COVID-19 Vaccine Update

October 2021

AMA

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AMA Liaison to CDC's Advisory Committee on Immunization Practices (ACIP)

Member, ACIP's COVID -19 Vaccine Work Group

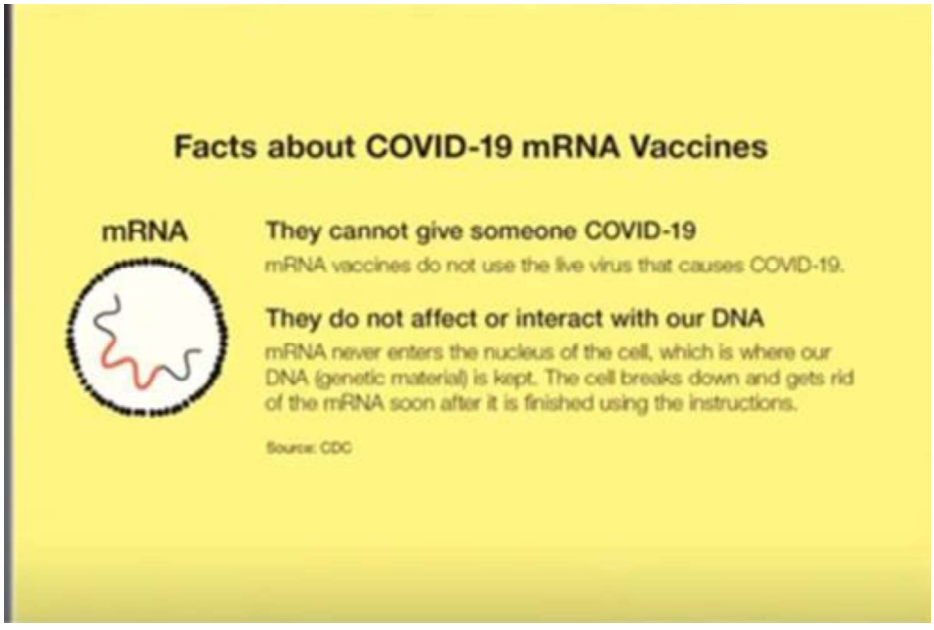
Adjunct Associate Professor of Medicine, Emory University School of Medicine

COVID – 19 Vaccines in US under FDA

Pfizer	***Moderna***	***Janssen***
12/11/2020	*12/18/2020*	*2/27/2021*
mRNA BNT 162 b2	*mRNA 1273*	*Ad26-COV 2 S viral vector*
VE: 95%	**VE: 94%**	**VE (overall): 66.3%**
Two doses *(0,21)*	***Two doses*** *(0,28)*	***One dose***
12 & older* *(BLA:≥16/ EUA:12-15)*	***EUA:18 & older****	***EUA: 18 & older*****
(EUA: additional dose for immunocompromised)	*(EUA: additional dose for Immunocompromised)*	
(EUA for "many more"- 9/22/21)		

*** reports of myocarditis***

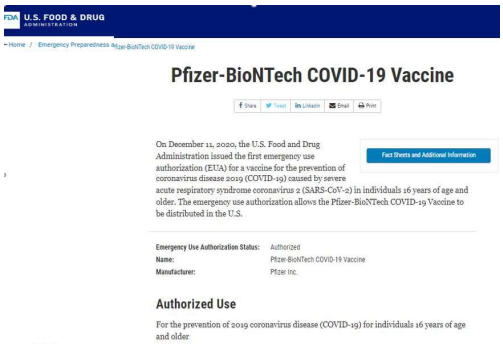
****TTS** warning: females <50 / **GBS***



FDA's Emergency Use Authorization (EUA) of mRNA COVID 19 vaccines

December 11, 2020:

Pfizer / BioNTech BNT 162 B2 (mRNA)



U.S. FOOD & DRUG ADMINISTRATION

Home / Emergency Preparedness / Pfizer-BioNTech COVID-19 Vaccine

Pfizer-BioNTech COVID-19 Vaccine

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On December 11, 2020, the U.S. Food and Drug Administration issued the first emergency use authorization (EUA) for a vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The emergency use authorization allows the Pfizer-BioNTech COVID-19 Vaccine to be distributed in the U.S.

