What Clinicians Need to Know About Pfizer-BioNTech COVID-19 Vaccination of Adolescents

Clinician Outreach and Communication Activity (COCA) Webinar

Friday, May 14, 2021

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Today's Presenters

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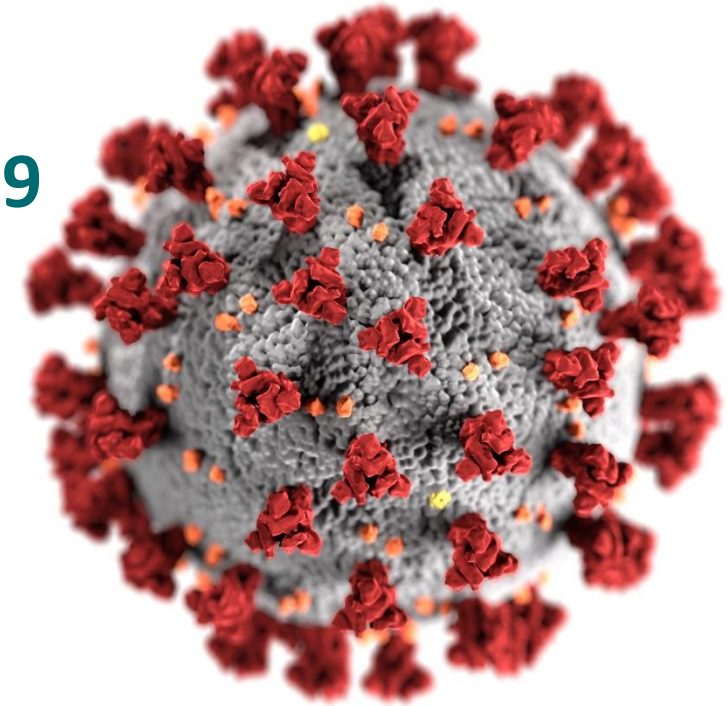
What Clinicians Need to Know About Pfizer-BioNTech COVID-19 Vaccination of Adolescents

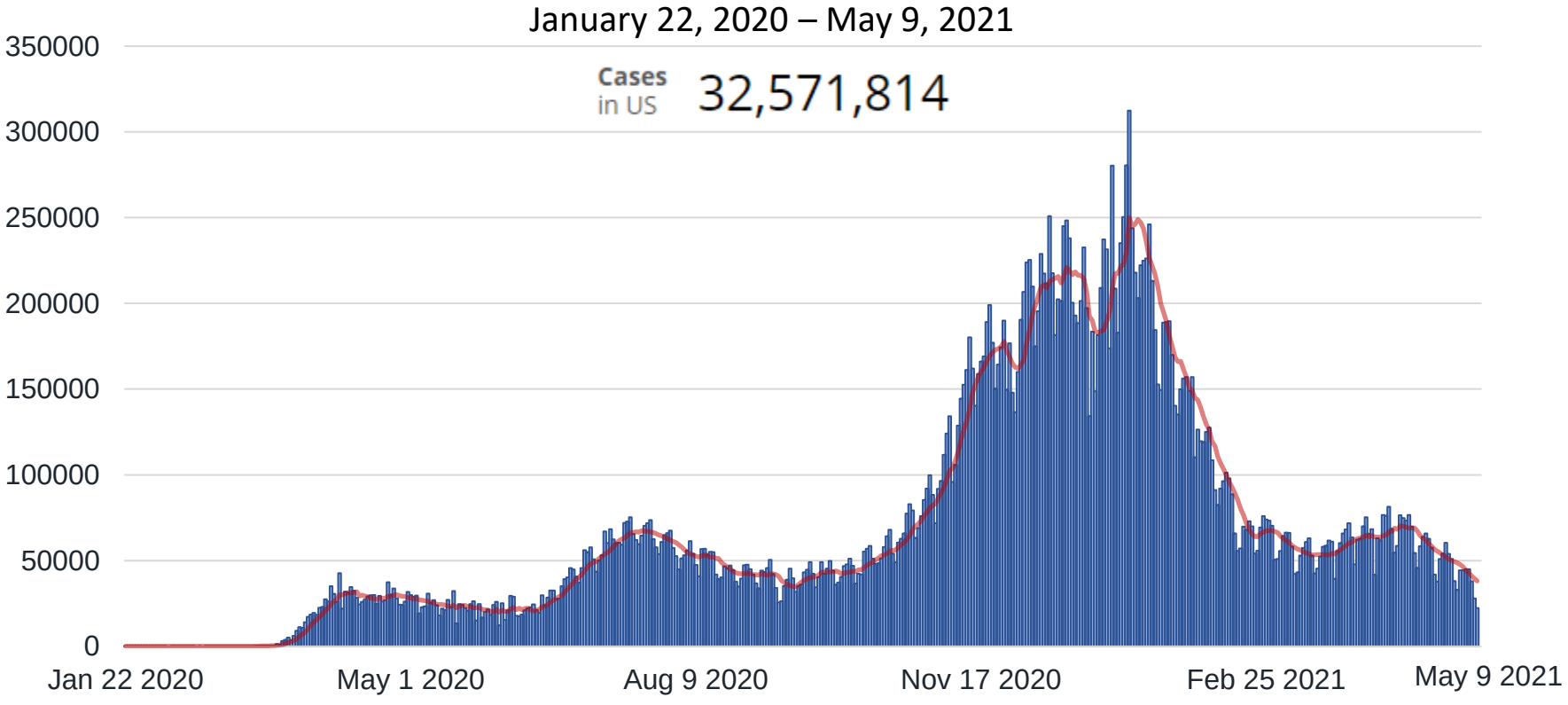


COCA Call
May 14, 2021

cdc.gov/coronavirus

COVID-19 Epidemiology among Adolescents

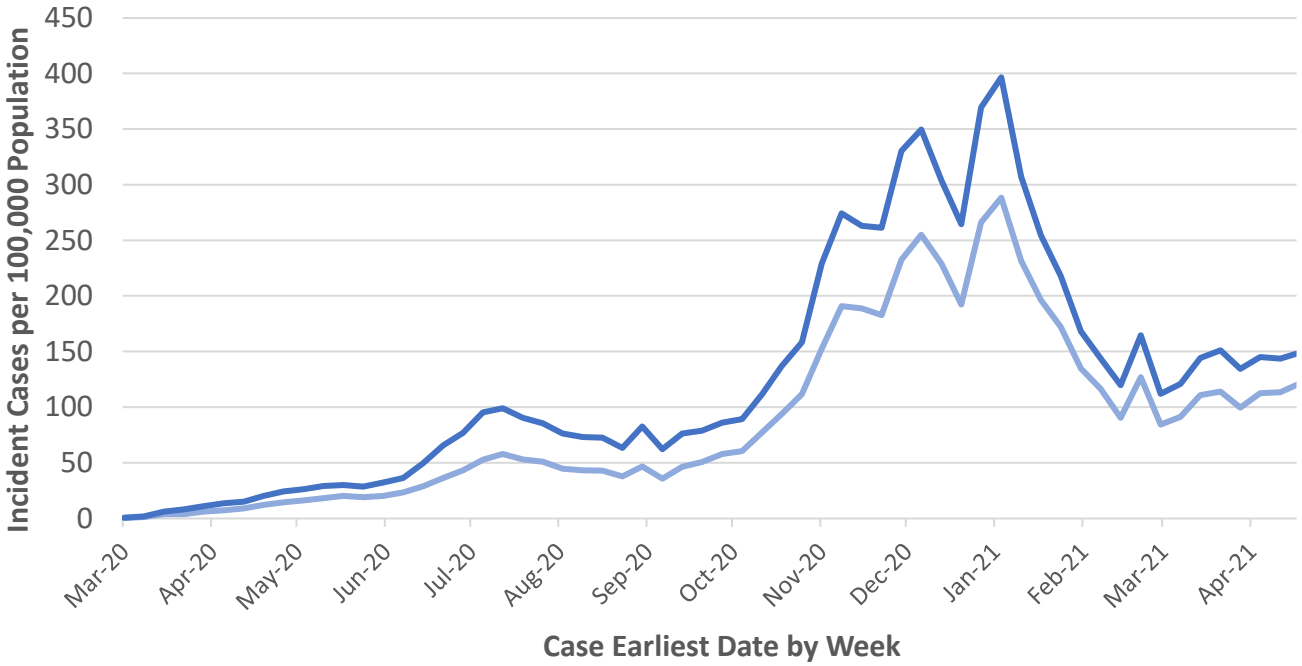
Trends in Number of COVID-19 Cases in the US



