COVID-19 Vaccine Primer and Adult Immunization Review

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IAC
immunize.org

Disclosure

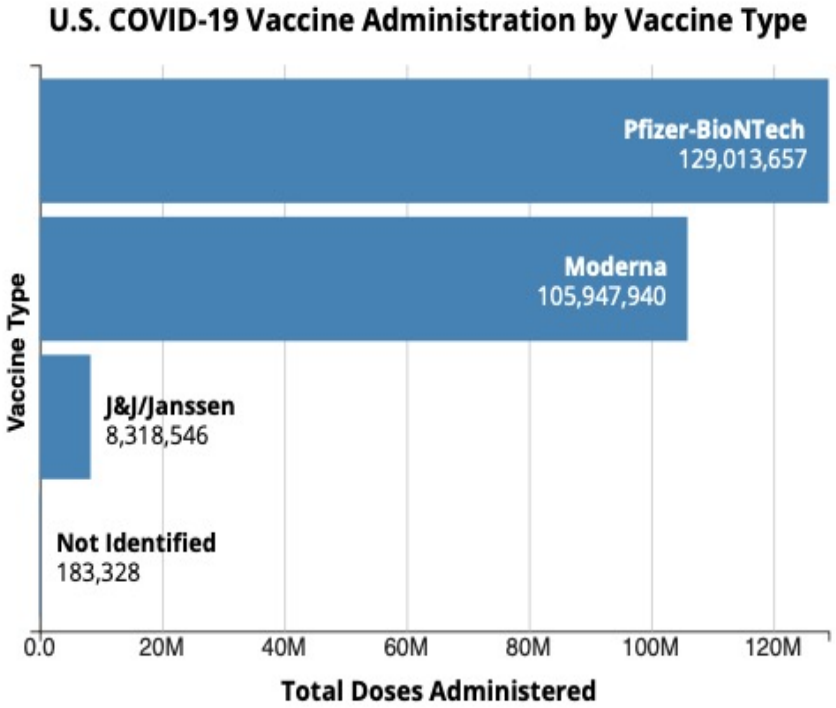
I, Carolyn B. Bridges, have been asked to disclose any significant relationships with commercial entities that are either providing financial support for this program or whose products or services are mentioned during this presentation. I have no financial conflicts of interest to disclose. I have served on a single scientific advisory board with Pfizer regarding pneumococcal vaccines. I have not worked with any manufacturers on COVID-19 vaccines.

Learning Objectives

1. Identify differences among currently available COVID-19 vaccines in the United States
2. Understand contraindications and precautions for COVID-19 vaccines
3. Understand storage and handling requirements for COVID-19 vaccines
4. Identify 3 or more evidence-based strategies for improving adult immunizations

Currently Available COVID-19 Vaccines

COVID-19 Vaccine Distribution



- Pfizer BioNTech mRNA vaccine
  - Distribution and administration began on Dec. 14
- Moderna mRNA vaccine
  - Distribution and vaccination began week of Dec. 21
- Johnson and Johnson/Janssen replication-incompetent adenovirus 26-virus vector vaccine
  - Distribution and vaccination began week March 2

COVID-19 Vaccines with Emergency Use Authorization in United States

	BioNTech with Pfizer	ModernaTX USA	Janssen/J&J
Vaccine	BNT162-b2 mRNA	mRNA-1273	JNJ-78436735
Type	mRNA	mRNA	Rep. Incomp. Ad26
Dosing	Days 0 + 21	Days 0 + 28	Single dose
Age groups (yrs.)	16+	18+	18+
Shipping/storing before puncture	-80 to -60 °C until expiration -25 to -15 °C for 2 weeks 2 to 8 °C up to 5 days (120 hrs.)	-50 to -15 °C until expiration 2 to 8 °C for 30 days 8 to 25 °C up to 24 hrs.	2-8 °C until expiration 9-25 °C up to 12 hours
Transportation temp. BEFORE puncture	-80 to -60 °C until expiration -25 to -15 °C for 2 weeks 2 to 8 °C up to 5 days (120 hrs.)	-50 to -15 °C until expiration 2 to 8 °C up to 12 hrs cumulative.	2-8 °C
AFTER vial puncture	Up to 6 hours at 2 to 25 °C	Up to 12 hours at 2 to 25 °C	Up to 6 hours at 2 to 8 °C OR Up to 2 hours at 9 to 25 °C
Minimum shipping volume	195 vials (975-1170 doses) with 5-6 doses/vial	10 vials with 10-11 or 14-15 dose /vials	100 doses in 5-dose vials
Other vaccine handling issues	Protect from light Do not re-freeze once thawed Gently invert, do not shake	Protect from light Do not re-freeze Swirl, do not shake	Protect from light Do not freeze Swirl, do not shake

COVID-19 Vaccines with Emergency Use Authorization in United States

	BioNTech with Pfizer	ModernaTX USA	Janssen/J&J
Vaccine	BNT162-b2 mRNA	mRNA-1273	JNJ-78436735
Diluent/reconstitute	Yes (1.8mL 0.9% NaCl, Preservative Free)	No	No
Preservative	No	No	No
Dose size	0.3mL	0.5mL	0.5mL
Contraindications	• Severe allergic reaction (e.g., anaphylaxis) or immediate allergic reaction* after a previous dose or to a vaccine component • NOTE: Contraindication to mRNA vaccine is precaution for J&J vaccine and vice versa • mRNA vaccines include PEG and J&J includes polysorbate-80 which may cross-react		
Precautions	• Hx immediate allergic reaction to any other vaccine or injectable therapy • Moderate to severe acute illness		
Warnings	Be prepared to recognize and manage anaphylaxis	Be prepared to recognize and manage anaphylaxis	• Be prepared for anaphylaxis • Thrombosis with Thrombocytopenia Syndrome (TTS)

*immediate allergic reaction includes urticaria, angioedema, respiratory distress, or anaphylaxis within 4 hours after exposure

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html.

Additional COVID-19 Vaccines In Development or Utilized Elsewhere Possibly for U.S. Market

Selected COVID-19 Vaccines Possibly for U.S.

	Univ. of Oxford/AstraZeneca[2-4]	Novavax[1]
Vax candidate/ type	ChAdOx1 Adenovirus vector	NVX-CoV2373 Subunit protein with Matrix-M
Dosing	Days 0 and 28+	Days 0 and 21+
Storage	2-8°C	2-8°C
Clinical Trial Enrollment	Completed	Completed
Ages Studied (y)	18+	18-84

Ref.: 1. Keech C, et al. Phase 1-2 Trial of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine. N Engl J Med. 2020 Dec 10;383(24):2320-2332. doi: 10.1056/NEJMoa2026920. Epub 2020 Sep 2.
2. Ramasamy MN, *et al*. Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults (COV002): A single-blind, randomized, controlled, phase 2/3 trial. *Lancet* 2020;396:1979-93. Doi.org/10.1016/S0140-6736(20)32481-8
3. Voysey M, *et al.* Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: An interim analysis of four randomized controlled trials in Brazil, South Africa, and the UK. *Lancet* 2021;397(Jan 9):99-111. doi.org/10.1016/S0140-6736(20)32661-1
4. Voysey M, *et al*. Single dose administration, and the influence of the timing of the booster dose on immunogenicity and efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine. *Lancet* 2021;397(Mar 6):881-91. doi.org/10.1016/S0140-6736(21)00432-3.

Pfizer BioNTech Vaccine

Pfizer/BioNTech Vaccine Efficacy

- EUA for use among persons 16 years and older, 2 doses at least 21 days apart given intramuscular
- Assessed in clinical trial of ~44,000 people comparing vaccinated people to people who received saline placebo
- Pregnant women and immunocompromised people excluded
- Among participants with no evidence of SARS-CoV-2 who completing 2 doses at least 7 days:
  - 95.0% effective
  - Similar across age groups, genders, racial and ethnic groups, high risk conditions, and if include those with prior SARS-CoV-2 infection

https://www.fda.gov/media/144245/download and Pollack NEJM 2020 DOI: 10.1056/NEJMoa2034577.

