# Ashe County School District Community Seminar

Uniting science and schools for a data-driven solution to decision making and implementation

September 20, 2021

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#### Meet the ABC Science Collaborative

- The ABC Science Collaborative is an initiative that extends across 18 states, connecting scientists and physicians with school and community leaders to help understand the most current and relevant information about COVID-19.
- The program helps school leaders make informed decisions about safety within the school setting using data from their own communities.
- **Ultimate goal:** keep teachers, children, and their local communities healthy and safe
- The ABC Science Collaborative is coordinated by the Duke Clinical Research Institute at the Duke University School of Medicine and UNC School of Medicine; it is funded through grants from the National Center for Advancing Translational Sciences, the National Institutes of Health, and the Food and Drug Administration.
- The ABC SC does not receive funding from NC school districts





The information presented here is the most up-to-date, datadriven and evidence-based science to help school districts make important decisions regarding face-to-face instruction. Duke University and its partners will not make decisions nor will they advise specific action.



#### Overview

COVID-19 Cases in the US and NC

Increase in Cases and Hospitalizations in Children

North Carolina Hospitals and Pediatric Intensive Care Units (ICUs)

- SARS-CoV-2/COVID-19 Vaccination Update
  - Address common questions

#### SARS-CoV-2 or COVID-19 Pandemic

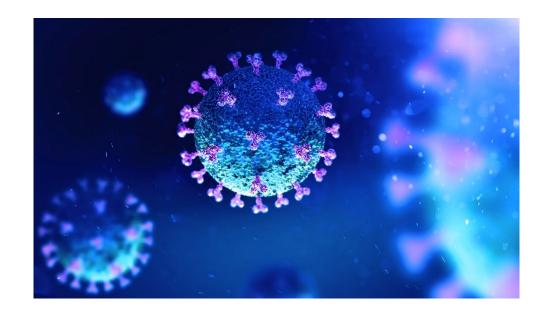
- Once a century (hopefully) Pandemic
  - Unprecedented times for everyone

- Goal to keep children in school and health so they can learn and reap all the benefits of in-person schooling
  - avoid other effects on children seen during the pandemic, partly associated with virtual learning
  - including increased obesity, anxiety, depression, suicide attempts, suicides, and sense of isolation

#### COVID-19 Pandemic continues to take its Toll

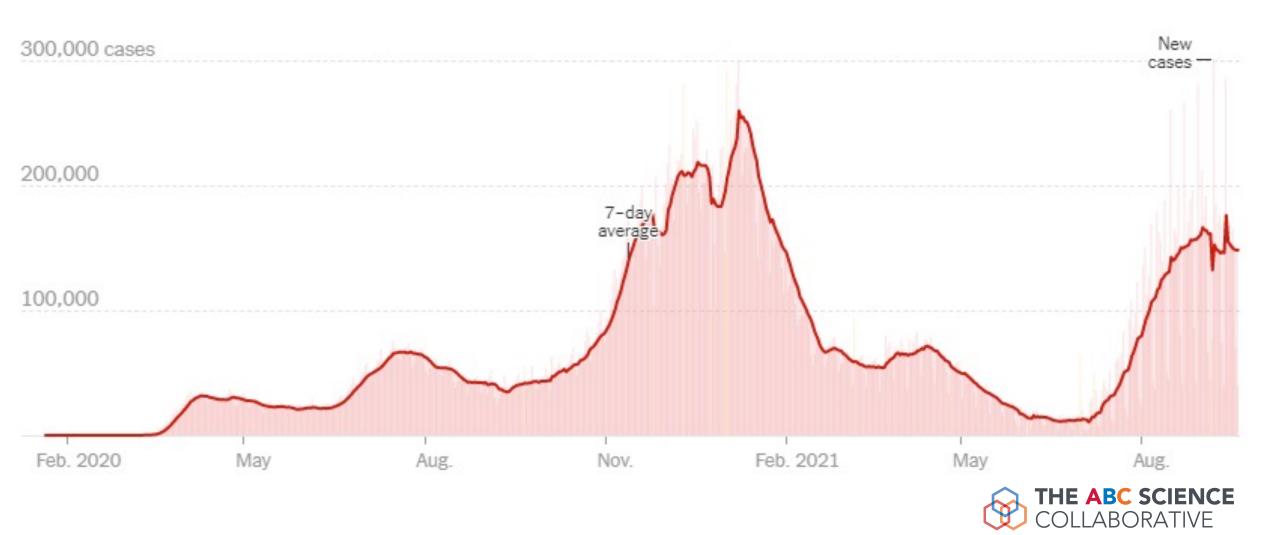
• 41.9 million infected in the US since January 2020