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

Trends in COVID-19 Incidence among Adolescents 12-17 Years of Age

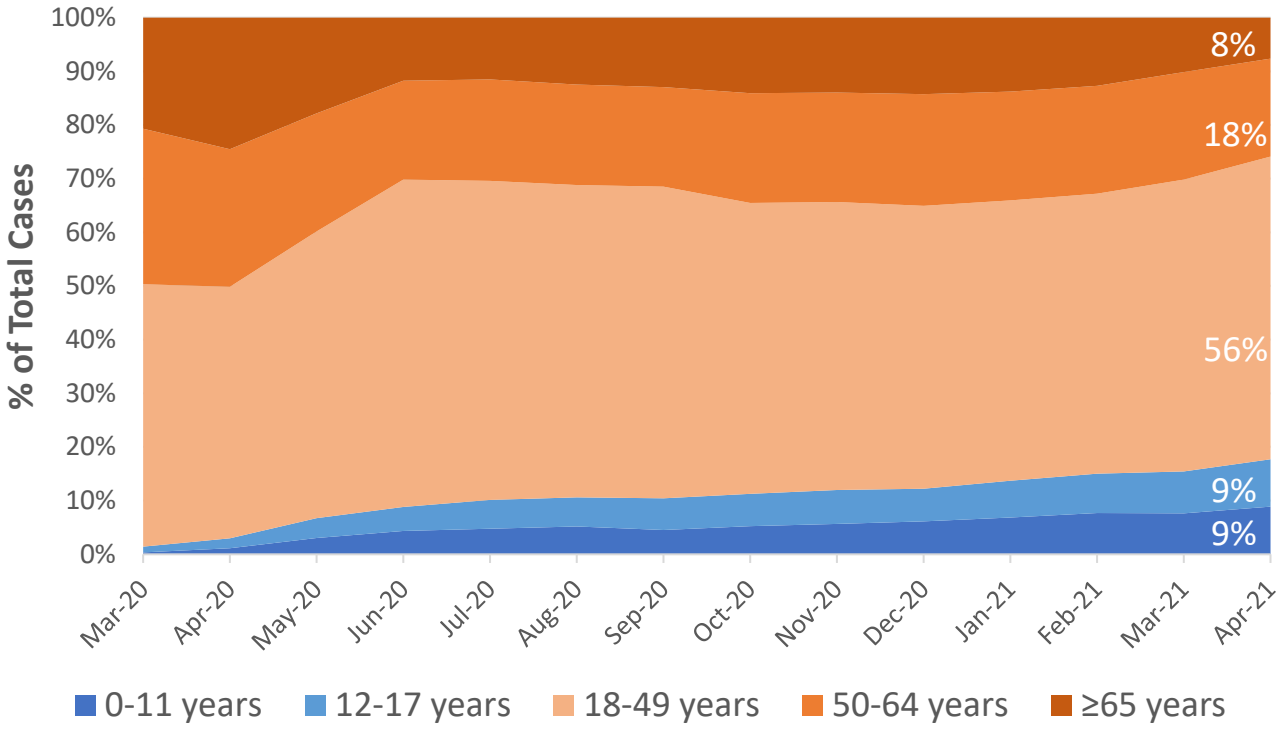
March 1, 2020 – April 30, 2021



>1.5 million cases among adolescents 12-17 years of age

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

Proportion of Total COVID-19 Cases by Age Group — United States, March 1, 2020–April 30, 2021

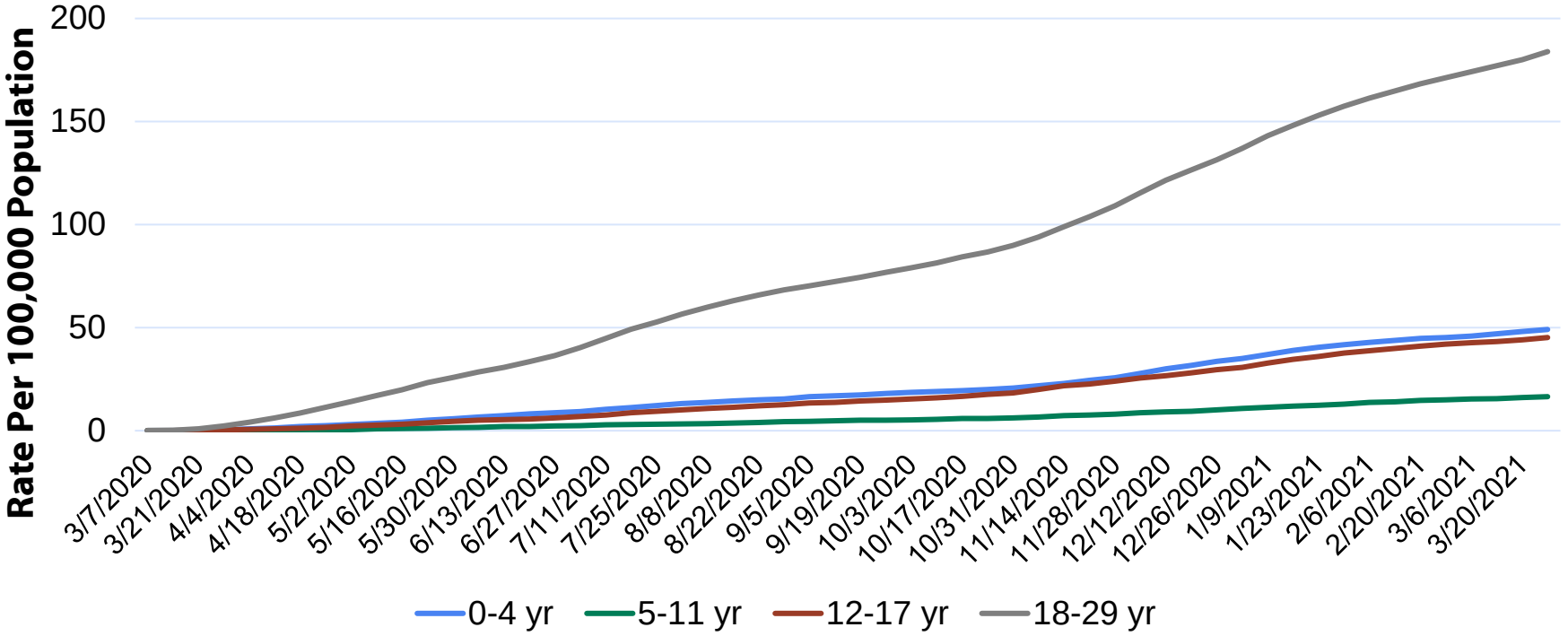


As more adults are vaccinated, adolescents 12-17 years of age make up a greater proportion of total cases:

9% of cases reported in April 2021

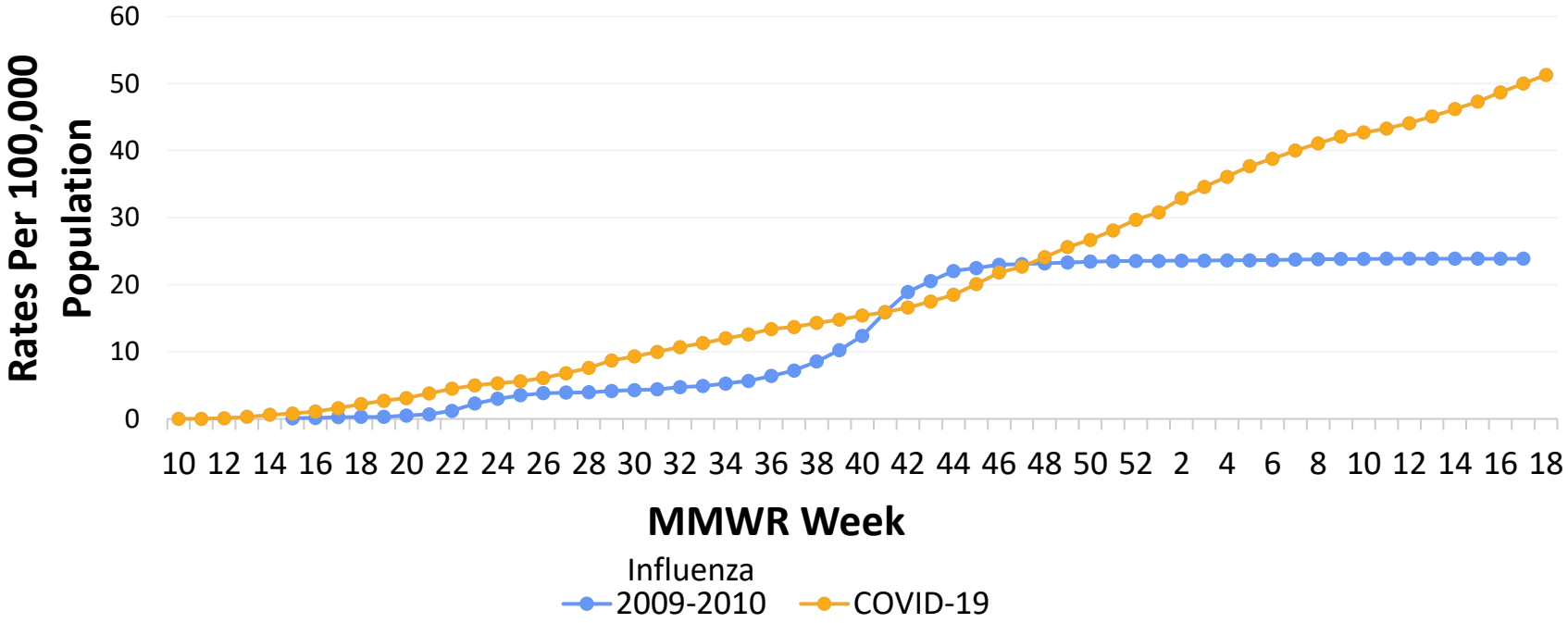
https://covid.cdc.gov/covid-data-tracker/#demographicsovertime

Cumulative Rates of COVID-19-Associated Hospitalizations by Select Age Groups — COVID-NET, Mar 1, 2020–Mar 27, 2021