FDA Review of Pfizer/BioNTech EUA Application – Safety

Solicited adverse reactions

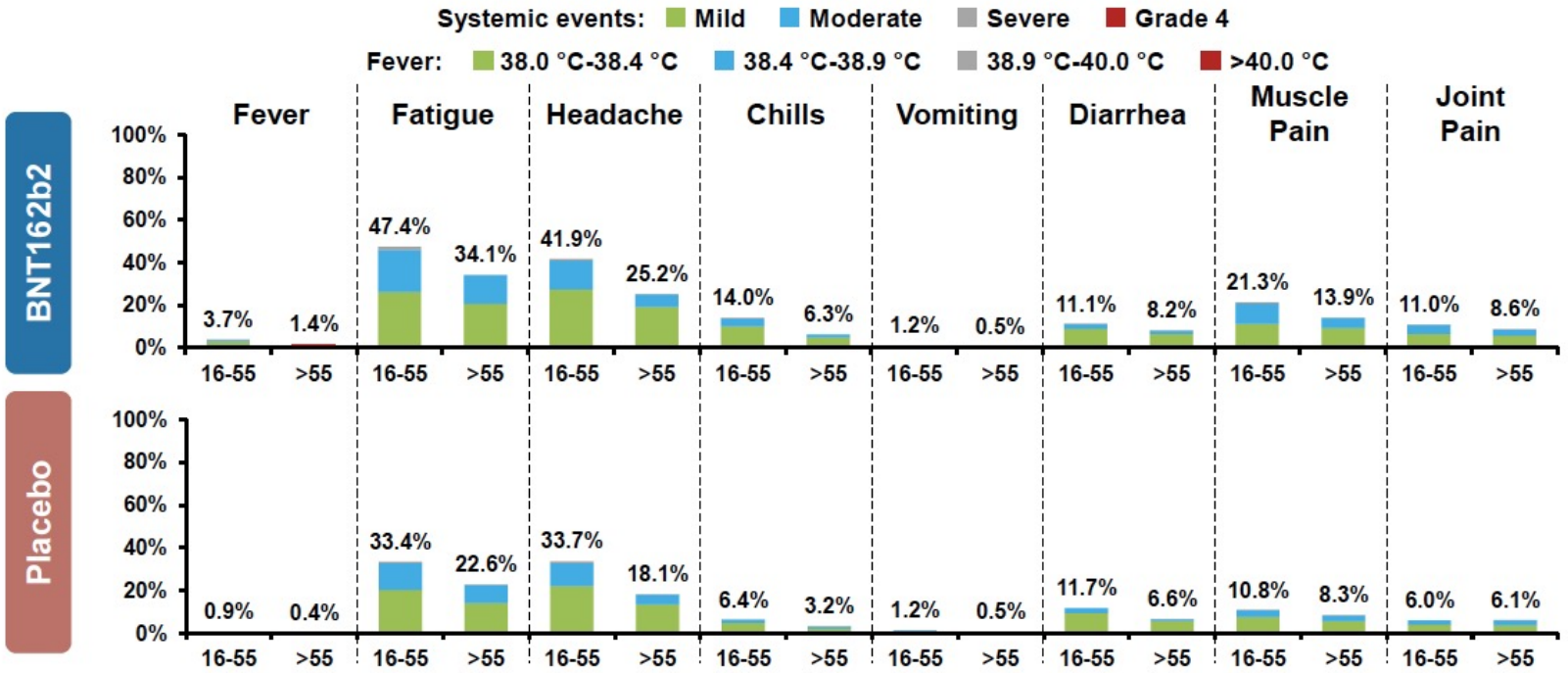
- Injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%)
- Severe adverse reactions: 0.0% to 4.6% for Dose 1 vs Dose 2
  - ≥55 years of age (≤2.8%) as compared to <55 years (≤4.6%).
- Serious adverse events low (<0.5%) and did not differ by vaccine vs placebo

Unsolicited adverse events

- Lymphadenopathy: 64 cases in vaccine group vs. 6 in placebo group
- 4 cases Bell's palsy among vaccine recipients (3, 9, 37, and 48 days after vaccination) vs none in placebo group

https://www.fda.gov/media/144245/download and Pollack NEJM 2020 DOI: 10.1056/NEJMoa2034577.

eDiary: Systemic Events Within 7 Days From Dose 1 in 16-55 and >55 Year Olds (N=8,183)

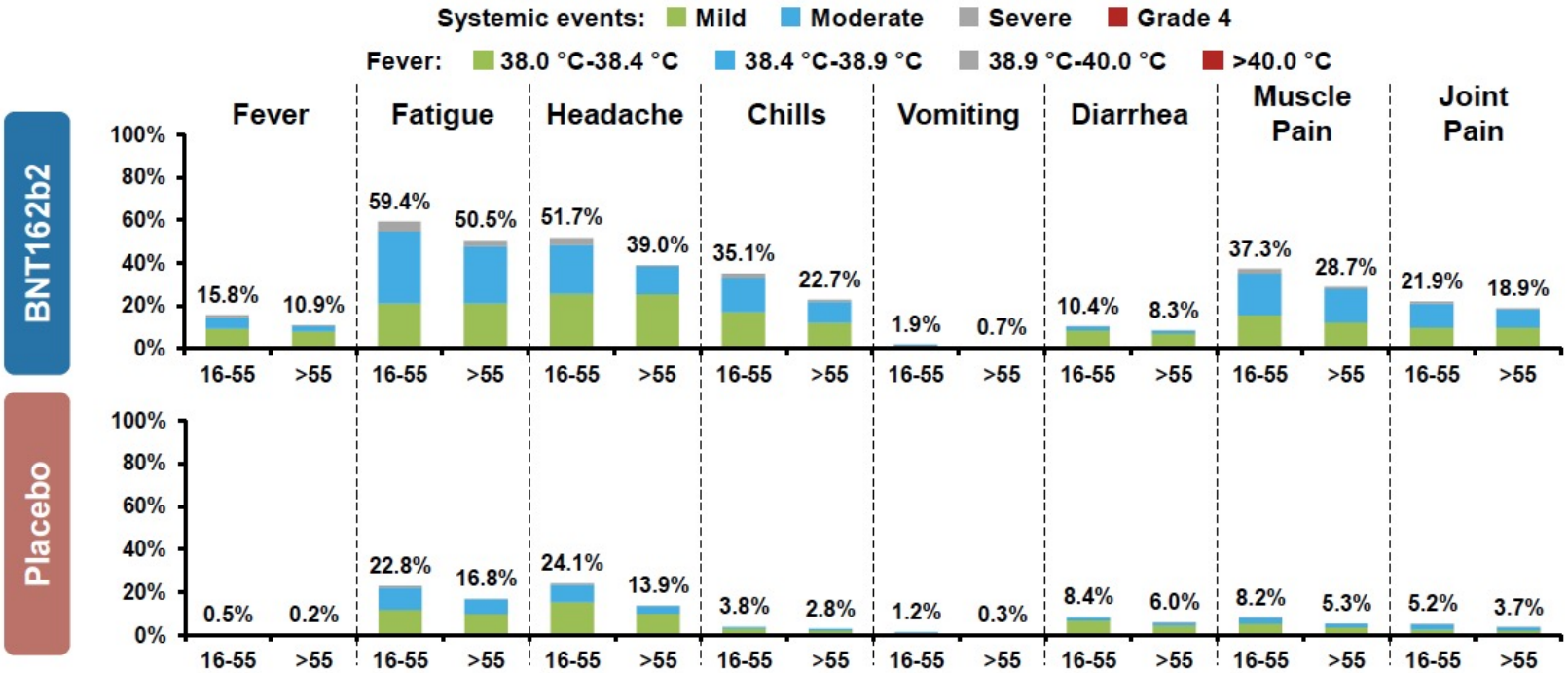


Fatigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
Vomiting severity definition: Mild=1-2 time in 24h; Moderate=>2times in 24h; Severe=Requires IV hydration; Grade 4=ER visit or hospitalization
Diarrhea severity definition: Mild=2-3 times in 24h; Moderate=4-5 times in 24h; Severe=6 or more times in 24h; Grade 4=ER visit or hospitalization
Dose 1: 18-55 yrs N=3529; 56-85 yrs N=3027 Dose 2: 18-55 yrs N=3345; 56-85 yrs N=2899

CC-18

https://www.fda.gov/media/144245/download . Pfizer presentation at Dec 12, 2020 ACIP Meeting.

eDiary: Systemic Events Within 7 Days From Dose 2 in 16-55 and >55 Year Olds (N=8,183)



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https://www.fda.gov/media/144245/download . Pfizer presentation at Dec 12, 2020 ACIP Meeting.