Fact Sheets and Additional Information

Emergency Use Authorization Status:	Authorized
Name:	Pfizer-BioNTech COVID-19 Vaccine
Manufacturer:	Pfizer Inc.

Authorized Use

For the prevention of 2019 coronavirus disease (COVID-19) for individuals 16 years of age and older

December 18, 2020:

Moderna 1273 (mRNA)

U.S. FOOD & DRUG ADMINISTRATION

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FDA NEWS RELEASE

FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine

Action Follows Thorough Evaluation of Available Safety, Effectiveness, and Manufacturing Quality Information by FDA Career Scientists, Input from Independent Experts

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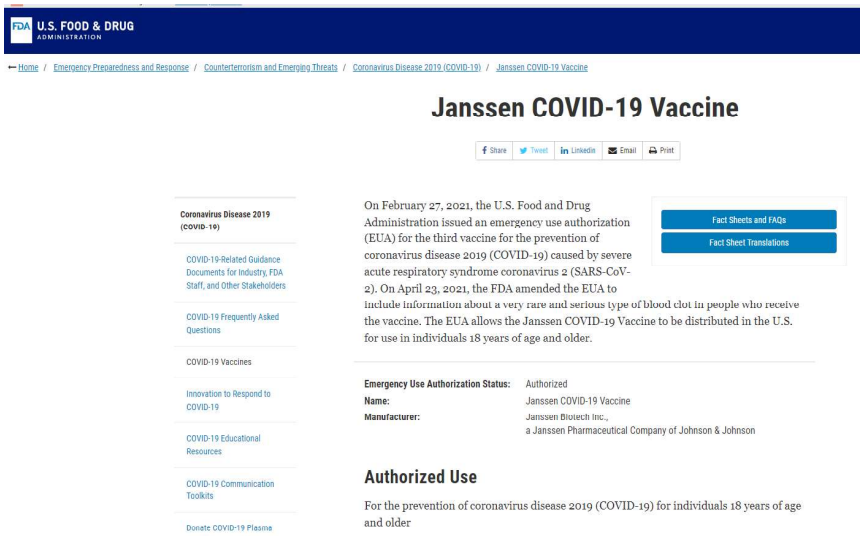
For Immediate Release: December 18, 2020

Español

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the second vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The emergency use authorization allows the Moderna COVID-19 Vaccine to be distributed in the U.S. for use in individuals 18 years of age and older.

2/27/2021



U.S. FOOD & DRUG ADMINISTRATION

Home / Emergency Preparedness and Response / Counterterrorism and Emerging Threats / Coronavirus Disease 2019 (COVID-19) / Janssen COVID-19 Vaccine

Janssen COVID-19 Vaccine

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Coronavirus Disease 2019 (COVID-19)

- COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders
- COVID-19 Frequently Asked Questions
- COVID-19 Vaccines
- Innovation to Respond to COVID-19
- COVID-19 Educational Resources
- COVID-19 Communication Toolkits
- Donate COVID-19 Plasma

On February 27, 2021, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the third vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). On April 23, 2021, the FDA amended the EUA to include information about a very rare and serious type of blood clot in people who receive the vaccine. The EUA allows the Janssen COVID-19 Vaccine to be distributed in the U.S. for use in individuals 18 years of age and older.

Fact Sheets and FAQs

Fact Sheet Translations

Emergency Use Authorization Status:	Authorized
Name:	Janssen COVID-19 Vaccine
Manufacturer:	Janssen Biotech Inc., a Janssen Pharmaceutical Company of Johnson & Johnson

Authorized Use

For the prevention of coronavirus disease 2019 (COVID-19) for individuals 18 years of age and older

1.