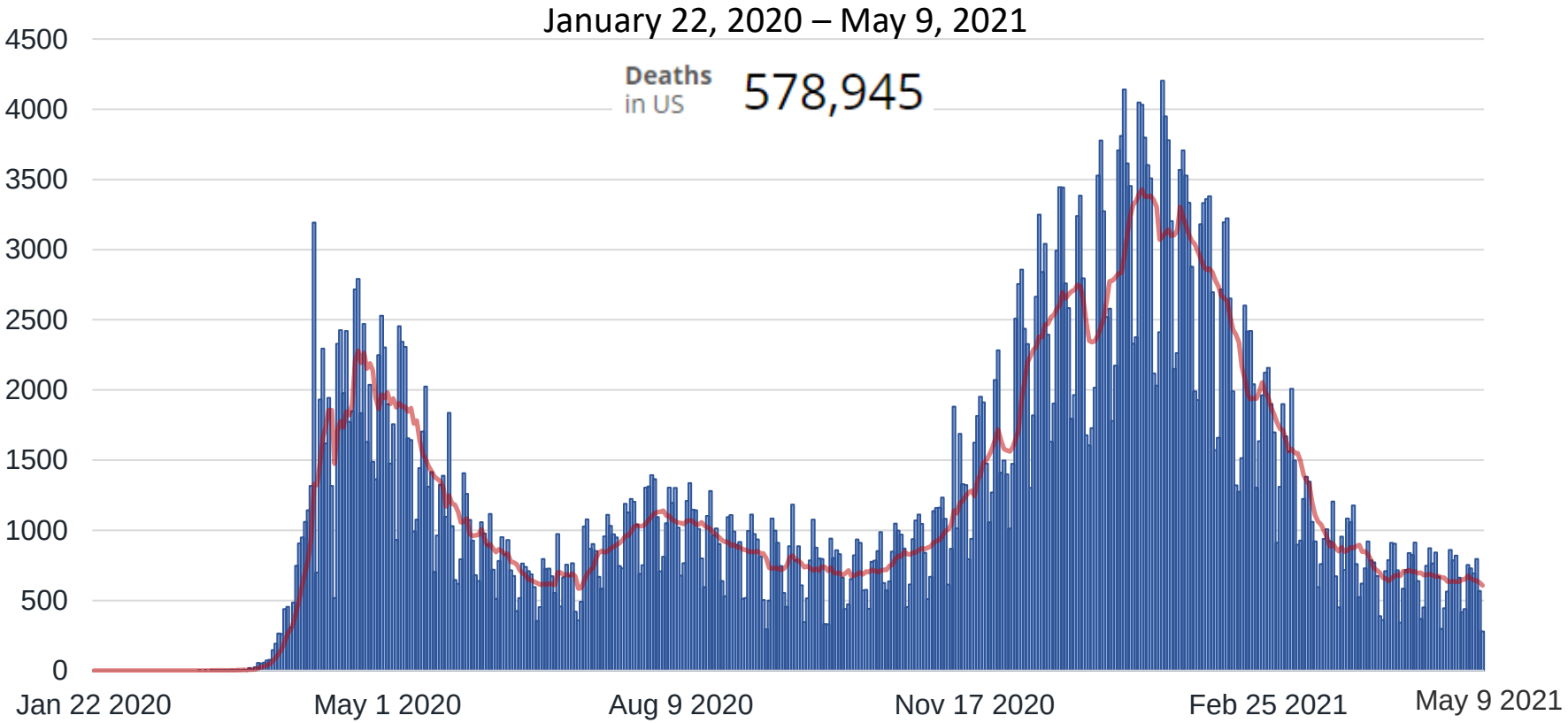
https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html

Cumulative 2009 H1N1 Influenza- and COVID-19-Associated Hospitalization among Adolescents 12-17 years by MMWR week —FluSurv-NET and COVID-NET



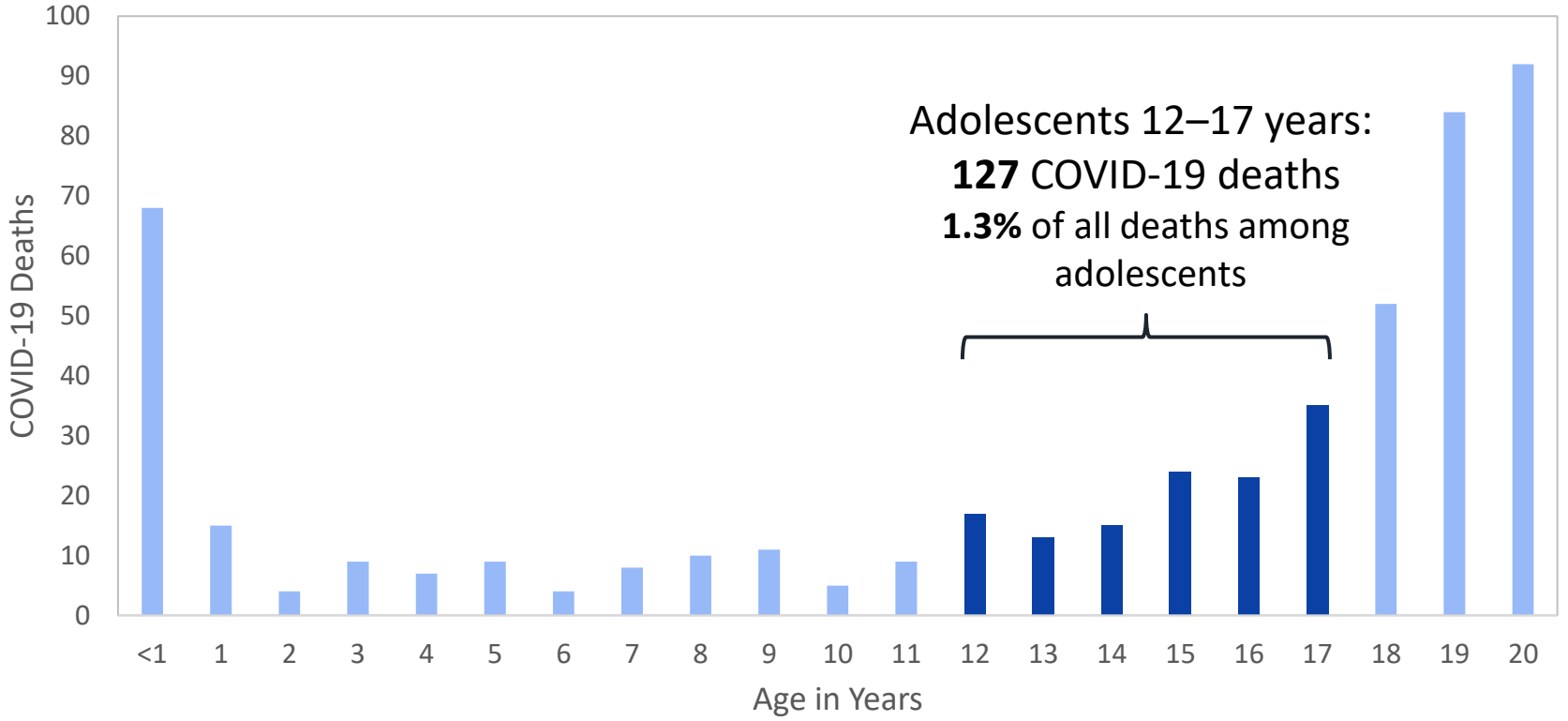
*The 2009-2010, H1N1 pandemic season, includes data from MMWR week 15-39 of the 2008-2009 season

Trends in Number of COVID-19 Deaths in the US



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

COVID-19 Deaths by Age Group, NCHS
—January 1, 2020–April 30, 2021



https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Counts-by-Age-in-Years/3apk-4u4f/data

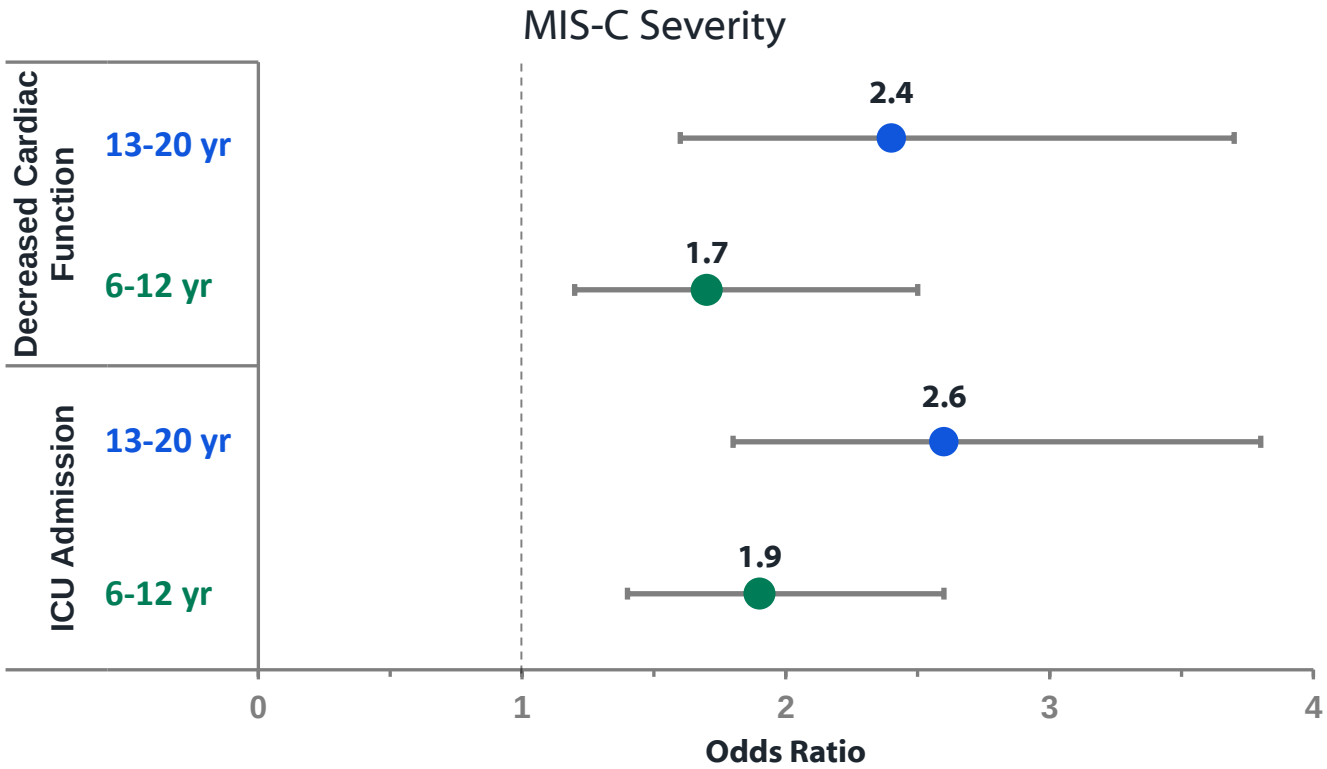
Multisystem Inflammatory Syndrome in Children (MIS-C)

- Severe hyperinflammatory syndrome occurring 2-6 weeks after acute SARS-CoV-2 infection, resulting in a wide range of manifestations and complications
  - 60-70% of patients are admitted to intensive care, 1-2% die[1,2]

- **3,742 MIS-C cases** have been reported to national surveillance as of May 3, 2021[3]
  - Median age of 9, with 21% (804) of cases occurred in adolescents 12-17 years
  - 63% of reported cases occurred in children who are Hispanic/Latino or Black, Non-Hispanic
  - Estimated incidence of 1 to 8.5 MIS-C cases per million person-months