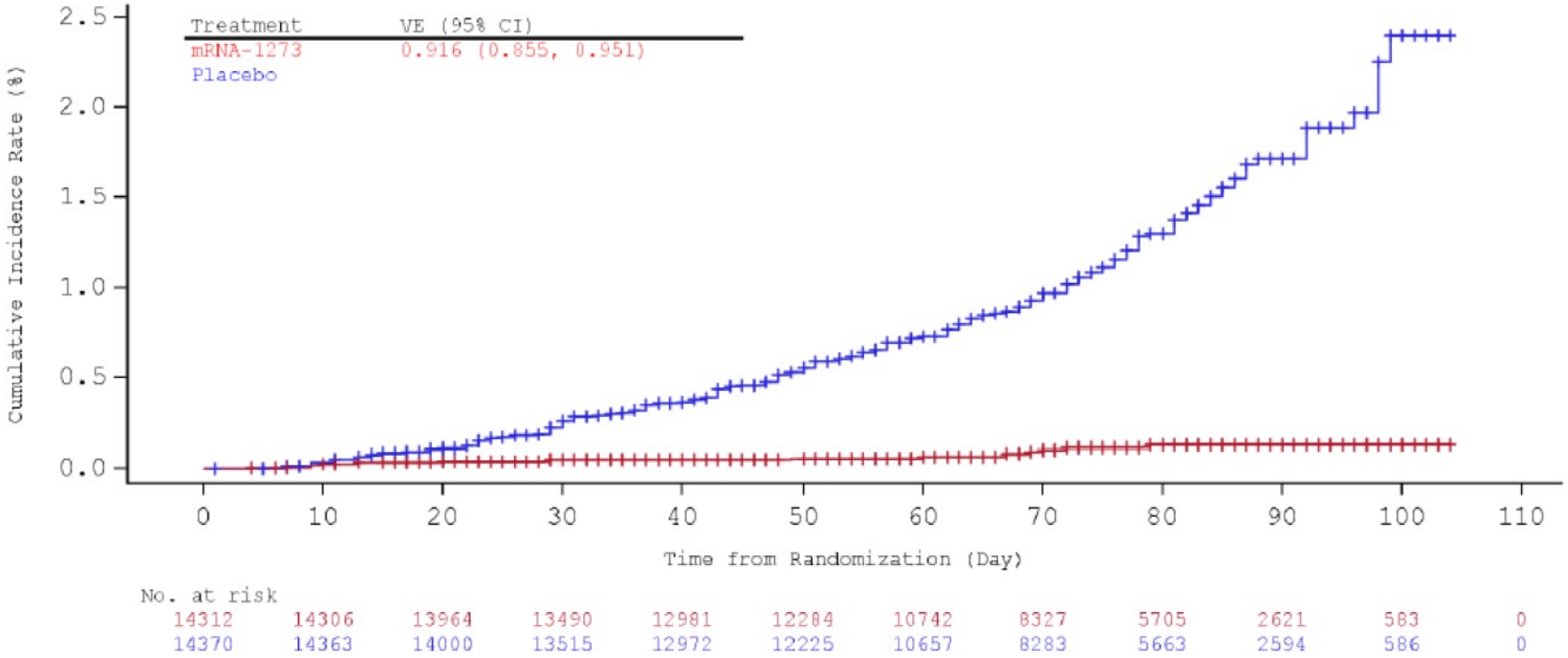
Moderna Vaccine Safety and Efficacy

Moderna Vaccine

- FDA EUA approved for use
  - 18 years of age and older.
  - 2 doses, 100 µg each, 0.5mL/dose, administered 1 month apart
- Among ~30,000 study participants – half received vaccine, and half received saline placebo
- Among those without evidence of SARS-CoV-2 infection before the first dose of vaccine AND 14 days after dose 2:
  - 94.1% (95% CI 86.5%, 97.8%) efficacy
  - Similar efficacy across age groups, genders, racial and ethnic groups, participants with medical comorbidities, and +/- prior SARS-CoV-2

Dec 15, 2020 VRBPAC Briefing Document https://www.fda.gov/media/144434/download

Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Randomization, mITT Set



Dec 15, 2020 VRBPAC Briefing Document https://www.fda.gov/media/144434/download

Moderna Vaccine Safety Results

- Most common solicited adverse reactions [AEs]: injection site pain (91.6%), fatigue (68.5%), headache (63.0%), muscle pain (59.6%), joint pain (44.8%), chills (43.4%)

- Severe adverse reactions in 0.2% - 9.7% of participants,
  - more frequent after dose 2 than after dose 1
  - more frequent among <65 years

Solicited AEs Among <65 years	Vaccine Dose 1 (%)	Placebo Dose 1 (%)	Vaccine Dose 2 (%)	Placebo Dose 2 (%)
Fever – any	0.9	0.3	17.4	0.4
Fever –Grade 3/4	1.2	0.02	1.7	0.03
Headache – any	35.4	29.0	62.8	25.4
Headache – Grade 3	1.9	1.4	5.0	1.2
Fatigue – any	38.5	28.8	67.6	24.5
Fatigue – Grade 3/4	1.1	0.7	10.6	0.8
Myalgia – any	23.7	14.3	61.3	12.7
Myalgia – Grade 3	0.6	0.3	10.0	0.4
Arthralgia – any	16.6	11.6	45.2	10.5
Arthralgia – Grade 3/4	0.4	0.3	5.8	0.3
Chills – any	9.2	6.4	48.3	5.9
Chills – Grade 3	0.1	0.07	1.5	0.1

Moderna Vaccine Safety Results

- Unsolicited adverse events reported:
  - lymphadenopathy (axillary swelling and tenderness)
    - 21.4% of vaccine recipients <65 years of age vs 7.7% placebo
    - 12.4% of vaccine recipients ≥65 years of age vs 5.8% placebo
  - hypersensitivity adverse events
    - 1.5% of vaccine recipients and 1.1% of placebo recipients
    - No anaphylactic or severe hypersensitivity reactions with close temporal relation to the vaccine (>10 days after vaccination)
  - Bell's palsy – three in vaccine group and one in placebo.

Moderna Vaccine Safety, continued

- Among unsolicited reactions, 2 cases of facial swelling after vaccination thought to be related to vaccination
  - Both with prior dermal cosmetic filler injections

- Pregnant women and immunocompromised persons excluded from the study

Janssen/J&J COVID-19 Vaccine

Janssen/Johnson & Johnson Vaccine

- EUA for adults 18+, single dose given I.M.
- Efficacy study n=39,321 persons randomized 1:1, vaccine vs saline
- Vaccine efficacy (VE) against COVID-19 ≥14 days after vaccination: 66.9%
  - No significant differences in 18-59 vs 60+ years
- VE against severe/critical COVID-19: 76.6%
  - 2 COVID-related hospitalizations and no deaths in vaccine group versus 29 hospitalizations and 5 deaths in placebo group
- VE in South African participants, where variant predominated, was 52% for moderate/severe and 64% against severe/critical

Sadoff J, et al. NEJM 2021. DOI: 10.1056/NEJMoa2102544.

Side Effects and Serious Adverse Events – J&J Vaccines

- Similar to other COVID-19 vaccines, younger adults reported side effects more often than older adults
- Most common
  - injection site pain (59% in 18-59 yo vs 33% in 60+ yo),
  - headache (44% vs 30%),
  - fatigue (44% vs 30%),
  - myalgia (39% vs 24%),
  - nausea (15 vs 12%), and
  - fever (13% vs 3%)
- Serious adverse events: 0.4% vaccine vs 0.4% placebo

Numerical imbalances of serious and other adverse events – J&J Vaccines

- Thromboembolic events:
  - Deep vein thrombosis: 6 vaccine group, 2 placebo group
  - Pulmonary embolism: 4 events vs. 1 event
  - Transverse sinus thrombosis with thrombocytopenia: 1 vaccinee vs 0 in placebo group
- Seizures: 4 vaccinees vs 1 placebo
- Tinnitus: 6 vaccinees vs 0 placebo group

Thrombosis with Thrombocytopenia Syndrome (TTS) Associated with Janssen/J&J Vaccination

- From April 13-23, CDC and FDA recommended pausing the use of J&J COVID-19 vaccine due to reports of 6 cases of cerebral venous sinus thrombosis (CVST) with thrombocytopenia.
- Recommended not to use heparin in these patients due to increasing risk of bleeding
  - Use alternative drug
  - Test for anti-heparin antibody

Cerebral venous sinus anatomy

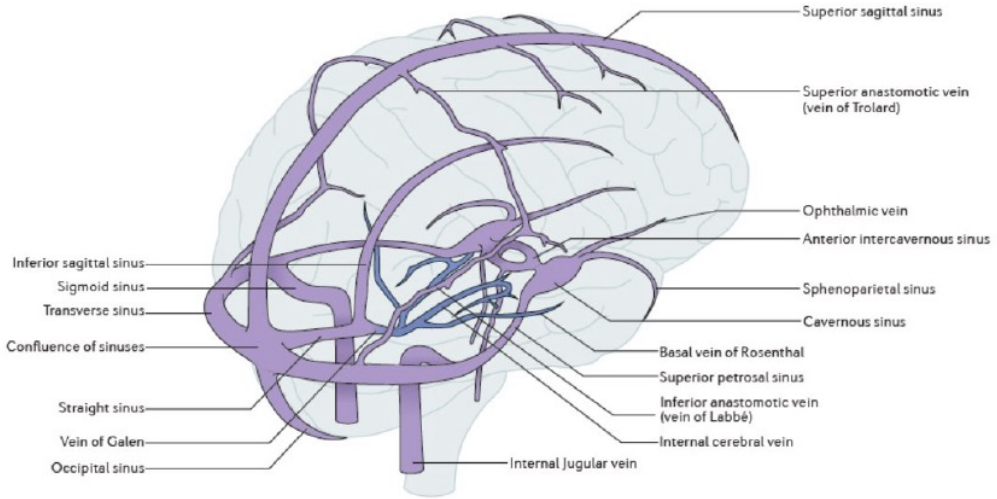


Figure 1 | **Anatomy of the cerebral venous system.** Diagram showing the main components of the cerebral venous system. Blue vessels represent the deep venous system.

Silvis SM et al, Nature Reviews Neurology 13, 555-565(2017)

Thrombosis with Thrombocytopenia Syndrome (TTS) Associated with Janssen/J&J Vaccination

- Additional review of VAERS data identified[1,2,3]:
  - 3 cases non-CVST TTS
  - 14 cases CVST with TTS (13 women, 1 man, all <60 years old)
- Clots have occurred often in multiple arteries/veins per person
  - E.g., carotid arteries, splenic veins, femoral arteries and veins, cerebral veins

Risk estimates as of April 23, 2021

	Females			Males		
Age group	TTS cases	Doses admin	Reporting rate‡	TTS cases	Doses admin	Reporting rate‡
18-49 years old	**13**	1,866,294	7.0 per million	**0**	1,977,330	0 per million
50+ years old	**2**	2,125,239	0.9 per million	**0**	2,010,144	0 per million

1. CDC. www.cdc.gov/mmwr/volumes/70/wr/mm7018e2.htm?s_cid=mm7018e2_w. April 30, 2019
2. Shimabukuro T, et al. CDC/ACIP meeting April 23, 2021.
3. See I, et al. JAMA 2021 DOI:10.1001/jama.2021.7517. April 30

Thrombosis with Thrombocytopenia Syndrome (TTS) Associated with Janssen/J&J Vaccination

- American Society for Hematology has provided guidance for diagnosing, evaluating and initiating therapy for cases of TTS at www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia.
- FDA has included a warning in J&J vaccine EUA patient and provider fact sheets that rare clotting events may occur after Janssen COVID-19 vaccination predominantly among women 18-49 about 1-2 weeks after vaccination.

https://www.fda.gov/media/146304/download.