U.S. FOOD & DRUG ADMINISTRATION

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Pfizer-BioNTech COVID-19 Vaccine

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U.S. FOOD & DRUG ADMINISTRATION

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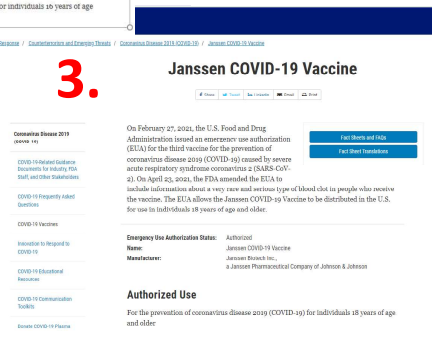

Janssen COVID-19 Vaccine

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Pfizer / BioNTech mRNA vaccine

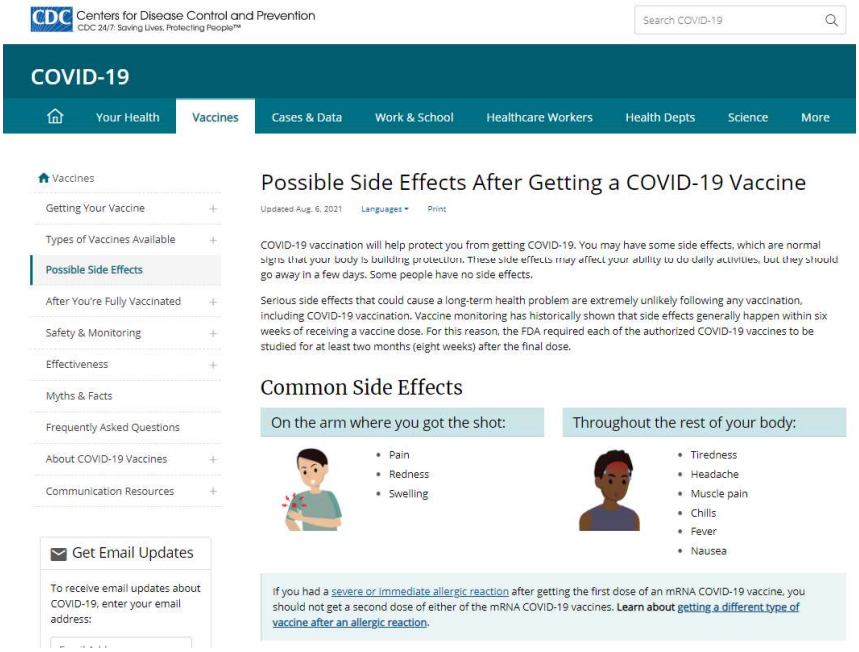
BLA: 8/23/2021

Full approval for ≥ 16

***EUA:* age 12-15**

***EUA:* Additional dose for immunocompromised**

EUA = Emergency Use Authorization ----- BLA = Biologics license application



Warnings!

Viral vector vaccine Janssen:

-TTS: Thrombosis with Thrombocytopoenia Syndrome (rare)
(more common in women < 50)

-GBS: Guillain-Barre Syndrome (rare)

mRNA vaccines- Pfizer & Moderna

-Myocarditis (heart inflammation)

FDA U.S. FOOD & DRUG ADMINISTRATION

Prescribing information
Pfizer –BioNTech

← Home / News & Events / FDA Newsroom /

Excerpt from Prescribing Information for Pfizer mRNA vaccine (Comirnaty):

5 WARNINGS AND PRECAUTIONS

5.2 Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

Myocarditis Risk

- There is risk of myocarditis *after* COVID mRNA vaccination.
- There is also risk of myocarditis with COVID infection.

Myocarditis after COVID infection …occurs at higher rates than after mRNA vaccination!

Why COVID vaccination is important for children and adolescents (age 12 and older…)

COVID infections can cause:
MIS-C (Multisystem inflammatory disorder in children,
Post COVID condition --long haul COVID, Hospitalization , Death

Delta Is the dominant circulating SARS-CoV-2 variant

Delta represents **99%** of recently sequenced lineages

Delta is more than 2x as contagious than previous variants

Delta, B.1.617.2

Alpha, B.1.1.7

https://covid.cdc.gov/covid-data-tracker/#variant-proportions; https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html

New Recommendation:

Additional vaccine dose for Immunocompromised

Honor System: (no Rx or doctor note needed)