1. Feldstein LR, Tenforde MW, Friedman KG, et al. Characteristics and Outcomes of US Children and Adolescents With Multisystem Inflammatory Syndrome in Children (MIS-C) Compared With Severe Acute COVID-19. *JAMA*. 2021;325(11):1074-1087. doi:10.1001/jama.2021.2091
2. Belay ED, Abrams J, Oster ME, et al. Trends in Geographic and Temporal Distribution of US Children With Multisystem Inflammatory Syndrome During the COVID-19 Pandemic [published online ahead of print, 2021 Apr 6]. *JAMA Pediatr*. 2021;e210630. doi:10.1001/jamapediatrics.2021.0630
3. Health Department-Reported Cases of Multisystem Inflammatory Syndrome in Children (MIS-C) in the United States. https://www.cdc.gov/mis-c/cases/index.html

Severity of MIS-C by Age



Reference:
MIS-C patients
0–5 years of age

Abrams JY, Oster ME, Godfred-Cato SE, et al. Factors linked to severe outcomes in multisystem inflammatory syndrome in children (MIS-C) in the USA: a retrospective surveillance study. *Lancet Child Adolesc Health*. 2021;5(5):323-331. doi:10.1016/S2352-4642(21)00050-X

Adolescents and Transmission of SARS-CoV-2

- Some studies observed similar infection rates between children and adults, while others found lower infection rates among children compared with adults[1,2]
- Adolescents may be more likely to be infected than younger children (<10 years)
  - Supported by contact tracing, test positivity, and population-based seroprevalance data[2]
- Secondary transmission from adolescents can and does occur
  - While SARS-CoV-2 transmission among students relatively rare, several studies suggest transmission more likely within high school than elementary school settings[3,4]
- Outbreak investigations have demonstrated efficient transmission among children, adolescents, and young adults, including transmission to older household members[5,6]

1. Bi Q et al. Lancet Infect Dis. 2020;20(8):911-919
2. CDC Science Brief: Transmission of SARS-CoV-2 in K-12 schools. https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/transmission_k_12_schools.html
3. Goldstein E et al. On the Effect of Age on the Transmission of SARS-CoV-2 in Households, Schools, and the Community. J Infect Dis. 2021 Feb 13;223(3):362-369.
4. Larosa E et al. Secondary transmission of COVID-19 in preschool and school settings in northern Italy after their reopening in September 2020. *Euro Surveill.* 2020;25(49):2001911.
5. Lopez A et al. MMWR Morb Mortal Wkly Rep 2020;69:1319–1323
6. Schwartz N et al. MMWR Morb Mortal Wkly Rep 2020;69:1457–1459

Public Health Problem:
Summary of the available evidence

Adolescents 12–17 years of age are at risk of severe illness from COVID-19

- Over 1.5 million reported cases and >13,000 hospitalizations to date
  - Hospitalization rate higher than 2009-10 H1N1 pandemic
- Clinical presentation of MIS-C more severe in adolescents than in younger children

COVID-19 in adolescents may also indirectly impact others' health

- Adolescents contribute to transmission in households and communities
  - Including older adults at higher risk of COVID-19
- Adolescents represent an increasing proportion of recent COVID-19 cases

Safety, Efficacy and Immunogenicity of Pfizer-BioNTech COVID-19 Vaccine in Adolescents

Clinical Efficacy

Pfizer-BioNTech COVID-19 vaccine, 12-15 year olds

- The clinical trial demonstrated efficacy against symptomatic, laboratory-confirmed COVID-19. The efficacy was **100%**

Population	Events/Vaccine (n/N)	Events/Placebo (n/N)	Vaccine efficacy (95% CI)
Primary outcome			
No evidence of prior infection, ≥7 d post dose 2	0/1001[a]	16/972[a]	100.0%[b]
Secondary outcomes			
± evidence of prior infection, ≥7 d post dose 2	0/1109[a]	18/1094[a]	100.0%[c]
All available efficacy (± evidence of prior infection, post dose 1)	3/1120[a]	35/1119[a]	91.4% (72.2%, 97.4%)

a. Number of subjects at risk for the endpoint; b. With a standard continuity correction of 0.5 applied, the estimated VE (95% CI) is 97.1% (51.0%, 99.8%)
c. With a standard continuity correction of 0.5 applied, the estimated VE (95% CI) is 97.3% (55.8%, 99.8%)

Immunobridging
Pfizer-BioNTech COVID-19 vaccine, 12-15 year olds

- The geometric mean ratio (GMR) for antibodies in 12–15-year-olds compared with 16–25-year-olds was **1.76** (95% CI:1.47, 2.10), and **met the noninferiority criteria**

	12-15 Years		16-25 Years			
	n[c]	GMT (95% CI)	n[c]	GMT (95% CI)	GMR (95% CI)	Met Noninferiority Objective[d]
SARS-CoV-2 neutralization assay – NT50[a,b]	190	1239.5 (1095.5, 1402.5)	170	705.1 (621.4, 800.2)	1.76 (1.47, 2.10)	Yes

Abbreviations: NT50 = 50% neutralizing titer; GMT = geometric mean titer; GMR = geometric mean ratio; LLOQ = lower limit of quantitation

[a]Among participants with no serologic/virologic evidence (up to 1 month after second dose) of past SARS-CoV-2 infection and negative NAAT at any visit up to one month after dose two. [b]Sampling time point was one month after dose two.

[c]Number of subjects with valid and determinate assay results for the specified assay at the given dose and sampling time point.

[d]Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67

Safety: Serious adverse events
Pfizer-BioNTech COVID-19 vaccine, 12-15 year olds

- Serious adverse events (SAE) were reported in a higher proportion of recipients of vaccine versus placebo based on 5 SAEs in the vaccine group and 2 in the placebo group
- **No deaths** were reported among any trial participants

Study/population[a]	Events/Vaccine (n/N)[b]	% SAE Vaccine	Events/Placebo (n/N)	% SAE Placebo	Associated with vaccination
Pfizer/BioNTech, unpublished	5/1131	0.4	2/1129	0.2	0

Serious adverse event (SAE) is defined as any untoward medical occurrence that, results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent disability/incapacity, or is a congenital anomaly/birth defect

a. Included all randomized participants who received at least 1 dose of vaccine

b. Data cutoff of March 13, 2021

Safety: Reactogenicity
Pfizer-BioNTech COVID-19 vaccine, 12-15 year olds

- Local reactions within 7 days occurred in **91**% of vaccine recipients
  - Pain at the injection site most common
- Systemic reactions within 7 days occurred in **91**% of vaccine recipients
  - Fatigue and headache most common
- Most symptoms resolved in 1-2 days
- Severe reactions were more common in vaccine recipients; a grade ≥3 reaction (interfering with daily life) was reported by **10.7**% of vaccinated versus **1.9**% of placebo group
  - Fatigue, fever, headache most common

Safety
Pfizer-BioNTech COVID-19 vaccine, 12-15 year olds

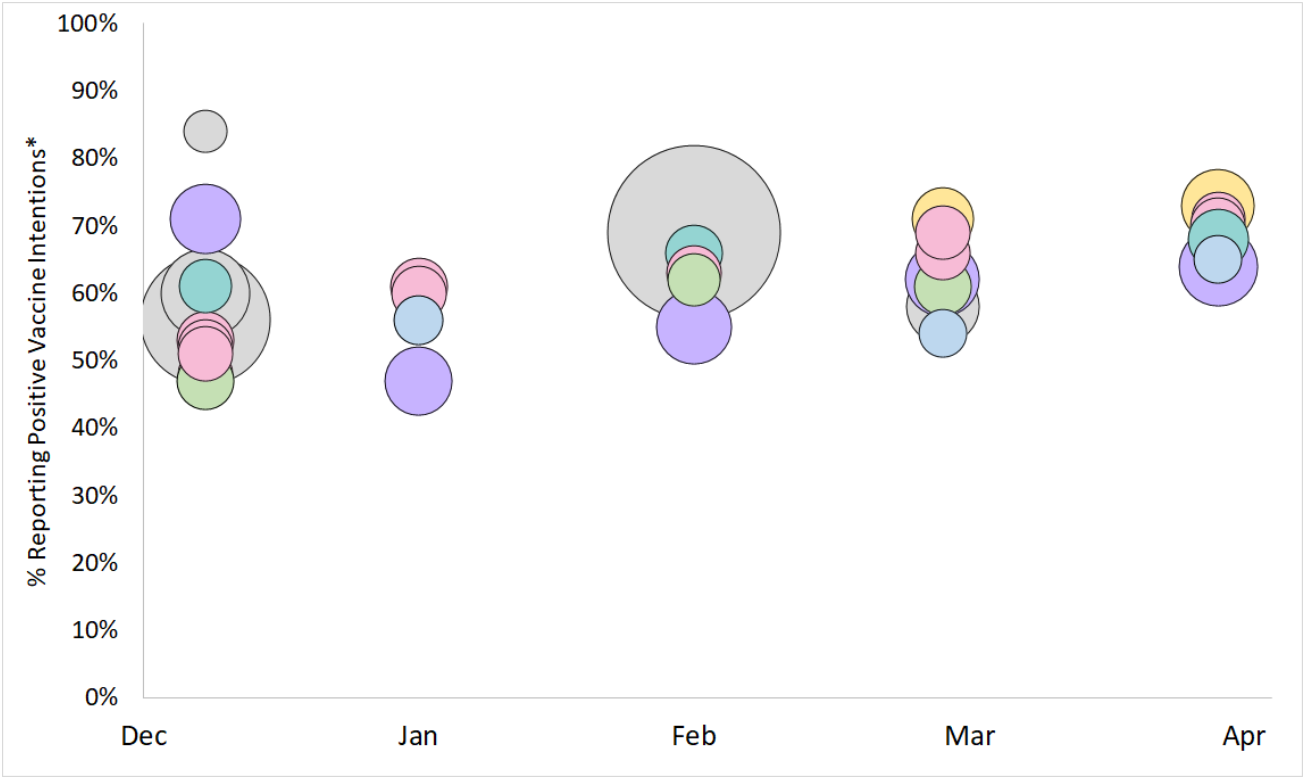
- No cases of anaphylaxis reported in the adolescent (12-15 years of age) study participants

