

# COVID-19 Vaccine: Considerations for Pregnancy

Arkansas Medical Society  
August 13, 2021

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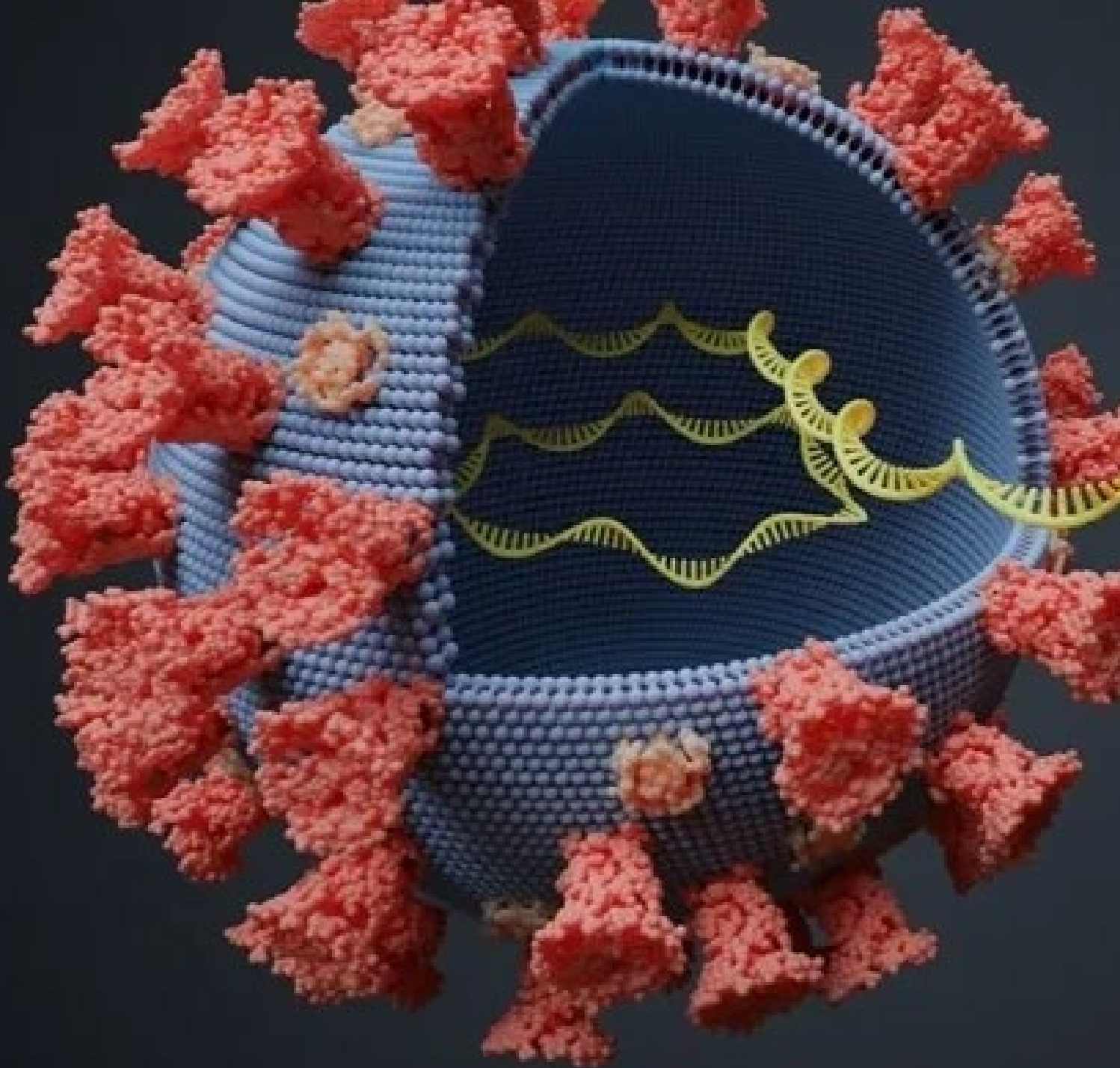
Obstetrics & Gynecology

University of Arkansas for Medical Sciences

# Objectives

- Situational Awareness
- Vaccines Development, Efficacy, and Safety
- Considerations for the pregnant patient





# What's in a Name?

- The Coronavirus Study Group of the International Committee on Taxonomy of Viruses
  - Designated severe acute respiratory syndrome coronavirus 2
  - SARS-CoV-2
- World Health Organization
  - Coronavirus disease 2019 (COVID-19)

## *In Undervaccinated Arkansas, Covid Upends Life All Over Again*

While much of the nation tiptoes toward normalcy, the coronavirus is again swamping hospitals in places like Mountain Home, in a rural county where fewer than one-third of residents are vaccinated.



LOCAL NEWS

**'They told me I was already dying': New mom describes close call with COVID-19 while pregnant**

## **Vanderbilt doctors see uptick of COVID-19 in pregnant patients**

by Kaylin Jorge | Wednesday, August 4th 2021

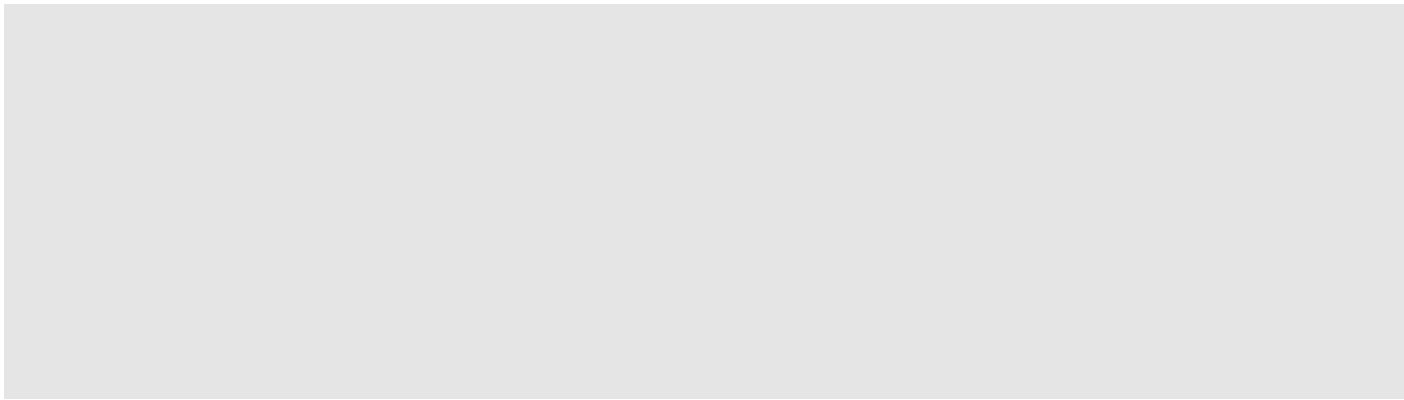
COVID-19 PANDEMIC

**Memorial Hermann brings back 'No visitors' policy due to COVID-19 spike in Houston**



Monday, August 9, 2021 7:39PM

# Situational Awareness



# COVID-19 Update

## August 10, 2021



### CASES

	Total	Change from yesterday
TOTAL CASES:	407,892	+2,620
TOTAL ACTIVE CASES:	23,377	+562
TOTAL DEATHS:	6,346	+24

### TESTING

	Total this month	Results yesterday
PCR:	78,184	6,169
ANTIGEN:	39,068	3,782

### VACCINATIONS

	Total	Change from yesterday
DOSES RECEIVED:	3,041,240	+5,980
DOSES GIVEN:	2,458,039	+11,466
PERCENT DOSES GIVEN:	80.80%	
INDIVIDUALS PARTIALLY IMMUNIZED:	341,886	+3,158
INDIVIDUALS FULLY IMMUNIZED:	1,101,327	+4,380

### TODAY'S NEW CASES

Counties with most new cases added today:

Pulaski	356
Benton	225
Washington	154

Active Cases by Type:

Correctional: 63  
Community: 23,314

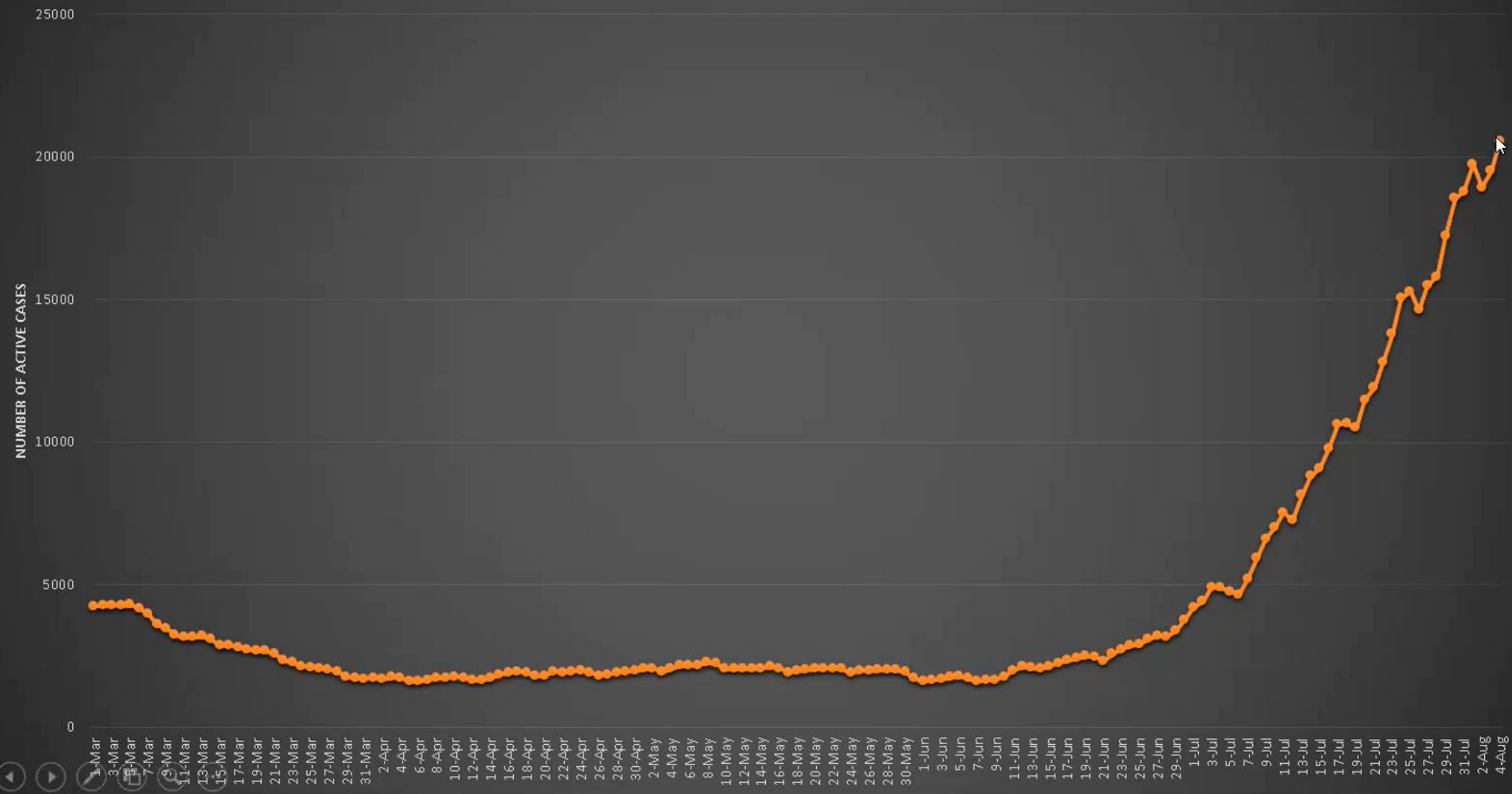
### HOSPITAL DATA

		Change from yesterday		
CURRENTLY HOSPITALIZED:	1,435	+59	EVER HOSPITALIZED:	19,462
CURRENTLY ON VENTILATORS:	294	+8	EVER ON VENTILATORS:	1,977

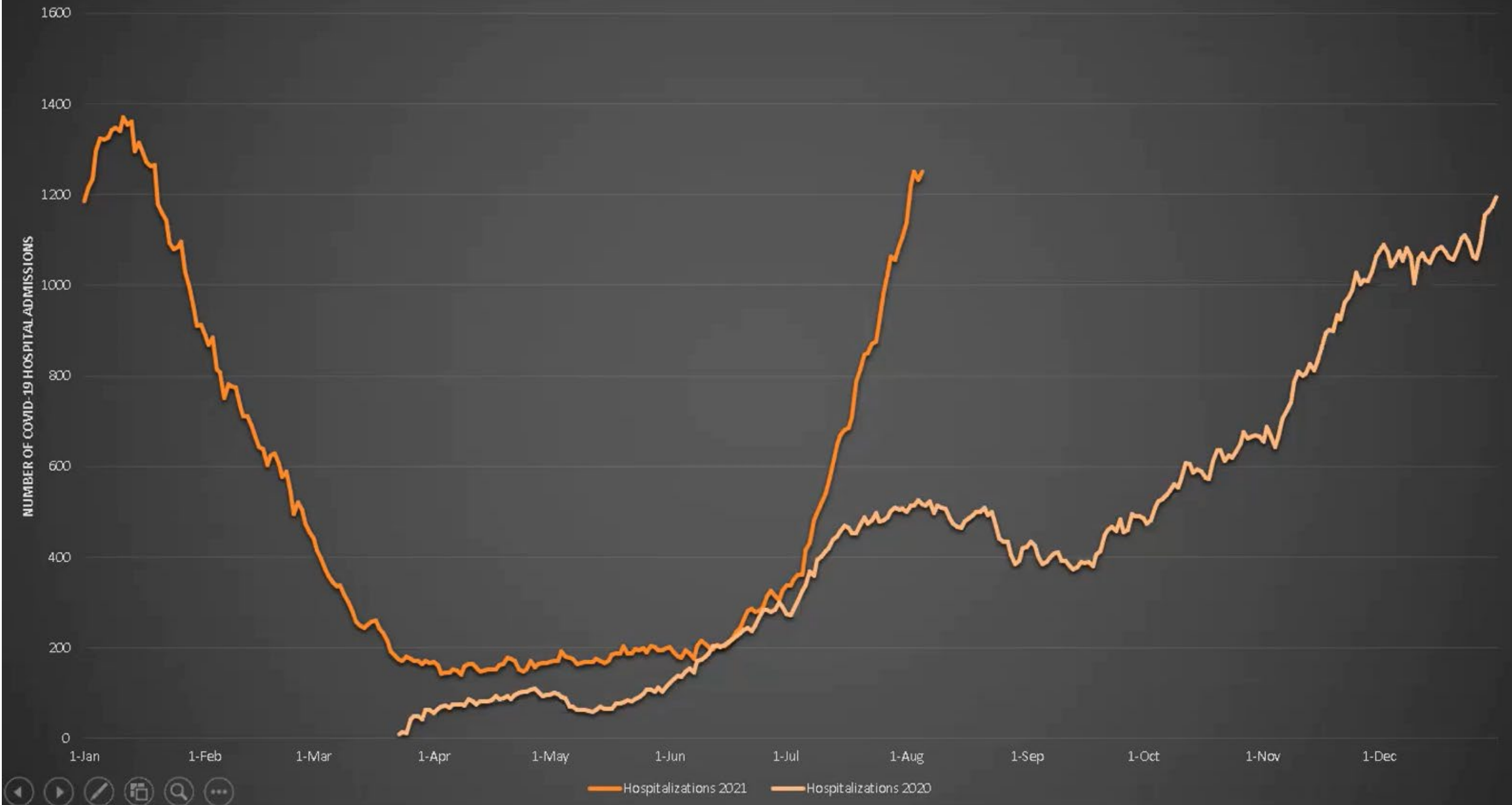
*\*All data are provisional and subject to change. Testing data reflects result date. Case data includes confirmed and probable cases and deaths. Cases and deaths may decrease if they are reclassified. The net change is shown. Vaccination numbers include the state and federal program. As more Arkansans are fully immunized, the number of partially immunized may decline from day to day.*

[www.healthy.arkansas.gov](http://www.healthy.arkansas.gov)

# Number of Active COVID-19 Cases in Arkansas



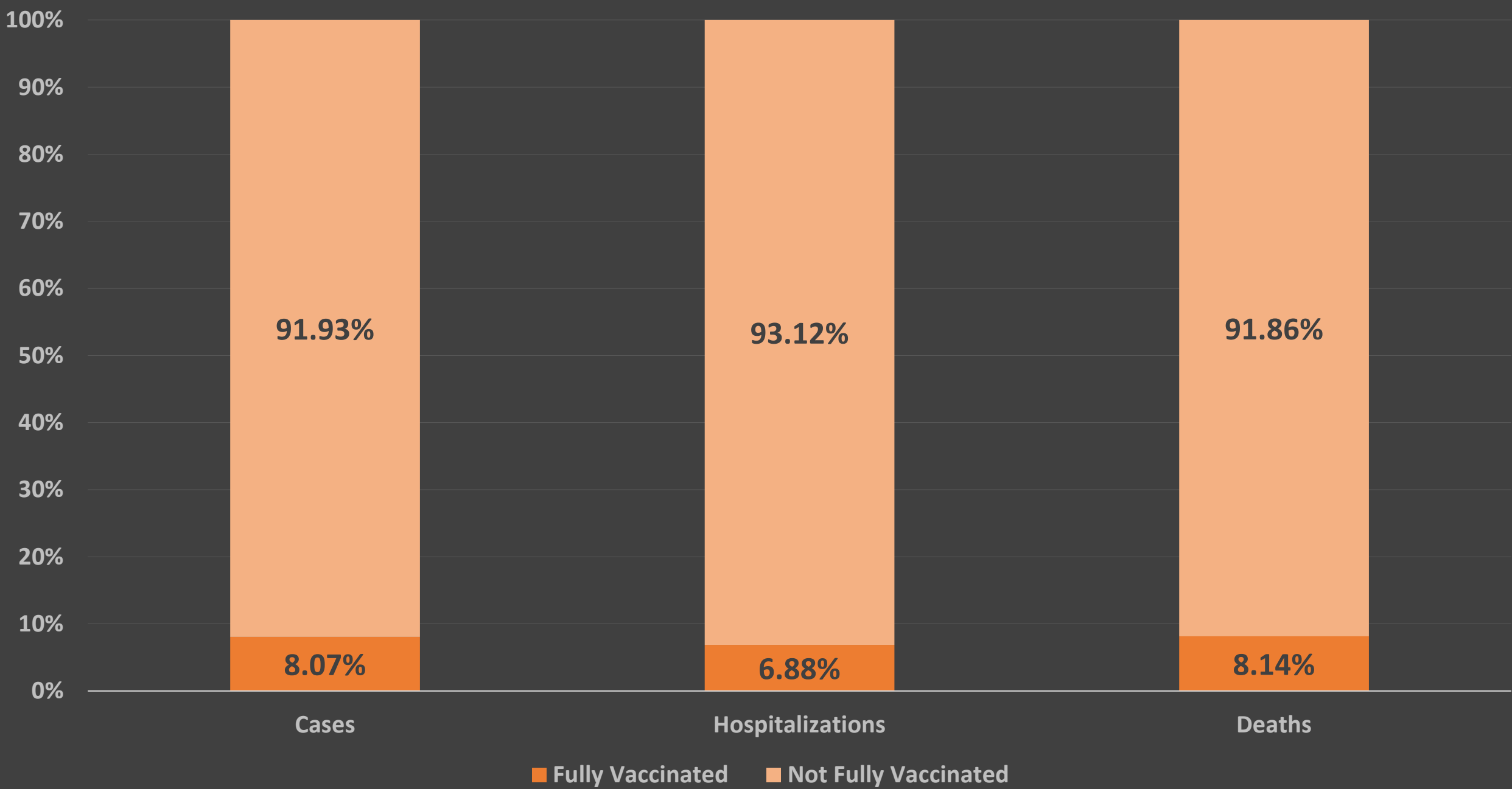
# Hospitalizations in Arkansas since the beginning of the COVID-19 pandemic