- COVID-19 has killed
  - > 4.5 million people worldwide
  - 670, 565 people in the US
  - 1 in 500 Americans has died of Covid-19

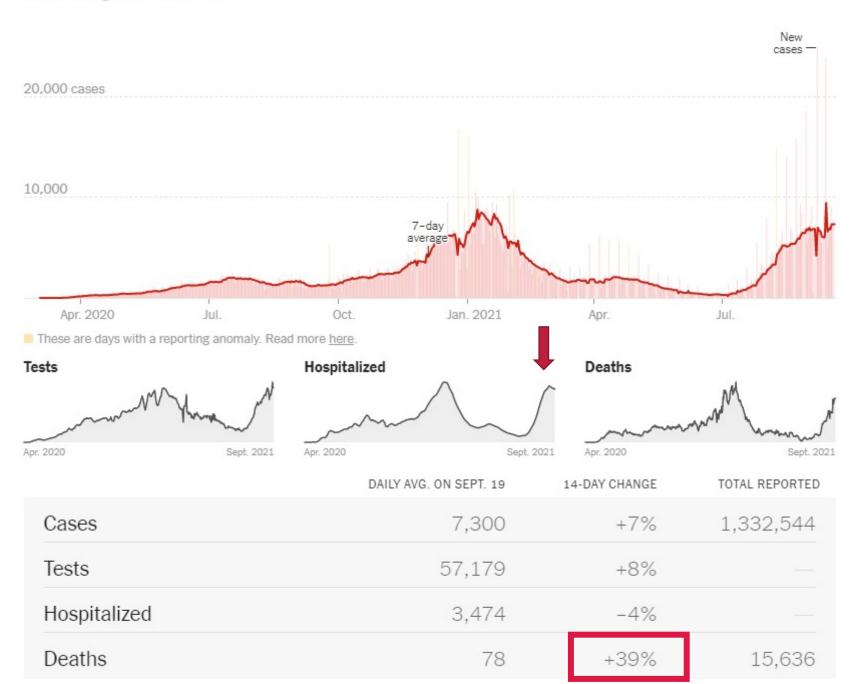


#### **Trends in Daily COVID-19 Cases & Deaths in US, 2/2020 – 9/20/2021**

#### New reported cases



#### New reported cases (North Carolina)



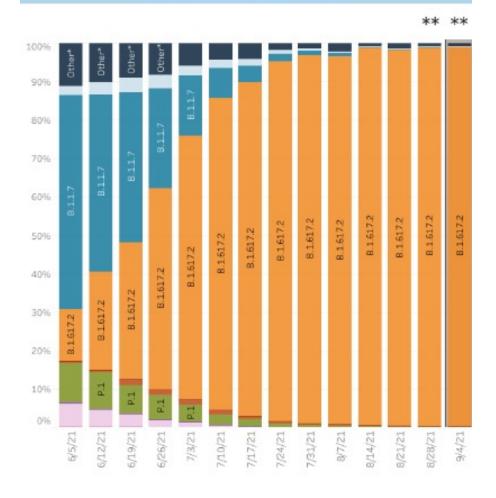
#### COVID-19 Cases, Hospitalizations and Deaths in NC, 4/2020 – 9/20/2021



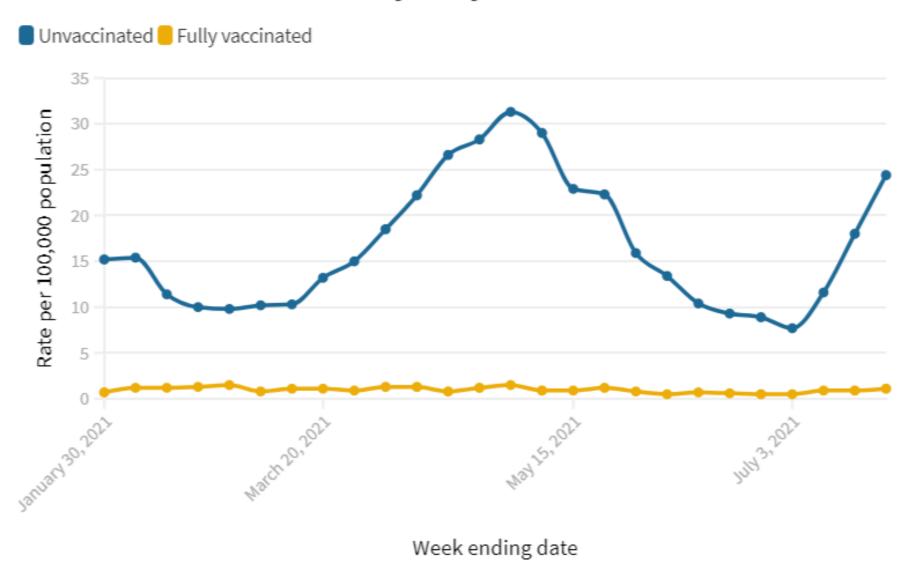
## WHAT'S DRIVING THE RECENT INCREASE IN COVID-19?