Additional Clinical Considerations for COVID-19 Vaccines

Clinical Considerations for COVID-19 Vaccines– Special Populations With Limited Information

- Pregnant women may be vaccinated after counseling[1]
  - Initial review of safety data from multiple vaccine safety surveillance systems preliminarily found no obvious safety signals[2]
  - Take fever reducing medicines since fever can lead to congenital defects early in pregnancy
  - Consider risk of exposure to COVID-19, limited data and other considerations
  - Not required to provide a note from their obstetrician to get vaccinated

- Lactating women may be vaccinated[1]
  - No data, but no known risk to breastfeeding infant

1. CDC Interim clinical considerations for use of COVID-19 vaccines currently authorized in the United States. https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.
2. Shimabukuro T, et al. NEJM 2021. DOI: 10.1056/NEJMoa21204983.

COVID-19 Vaccine Clinical Trial Populations

- Pediatric vaccination studies
  - Pfizer recently submitted EUA request for children 12-15 years – 100% effective[1]
    - Other studies planned or ongoing include 6 months -11 years
  - Moderna conducting study among 6 months - 17 year olds
    - Fully enrolled[2]
- Immunocompromised persons
  - Initial vaccine studies included persons with stable HIV, persons on biologics for autoimmune diseases; no safety signals
  - Additional studies ongoing[2]

1. https://www.businesswire.com/news/home/20210331005503/en/.
2. www.Clinicaltrials.gov.

Clinical Considerations for mRNA COVID-19 vaccines – Persons with COVID-19 Infection

- Offer regardless of prior COVID-19 infection
  - Antibody testing prior to vaccination not recommended
  - Since reinfection risk low in 90 days after COVID-19, can delay until 90 days post-infection
- DO defer for 90 days after receipt of monoclonal antibody or convalescent serum

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

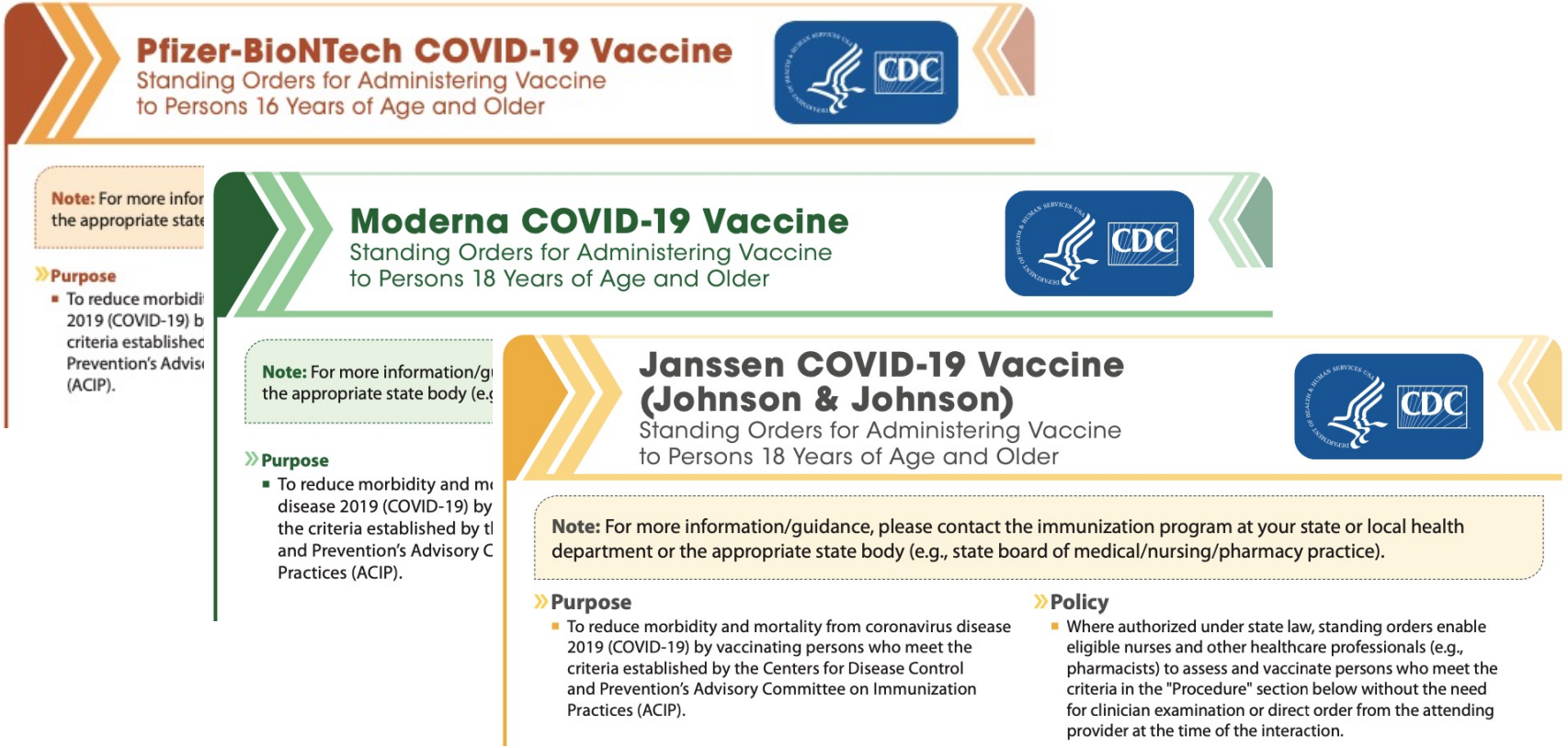
Additional Vaccines Clinical Guidance

- Do not co-administer with other vaccines in 14 days before or after COVID-19 vaccination – exception if benefits outweigh unknown risks, e.g., after hepatitis A or rabies exposure

- COVID-19 mRNA vaccines not interchangeable, but if inadvertently get different mRNA vaccines for dose 1 and 2, do not give a 3rd dose

- If fully vaccinated with a WHO, but not US authorized vaccine, no additional FDA-authorized vaccine doses needed
  - May offer COVID-19 vaccination to persons vaccinated with non-WHO authorized vaccine – minimum interval 28 days

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.



Pfizer-BioNTech COVID-19 Vaccine
Standing Orders for Administering Vaccine
to Persons 16 Years of Age and Older

Note: For more infor
the appropriate state

Purpose
- To reduce morbidi
2019 (COVID-19) b
criteria established
Prevention's Advis
(ACIP).

Moderna COVID-19 Vaccine
Standing Orders for Administering Vaccine
to Persons 18 Years of Age and Older

Note: For more information/g
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Purpose
- To reduce morbidity and m
disease 2019 (COVID-19) by
the criteria established by t
and Prevention's Advisory C
Practices (ACIP).

Janssen COVID-19 Vaccine (Johnson & Johnson)
Standing Orders for Administering Vaccine
to Persons 18 Years of Age and Older

Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Purpose
- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy
- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders.pdf.
https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/standing-orders.pdf.
https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/Janssen-Standing-Orders.pdf.

Safety Monitoring and Reporting

CDC Reported Risk of Severe Allergic Reactions After mRNA COVID-19 vaccines – T. Shimabukuro, ACIP, Jan 27, 2021

Estimated anaphylaxis reporting rates following COVID-19 vaccines based on VAERS reports and reported doses administered*

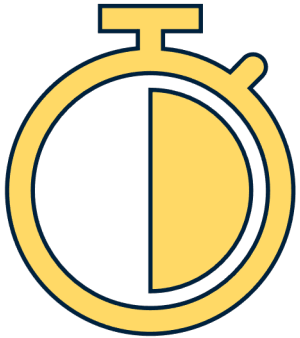
Reported vaccine doses administered	Anaphylaxis cases	Reporting rate (analytic period Dec 14-Jan 18)
Pfizer-BioNTech: **9,943,247**	50	5.0 per million doses admin.
Moderna: **7,581,429**	21	2.8 per million doses admin.

- Total COVID-19 vaccine doses administered thru Jan 18 by sex: Female 61%, Male 36%, Unk 3%

https://www.cdc.gov/vaccines/acip/meetings/slides-2021-1-27-21.html.

Observation periods following COVID-19 Vaccination

- 30 minutes
  - Previous immediate allergic reaction of any severity to another vaccine or injectable therapy
  - Contraindication to a different COVID-19 vaccine type (e.g., person with allergy to mRNA getting J&J vaccine)
  - History of anaphylaxis due to any cause



- 15 minutes for everyone else

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

Preparing for Potential Severe Allergic Reactions

- All vaccine providers should be prepared to manage severe allergic reactions after vaccination
- Guidance for preparing for immediate medical management of severe reactions is available at:
  - www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html.
  - www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html.
  - www.immunize.org/handouts/vaccine-reactions.asp.