# Number of Currently Hospitalized COVID-19 Patients



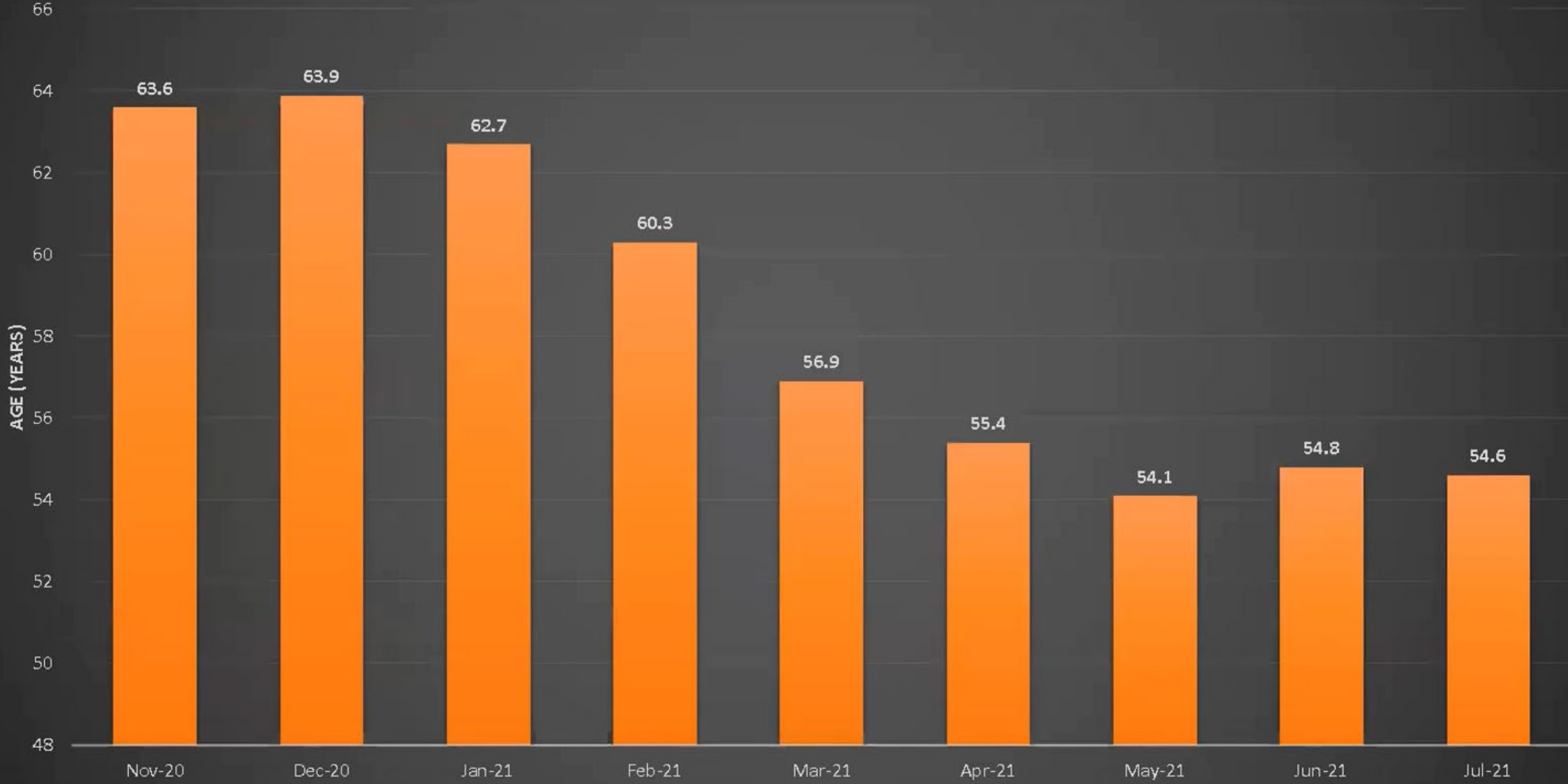
Vaccination Status of Cases, Hospitalizations, and Deaths Since February 1, 2021





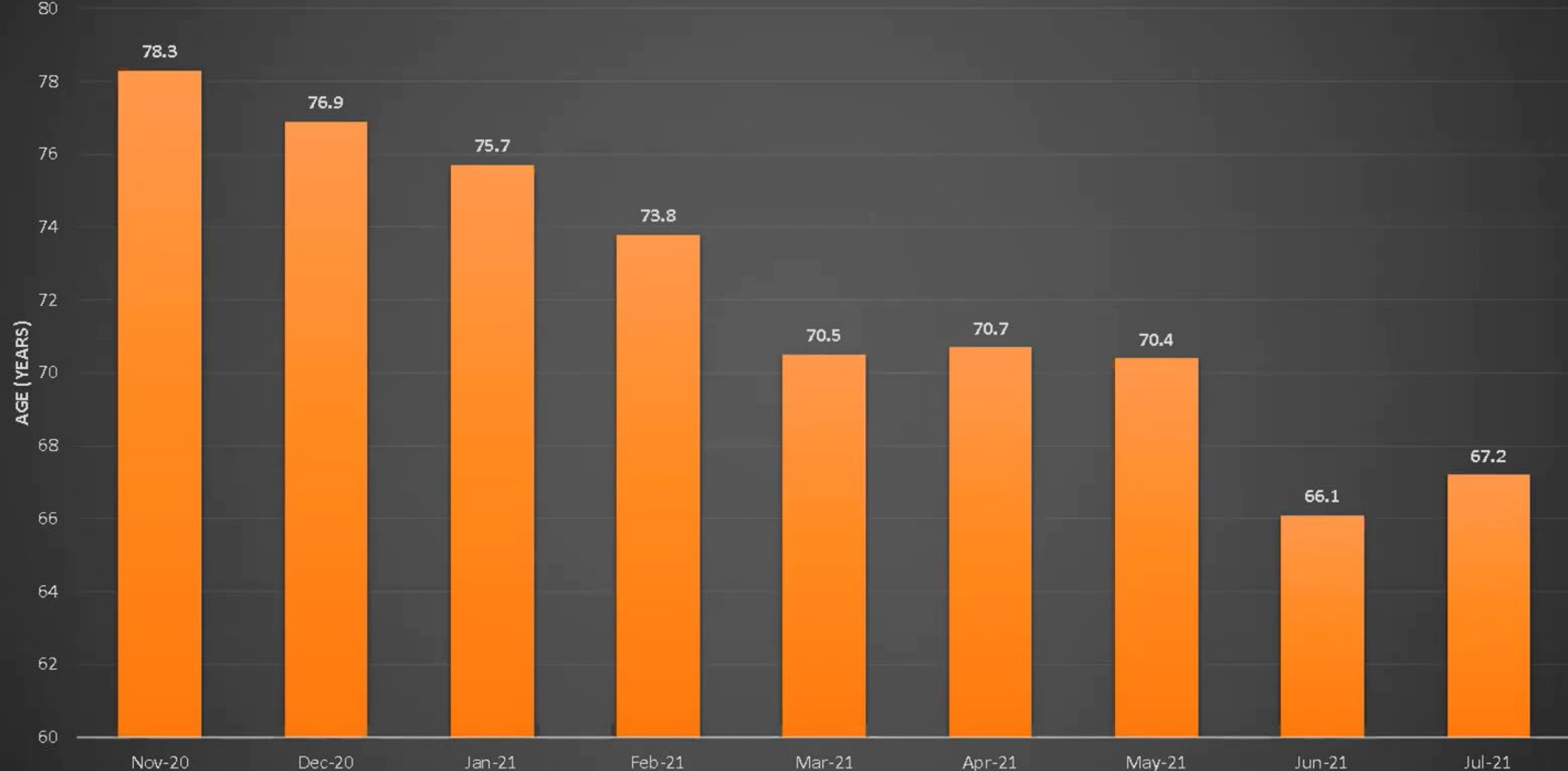
# Average Age Among Those Hospitalized Due to COVID-19

## Arkansas, November 2020 through July 2021



# Average Age Among Decedents Due to COVID-19

## Arkansas, November 2020 through July 2021



# SARS-CoV-2 Variants of Concern



## Alpha - B.1.1.7

**First identified:** United Kingdom

**Spread:** Spreads much faster than other variants

**Severe illness and death:** May potentially cause more people to get sicker and to die

**Vaccine:** Currently authorized vaccines do work against this variant. Some breakthrough infections in fully vaccinated people are expected but remain rare. All vaccines are particularly effective against severe illness, hospitalization, and death.

**Treatments:** Treatments are effective against this variant



## Gamma - P.1

**First identified:** Japan/Brazil

**Spread:** Spreads faster than other variants

**Severe illness and death:** Current data do not indicate more severe illness or death than other variants

**Vaccine:** Currently authorized vaccines do work against this variant. Some breakthrough infections are expected, but remain rare. All vaccines are particularly effective against severe illness, hospitalization and death.

**Treatments:** Certain monoclonal antibody treatments are less effective against this variant



## Beta - B.1.351

**First identified:** South Africa

**Spread:** May spread faster than other variants

**Severe illness and death:** Current data do not indicate more severe illness or death than other variants

**Vaccine:** Currently authorized vaccines do work against this variant. Some breakthrough infections are expected, but remain rare. All vaccines are particularly effective against severe illness, hospitalization and death.