- Exponential increase in Delta variant, which is highly contagious, more easily transmitted than prior strains, more aggressive virus, decreased protection from vaccines for symptomatic infection (but good protection against severe disease)
- Elimination of mask mandates in many locales
- Vaccine hesitancy
- Holidays (Memorial Day, 4th of July, Labor Day) and resumption of Fall activities
- Breakthrough infections in fully vaccinated individuals also plays a role
- Studies report Delta variant causes more severe disease

#### United States: 5/30/2021 - 9/4/2021



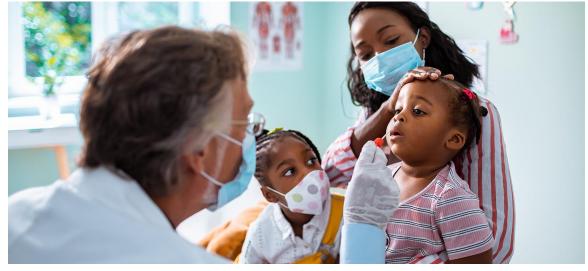
### Weekly rates of U.S. COVID-19 hospitalizations of adults by vaccination status, January–July 2021



Source: F.P. Havers et al/medRxiv.org

## Children and COVID-19 Disease: American Academy of Pediatrics (AAP) Data Report (9/9/21)

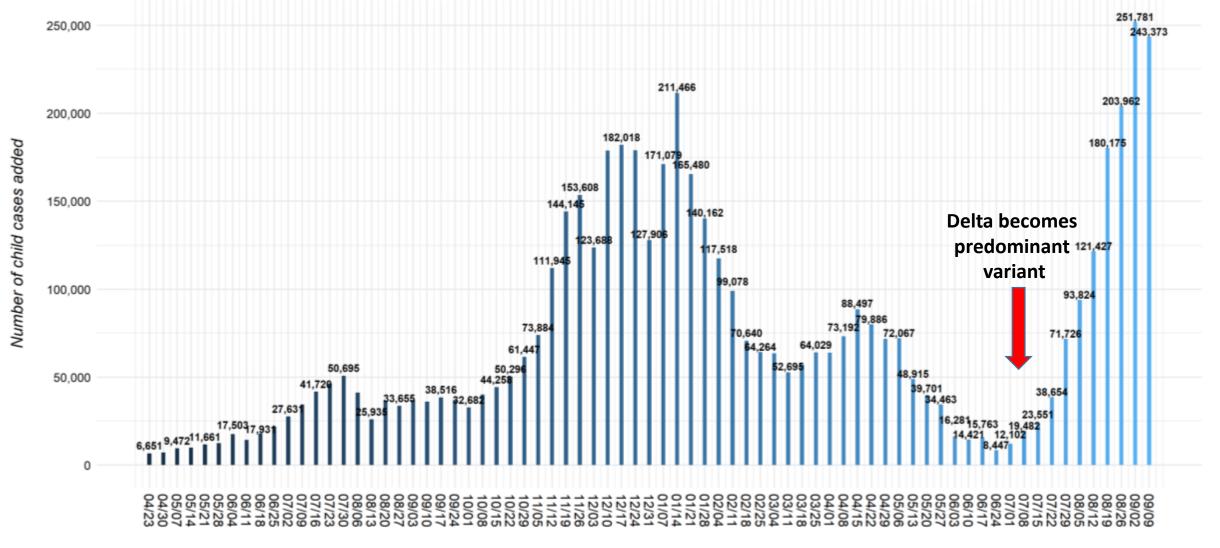
- >5.2 million children have tested positive for COVID-19 since pandemic onset
- In recent weeks, children account for increasing proportion of COVID cases
  - 28.9% of COVID cases, compared to 15.5% in pandemic overall
  - 240% increase in pediatric cases since July
- Pediatric cases steadily increasing
  - >243,000 cases in prior week, 2<sup>nd</sup> highest number of child cases in a week since pandemic began
  - Although the majority of children don't require hospitalization, CDC is reporting marked increases in pediatric hospitalizations



AAP. (9/2/21). Children and covid-19: State-level data report. Children and COVID-19: State-Level Data Report. <a href="https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/">https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/</a>



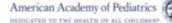
#### Number of New Child COVID-19 Cases in Prior Week, through 9/9/21



