the FDA has not yet provided a PDUFA* date
- J&J/Janssen has not yet begun their submission of their BLA with the FDA. Tentative timeline 4Q21.



* Prescription Drug User Fee Act (PDUFA) date: Once the FDA accepts a filing for the approval of a drug, the agency must complete its review process a specified time period. The date at the end of the review period is referred to as the PDUFA date.

Interim Estimates of COVID-19 Vaccine Effectiveness Against COVID-19–Associated Emergency Department or Urgent Care Clinic Encounters and Hospitalizations Among Adults During SARS-CoV-2 B.1.617.2 (Delta) Variant Predominance — Nine States, June–August 2021

- CDC used the VISION Network* to examine medical encounters (32,867) from 187 hospitals and 221 emergency departments (EDs) and urgent care (UC) clinics across nine states during June–August 2021, beginning on the date the Delta variant accounted for >50% of sequenced isolates in each medical facility's state.
- Among fully vaccinated patients, the proportion who had received each vaccine product among hospitalizations and ED/UC encounters, respectively, were Pfizer-BioNTech, 55.3% and 53.6%; Moderna, 38.8% and 36.1%; and Janssen, 6.0% and 10.3%.
- The median interval from becoming fully vaccinated to the hospital admission or ED/UC encounter, respectively, were 110 and 93 days (Pfizer-BioNTech), 106 and 96 days (Moderna), and 94 and 94 days (Janssen).
- Overall, VE against COVID-19 hospitalization was 86% (95% CI = 82%–89%).
- VE was significantly lower among adults aged ≥75 years (76%) than among those aged 18–74 years (89%) (Table). The difference in VE point estimates between age groups was similar for Pfizer-BioNTech and Moderna vaccines.
- Across all ages, VE was significantly higher among Moderna vaccine recipients (95%) than among Pfizer-BioNTech (80%) or Janssen (60%) vaccine recipients.

*Columbia University Irving Medical Center (New York), HealthPartners (Minnesota and Wisconsin), Intermountain Healthcare (Utah), Kaiser Permanente Northern California (California), Kaiser Permanente Northwest (Oregon and Washington), Regenstrief Institute (Indiana), and University of Colorado (Colorado).

https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e2.htm?s_cid=mm7037e2_e&ACSTrackingID=USCDC_921-DM65565&ACSTrackingLabel=MMWR%20Early%20Release%20-%20Vol.%2070%2C%20September%2010%2C%202021&deliveryName=USCDC_921-DM65565

TABLE. COVID-19 vaccine effectiveness* against laboratory-confirmed COVID-19–associated emergency department and urgent care clinic encounters and hospitalizations† among adults during SARS-CoV-2 B.1.617.2 (Delta) variant predominance,§ by outcome, age group, and vaccine — nine states,¶ June–August 2021