**Treatments:** Certain monoclonal antibody treatments are less effective against this variant



## Delta - B.1.617.2

**First identified:** India

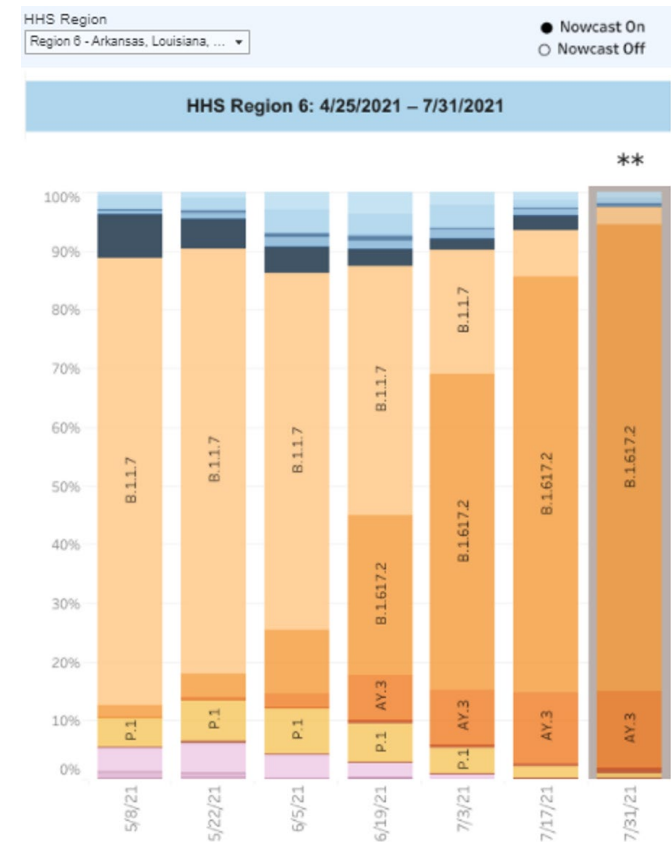
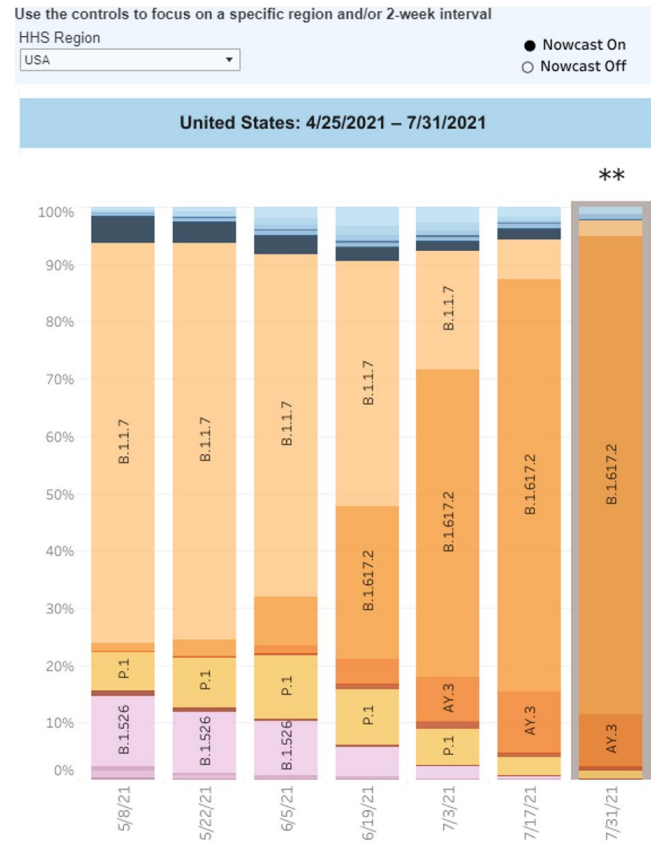
**Spread:** Spreads much faster than other variants

**Severe illness and death:** May cause more severe cases than the other variants

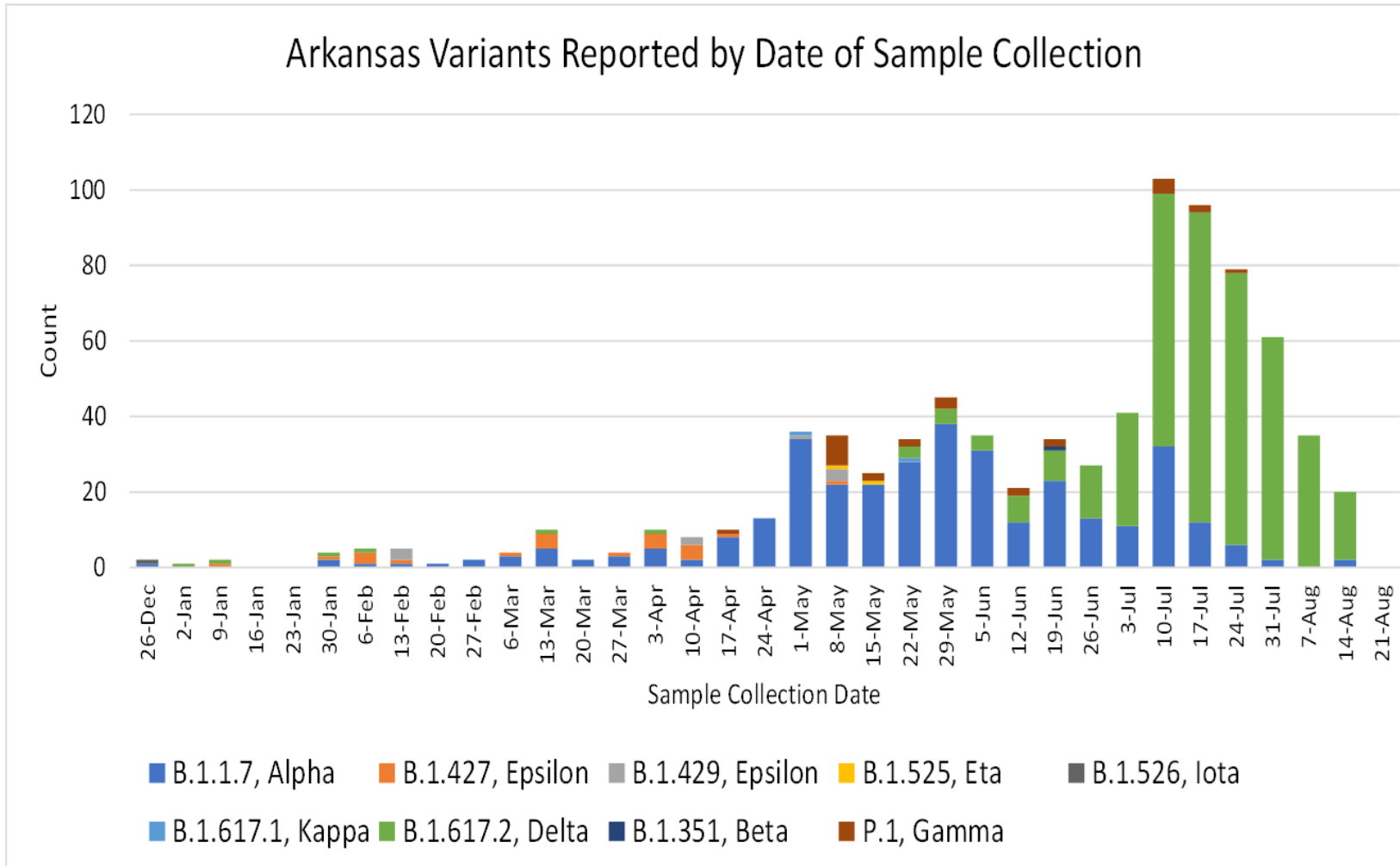
**Vaccine:** Infections happen in only a small proportion of people who are fully vaccinated, even with the Delta variant. Some breakthrough infections are expected, but remain rare. However, preliminary evidence suggests that fully vaccinated people who do become infected with the Delta variant can spread the virus to others. Learn more [here](#). All vaccines are particularly effective against severe illness, hospitalization and death.