CDC ACIP

FDA: Emergency Use Authorization (EUA) Amendment

- **August 12, 2021**: FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals*
  - Other fully vaccinated individuals do not need an additional dose right now
  - Amendment applies to:
  - **Pfizer-BioNTech** COVID-19 vaccine (BNT162b2) (≥12 years old)
  - **Moderna** COVID-19 vaccine (mRNA-1273) (≥18 years old)
- Due to insufficient data, the EUA amendment for an additional dose does not apply to Janssen COVID-19 vaccine or to individuals who received Janssen COVID-19 as a primary series. CDC and FDA are actively engaged to ensure that immunocompromised recipients of Janssen COVID-19 vaccine have optimal vaccine protection

tps://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised

Roles of an Additional Dose

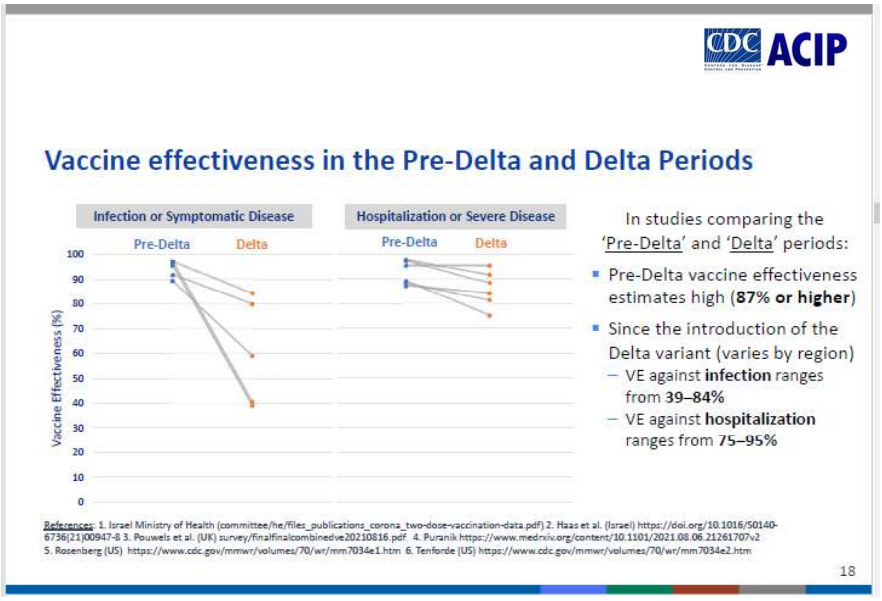
CDC ACIP

There are two distinct potential uses for an additional dose:

- **Additional dose after an initial primary vaccine series**: administration of an additional vaccine dose when the initial immune response following a primary vaccine series is likely to be insufficient.

- **Booster dose:** a dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time. The need for and timing of a COVID-19 booster dose have not been established

BOOSTERS? *What? When?*



FDA U.S. FOOD & DRUG ADMINISTRATION

September 22, 2021
EUA for single Pfizer booster dose

FDA expanded Pfizer-BioNTech EUA to include a single booster dose, to be administered at least six months after completion of the primary series in:

- individuals 65 years of age and older;
- individuals 18 through 64 years of age at high risk of severe COVID-19; and
- individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

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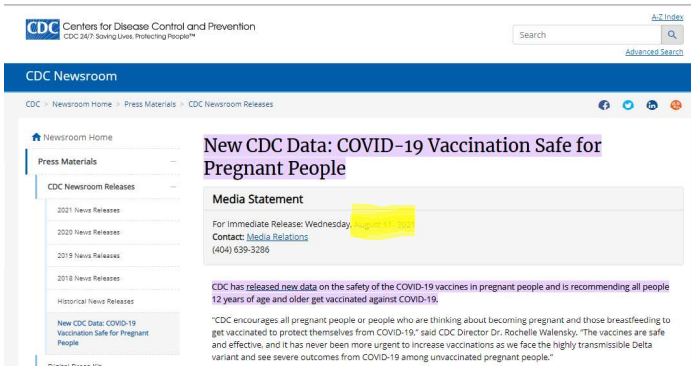
CDC Statement on ACIP Booster Recommendations

receive a Pfizer-BioNTech COVID-19 booster shot to help increase their protection.