Outcome	Total	No. of SARS-CoV-2–positive tests (row %)	VE, % (95% CI)
All adults (aged ≥18 yrs), any COVID-19 vaccine			
COVID-19 hospitalizations			
Unvaccinated (ref)	6,960	1,316 (18.9)	—
Fully vaccinated**	7,676	235 (3.1)	86 (82–89)
COVID-19 ED/UC encounters			
Unvaccinated (ref)	10,872	3,145 (28.9)	—
Fully vaccinated**	7,359	512 (7.0)	82 (81–84)
COVID-19 hospitalizations, any COVID-19 vaccine, by age			
Age group = 18–74 yrs			
Unvaccinated (ref)	5,708	1,185 (20.8)	—
Fully vaccinated**	4,551	134 (2.9)	89 (85–92)
Age group = ≥75 yrs			
Unvaccinated (ref)	1,252	131 (10.5)	—
Fully vaccinated**	3,125	101 (3.2)	76 (64–84)
COVID-19 hospitalizations by COVID-19 vaccine			
BNT162b2 (Pfizer-BioNTech)			
Unvaccinated (ref)	6,960	1,316 (18.9)	—
Fully vaccinated**	4,243	135 (3.2)	80 (73–85)
mRNA-1273 (Moderna)			
Unvaccinated (ref)	6,960	1,316 (18.9)	—
Fully vaccinated**	2,975	70 (2.4)	95 (92–97)
Ad26.COV2.S (Janssen)			
Unvaccinated (ref)	6,960	1,316 (18.9)	—
Fully vaccinated**	458	30 (6.5)	60 (31–77)
COVID-19 ED/UC encounters by COVID-19 vaccine			
BNT162b2 (Pfizer-BioNTech)			
Unvaccinated (ref)	10,872	3,145 (28.9)	—
Fully vaccinated**	3,946	314 (8.0)	77 (74–80)
mRNA-1273 (Moderna)			
Unvaccinated (ref)	10,872	3,145 (28.9)	—
Fully vaccinated**	2,656	98 (3.7)	92 (89–93)
Ad26.COV2.S (Janssen)			
Unvaccinated (ref)	10,872	3,145 (28.9)	—
Fully vaccinated**	757	100 (13.2)	65 (56–72)

COVID-19 Vaccine Boosters



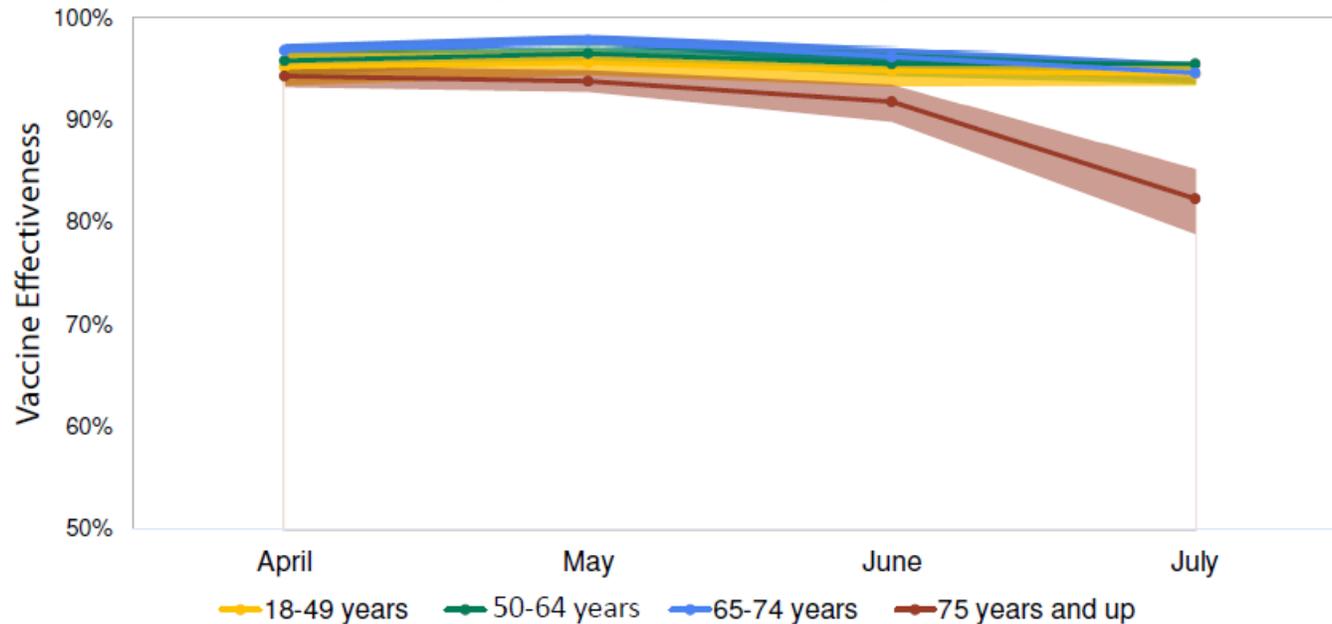
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Booster doses of COVID-19 vaccines: Adults ≥ 65 years of age