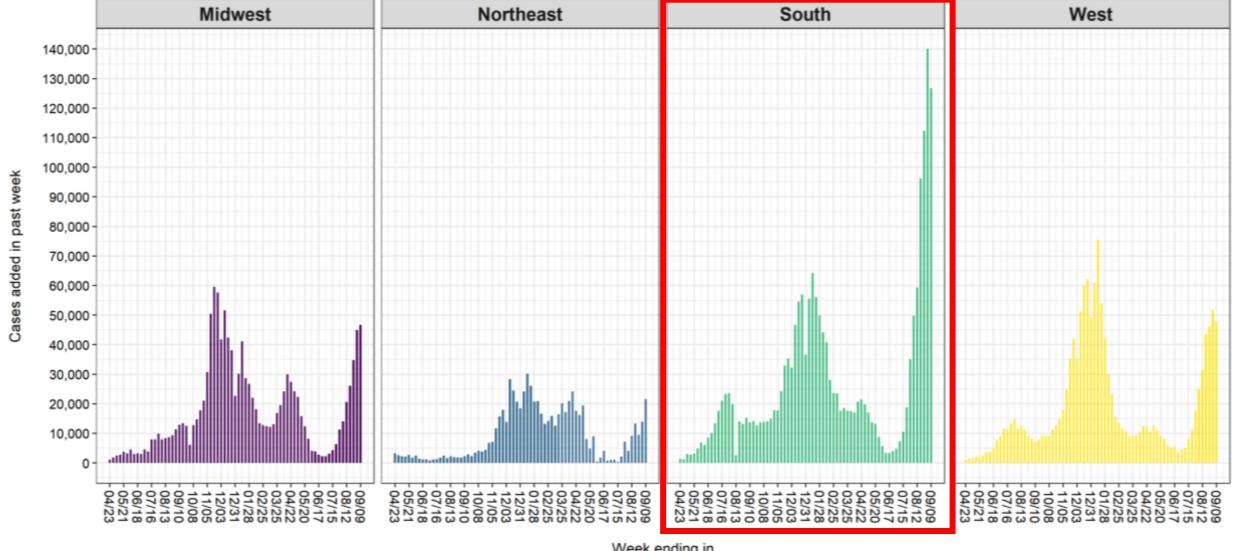
#### Week ending in

\* Note: 5 states changed their definition of child cases: AL as of 8/13/20, HI as of 8/27/20, RI as of 9/10/20, MO as of 10/1/20, WV as of 8/12/21 TX reported age for only a small proportion of total cases each week (eg, 3-20%); TX cumulative cases through 8/26/21 As of 6/30/21, NE COVID-19 dashboard is no longer available; NE cumulative cases through 6/24/21 Due to available data and changes made to dashboard, AL cumulative cases through 7/29/21 Due to available data and calculations required to obtain MA child cases, weekly estimates fluctuate See detail in Appendix: Data from 49 states, NYC, DC, PR and GU





#### Child COVID-19 Cases each week by Region, marked increase in South



Week ending in

5 states changed their definition of child cases: AL as of 8/13/20, HI as of 8/27/20, RI as of 9/10/20, MO as of 10/1/20, WV as of 8/12/21;

TX reported age for only a small proportion of total cases each week (eg. 3-20%); TX cumulative cases through 8/26/21

As of 6/30/21, NE COVID-19 dashboard is no longer available; NE cumulative cases through 6/24/21

Due to available data and changes made to dashboard, AL cumulative cases through 7/29/21

Due to available data and calculations required to obtain MA child cases, weekly estimates fluctuate

See detail in Appendix: Data from 49 states, NYC, DC, PR and GU All data reported by state/local health departments are preliminary and subject to change; Analysis by American Academy of Pediatrics and Children's Hospital Association





<sup>\*</sup> Note: Regions are the US Census Regions

#### Trends in New COVID-19 Hospitalizations in Children Ages 0–17 yrs, CDC







### Hospitalizations Associated with COVID-19 Among Children and Adolescents — COVID-NET, 14 States, 3/01/20 – 8/14/21

Increasing COVID-19 hospitalizations among U.S. children and adolescents since the rise of the Delta variant\*

Hospitalizations among ages 0-4



Hospitalizations among unvaccinated adolescents

10x higher

than fully vaccinated

#### PREVENT COVID-19 AMONG CHILDREN

Everyone ages 2 and up:

Wear a mask in public indoor spaces, schools, and childcare centers



Everyone ages 12 and up: Get vaccinated

\* During June 20-August 14, 2021

bit.ly/MMWR9321b

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- COVID-19 can cause severe illness in children and youth
- COVID—associated hospitalization rates rose nearly 5fold among children and adolescents from late June to mid-Aug '21, coinciding with increase in the highly transmissible Delta variant
- Hospitalization rates were 10 times higher among unvaccinated than fully vaccinated adolescents
  - **Preventive measures** to reduce transmission and severe outcomes in children and adolescents are critical:
    - Vaccination
    - Universal masking in schools
    - Masking in ≥2 yr olds in indoor public spaces



### Increasing Child COVID Hospitalizations Filling Pediatric ICUs in NC Triangle Hospitals and through the South



Sessoms, B. (2021, August 30). Increasing child COVID hospitalizations filling pediatric ICUs, Triangle hospitals say. Coronavirus. https://www.heraldsun.com/news/coronavirus/article253777613.html?