**Treatments:** Certain monoclonal antibody treatments are less effective against this variant

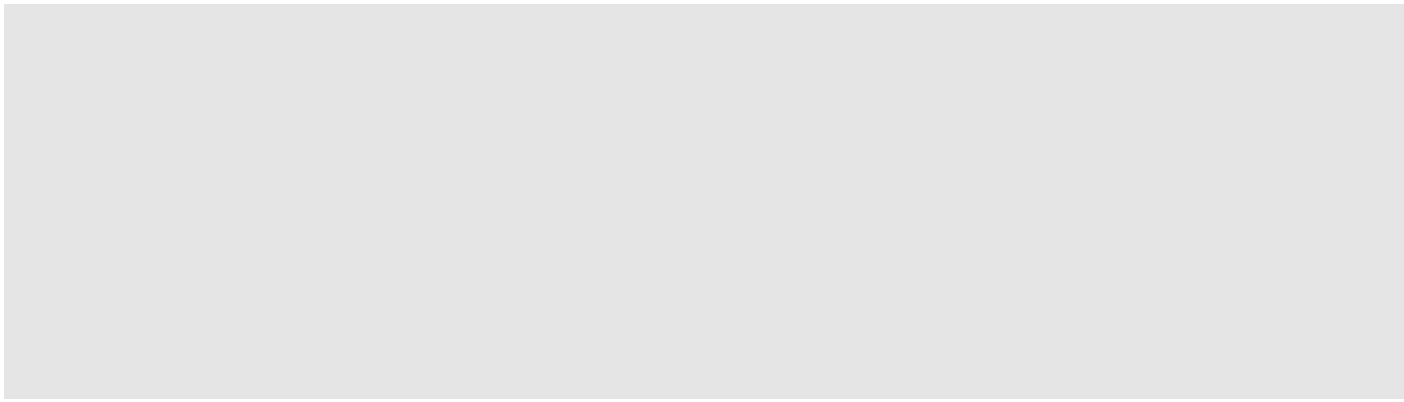
# Variant Proportions



# Arkansas SARS-CoV-2 Virus Variants by Date of Sample Collection as of July 31, 2021

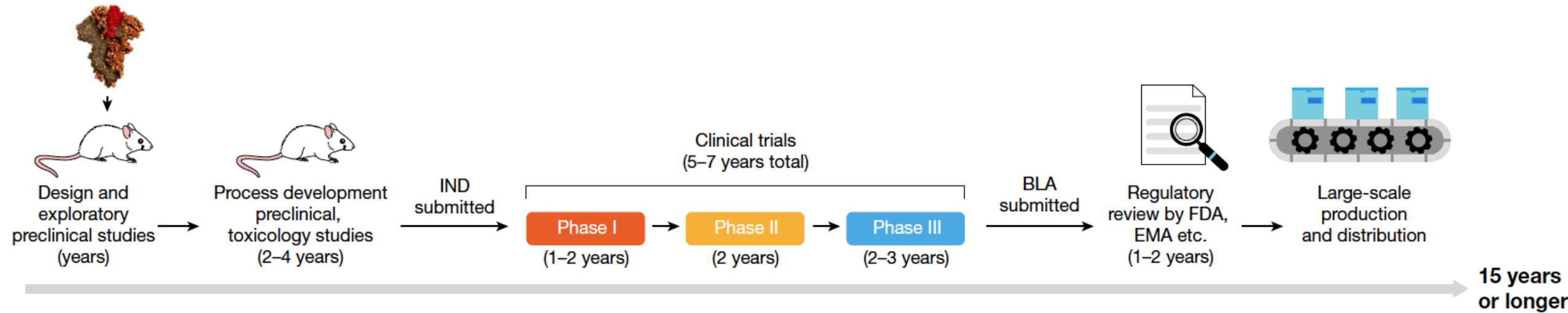


# Vaccines



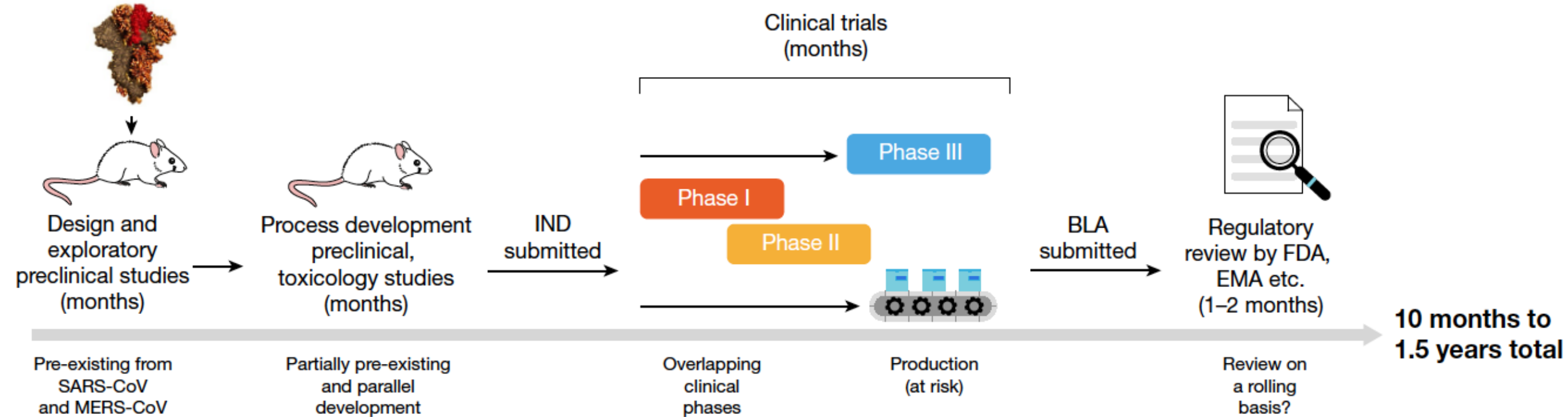
# Traditional Vaccine Development Pathway

## Traditional development



# COVID-19 Vaccine Development

## SARS-CoV-2 vaccine development





# COVID-19 Vaccine Authorization Overview

- **Advisory Committee on Immunization Practices**
  - Develops recommendations for vaccine use
  - ACIP recommendations reviewed and approved by the CDC Director and HHS
  - published in CDC's Morbidity and Mortality Weekly Report (MMWR)
  - MMWR publication represents the final and official CDC recommendations
- **FDA Emergency Use Authorization and Approval**
  - EUA authority allows the FDA to strengthen the nation's public health protections
  - Section 564 of the Federal Food, Drug, and Cosmetic Act

Interim Clinical  
Considerations for  
Use of Covid-19  
Vaccines Currently  
Authorized in the  
US as of July 27,  
2021

- Authorized Age Groups
  - Pfizer- BioNTech: Age 12 years and older
  - Moderna: 18 years and older
  - Janssen: 18 years and older
- Administration
  - Intramuscularly
  - Pfizer-BioNTech: Two doses 21 days minimum interval
  - Moderna: Two doses 28 days minimum interval
  - Janssen: Single dose

<https://www.cdc.gov/vaccines/covid-19/info-by-product/>

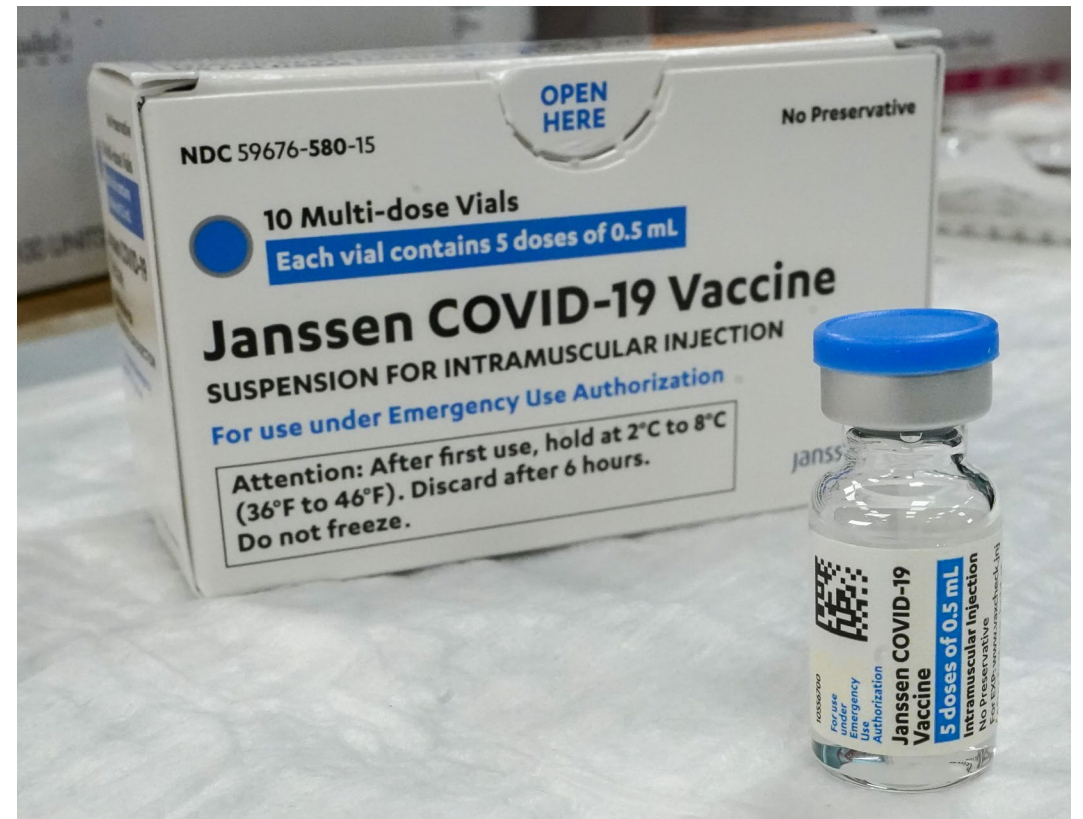
# mRNA COVID-19 Vaccines (Pfizer-BioNtech & Moderna)

- Messenger RNA (mRNA) encapsulated by a lipid nanoparticle (LNP)
- Utilize the body's own cells to generate the coronavirus spike protein
- Stimulates antibody production
- Do not enter the nucleus
- Do not alter human DNA



# Adenovirus-vector Vaccines (Janssen)

- Monovalent vaccine composed of a recombinant, replication-incompetent human adenovirus type 26 (Ad26) vector
- Encodes a stabilized form of the SARS-CoV-2 Spike (S) protein.
- Ad26 vector cannot replicate following administration to humans
- It is cleared from tissues following injection
- Ad26.COVS.S is not a live virus vaccine
- Does not contain preservatives
- Does not replicate in the cells



# Efficacy of Available Vaccines

## **Pfizer-BioNtech COVID-19**

- 95% effective at preventing laboratory-confirmed COVID-19 illness

## **Moderna**

- 94.1% effective at preventing laboratory-confirmed COVID-19 illness

Comparable immune responses to non-pregnant controls

Higher antibody titers than those observed following SARS-CoV-2 infection

Vaccine-generated antibodies were present in umbilical cord blood and breastmilk

(Gray 2021, Prabhu 2021, Juncker 2021)

## **Janssen COVID-19 vaccine**

- Based on the results from clinical trials in the U.S
- 66.9% effective at preventing moderate/severe COVID-19 illness
- 76.7% effective at preventing severe/critical COVID-19 illness after a single dose.
- 93.1% effective at preventing hospitalizations 14 days following vaccination

(Janssen 2021)

# Vaccine Safety Monitoring

- **Vaccine Adverse Event Reporting System (VAERS)**
  - Early warning public health system where people report adverse health effects following vaccination
- **Vaccine Safety Datalink (VSD)**
  - Collaboration between CDC and several health organizations
  - Uses de-identified health records to monitor and evaluate adverse events following vaccination
- **Post-Licensure Rapid Immunization Safety Monitoring (PRISM)**
  - FDA uses data base of health insurance claims to identify and evaluate possible safety issues for licenses vaccines
- **Clinical Immunization Safety Assessment (CISA)**
  - Collaboration between CDC and medical research centers in U.S.
  - Conduct research to understand how adverse events might be caused by vaccines



# Vaccine Safety Monitoring, as of July 26, 2021



- Severe allergic reactions, including anaphylaxis occurs in approximately 2 to 5 per million vaccinated
- Thrombosis with thrombocytopenia syndrome (TTS) after Johnson & Johnson's Janssen vaccination
  - 39 confirmed reports after 13 million doses
  - Women younger than 50 years of age
- Guillain-Barre' Syndrome after Johnson & Johnson's Janssen vaccination
  - 137 preliminary reports
  - Men aged 50 and older

# Vaccine Safety Monitoring, as of July 26, 2021



- Myocarditis and pericarditis after COVID-19 vaccination
  - 1,194 VAERS reports with 699 confirmed among people ages 30 and younger
  - Most after Pfizer or Moderna vaccination among adolescent and young adult males
- Deaths after COVID-19 vaccination are rare
  - 342 million doses administered in U.S.
  - 6,340 reports of deaths (0.0019%) among people who received vaccine
  - All deaths after vaccination are required to be reported, even if it is unclear whether the vaccine was the cause
  - A review of available clinical information has not established a causal link of deaths to COVID-19 vaccines
- Reports of adverse events to VAERS following vaccination do not necessarily mean that a vaccine caused the adverse events.