Mandatory Reporting Requirements to Vaccine Adverse Events Reporting System (VAERS) Under EUA

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of COVID-19 that result in hospitalization or death

*Serious adverse events are defined as:

- Death
- Life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

How to report an adverse event to VAERS

- Go to vaers.hhs.gov
- Submit a report online

For help:

call
1-800-822-7967

email
info@VAERS.org

video instructions
https://youtu.be/sbCWhcQADFE

For COVID-19, FDA will issue VAERS reporting requirements under EUA; in addition, CDC encourages reporting of any clinically important adverse event following immunization

1. Text message check-ins from CDC (daily 1st week; weekly thru 6 weeks; then 3, 6, and 12 mo.)

   vaccine recipient completes web survey

Vaccine recipient

2. Clinically important health impact reported

- ✓ missed work
- ✓ unable to do normal daily activities
- ✓ received medical care

v-safe℠ after vaccination health checker

Call center

3. A CDC representative conducts active telephone follow-up on a clinically important health impact event and takes a report if appropriate

CDC ↔ FDA

COVID-19 Vaccine Effectiveness

Vaccine Effectiveness (VE)* in outbreaks in two skilled nursing facilities in Connecticut

- Retrospective cohort study in two skilled nursing facilities in Connecticut with COVID-19 cases occurring among residents following first vaccination clinics

- Partial regimen with Pfizer-BioNTech mRNA vaccine provided significant protection against infection:
  - VE against infection from 14 days after dose 1 to 7 days after dose 2
    63% (95% CI: 33–79%)

Britton et al. Effectiveness of the Pfizer-BioNTech COVID-19 Vaccine Among Residents of Two Skilled Nursing Facilities Experiencing COVID-19 Outbreaks — Connecticut, December 2020–February 2021 | *MMWR* (cdc.gov)

*Different COVID-19 Vaccines | CDC for vaccines' clinical trials vaccine efficacy summaries

HEROES-RECOVER interim VE estimates

- 3,950 participants without evidence of previous SARS-CoV-2 infection
- Overall participants were young and healthy
  - 69% had no chronic medical conditions
  - 72% were aged 18–49 years
- 205 (5.2%) SARS-CoV-2 infections from December 14, 2020–March 13, 2021
  - 87% were symptomatic
- Vaccination status
  - 63% received 2 doses mRNA vaccine
  - 12% received 1 dose mRNA vaccine
  - Of vaccinated, 63% received Pfizer-BioNTech and 30% Moderna

Thompson et al. Interim Estimates of Vaccine Effectiveness of BNT162b2 and mRNA-1273 COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Health Care Personnel, First Responders, and Other Essential and Frontline Workers — Eight U.S. Locations, December 2020–March 2021 | MMWR (cdc.gov)

HEROES-RECOVER interim VE estimates (cont.)

- VE against infection
  - 1 dose: 80% (95% CI 59-90%)
  - 2 doses: 90% (95% CI 68-97%)

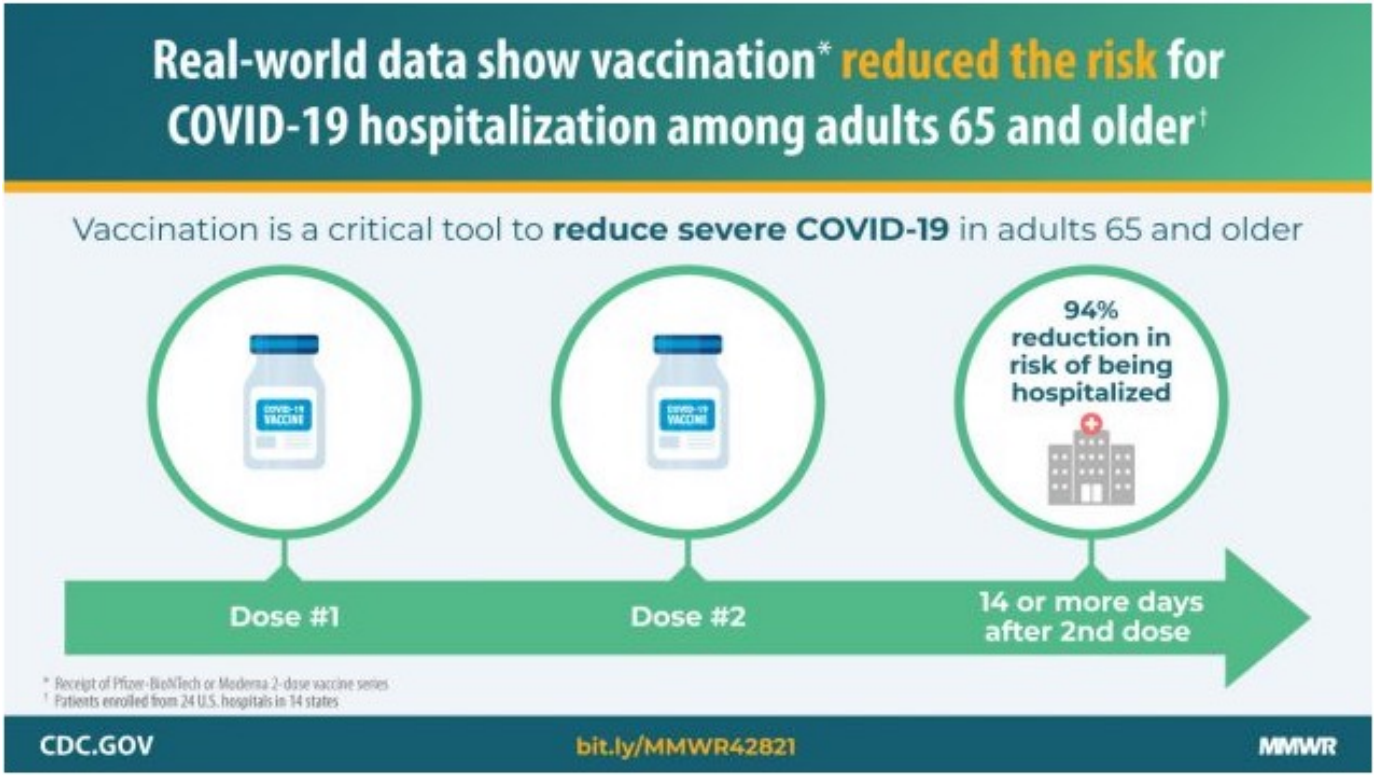
Thompson et al. Interim Estimates of Vaccine Effectiveness of BNT162b2 and mRNA-1273 COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Health Care Personnel, First Responders, and Other Essential and Frontline Workers — Eight U.S. Locations, December 2020–March 2021 | MMWR (cdc.gov)

VE against infection

- Tande et al: Retrospective cohort of 39,156 asymptomatic patients screened by SARS-CoV-2 PCR prior to surgical procedures from 12/17-2/8
  - Outcome: PCR-detected infection
  - Moderna and Pfizer-BioNTech vaccines
  - VE >0 days after dose 2 = 80% (95% CI 56-91%)

Tande et al. Clin Infect Dis, March 2021 , epub doi: 10.1093/cid/ciab229.

Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Among Hospitalized Adults Aged ≥65 Years — United States, January–March 2021 | MMWR (cdc.gov)



www.cdc.gov/mmwr/volumes/70/wr/mm7018e1.htm?s_cid=mm7018e1_w.

Uptake of COVID-19 Vaccination in the United States

COVID-19 Vaccinations in the United States

Overall US COVID-19 Vaccine | Deliveries and Administration; Maps, charts, and data provided by CDC, updates daily by 8 pm ET†
Represents all vaccine partners including jurisdictional partner clinics, retail pharmacies, long-term care facilities, dialysis centers, Federal Emergency Management Agency and Health Resources and Services Administration partner sites, and federal entity facilities.

Total Vaccine Doses

Delivered	301,857,885
Administered	234,639,414

Learn more about the distribution of vaccines.

People Vaccinated	At Least One Dose	Fully Vaccinated
Total	142,692,987	98,044,421
% of Total Population	43%	29.5%
Population ≥ 18 Years of Age	140,792,606	97,514,016
% of Population ≥ 18 Years of Age	54.5%	37.8%
Population ≥ 65 Years of Age	44,855,147	37,332,498
% of Population ≥ 65 Years of Age	82%	68.3%

About these data

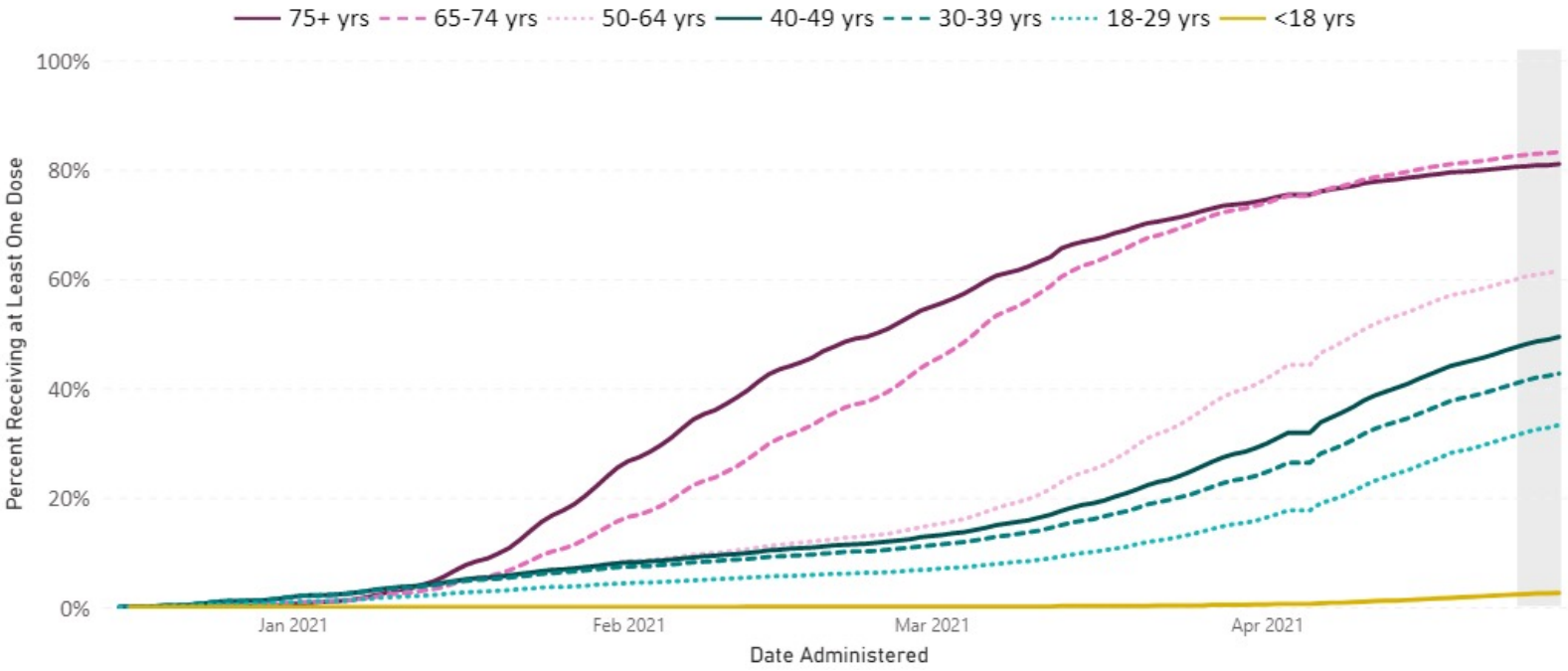
CDC | Data as of: April 28, 2021 6:00am ET. Posted: Wednesday, April 28, 2021 3:25 PM ET