- No cases of Bell's palsy or facial paralysis reported in adolescent participants

- Among adolescents 12-15 years of age, 7 (0.6%) in the vaccine group had lymphadenopathy, compared to 1 (0.1%) participant in the placebo group
  - Most lymphadenopathy was local (arm or neck region), occurred on the same side as vaccination, and occurred within 2-10 days

Values and Implementation

Positive COVID-19 Vaccination Intention among Adults†



Reference	Date	N	% Intent
Szilagyi	Dec	5,660	56%
Savoia	Dec	2,650	60%
KFF	Dec	1,676	71%
APNORC	Dec	1,117	47%
Axios-Ipsos	Dec	1,101	53%
Axios-Ipsos	Dec	1,009	48%
Axios-Ipsos	Dec	1,003	52%
Axios-Ipsos	Dec	1,002	51%
Quinnipiac	Dec	978	61%
ABC/IPSOS	Dec	621	84%
Axios-Ipsos	Jan	1,112	61%
KFF	Jan	1,563	51%
Axios-Ipsos	Jan	1,038	60%
Monmouth	Jan	809	50%
Pew	Feb	10,121	69%
KFF	Feb	1,874	55%
Quinnipiac	Feb	1,075	66%
Axios-Ipsos	Feb	1,038	63%
APNORC	Feb	914	62%
COVID Collab	Mar	1,845	58%
NPR/Marist Poll	Mar	1,309	71%
KFF	Mar	1,862	62%
APNORC	Mar	1,103	61%
Axios-Ipsos	Mar	1,001	66%
Axios-Ipsos	Mar	995	69%
Monmouth	Mar	802	54%
NPR/Marist Poll	Apr	1,809	73%
Axios-Ipsos	Apr	979	71%
Axios-Ipsos	Apr	1,033	70%
Quinnipiac	Apr	1,237	68%
Monmouth	Apr	800	65%
KFF	Apr	2,097	64%

†Surveys with multiple time points are shown with the same color bubble for each time point. Surveys with only one time point are shown in gray.

*Positive vaccine intentions includes persons reporting definitely, probably, or somewhat likely to get vaccinated themselves. Some surveys also included persons who already received vaccine.

Surveys of Parents (intent to have children vaccinated)

- Among parents surveyed, **46-60**% plan to get their children vaccinated[1-4]
- Reasons for not vaccinating[2]:
  - not sure it will be safe (59%)
  - vaccine developed too quickly (59%)
  - don't trust info being published about the vaccine (48%)
  - won't trust right away (44%)
  - don't have enough info (43%)
- Parents reported similar or slightly lower intent to vaccinate their children compared to intent to vaccinate themselves[3,4]

1. Axios/Ipsos April 2-5; Axios/Ipsos April 16-19; Calarco and Anderson preprint; WebMD March 2021.
2. National Parents Union Survey January 2021
3. Simonson M, Baum M, Lazer D, et al. The COVID States Project #45: Vaccine hesitancy and resistance among parents.OSF Preprints, 19 Mar. 2021. https://doi.org/10.31219/osf.io/e95bc
4. Parents Together March 2021 Survey

Surveys of Parents (intent to have children vaccinated)

- Intent to vaccinate children differed by parents' **gender**, **age** & **income** status

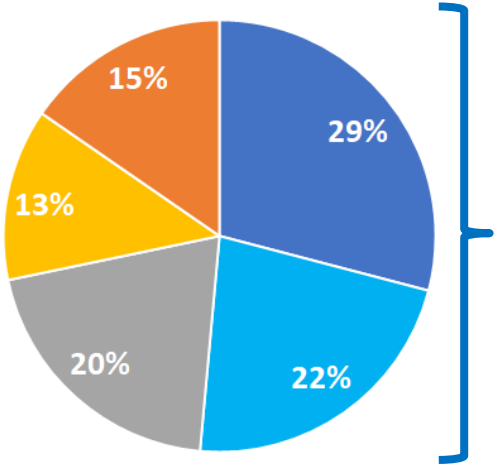
- Fathers were more willing than mothers to vaccinate their children
- Older mothers were more willing than younger mothers to vaccinate their children

- Households with higher income were more likely to report intent to vaccinate
- Households with lower income were twice as likely to say "not sure" about vaccinating their children compared to higher income households

Simonson preprint; Calarco and Anderson preprint; National Parents Union Survey January 2021; Parents Together March 2021 Survey

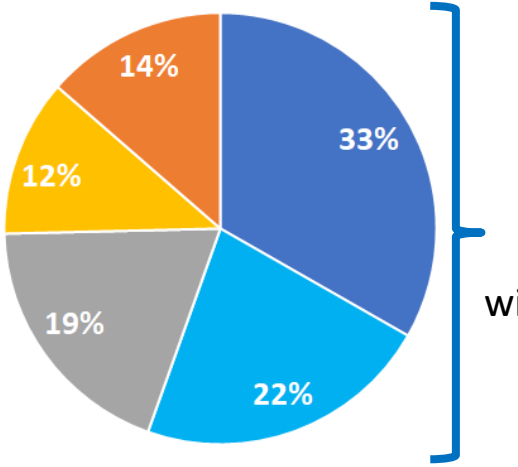
Values: Surveys of Adolescents and Parents
Intent to get vaccine/have children vaccinated

Adolescents 13-17 years
(n=839)



51%
definitely/probably
will get vaccinated

Parents of Adolescents 12-17 years
(n=766)