CDC recommends:

- ≥ 65 → people 65 years and older and residents in long-term care settings **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- Health condition → people aged 50–64 years with underlying medical conditions **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,
- people aged 18–49 years with underlying medical conditions **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks, and
- High exposure job or conditions → people aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.



Previously, data from three safety monitoring systems did not find any safety concerns for pregnant people who were vaccinated late in pregnancy or for their babies. Combined, these data and the known severe risks of COVID-19 during pregnancy demonstrate that the benefits of receiving a COVID-19 vaccine for pregnant people outweigh any known or potential risks.

A new CDC analysis of current data from the v-safe pregnancy registry assessed vaccination early in pregnancy and did not find an increased risk of miscarriage among nearly 2,500 pregnant women who received an mRNA COVID-19 vaccine before 20 weeks of pregnancy. Miscarriage typically occurs in about 11-16% of pregnancies, and this study found miscarriage rates after receiving a COVID-19 vaccine were around 13%, similar to the expected rate of miscarriage in the general population.

Some vaccination hesitancy may be vaccine inconvenience

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PRESS RELEASES

AMA in support of COVID-19 vaccine mandates for health care workers

JUL 26, 2021

"It is critical that all people in the health care workforce get vaccinated against COVID-19 for the safety of our patients and our colleagues," said Susan R. Bailey, M.D., immediate past president of the American Medical Association. "With more than 300 million doses administered in the United States and nearly 4 billion doses administered worldwide, we know the vaccines are safe and highly effective at preventing severe illness and death from COVID-19. Increased vaccinations among health care personnel will not only reduce the spread of COVID-19 but also reduce the harmful toll this virus is taking within the health care workforce and those we are striving to serve."

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E WHITE HOUSE

Administration Priorities COVID Plan Brie

September 9, 2021

PATH OUT OF THE PANDEMIC

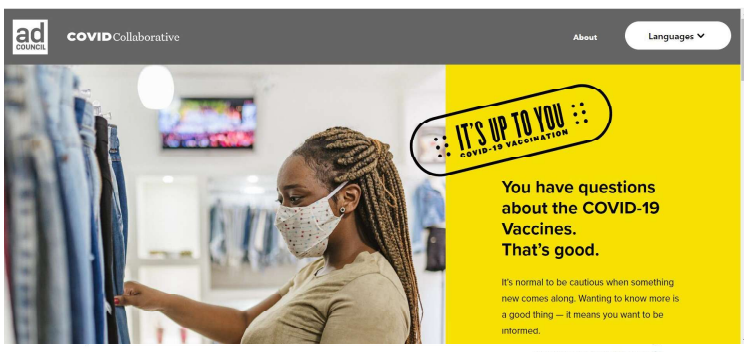
PRESIDENT BIDEN'S COVID-19 ACTION PLAN

- Requiring All Employers with 100+ Employees to Ensure their Workers are Vaccinated or Tested Weekly
- Requiring Vaccinations for all Federal Workers and for Millions of Contractors that Do Business with the Federal Government
- Requiring COVID-19 Vaccinations for Over 17 Million Health Care Workers at Medicare and Medicaid Participating Hospitals and Other Health Care Settings
- Calling on Large Entertainment Venues to Require Proof of Vaccination or Testing for Entry
- Requiring Employers to Provide Paid Time Off to Get Vaccinated

Vaccinating the Unvaccinated | Further Protecting the Vaccinated | Keeping Schools Safely Open | Increasing Testing & Requiring Masking | Protecting Our Economic Recovery | Improving Care for those with COVID-19

The COVID Collaborative

We've assembled a diverse and comprehensive team of leading experts in health, education, and the economy to shape the work of the COVID Collaborative, develop consensus recommendations, and engage with state and local leaders across America – ensuring that our efforts are truly from the nation, for the nation.