CDC COVID Data Tracker

Percent of People Receiving at Least One Dose of any COVID-19 Vaccine by Age Group and Date Administered, United States

December 14, 2020 – April 28, 2021

At Least One Dose | Fully Vaccinated



Age Range	People Receiving ≥ 1 Doses
75+ yrs	81.0%
65-74 yrs	83.2%
50-64 yrs	61.5%
40-49 yrs	49.4%
30-39 yrs	42.7%
18-29 yrs	33.3%
<18 yrs	2.6%

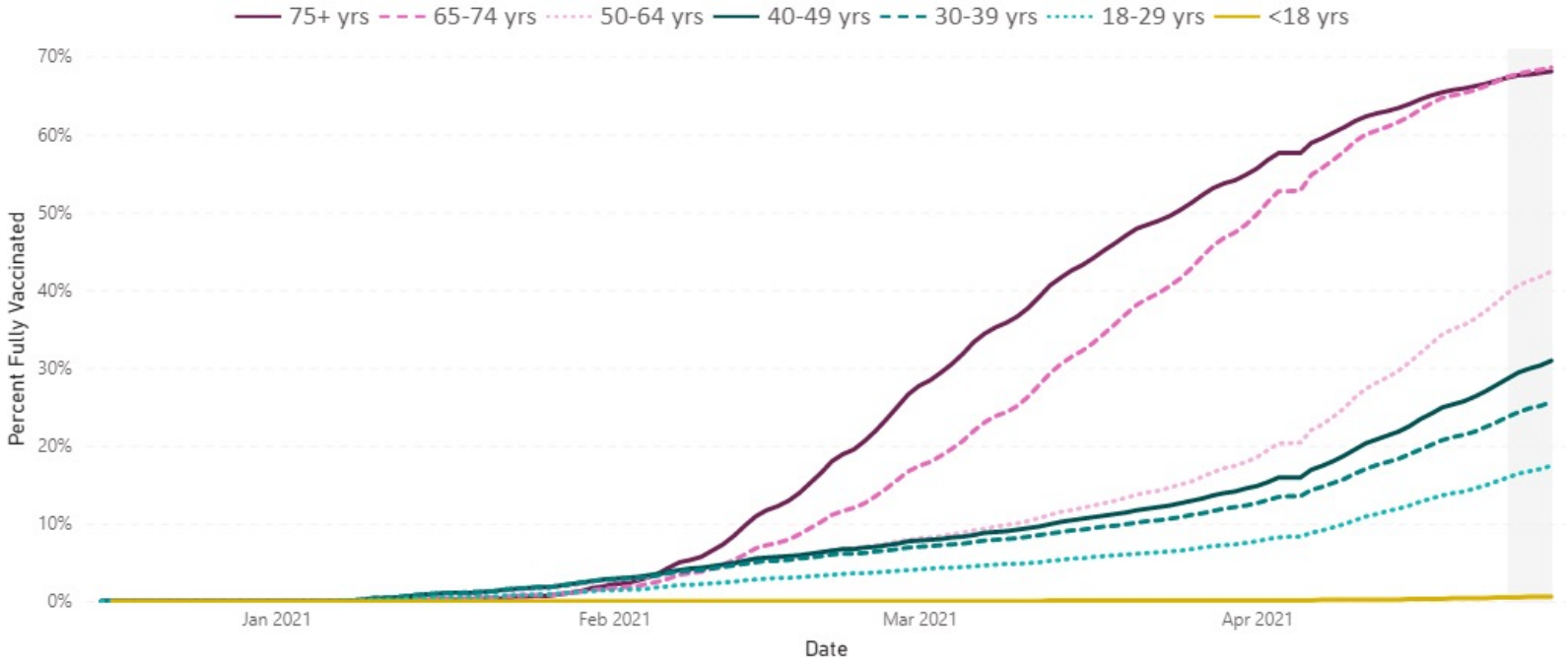
*Age data was available for 99% of vaccinations. Texas has been excluded from all calculations on this page.**

CDC COVID Data Tracker

Percent of People Fully Vaccinated with any COVID-19 Vaccine by Age Group and Date Administered, United States

December 14, 2020 – April 28, 2021

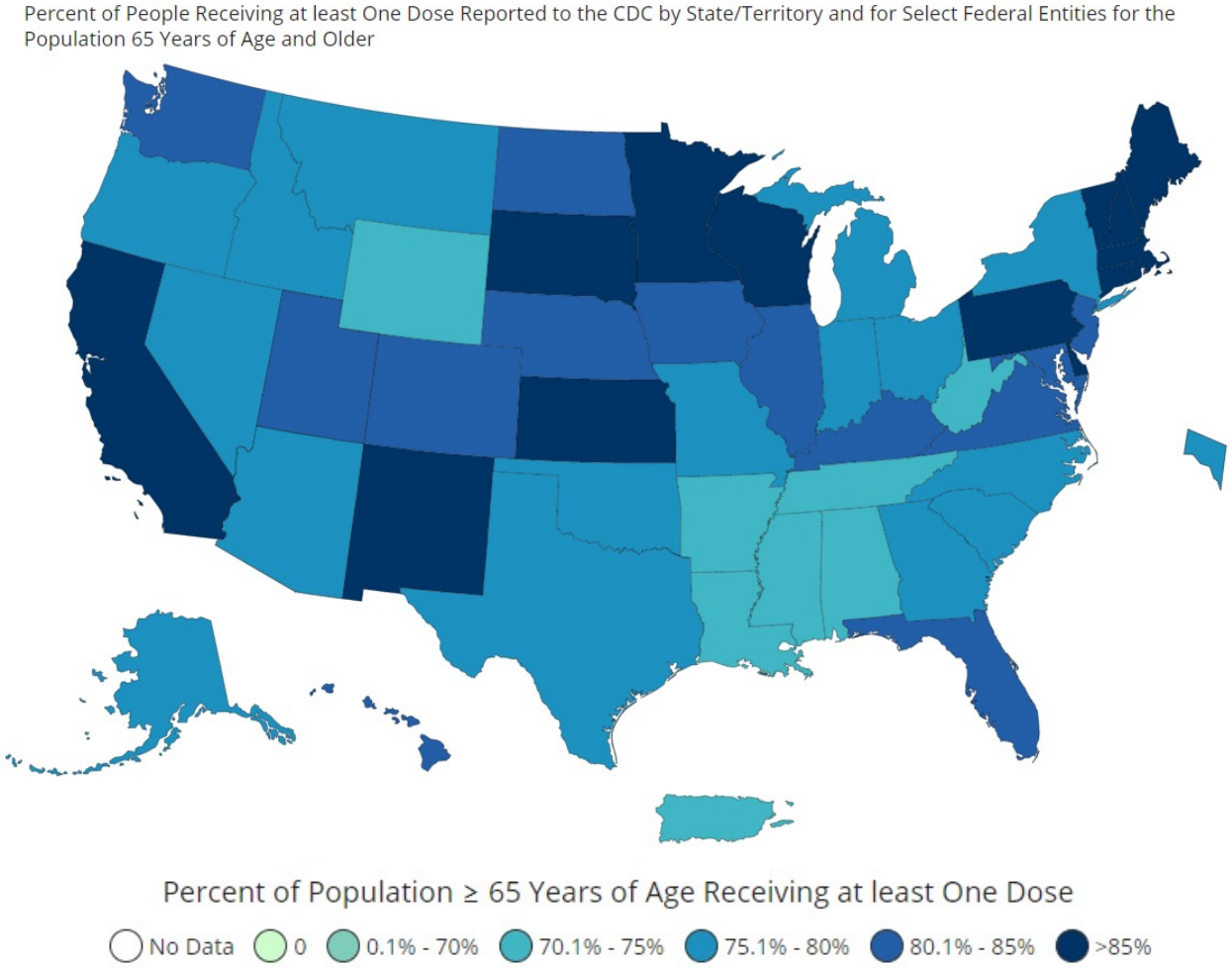
At Least One Dose | **Fully Vaccinated**



Age Range	People Fully Vaccinated
75+ yrs	68.1%
65-74 yrs	68.6%
50-64 yrs	42.4%
40-49 yrs	30.9%
30-39 yrs	25.6%
18-29 yrs	17.4%
<18 yrs	0.6%

*Age data was available for 99% of vaccinations. Texas has been excluded from all calculations on this page.**

[CDC COVID Data Tracker]



https://covid.cdc.gov/covid-data-tracker/#vaccinations.