Table 1. Mild Side Effects Among All Study Participants\*

	Injection Site Reactions	Fatigue	Chills	Muscle Pain	Joint Pain
Moderna	91.6%	68.5%	43.4%	59.6%	44.8%
Pfizer- BioNTech	84.10%	62.90%	31.90%	38.30%	23.60%
Janssen Biotech Inc.	48.6%	38.2%	N/A	33.2%	N/A

*\*Fever was the least common side effect reported; see text above for data on frequency of fever*

Safety of  
Available  
COVID-19  
Vaccines

# Vaccine Safety Monitoring in Pregnancy

## V-safe

- smartphone based tool
- text messaging & web survey
- method to inform CDC of side effects
- No specific safety signals have been observed in pregnant people enrolled in v-safe

v-safe After Vaccination Health Checker  
Pregnant people reported, United States, as of July 26,  
2021

139,562

## V-safe Pregnancy Registry

- vaccinated during periconception or pregnancy
- must be enrolled in v-safe
- registry staff contacts participant for health check-ins
- Data collected through February 28 from the v-safe pregnancy registry did find any safety concerns

v-safe COVID-19 Vaccine Pregnancy Registry  
Pregnant people enrolled, United States, as of July 26,  
2021

5,104

# V-safe pregnancy registry outcomes of interest in COVID-19 vaccinated pregnant individuals

Pregnancy Complications <sup>†</sup>	Background Rate	V-safe Pregnancy Registry Overall
Gestational diabetes	7-14%	10%
Preeclampsia or gestational hypertension	10-15%	15%
Eclampsia	0.27%	0%
Intrauterine growth restriction	3-7%	1%

Neonatal Outcomes*	Background Rate	V-safe Pregnancy Registry Overall
Preterm birth	8-15%	9.4%
Congenital anomalies	3%	2.2%
Small for gestational age	3.5%	3.2%
Neonatal death	0.38%	0%

*The* NEW ENGLAND  
JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

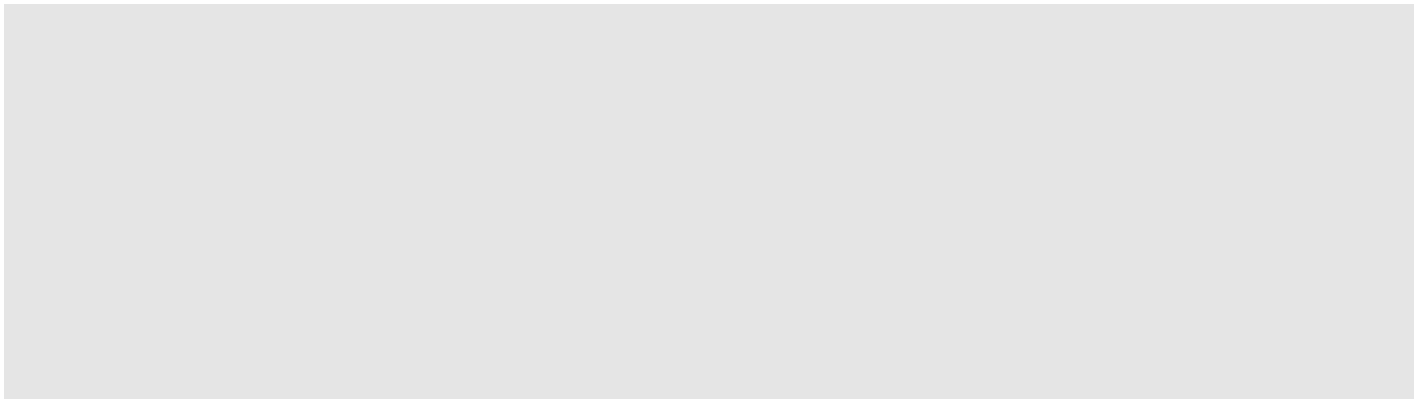
JUNE 17, 2021

VOL. 384 NO. 24

Preliminary Findings of mRNA Covid-19 Vaccine Safety  
in Pregnant Persons

- December 14, 2020-  
February 28, 2021
- V-safe after vaccination  
health checker
- V-safe pregnancy registry
- VAERS
- Preliminary findings did not  
show obvious safety signals

# COVID-19 and Pregnancy



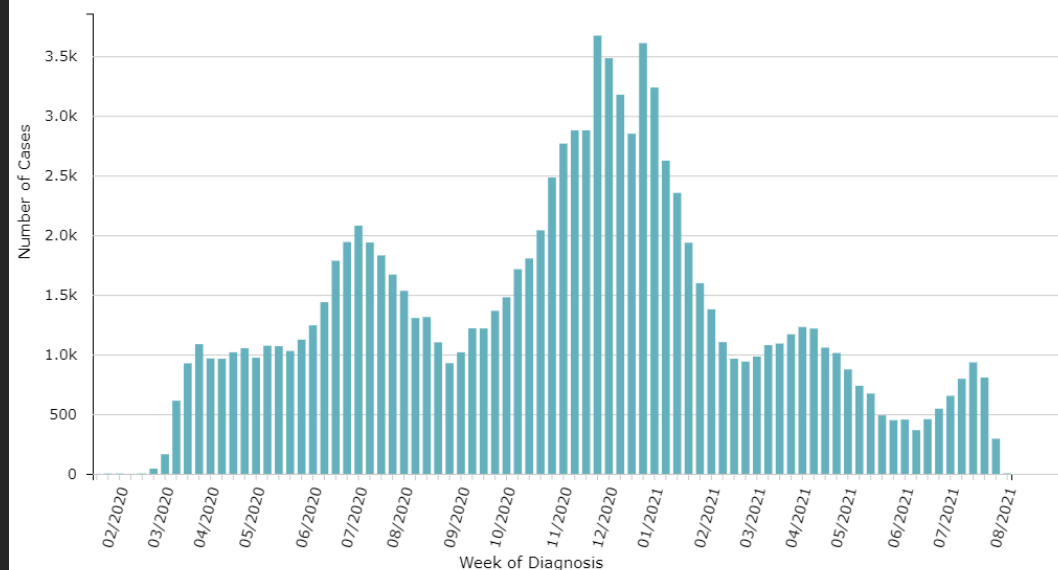
# COVID-19 Infection Risk in Pregnancy

- Increased risk of more severe illness
- Increased risk of ICU admission
- Increased need for mechanical ventilation
- Increased need ventilatory support (ECMO)
- Increased death reported in pregnant women with symptomatic COVID-19 infection

Ellington MMWR 2020, Collin 2020, Delahoy MMWR 2020, Khan 2021, Ellington MMWR 2020, Panagiotakopoulos MMWR 2020, Knight 2020, Zambrano MMWR 2020, Allotey 2020, Metz 2021, Galang 2021

### Cases of COVID-19 among Pregnant Women by Week of Diagnosis\*

Data were collected from 105,645 women and date of diagnosis\*\* was available for 105,645 (100%) women.



\*There is about a 2-4 week delay in the data for a jurisdiction to confirm a case of SARS-CoV-2 in a pregnant woman and report it to CDC.

\*\*Date of diagnosis is derived from the earliest date of either 1) when the case report was received by CDC from a jurisdictional health department or 2) the earliest available date related to the illness or specimen collection.

TOTAL CASES<sup>1</sup>

105,645

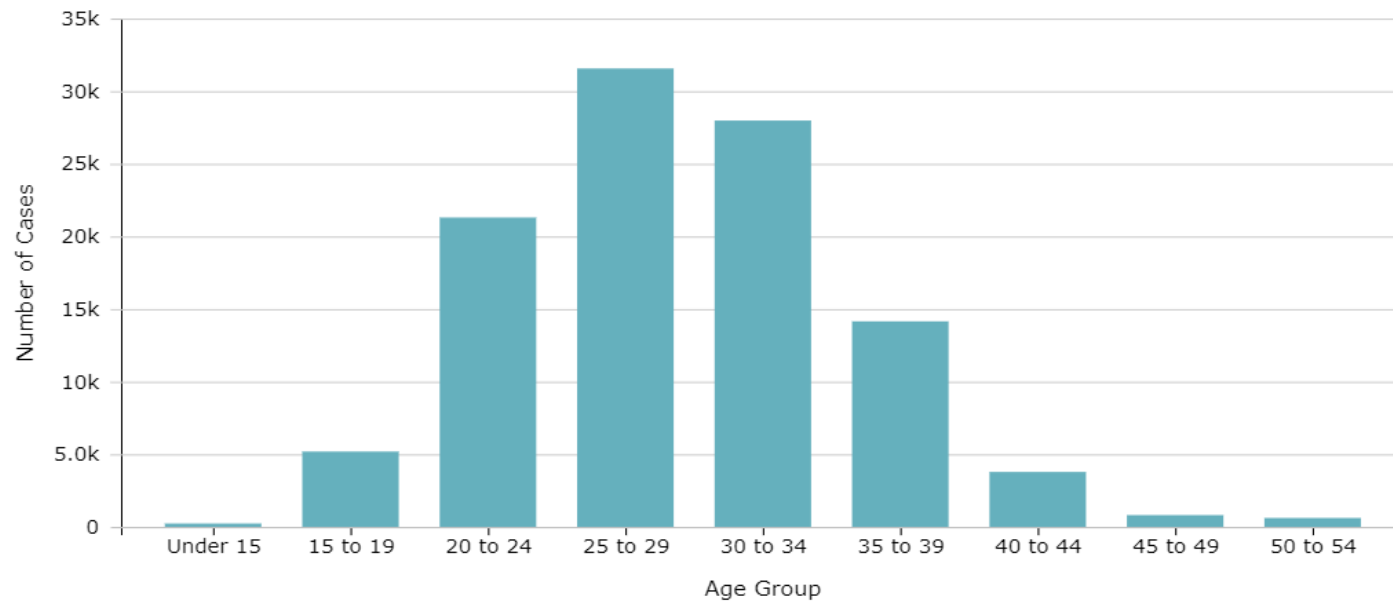
TOTAL DEATHS

124

Pregnant women with  
COVID-19, United States,  
January 22, 2020 - August 9,  
2021