- As COVID-19 cases surge in NC, children are being admitted with SARS-CoV-2 and other respiratory diseases
- Pediatric intensive care units are full in many areas in the South
- The number of children with COVID-19 who require intensive care is still relatively low but those in ICUs are quite sick
- Health professionals encourage all school staff and older students to get vaccinated to protect younger children who are not eligible.



#### **SARS-CoV-2 Vaccination Updates**



## Vaccination against COVID-19 is Recommended for All who are Eligible

Vaccination is **the leading public health prevention strategy** to end the COVID-19 pandemic.

People who are fully vaccinated against COVID-19 are at low risk of symptomatic or severe illness, including hospitalization or death.

NCDHHS StrongSchoolsTookit: Achieving high levels of COVID-19 vaccination among eligible students as well as teachers, staff, and household members is one of the most critical strategies to help schools safely resume full operations.

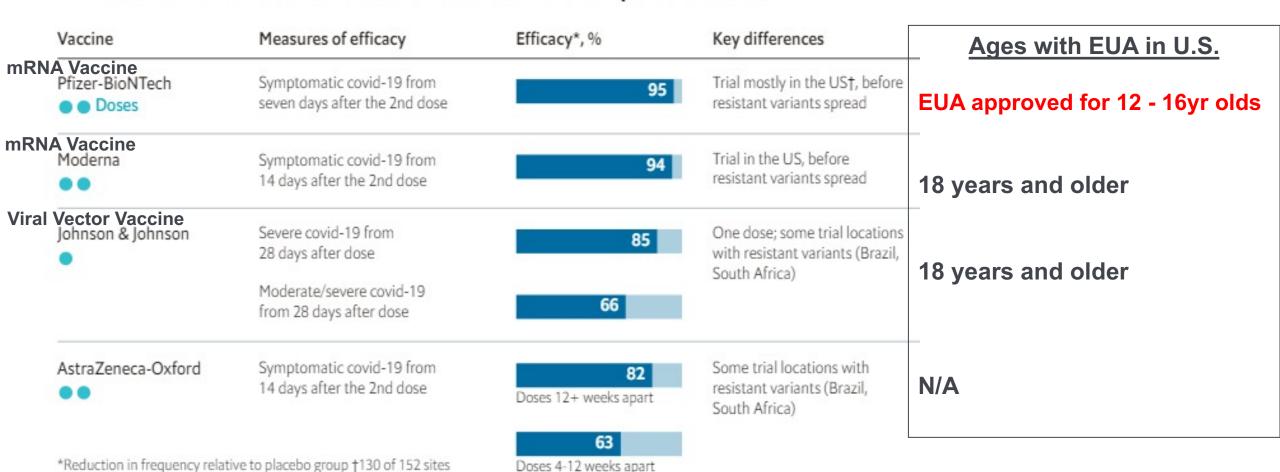




#### Four SARS-CoV-2 Vaccines Compared

MAR 6TH 2021

#### → Trials of covid-19 vaccines are too different to have comparable results





New data show that leading covid-19 vaccines have similarly high efficacy

Publication: The Economis

Publisher: The Economist Group Limited

Date: Mar 6, 2021

## COVID-19 VACCINES: Advisory Committee on Immunization Practices (ACIP) Update, 8/31/2021

- The Pfizer vaccine received Full FDA approval for ages 16 and over (8/23/21)!!
- The Pfizer vaccine has received FDA authorization (EUA) for the following\*:
  - 2-dose series for adolescents 12 15+ years old (May 2021)
  - Additional (3<sup>rd</sup>) dose for individuals >12 years old who are immunocompromised
- No change in FDA EUAs or CDC recommendations for the Moderna or J&J vaccines



#### **SARS-CoV-2 Vaccination in the US**

**5.95 billion** vaccinations administered globally On 9/19/21, CDC indicated in US:

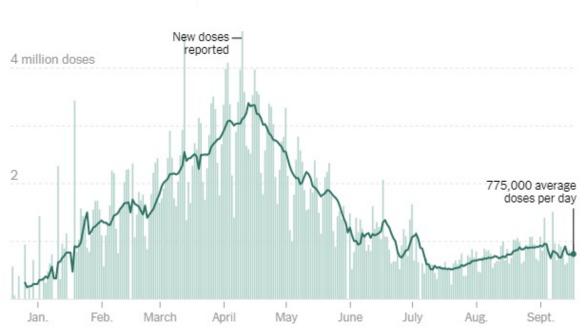
>385 million vaccinations administered

>211 million people have received one vaccine dose (~64% total population; 75% > 12yo)