Courtesy of Ad Council

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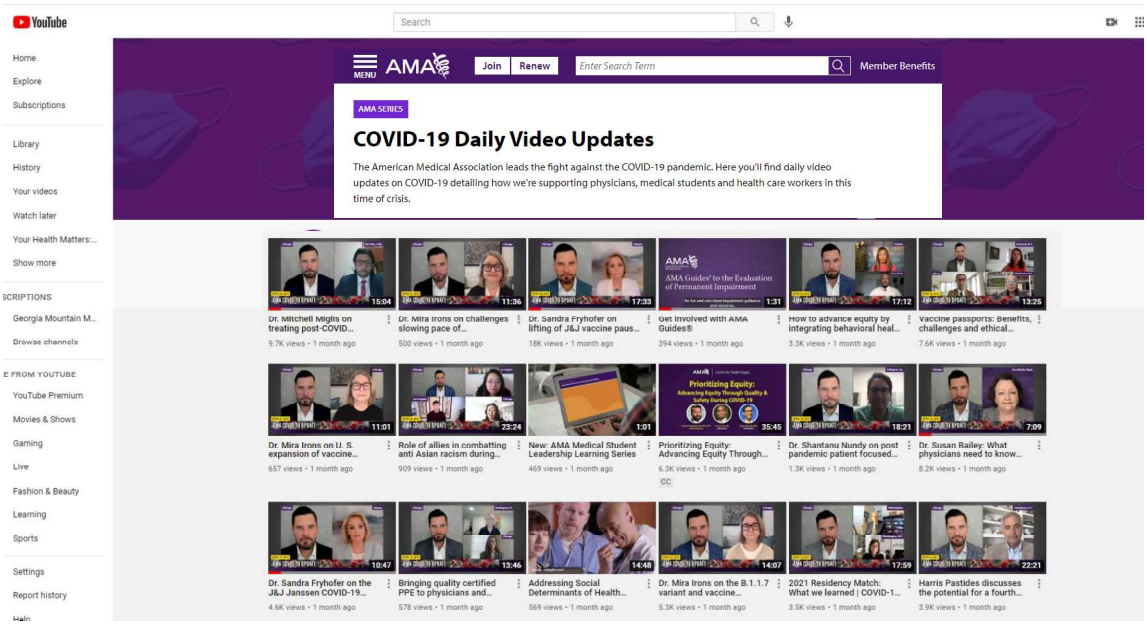

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

-Oct 14 Moderna boosters

On Oct. 14, the committee will discuss an amendment to the emergency use authorization of the Moderna COVID-19 Vaccine for the administration of a booster dose, in individuals 18 years of age and older.

-Oct 15 J & J booster

On Oct. 15, the VRBPAC will discuss amending the emergency use authorization of Johnson and Johnson's Janssen COVID-19 Vaccine for the administration of a booster dose, in individuals 18 years of age and older.

-Mix n' match boosters

Additionally, on Oct. 15, the committee will hear a presentation from the National Institute of Health's National Institute of Allergy and Infectious Diseases on the heterologous use of booster doses following the primary series of the three currently authorized or approved COVID-19 vaccines.

Release: October 01, 2021

.S. Food and Drug Administration is announcing two upcoming meetings of nd Related Biological Products Advisory Committee (VRBPAC) to discuss le data for the currently available COVID-19 vaccines.

Meeting on Janssen and Moderna COVID-19 Vaccine

Total Vaccine Doses

Delivered	478,362,045
Administered	394,690,283

Learn more about the distribution of vaccines.

185.1M
People fully vaccinated

4.74M
People received a booster dose**

At Least One Dose | Fully Vaccinated | Booster Dose

Fully Vaccinated* People	Count	Percent of US Population
Total	185,143,698	55.8%
Population ≥ 12 Years of Age	185,011,183	65.2%
Population ≥ 18 Years of Age	173,230,020	67.1%
Population ≥ 65 Years of Age	45,660,393	83.5%

** The count of people who received a booster dose includes anyone who is fully vaccinated and has received another dose of COVID-19 vaccine since August 13, 2021. This includes doses previously referred to as "additional doses".

About these data

CDC | Data as of: October 2, 2021 6:00am ET. Posted: Saturday, October 2, 2021 2:01 PM ET

??Questions??

END