# Pregnant women with COVID-19 by age, United States, January 22, 2020 - August 9, 2021

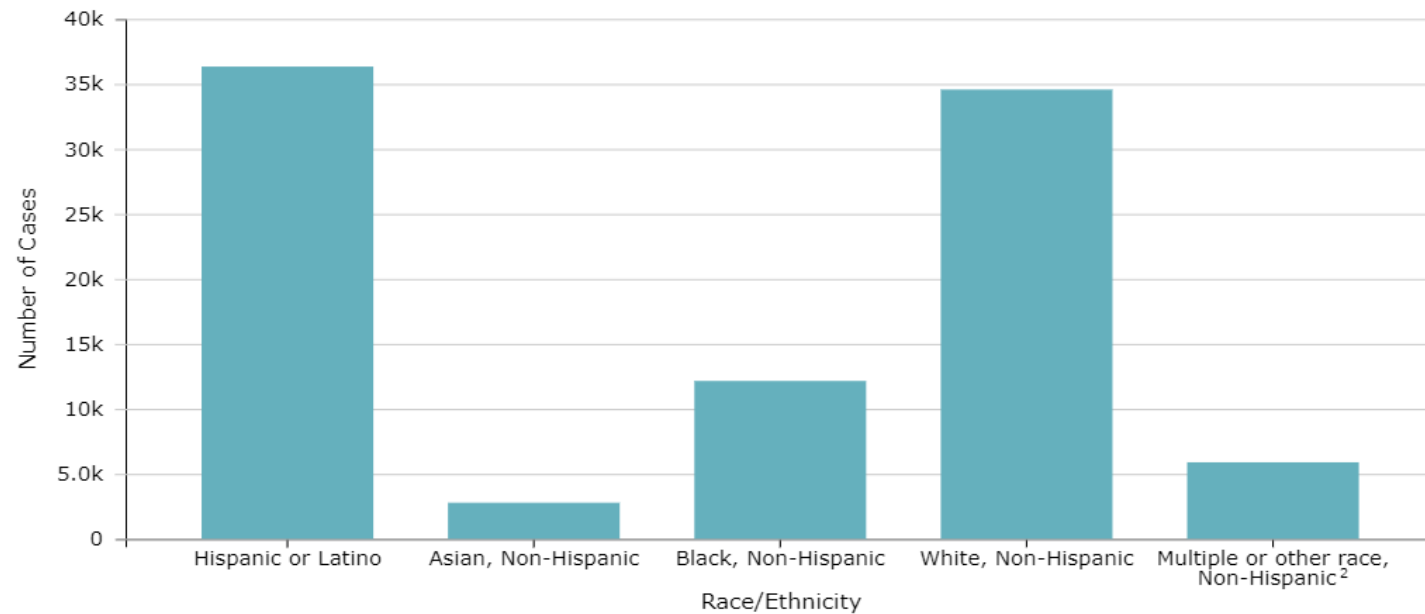
Pregnant women with COVID-19 by age, United States, January 22, 2020 - August 9, 2021  
Data were collected from 105,645 women, and age was available for 105,645 (100%) women.



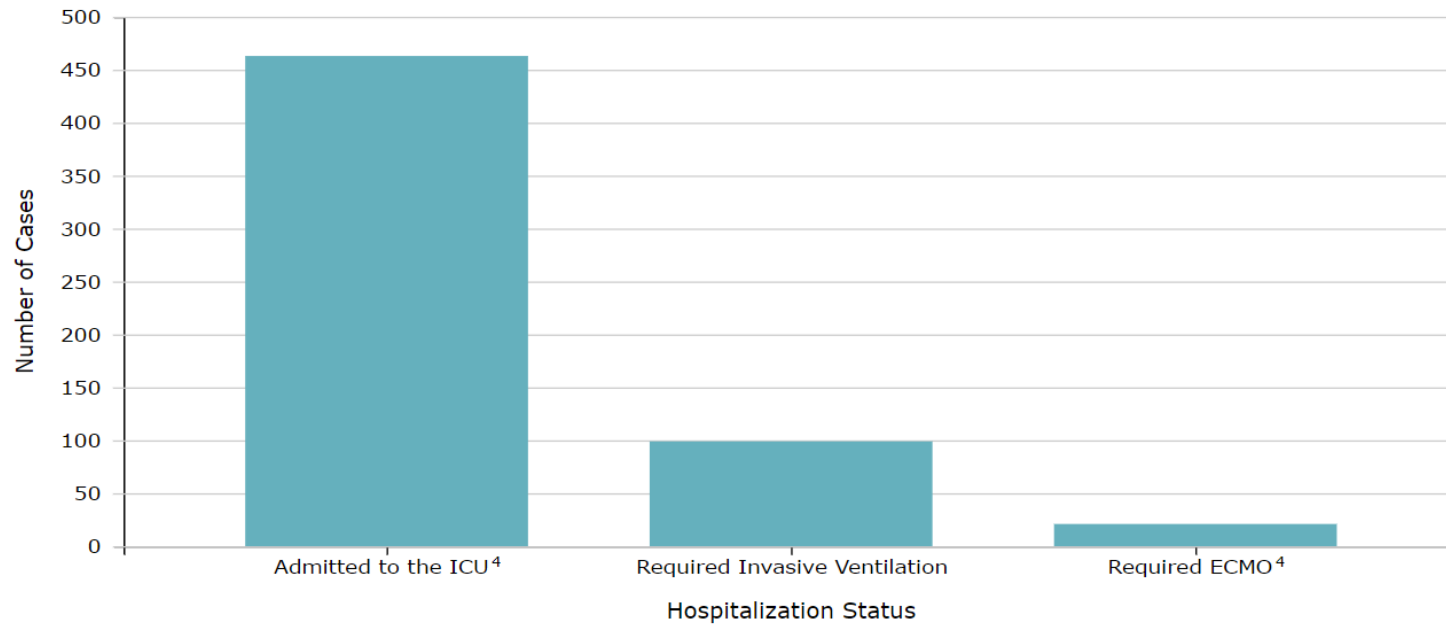


# Pregnant women with COVID-19 by race/ethnicity, United States, January 22, 2020 - August 9, 2021

Pregnant women with COVID-19 by race/ethnicity, United States, January 22, 2020 - August 9, 2021  
Data were collected from 105,645 women, but race/ethnicity was only available for 91,734 (86.8%) women.

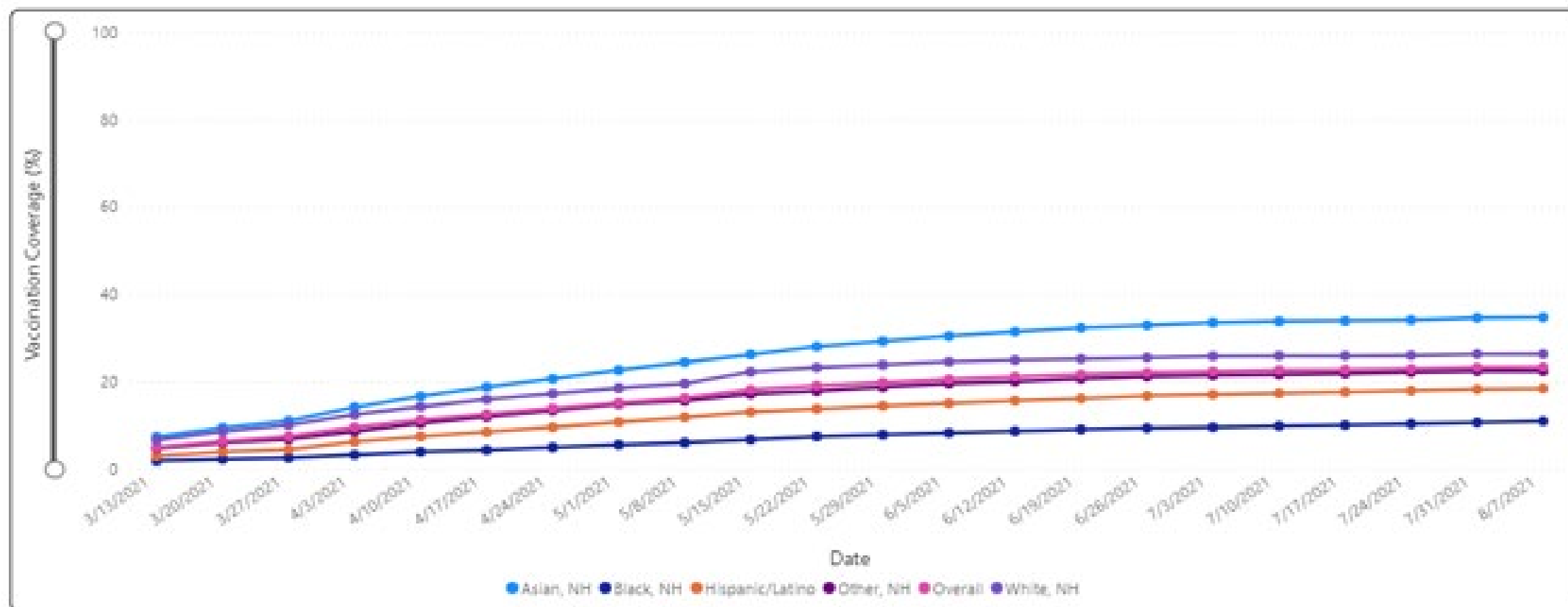


# Pregnant women with COVID-19 admitted to the ICU, who required invasive ventilation, or who required ECMO, United States, January 22, 2020 - August 9, 2021



HOSPITALIZED CASES<sup>3</sup>  
**18,006**

# Percent of Pregnant People Aged 18-49 Years Receiving at Least One Dose of a COVID-19 Vaccine during Pregnancy Overall, by Race/Ethnicity, and Date Reported to CDC — Vaccine Safety Datalink\*, United States December 14, 2020 — August 7, 2021



NH = Non-Hispanic; "Other, NH" race includes American Indian or Alaska Native, Native Hawaiian or Pacific Islander, and Multiple or Other race; Vaccination coverage represents the total number of pregnant people (denominator as of August 7, 2021 = 174,744) who received at least one dose of a COVID-19 vaccine, including either first or second dose of the Pfizer-BioNTech or Moderna vaccines or a single dose of the Johnson & Johnson Janssen vaccine during pregnancy.