Public
Health
Problem

Preliminary VE against COVID-19–associated **hospitalization** among fully vaccinated† patients aged ≥ 18 years, by age group and month — COVID-NET



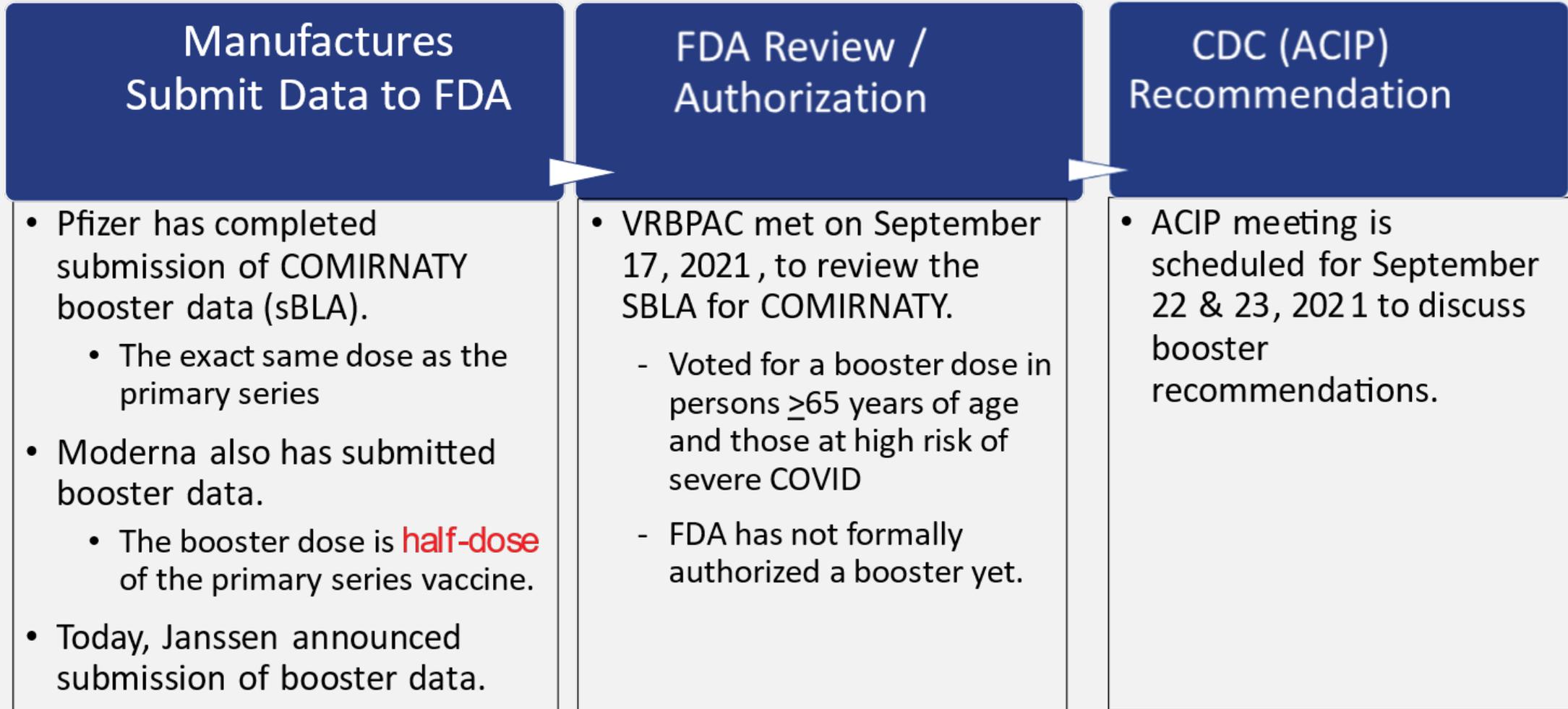
- Preliminary VE against **hospitalization** in adults ≥ 75 years of age decreased in July, but remains **>80%**