U.S. adult vaccine recommendations and potential lessons for COVID-19

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2021

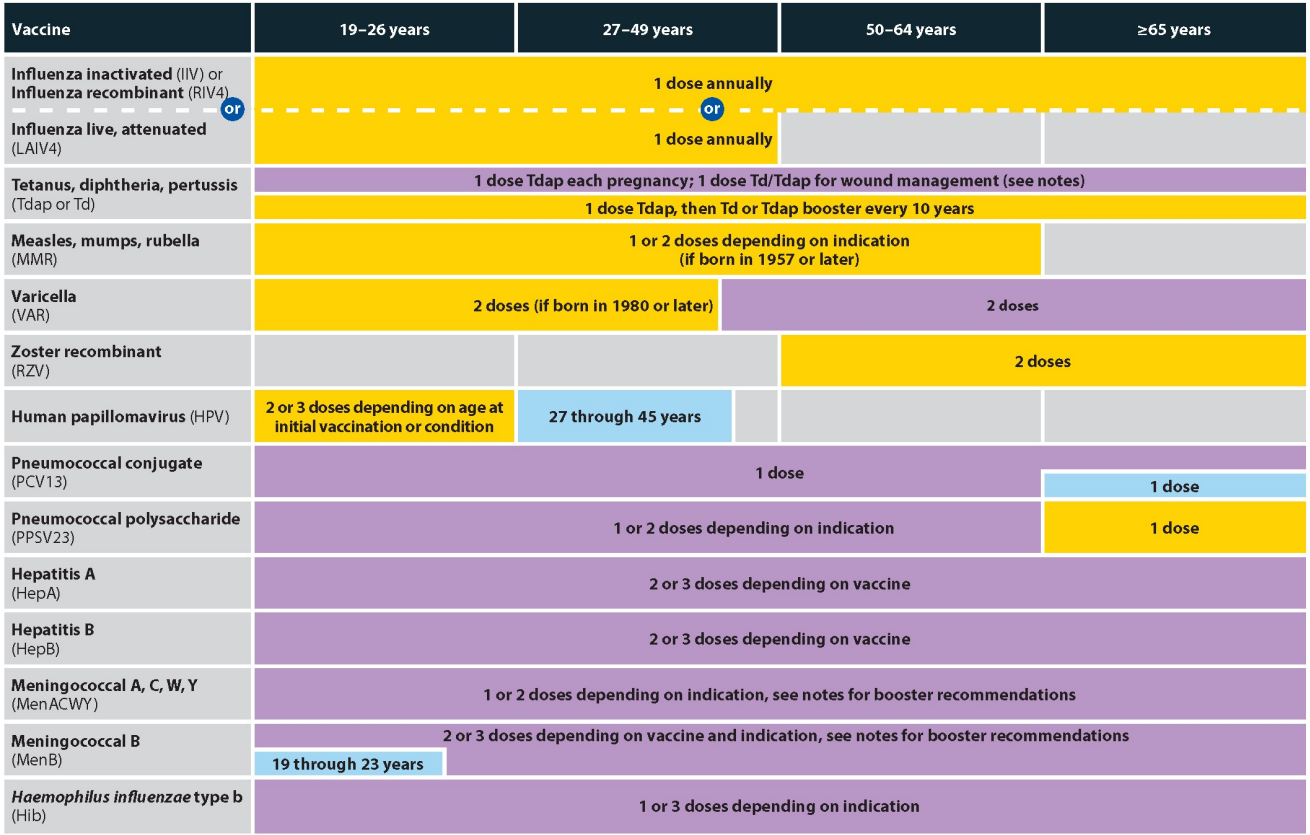


Table 2 Recommended Adult Immunization Schedule by Medical Condition and Other Indications, United States, 2021

Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 count		Asplenia, complement deficiencies	End-stage renal disease; or on hemodialysis	Heart or lung disease, alcoholism[1]	Chronic liver disease	Diabetes	Health care personnel[2]	Men who have sex with men
			<200 mm³	≥200 mm³							
IIV or RIV4	1 dose annually										
or										or	
LAIV4	Not Recommended					Precaution				1 dose annually	
Tdap or Td	1 dose Tdap each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 years									
MMR	Not Recommended*	Not Recommended	1 or 2 doses depending on indication								
VAR	Not Recommended*	Not Recommended			2 doses						
RZV					2 doses at age ≥50 years						
HPV	Not Recommended*	3 doses through age 26 years			2 or 3 doses through age 26 years depending on age at initial vaccination or condition						
PCV13		1 dose									
PPSV23		1, 2, or 3 doses depending on age and indication									
HepA					2 or 3 doses depending on vaccine						
HepB					2, 3, or 4 doses depending on vaccine or condition				<60 years		
									≥60 years		
MenACWY	1 or 2 doses depending on indication, see notes for booster recommendations										
MenB	Precaution	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations									
Hib		3 doses HSCT[3] recipients only			1 dose						

- Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection
- Recommended vaccination for adults with an additional risk factor or another indication
- Precaution—vaccination might be indicated if benefit of protection outweighs risk of adverse reaction
- Recommended vaccination based on shared clinical decision-making
- Not recommended/ contraindicated—vaccine should not be administered.
  *Vaccinate after pregnancy.
- No recommendation/ Not applicable

1. Precaution for LAIV4 does not apply to alcoholism. **2.** See notes for influenza; hepatitis B; measles, mumps, and rubella; and varicella vaccinations. **3.** Hematopoietic stem cell transplant.

Vaccination coverage estimates using an age-appropriate adult vaccination composite measure, by age group — National Health Interview Survey, United States, 2017*

Age group	≥19 years	19-59 years	60-64 years	≥65 years
	(n†=26,430)	(n†=16,651)	(n†=2,445)	(n†=7,334)
Coverage	25.2	26.7	14.5	24.3
	(24.4-26.1)¶	(25.8-27.7)	(12.9-16.2)	(22.9-25.8)

*Estimates for tetanus toxoid-containing, pneumococcal, herpes zoster, and influenza vaccines. Td/Tdap vaccination was “receipt in the past 10 years”. Pneumococcal and zoster vaccination were “ever received” at least one dose. Influenza vaccination in past 12 months.

https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2017.html#adult-vaccination-composite-measure.

Evidence-based Interventions to Improve Vaccination Rates: Summary from Community Preventive Services Task Force (CPSTF)

- **Enhancing access to vaccination services**
  - Home visits
  - Reducing client out of pocket costs
  - Vaccination programs in convenient locations like schools
- **Increasing community demand**
  - Client/patient reminder and recall systems
  - Vaccination requirements
  - Community-based interventions implemented in combination
  - Incentives or rewards
- **Provider- or system-based interventions**
  - Healthcare system-based interventions implemented in combination
  - Immunization information systems
  - Provider assessment and feedback
  - Standing orders
  - Provider reminders

The Community Guide

www.thecommunityguide.org

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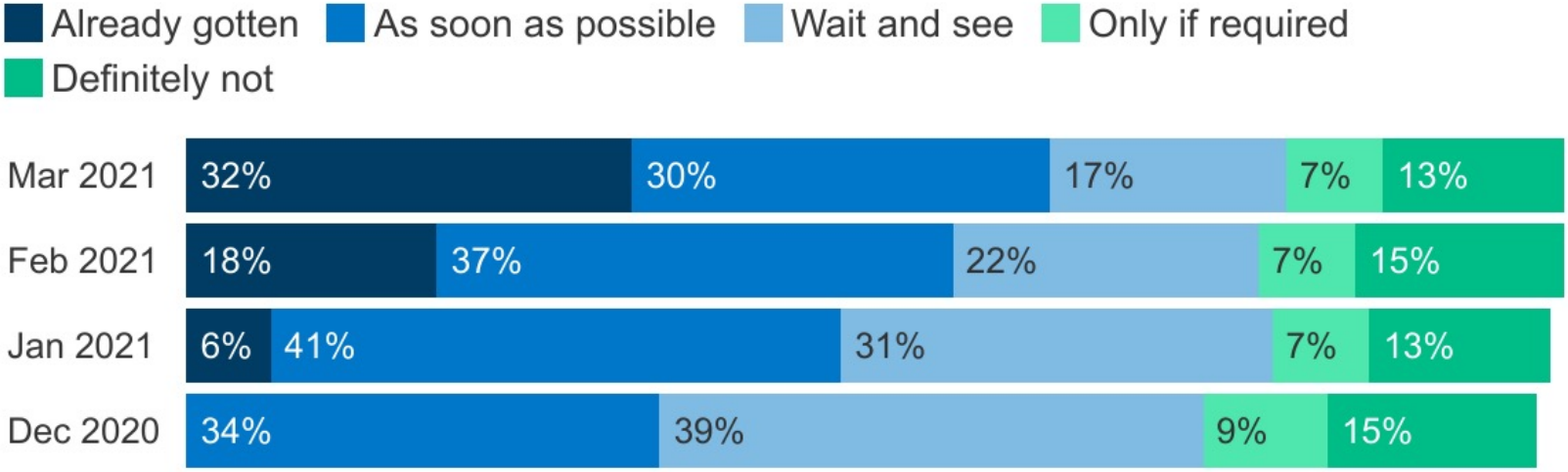
Communicating Vaccine Recommendations