Last updated: August 7, 2021

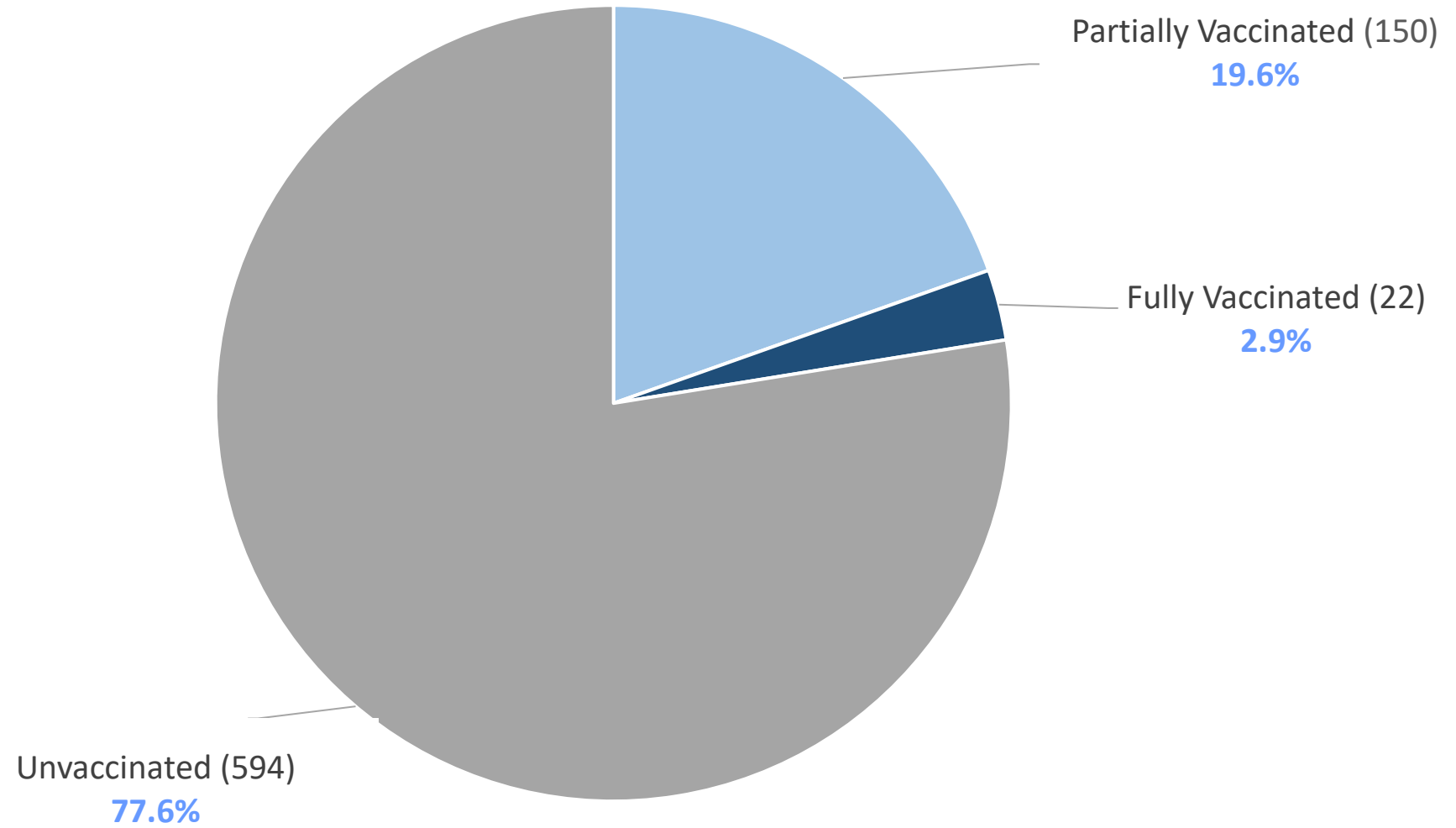
Data source: Vaccine Safety Datalink.

# Pregnant Women in Arkansas-Dashboard

Total Pregnant COVID-19 Cases	Active Pregnant COVID-19 Cases	Deaths Among Pregnant Women due to COVID-19
<b>2,291</b>  0.57% of all COVID-19 cases are among pregnant women (2,291 / 405,272)	<b>59</b>  0.26% of active COVID-19 cases are among pregnant women (59 / 22,815)	<b>&lt; 5</b>  Less than 5 deaths due to COVID-19 are among pregnant women (Total deaths due to COVID-19: 6,322)

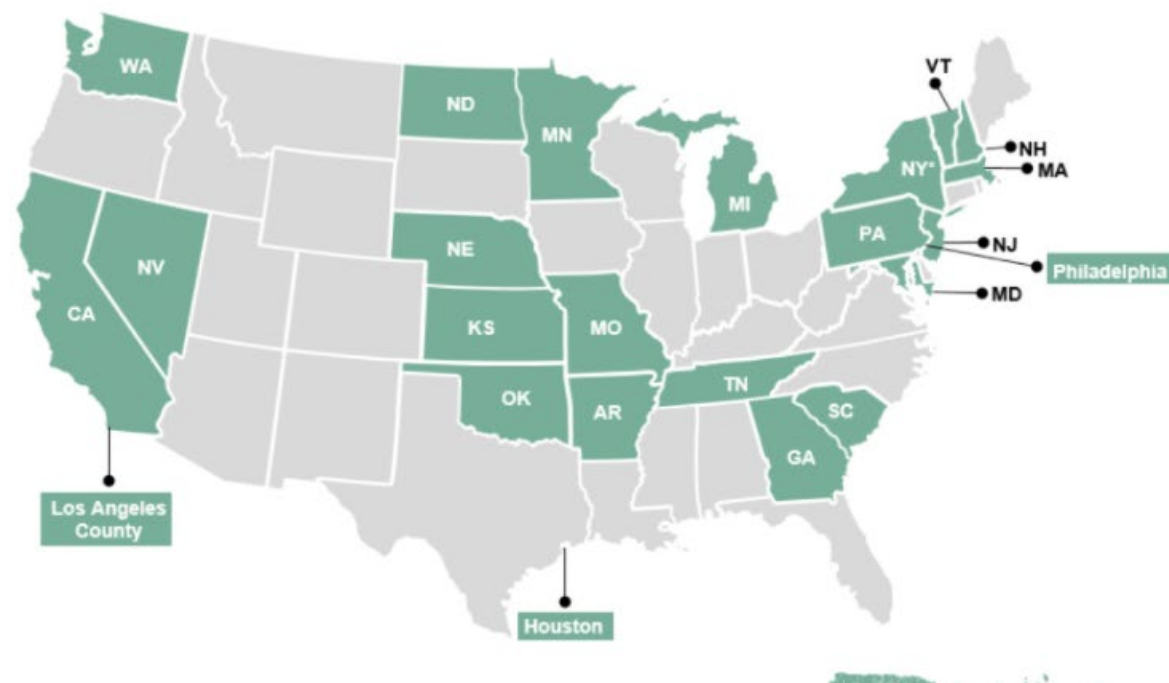
Ever Hospitalized for COVID-19	Ever Intubated for COVID-19
<b>67</b>  4.67% of hospitalizations due to COVID-19 are among pregnant women (67 / 1,435)	<b>5</b>  1.70% of COVID-19 cases intubated are among pregnant women (5 / 294)

## Vaccination Status of Pregnant COVID-19 Cases, Arkansas, 2021



# COVID-19 during Pregnancy: Birth and Infant Outcomes

Map of Jurisdictions Reporting Birth and Infant Outcome Data as of July 2021





# American College of Obstetricians and Gynecologists

## Summary of Key Information and Recommendations

- Obstetrician-gynecologists and other women's health care practitioners should lead by example
  - By being vaccinated & encouraging eligible patients to be vaccinated
- Pregnant & lactating individuals be vaccinated against COVID-19
- ACOG recommends vaccination for all eligible people who may consider future pregnancy
- Vaccine may occur in any setting authorized to administer these vaccines
- Pregnancy testing is not a requirement prior to receiving any EUA-approved COVID-19 vaccine.
- For patients who do not receive the vaccine, the discussion should be documented in the patient's medical record
- Expected side effects should be explained as part of counseling patients
  - Rare risk of TTS after Janssen vaccine and that over vaccines are available
- COVID-19 vaccines may be administered simultaneously with other vaccines, including within 14 days of receipt of another vaccine. This includes vaccines routinely administered during pregnancy, such as influenza and Tdap.

[https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care?utm\\_source=redirect&utm\\_medium=web&utm\\_campaign=int](https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care?utm_source=redirect&utm_medium=web&utm_campaign=int)





## CDC Update on COVID-19 Vaccination during Pregnancy: Key Messages and Talking Points for Partners

COVID-19 vaccination is recommended for all people aged 12 years and older, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future. Pregnant and recently pregnant people are more likely to get severely ill with COVID-19 compared with non-pregnant people. Getting a COVID-19 vaccine during pregnancy can protect you from severe illness from COVID-19.



# CDC Update on COVID-19 Vaccination during Pregnancy: Key Messages and Talking Points for Partners

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- Based on new evidence about the safety of the COVID-19 vaccines, CDC is strengthening its recommendation for COVID-19 vaccination during pregnancy.
- In a [new analysis](#) of current data from the v-safe pregnancy registry, scientists did not find an increased risk for miscarriage among people who received an mRNA COVID-19 vaccine before 20 weeks of pregnancy.
- Additionally, previous findings from three safety monitoring systems did not find any safety concerns for pregnant people who were vaccinated late in pregnancy or for their babies.
- Growing evidence about the safety and effectiveness of COVID-19 vaccination during pregnancy demonstrates that the benefits of receiving a COVID-19 vaccine outweigh any known or potential risks.
- COVID-19 vaccination is recommended for all people 12 years and older, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future.
- The increased circulation of the highly contagious Delta variant, the low vaccine uptake among pregnant people, and the increased risk of severe illness and pregnancy complications related to COVID-19 infection among pregnant people make vaccination for this population more urgent than ever.

# Getting Vaccinated is a Personal Choice

## **Key considerations you can discuss:**

- How likely you are to being exposed to the virus
- Risks of COVID-19 to you and the potential risks to your fetus or infant
- What is known about COVID-19 vaccines
- How well they work to develop protection in the body
- Known side effects of vaccination
- Acknowledge limited, but growing, information on the safety
- Vaccination might pass antibodies to the fetus.

# Health Equity Considerations

## **When discussing COVID-19 vaccines with an individual who expresses concerns**

- Be aware of historical and current injustices
- Actively listen to and validate expressed fears and concerns
- Be knowledgeable of avenues for vaccine access in traditionally underserved communities
- Continue to support patients who decide not to be vaccinated, share resources, and encourage the continued use of prevention measures

## **If the patient is amenable to further discussion**

- Inform about the testing process, existing safety data and continued monitoring of safety
- There have not been shortcuts with the testing of this vaccine
- Increased incidence of infection and severe illness from COVID-19 in communities of color
- Individuals from communities of color were included in clinical trials
- Equally effective among different demographics, including race and ethnicity

# Additional Resources

- **CDC Vaccination Considerations for People who are Pregnant or Breastfeeding**  
<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html>
- **Baystate Health & University of Massachusetts Medical School COVID-19 Vaccine Decision Tool**  
<https://foamcast.org/covidvacpregnancy/?fbclid=IwAR35gMR8Tdx-qEC2CBGAfNYiTMERhw7W-x0eGjABEh8eqODTujv49bkuzwE>
- **Frequently Asked Questions about COVID-19 Vaccination**  
<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>
- **CDC's Talking to Recipients about COVID-19 Vaccines**  
<https://www.cdc.gov/vaccines/covid-19/hcp/index.html>



**Protect yourself  
and your baby  
from COVID-19.  
Get vaccinated.**



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

Thank You