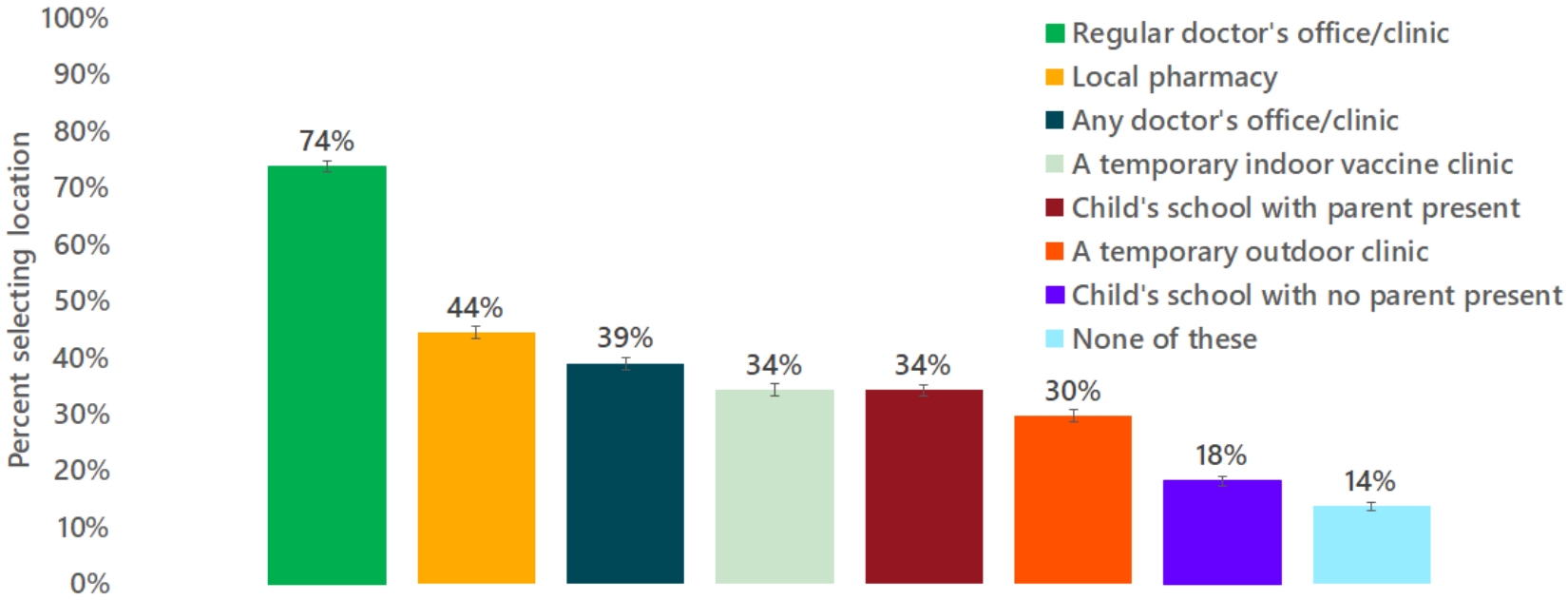


55%
definitely/
probably
will get adolescent
vaccinated

Definitely will | Probably will | Not sure | Probably not | Definitely not

CDC/U Iowa Survey of Parents and Adolescents, April 2021

Acceptability: Comfort with adolescent receiving COVID-19 vaccine at each site



CDC/U Iowa Survey of Parents and Adolescents, April 2021

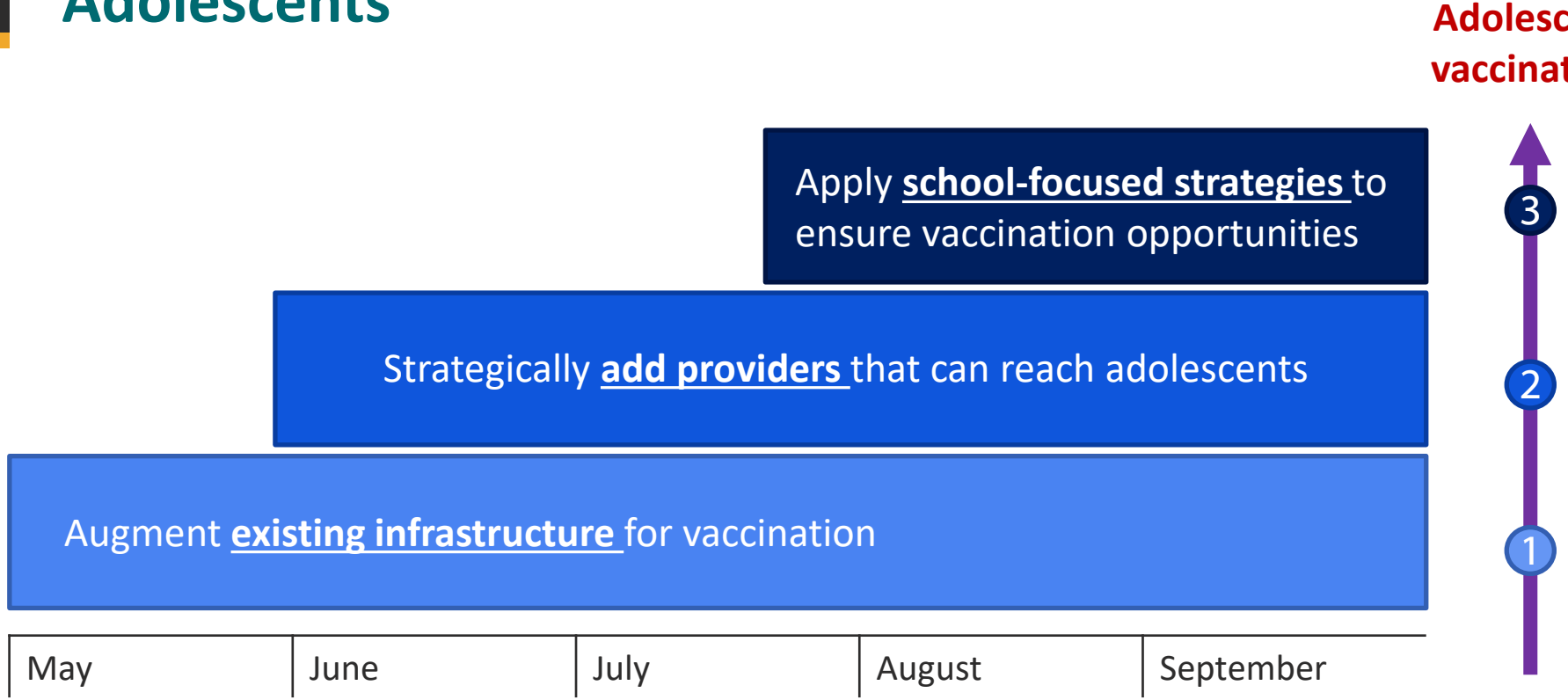
Implementation Objectives

- Promote adolescent vaccination as quickly and equitably as possible through a multi-pronged approach

- Jurisdictions and providers currently vaccinating adolescents 16-17 years

- Leverage current COVID-19 vaccination infrastructure to adapt over time:
  - Early summer sprint (May-June)
  - Increase access (June-July)
  - Back-to-school campaign (July-September)

Stepwise Approach to Increasing Vaccine Access for Adolescents



Opportunities to Increase Equitable Access to the Pfizer-BioNTech COVID-19 Vaccine

- Pfizer-BioNTech COVID-19 vaccine characteristics
  - Submitted new data to FDA supporting stability of vaccine when stored for up to one month (31 days) at 2-8°C[1]
  - Encourage strategies to efficiently utilize doses and support local redistribution, smaller tray sizes would improve access (e.g., smaller providers, rural areas)
- Need for 2-dose series
  - In adults, ~3-8% missed the second dose of a 2-dose series, but differences were seen by jurisdiction, race/ethnicity, and age[2]
- Multipronged approach to improve access
  - Primary care providers serving adolescents, FQHCs, rural health clinics, community health centers, children's hospitals, pharmacies, school-located vaccination clinics

1. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-allows-more-flexible-storage-transportation-conditions-pfizer
2. Kriss JL, Reynolds LE, Wang A, et al. COVID-19 Vaccine Second-Dose Completion and Interval Between First and Second Doses Among Vaccinated Persons — United States, December 14, 2020–February 14, 2021. MMWR Morb Mortal Wkly Rep 2021;70:389–395.

Vaccine Policy

Pfizer-BioNTech COVID-19 Vaccine Among Adolescents

Policy Question

- Should vaccination with Pfizer-BioNTech COVID-19 vaccine (2-doses, IM) be recommended for persons 12-15 years of age under an Emergency Use Authorization?

ACIP Vote – Interim Recommendation

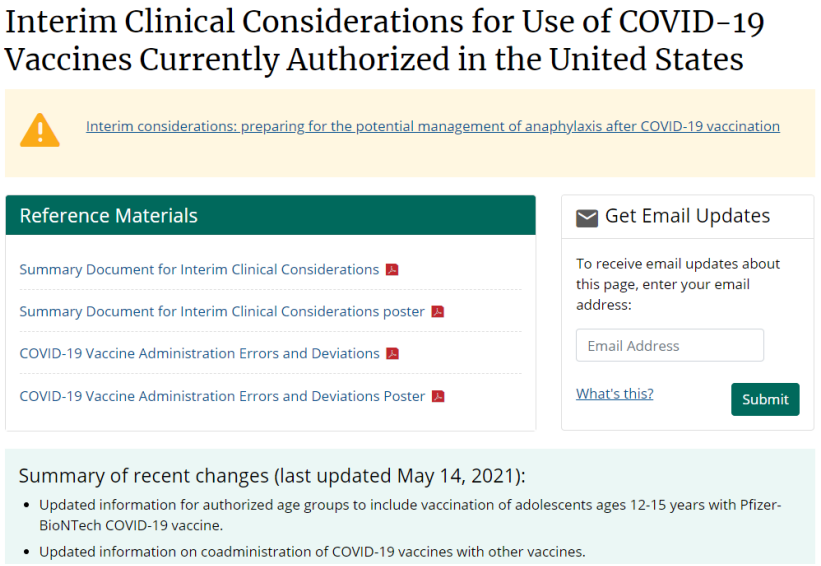
The Pfizer-BioNTech COVID-19 vaccine is recommended for persons 12–15 years of age in the U.S. population under the FDA's Emergency Use Authorization.

Clinical Considerations

Interim clinical considerations for COVID-19 vaccines

- Recommendations apply to the use of the Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines under the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA)

- Clinical considerations are being updated to include guidance for adolescents and recommendations regarding vaccine coadministration and vaccination after Multisystem Inflammatory Syndrome in Children (MIS-C) and Adults (MIS-A)


Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Reference Materials

Summary Document for Interim Clinical Considerations

Summary Document for Interim Clinical Considerations poster

COVID-19 Vaccine Administration Errors and Deviations

COVID-19 Vaccine Administration Errors and Deviations Poster

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Summary of recent changes (last updated May 14, 2021):

- Updated information for authorized age groups to include vaccination of adolescents ages 12-15 years with Pfizer-BioNTech COVID-19 vaccine.
- Updated information on coadministration of COVID-19 vaccines with other vaccines.

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

Pfizer-BioNTech Dosing and Administration

Authorized age groups	**≥ 12 years**
Number of doses in series	2 doses
Interval between 1st and 2nd doses*	3 weeks
Dose volume	0.3 ml
Route	Intramuscular

*If it is not feasible to adhere to the recommended interval, the second dose may be administered up to 6 weeks (42 days) after the first dose.

Consent

- The federal government does not have specific requirements for medical consent for vaccination.
- States/jurisdictions have medical consent laws that address the circumstances requiring and the processes for obtaining consent.
  - These laws vary across jurisdictions.
  - Providers may also be subject to policy requirements for consent within their own organizations.
- Sites administering vaccines should follow current state/jurisdictional policies and practices for other routine immunizations in this age group.

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/pfizer-bioNTech-faqs.html

Coadministration

- COVID-19 vaccines were previously recommended to be administered alone, with a minimum interval of 14 days before or after administration of any other vaccines. This was out of an abundance of caution and not due to any known safety or immunogenicity concerns.
- However, substantial data have now been collected regarding the safety of COVID-19 vaccines currently authorized for use by FDA for use under EUA.
- Although data are not available for COVID-19 vaccines administered simultaneously with other vaccines, extensive experience with non-COVID-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.

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

Coadministration

- COVID-19 vaccines and other vaccines **may now be administered without regard to timing**. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days.

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

Coadministration

- It is unknown whether reactogenicity is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines or live vaccines.

- When deciding whether to coadminister another vaccine(s) with COVID-19 vaccines, providers should consider:
  - whether the patient is behind or at risk of becoming behind on recommended vaccines
  - their risk of vaccine-preventable diseases (e.g., during an outbreak or occupational exposures)
  - the reactogenicity profile of the vaccines

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

Coadministration

- **If multiple vaccines are administered at a single visit, administer each injection in a different injection site.**
- For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection.
- Best practices for multiple injections include:
  - Label each syringe to identify the vaccine it contains.
  - Separate injection sites by 1 inch or more, if possible.
  - Administer COVID-19 and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.

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

Routine Adolescent Vaccines

- Updated coadministration recommendations may facilitate catch up vaccination of adolescents.
- As of May 2, 2021, overall VFC provider orders (other than influenza) are down by **11.7 million doses** compared with 2019.
- This gap is largest in vaccines primarily given to adolescents.
  - Tdap – down **18.9%**
  - HPV – down **19.3%**
  - Meningococcal conjugate vaccine – down **15.1%**

Multisystem Inflammatory Syndrome in Children (MIS-C) and Adults (MIS-A)

- MIS-C and MIS-A are severe hyperinflammatory syndromes occurring 2-6 weeks after acute SARS-CoV-2 infection, resulting in a wide range of manifestations and complications.

- The mechanisms of MIS-C and MIS-A are not well understood but include a dysregulated immune response to SARS-CoV-2.

Clinical Considerations for People with a History of MIS-C or MIS-A

- Children with MIS-C have high antibody titers to SARS-CoV-2; however, it is unknown if this correlates with protection against reinfection and for how long protective antibody levels persist.

- It is unclear if people with a history of MIS-C or MIS-A are at risk for recurrence of the same dysregulated immune response following reinfection with SARS-CoV-2 or in response to a COVID-19 vaccine.