Improving confident in and COVID-19 vaccines

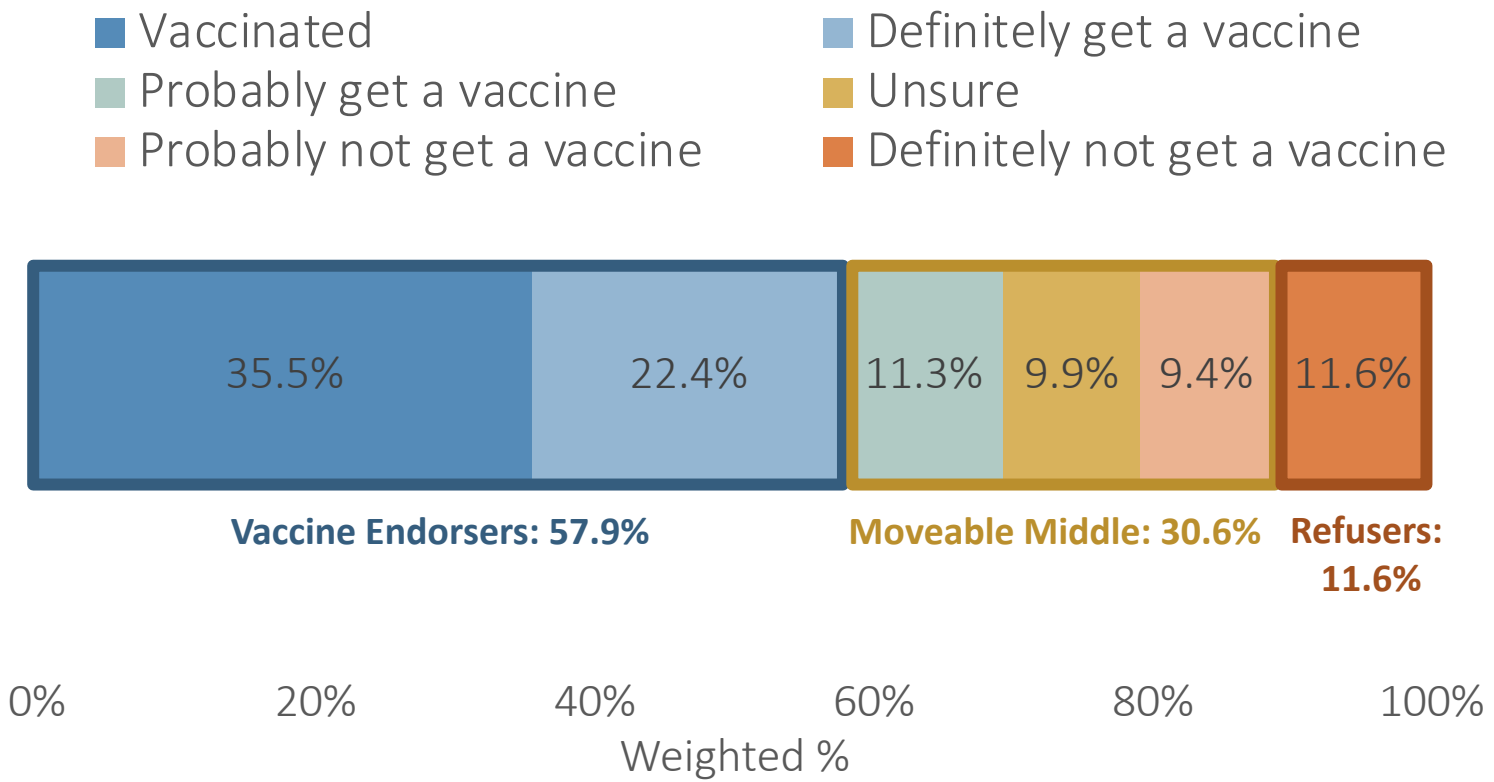
Have you personally received at least one dose of the COVID-19 vaccine, or not? When an FDA authorized vaccine for COVID-19 is available to you for free, do you think you will…?



NOTE: December 2020 survey did not have an option for respondents to indicate they had already been vaccinated. See topline for full question wording.
SOURCE: KFF COVID-19 Vaccine Monitor (March 15-22, 2021)

KFF COVID-19 Vaccine Monitor

Approximately What Percent of Adults Are in the Middle?



Source: IPSOS and NORC Omnibus Surveys, March Wave 2 (Mar 19-29, 2021) – Slide courtesy of **Brittney Baack, MPH, Centers for Disease Control and Prevention, April 2021. CDC unpublished data.**

Communicating Vaccine Recommendations*

- Vaccine safety is a key concern for vaccine hesitant persons, and many do not think vaccination is necessary
- Vaccine adopters and movable middle motivated by protecting their family, and community
- Ensure staff is well informed to address concerns with consistent information and convey the benefits of vaccine
  - Answer questions with empathy
- Similar messages from multiple different sources helpful to reinforce vaccine recommendations
- Utilize trusted messengers in the community

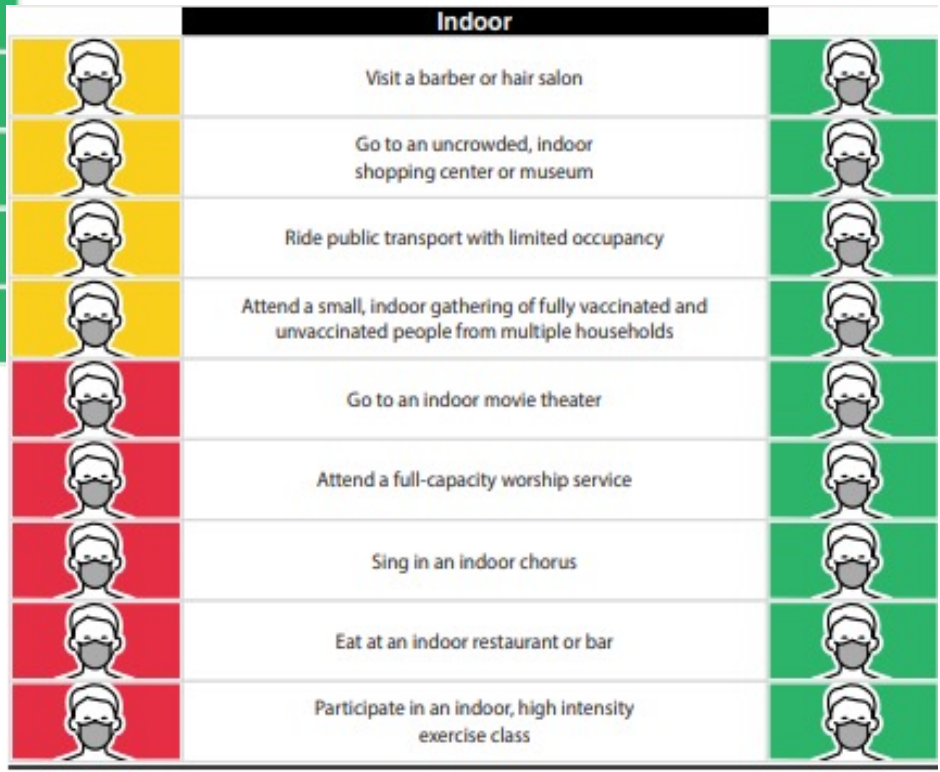
- Sources: CDC Vaccinate with Confidence: https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence.html. /www.forbes.com/sites/tommybeer/2020/05/26/poll-60-of-us-adults-plan-to-get-flu-vaccine-now-pharmacies-are-preparing-for-a-rush/#3edd927a4415l.

Communicating with Patients About Vaccines

- Healthcare provider recommendations are key factor in influencing vaccination decisions
  - Clear, unambiguous recommendation
- Vaccine hesitant patients may question the value, necessity, or safety of recommended vaccines
  - Want information to make the best choice
- For patients with questions, provide accurate information and additional sources of up-to-date information

Adapted from Aparna Ramakrishnan, CDC, focus groups on adult immunizations, 2013;
Bridges CB, et al. Vaccine 2015;33 Suppl 4:D114-20.

Choosing Safer Activities



Get a COVID-19 vaccine

Prevention measures not needed

Take prevention measures

Fully vaccinated people: wear a mask
Unvaccinated people: wear a mask, stay 6 feet apart, and wash your hands.

- Safety levels assume the recommended prevention measures are followed, both by the individual and the venue (if applicable).
- CDC cannot provide the specific risk level for every activity in every community. It is important to consider your own personal situation and the risk to you, your family, and your community before venturing out.

www.cdc.gov/coronavirus/2019-ncov/vaccines/pdfs/324153_choosingSaferActivities11.pdf.

Summary

Summary/Key Takeaways

- **Currently available COVID-19 vaccines provide substantial protection**
  - Clinical trials and community non-randomized studies demonstrate prevention of infection, illness, and hospitalization
- **Vaccines demonstrated high levels of safety**
  - EUA fact sheets for patients and providers with new safety information
- **Providers are critical to improving vaccination through**
  - Counseling of patients about benefits/risks of vaccination and active listening
  - Ensuring safe and effective vaccination through
    - Appropriate screening for precautions and contraindications
    - Readiness to recognize and manage severe reactions
    - Appropriate vaccine storage, handling and administration
  - Reporting to VAERS as required and encouraging patients to participate in V-Safe

Thank you!

Questions about this presentation?

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immunization action coalition
IAC
immunize.org

Resources

COVID-19 Vaccination

https://www.cdc.gov/vaccines/covid-19/index.html.

Clinical Resources for Each COVID-19 Vaccine

Find information for COVID-19 vaccination administration, storage and handing, reporting, and patient education for each specific vaccine

Product Information by US Vaccine

General Vaccine Administration

Storage and Handling Toolkit

ACIP Recommendations

COVID-19 Vaccine EUAs

V-safe

Training and Education

Recipient Education

Vaccination Data & Reporting Systems

Vaccination Provider Requirements & Support

mRNA COVID-19 Vaccines