Source: Unpublished COVID-NET data

†Fully vaccinated patients received both doses of Moderna or Pfizer-BioNTech vaccine, with second dose received ≥ 14 days before hospitalization, or a single dose of Janssen (Johnson & Johnson) vaccine ≥ 14 days before hospitalization

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Path to Booster Dose Recommendation



sBLA: supplemental Biologics License Application

VRBPAC: Vaccines and Related Biological Products Advisory Committee

ACIP: Advisory Committee on Immunization Practices

COVID-19 Vaccine for Pediatric Population



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Background

- COVID-19 vaccination of children is important to reduce transmission of SARS-CoV-2 and reduce disruptions to in-person learning.
- Focused efforts needed to vaccinate children aged 5-11 years
 - Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 vaccine in this age group is uncertain
 - For planning purposes, projecting as early as Q4/2021
 - Additional planning may be needed for <5-year population in the coming months



Approach for Reaching Children

Augment existing public health infrastructure and add new channels



Category	Approach
 <p>Providers serving children & primary care</p>	<ul style="list-style-type: none">• Utilize primary care and health department sites as trusted providers to notify, schedule, and vaccinate their patients, including managing routine immunizations
 <p>Pharmacies and HRSA sites¹</p>	<ul style="list-style-type: none">• Leverage broad pharmacy footprint to administer COVID-19 vaccine to children, as feasible
 <p>School-based vaccination</p>	<ul style="list-style-type: none">• Partner with Federally Qualified Health Centers, pharmacies, public health, and pediatric provider networks to hold targeted programs to ensure equity and coverage



1. Health Resources and Services Administration (HRSA) sites including: Federally Qualified Health Centers (FQHCs), Rural Health Clinics, Community Health Centers

COVID-19 Vaccine Updates

Children Younger than 11 Years of Age

- September 10th, 2021, the FDA issued a statement outlining the status and the steps it will take to authorize COVID-19 vaccine for this age group.
 - A follow-up period of at least about two months, to allow for proper safety monitoring following the administration of vaccine doses for at least half of the clinical trial vaccine recipients.
 - After manufacturers analyze their clinical trial data, they will compile the information and may request an emergency use authorization (EUA) or submit for approval a biologics license application (BLA), as appropriate, for this young population to the FDA.
 - When a completed request for EUA or approval has been received by the FDA, the agency will carefully, thoroughly and independently examine the data to evaluate benefits and risks and be prepared to complete its review as quickly as possible, likely in a matter of weeks rather than months.

https://www.fda.gov/news-events/press-announcements/fda-will-follow-science-covid-19-vaccines-young-children?utm_medium=email&utm_source=govdelivery



COVID-19 Vaccine Updates

Children Younger than 11 Years of Age

- Yesterday, Pfizer announced results from their Phase 2/3 study in children 5-11 years of age
 - The dose for 5-11 years being evaluated is 10 mcg (versus 30 mcg for adults), 2-dose series given 21 days apart
 - 2,268 participants randomized 2:1 (active vaccine:placebo)
 - “Showing a favorable safety profile and robust neutralizing antibody response”
 - “Plan to submit them to the FDA and other regulators with urgency”
- Pfizer is also studying the vaccine in children ages 6 months to 5 years of age.
 - The dose for this younger age cohort being evaluated is 3 mcg.
 - Anticipate timeline by 4Q21



COVID-19 Vaccine Updates

Children Younger than 11 Years of Age

- Moderna COVID-19 vaccine (mRNA-1273) study in young children ages 6 months to 11 years is ongoing.
 - The 6 years to <12 years old cohort is fully enrolled.
 - Dose selection studies are still underway for 2 years to < 6 years old and 6mos to <2 years of age groups.



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September 21, 2021

Thank you!



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