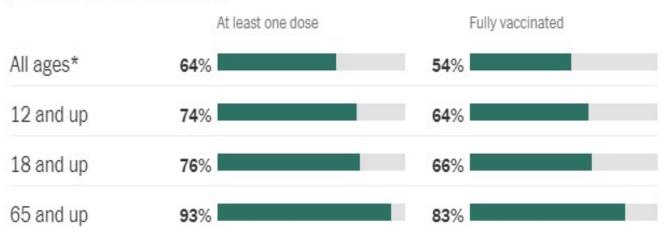
>181 million fully vaccinated (~55% total population; 64% ≥12yo)

New reported doses administered by day

U.S. Total\*



#### United States vaccinations as of 9/17/21



<sup>\*</sup>Includes those not yet eligible for the vaccine.

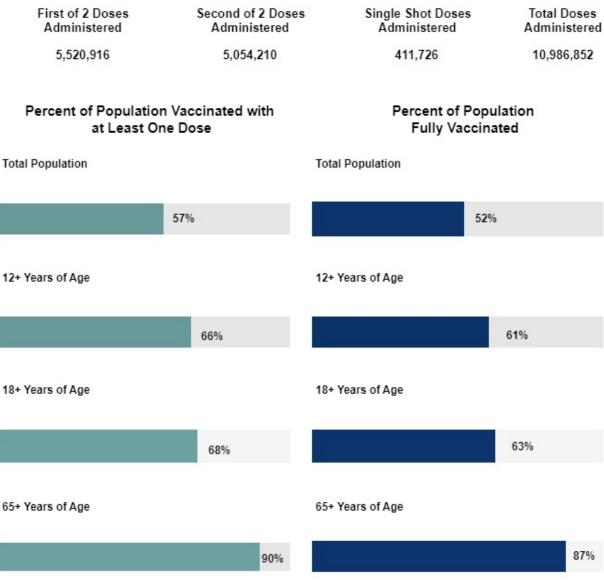
Source: Centers for Disease Control and Prevention | Note: Figures include the U.S. territories and three countries with <u>special agreements</u>.



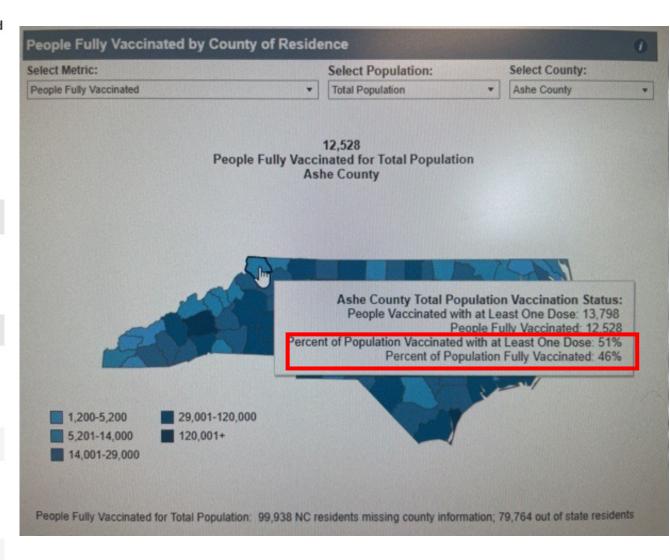
NYT & CDC: updated 9/19/21

#### SARS-CoV-2 Vaccinations in NC & in Ashe County, 9/17/21

#### **North Carolina**



#### **Ashe County, NC**



% Vaccinated by NC County: https://covid19.ncdhhs.gov/dashboard/vaccinations

#### Vaccination Rates:

- In the US, only 55% of the population is fully vaccinated
  - 64% of those eligible for vaccine are fully vaccinated
- In Ashe County 46% are fully vaccinated

## What are the commonly reported Side Effects from the mRNA Vaccines (Pfizer-BioNTech & Moderna)?

- Injection site reaction (84%)
- Fatigue
- Headache
- Muscle pain
- Chills
- Joint pain
- Fever (14%)
- Nausea
- Last 1-2 days

#### Side Effects and Events after the Vaccine

#### Side effects:

- More common after 2<sup>nd</sup> dose
- Less side effects seen in those >65 years old
- Normal part of body's reaction to the vaccine related to the immune system responding to the vaccine and indicates development of a protective response against COVID!