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

Clinical Considerations for People with a History of MIS-C or MIS-A

- People with a history of MIS-C or MIS-A may choose to be vaccinated.
- Considerations for vaccination may include:
  - Clinical recovery from MIS-C or MIS-A, including return to normal cardiac function
  - Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
  - Level of COVID-19 community transmission and personal risk of reinfection
  - Lack of safety data of COVID-19 vaccines following these illnesses
  - Timing of any immunomodulatory therapies

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

Clinical Considerations for People with a History of MIS-C or MIS-A

- Current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. Thus, people with a history of MIS-C or MIS-A should consider delaying vaccination until they have recovered from illness and **for 90 days after the date of diagnosis of MIS-C or MIS-A**, recognizing that the risk of reinfection and, therefore, the benefit from vaccination, might increase with time following initial infection.

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

Clinical Considerations for People with a History of MIS-C or MIS-A

Healthcare personnel or health departments can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project if they have complex COVID-19 vaccine safety questions not readily addressed by CDC guidance.

https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html

Contraindications for COVID-19 Vaccines

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine

- Known polysorbate allergy is no longer a contraindication to mRNA vaccination but is a contraindication to Janssen COVID-19 vaccine and thus, a precaution to mRNA COVID-19 vaccination.

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

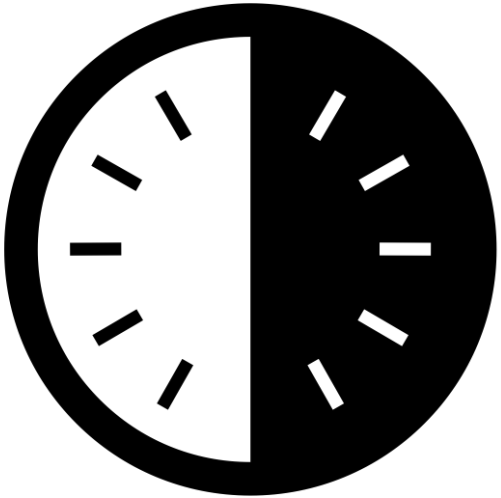
Syncope (fainting)

- Syncope (fainting) may occur in association with any injectable vaccine.
- Procedures should be in place to prevent falling injuries and manage syncopal reactions following vaccination.
- All people are recommended to be observed following vaccination for at least 15 minutes; patients should be seated or lying down during the observation period to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve.

https://www.cdc.gov/vaccinesafety/concerns/fainting.html

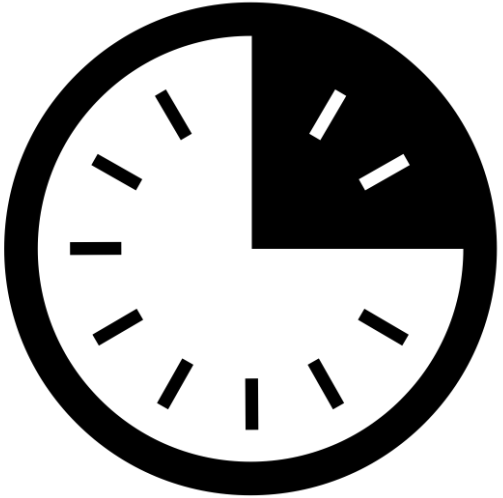
Observation Period Following Vaccination

- History of immediate allergic reaction (any severity) to a vaccine or injectable therapy
- Contraindication to a different type of COVID-19 vaccine
- History of anaphylaxis (due to any cause)



30 minutes

All other persons



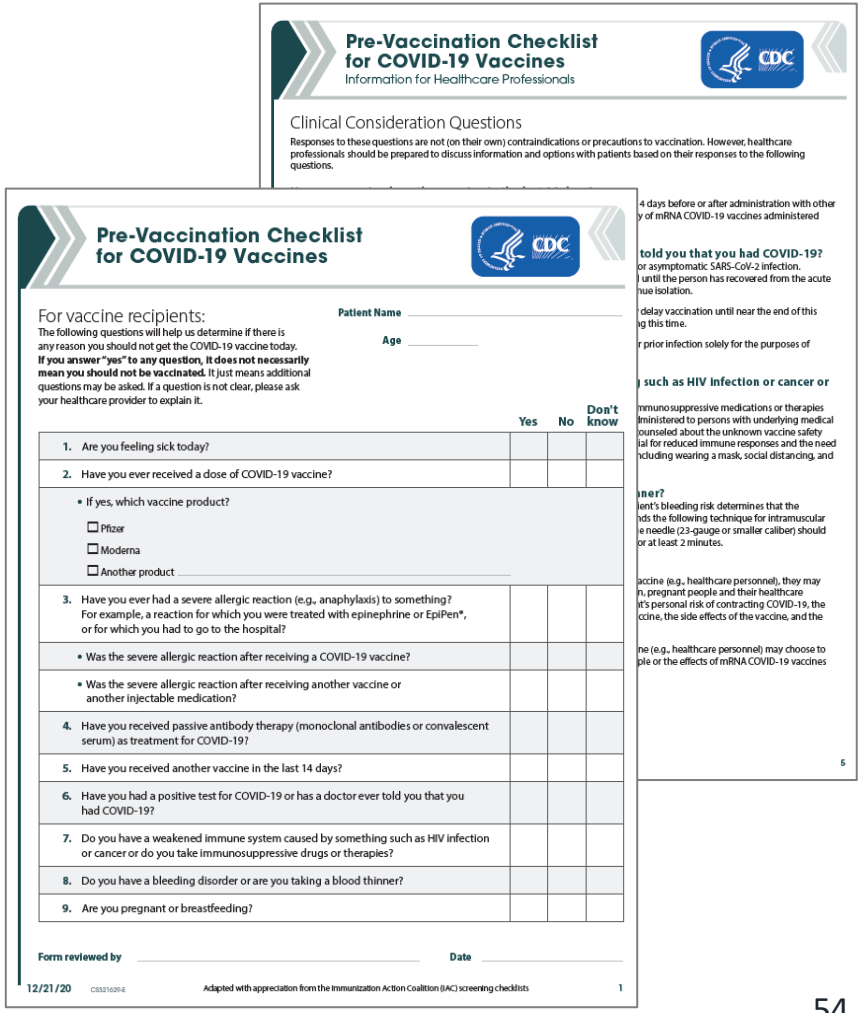
15 minutes

Additional resources

Additional Tools

- **Additional tools to identify persons with contraindications and precautions to vaccination**

https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf



Pre-Vaccination Checklist for COVID-19 Vaccines
Information for Healthcare Professionals

Clinical Consideration Questions

Responses to these questions are not (on their own) contraindications or precautions to vaccination. However, healthcare professionals should be prepared to discuss information and options with patients based on their responses to the following questions.

4 days before or after administration with other
y of mRNA COVID-19 vaccines administered

told you that you had COVID-19?
or asymptomatic SARS-CoV-2 infection.
until the person has recovered from the acute
nue isolation.

delay vaccination until near the end of this
g this time.

r prior infection solely for the purposes of

such as HIV infection or cancer or

mmunosuppressive medications or therapies
dministered to persons with underlying medical
ounseled about the unknown vaccine safety
ial for reduced immune responses and the need
ncluding wearing a mask, social distancing, and

ner?
ient's bleeding risk determines that the
nds the following technique for intramuscular
e needle (23-gauge or smaller caliber) should
or at least 2 minutes.

accine (e.g., healthcare personnel), they may
n, pregnant people and their healthcare
t's personal risk of contracting COVID-19, the
ccine, the side effects of the vaccine, and the

ne (e.g., healthcare personnel) may choose to
ple or the effects of mRNA COVID-19 vaccines

5

Pre-Vaccination Checklist for COVID-19 Vaccines

For vaccine recipients:

The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today. **If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated.** It just means additional questions may be asked. If a question is not clear, please ask your healthcare provider to explain it.

Patient Name _____

Age _____

	Yes	No	Don't know
1. Are you feeling sick today?			
2. Have you ever received a dose of COVID-19 vaccine?			
• If yes, which vaccine product? ☐ Pfizer ☐ Moderna ☐ Another product _____			
3. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something? For example, a reaction for which you were treated with epinephrine or EpiPen®, or for which you had to go to the hospital?			
• Was the severe allergic reaction after receiving a COVID-19 vaccine?			
• Was the severe allergic reaction after receiving another vaccine or another injectable medication?			
4. Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19?			
5. Have you received another vaccine in the last 14 days?			
6. Have you had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?			
7. Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?			
8. Do you have a bleeding disorder or are you taking a blood thinner?			
9. Are you pregnant or breastfeeding?			

Form reviewed by _____ **Date** _____

12/21/20 CS321629-E

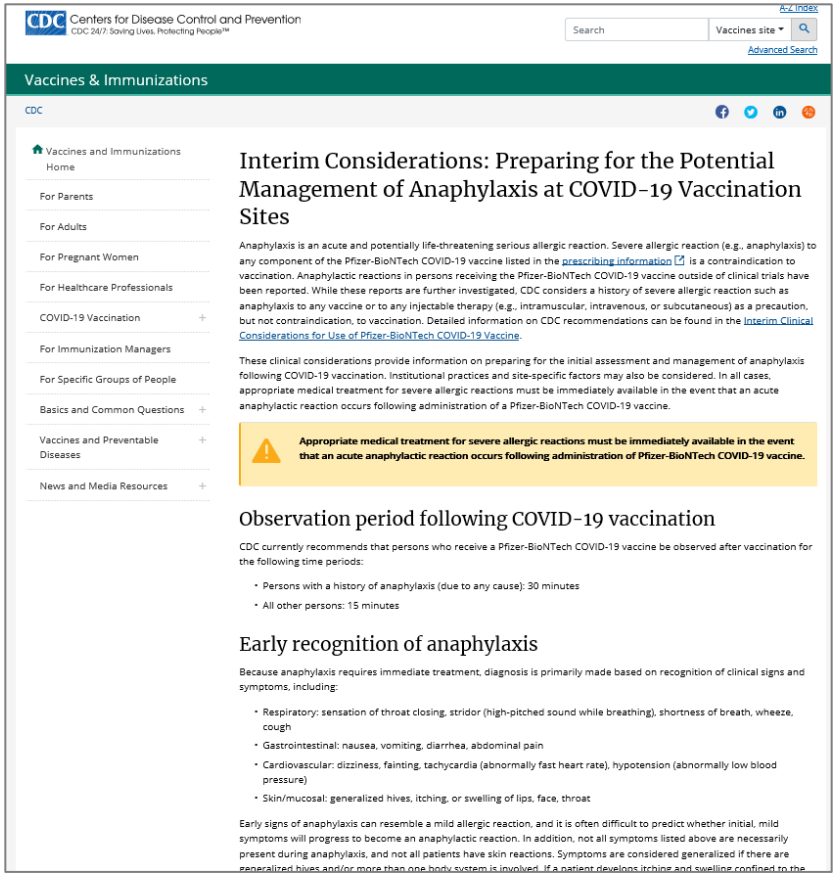
Adapted with appreciation from the Immunization Action Coalition (IAC) screening checklists