#### mRNA vaccine and safety





#### Vaccinations against SARS-CoV-2

COVID-19 mRNA vaccines (Pfizer and Moderna) are safe and effective.

- >203 million people in the US have received COVID-19 vaccines under the most intense safety monitoring in US history
- CDC, FDA, and others continue to monitor the safety of COVID-19 vaccines, and all vaccines.
- A few signals noted and evaluated in detail

**Resulted in reports of Rare Serious Adverse Events** – and found safe to continue using the vaccines:

- Severe allergic reaction, or anaphylaxis, after COVID vaccination is rare (2 5 per million vaccinated in the US). Severe allergic reactions can occur after any vaccination. If this occurs, vaccination providers can effectively and immediately treat the reaction.
  - All vaccine recipients observed for 15 minutes, longer if allergic to injectable medicines
- No reports of death after mRNA COVID-19 vaccination. More than 380 million doses of COVID-19 vaccines administered in the US from 12/1420, through 9/13/21. No deaths in the US have been linked to the mRNA vaccines as of September 13, 2021 report.
- Myocarditis and pericarditis (inflammation of the heart muscle or outer heart lining) after COVID-19 vaccination are rare. Most cases were seen in teen and young adult males, more often after the 2<sup>nd</sup> dose. Most with mild symptoms, recover quickly with rest and medications.

#### Myocarditis/Pericarditis from COVID-19 Disease

- The known risks of COVID-19 illness and its related, possibly severe complications (such as long-term health problems, hospitalization, and even death), far outweigh the potential risks of having a rare adverse reaction to vaccination, including the possible risk of myocarditis or pericarditis.
- According to the CDC: for each one million 2<sup>nd</sup> doses of mRNA COVID-19 vaccine administered to males 12–29 years old, they prevent
  - 11,000 COVID-19 cases
  - 560 hospitalizations
  - 138 ICU admissions
  - 6 deaths due to COVID-19

#### With actual COVID-19 disease:

- ~12 to 20% of COVID-19 hospitalized patients have heart injury
- ~1% to 3% of young athletes have evidence of myocarditis from COVID disease
- COVID-19 can also cause a multisystem inflammatory syndrome (MIS-C) in children & adolescents, after acute infection.
  - Although uncommon, MIS-C causes a dramatic inflammatory state involving many organs, including the heart
- Therefore, the CDC continues to recommend that everyone ≥12 years old get vaccinated against COVID-19

#### What about possible Long-term Side Effects?

#### **Long-Term Side Effects are very Unlikely**

- Serious side effects that could cause a long-term health problem are extremely unlikely following any vaccination, including COVID-19 vaccination.
- Vaccine monitoring has historically shown side effects generally happen within 6 weeks of receiving a vaccine dose.

Overall very reassuring vaccine safety and protection profiles

#### How do we know vaccines are safe?

- 1. Clinical trials
- 2. Long-standing post-licensure systems to monitor safety
  - Vaccine Adverse Event Reporting System (VAERS) For public awareness and in the interest of transparency, CDC provides timely updates on events of interest and tracks via <u>VAERS</u>
  - Vaccine Safety Datalink (VSD)
  - Clinical Immunization Safety Assessment (CISA)
  - V-Safe:



## Should I or my Child get vaccinated against COVID-19?

#### Yes.

- CDC recommends that everyone aged 12 years and older be vaccinated against COVID-19.
- The known risks of COVID-19 illness and its related, possibly severe complications, such as long-term health problems, hospitalization, and even death, far outweigh the potential risks of having a rare adverse reaction to vaccination.

• Let's talk about why – how well do the vaccinations work?

### COVID-19 Vaccines prevent Disease, Hospitalization and Death from COVID-19 Disease

 Currently >670,000 Deaths from COVID-19 Disease in the US

- All COVID-19 vaccines currently approved or authorized in the US (Pfizer, Moderna, and Janssen/J&J) are effective against COVID-19 disease, including against severe disease, hospitalization, and death in adults
  - And Pfizer vaccine was dramatically protective against symptomatic COVID-19 in 12-17 year olds

- COVID-19 vaccination remains highly effective in preventing COVID-19 serious disease, hospitalizations and deaths caused by the variants, including Alpha, Beta, Gamma and Delta
- Vaccines remain effective in largely preventing infection when Delta is predominant strain, but somewhat less effective with Delta than prior strains
- Vaccinated people had a 59% reduced risk of getting symptomatic Delta disease compared to unvaccinated
- Overall mRNA vaccine effectiveness against hospitalization among vaccinated adults remains relatively stable at 88 - 95%
- Fully vaccinated persons less likely to acquire SARS-CoV2 than unvaccinated individuals
  - Also less likely to transmit virus than unvaccinated
  - COVID-19 vaccines also reduce asymptomatic infection but vaccinated individuals seem to be able to transmit the highly replicating Delta variant to others