1

Interim Considerations

- **Preparing for the potential management of anaphylaxis at COVID-19 vaccination sites**

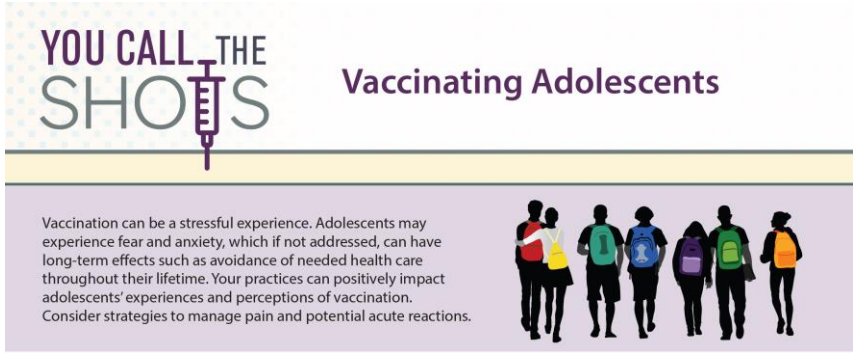
https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

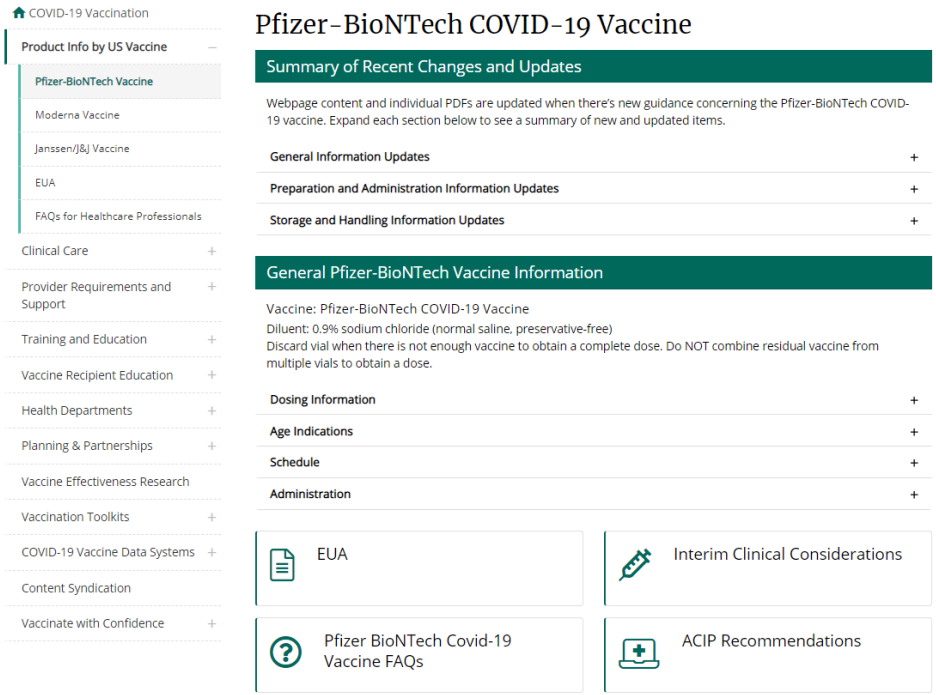


CDC Resources

Learn more with **CDC's COVID-19 vaccine tools and resources.** Find information for COVID-19 vaccination administration, storage, reporting, patient education, and more.

- COVID-19 Vaccination: https://www.cdc.gov/vaccines/covid-19/index.html
- For Healthcare Professionals: https://www.cdc.gov/vaccines/covid-19/hcp/index.html





COVID-19 Vaccine Communication Resources

- Toolkit for Medical Centers, Clinics, and Clinicians

  https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html

- Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit

  https://www.cdc.gov/coronavirus/2019-ncov/vaccines/toolkits/pediatrician.html

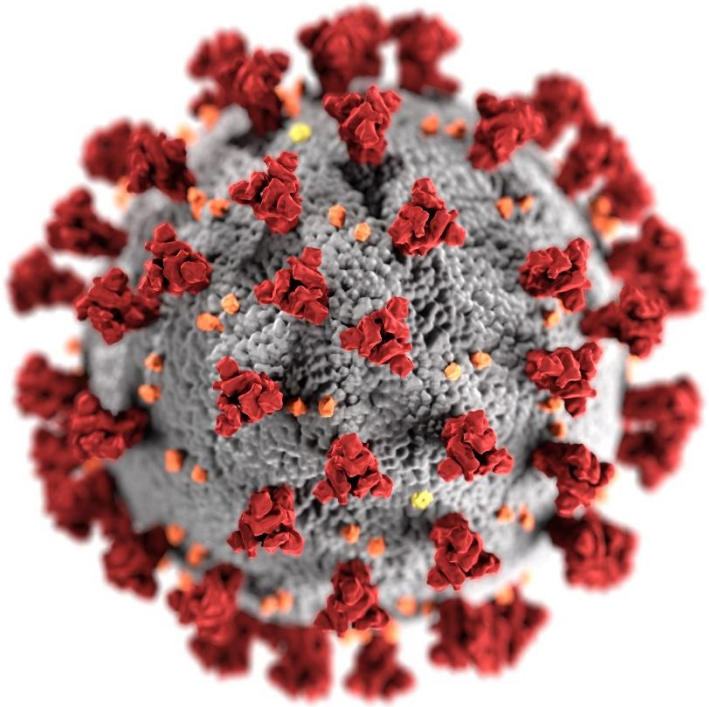
Your Patients Need to Hear from You!

- You are the most trusted resource for your patients in making health decisions. **Your strong recommendation to get a COVID-19 vaccine is one of the most important factors in your patients' decision to accept vaccination.**

- Engaging in Effective COVID-19 Vaccine Conversations
  https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html

Making a Strong Recommendation to Get a COVID-19 Vaccine

- Make it clear to your patients that you recommend COVID-19 vaccination for them.
- Tell your patients how important COVID-19 vaccines are to **protect their health, as well as the health of their family and friends.**
- COVID-19 vaccines are new, and it's understandable that your patients may have questions. Your answers can help them make an informed decision about getting vaccinated.
- Make it clear that you understand they may have questions, and you want to answer them, so they feel confident in choosing to get vaccinated.
- If you are not currently offering COVID-19 vaccination, send them to www.vaccines.gov to find a location.



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question

- If you are a patient, please refer your question to your healthcare provider.

- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov.

Today's COCA Call Will Be Available to View On-Demand

- **When:** A few hours after the live call
- **What:** Video recording
- **Where:** On the COCA Call webpage at https://emergency.cdc.gov/coca/calls/2021/callinfo_051421.asp

Upcoming COCA Calls / Additional COVID-19 Resources

- Next Scheduled COCA Calls:
  - **Thursday, May 20**: Lyme Disease Updates and New Educational Tools for Clinicians
  - **Thursday, May 27**: Underlying Medical Conditions and Severe COVID-19
  - **Thursday, June 3**: Evaluating and Caring for Patients with Suspected Long COVID
  - 2:00 PM-3:00 PM ET

- Subscribe to receive notifications about upcoming COCA calls and other COCA products and services at emergency.cdc.gov/coca/subscribe.asp

- Share call announcements with colleagues

- Sign up to receive weekly ***COVID-19 Science Updates*** by visiting cdc.gov/library/covid19/scienceupdates.html?Sort=Date%3A%3Adesc

COCA Products & Services

COCA Call Announcements contain all information subscribers need to participate in COCA Calls. COCA Calls are held as needed.

Monthly newsletter that provides information on CDC training opportunities, conference and training resources, the COCA Partner Spotlight, and the Clinician Corner.

As-needed messages that provide specific, immediate action clinicians should take. Contains comprehensive CDC guidance so clinicians can easily follow recommended actions.

COCA Products & Services

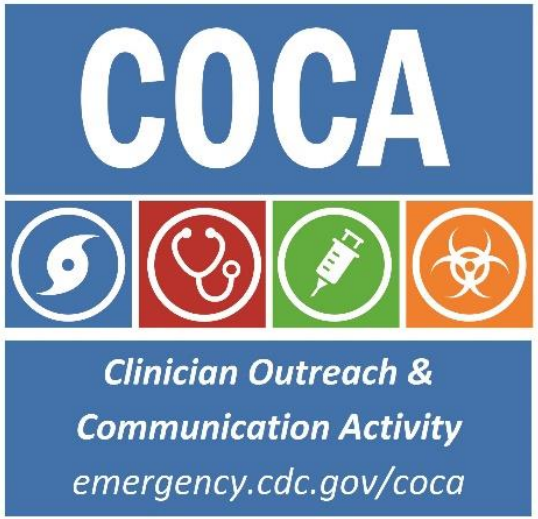
Monthly newsletter providing updates on emergency preparedness and response topics, emerging public health threat literature, resources for health professionals, and additional information important during public health emergencies and disasters.

Informs clinicians of new CDC resources and guidance related to emergency preparedness and response. This email is sent as soon as possible after CDC publishes new content.

CDC's primary method of sharing information about urgent public health incidents with public information officers; federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories.

Join COCA's Mailing List

- **Receive information about:**
  - Upcoming COCA Calls
  - Health Alert Network (HAN) messages
  - CDC emergency response activations
  - Emerging public health threats
  - Emergency preparedness and response conferences
  - Training opportunities



emergency.cdc.gov/coca/subscribe.asp

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