## Infections and Hospitalizations Among Persons Aged ≥16 Years, by Vaccination Status

- Vaccines REMAIN HIGHLY EFFECTIVE AGAINST COVID-19
- 43,127 SARS-CoV-2 infections in residents of Los Angeles County, California, from 5/1/21-7/25/21
- On July 25, infection and hospitalization rates among unvaccinated persons were 5 and 29 times, respectively, those in fully vaccinated persons.
- Efforts to enhance COVID-19 vaccination coverage, in coordination with other prevention strategies, are critical to preventing COVID-19—related hospitalizations and deaths

A July 2021 study of Los Angeles, CA public health records found...

Unvaccinated have

**5X** 

more COVID-19 infections than fully vaccinated Unvaccinated have

29X

more COVID-19 hospitalizations than fully vaccinated



Get vaccinated to reduce spread and protect yourself

MMWR



Trends in COVID-19 Cases, Emergency Dept Visits, and Hospital Admissions among Children and Adolescents, 0–17 yrs old in US, Aug 2020–Aug 2021



## After Delta became the most common variant,\* fully vaccinated people had reduced risk<sup>†</sup> of...

INFECTION

**5X** 

HOSPITALIZATION

>10X

DEATH

>10X



Vaccination offers strong protection against COVID-19

bit.ly/MMWR91021

\* June 20-July 17, 2021

Compared with people not fully vaccinated

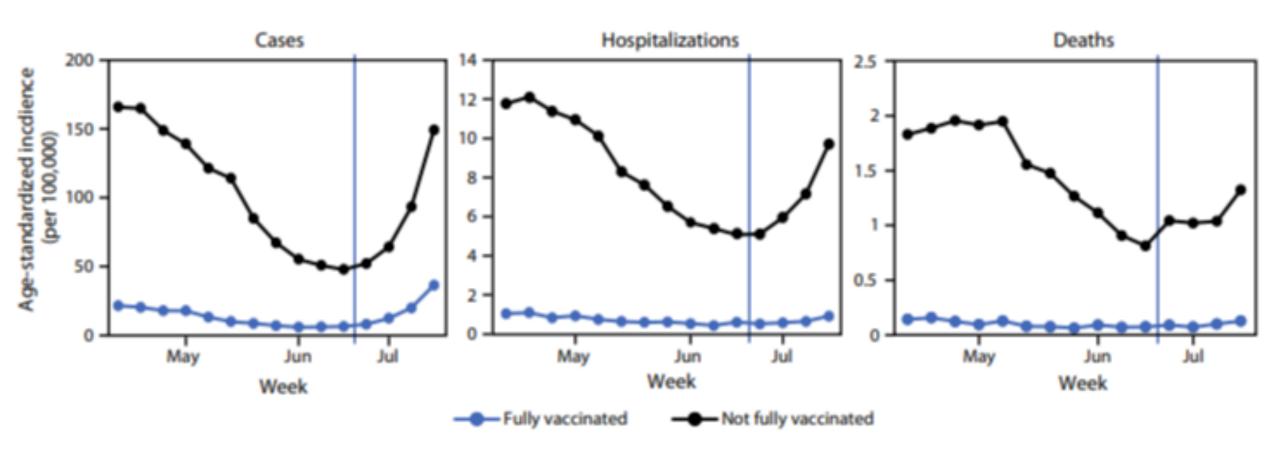


Scobie HM, Johnson AG, Suthar AB, et al. Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status — 13 U.S. Jurisdictions, April 4–July 17, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1284–1290. DOI: http://dx.doi.org/10.15585/mmwr.mm7037e1

# Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status - 13 U.S. Jurisdictions, 4/4/21 - 7/17/21

- Incidence of SARS-CoV-2 infection, hospitalization, and death is higher in unvaccinated than vaccinated persons
- Rates for hospitalization and death changed relatively little after the SARS-CoV-2 Delta became predominant, suggesting continued vaccine effectiveness against severe COVID-19
- Getting vaccinated decreases risk of severe illness from COVID-19, including the Delta variant.

## Markedly Increased COVID-19 Cases, Hospitalizations and Deaths in Unvaccinated vs Vaccinated Individuals 13 US Jurisdictions between April 4 – July 17, 2021



Scobie HM, Johnson AG, Suthar AB, et al. Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status — 13 U.S. Jurisdictions, April 4–July 17, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1284–1290. DOI: <a href="http://dx.doi.org/10.15585/mmwr.mm7037e1">http://dx.doi.org/10.15585/mmwr.mm7037e1</a>

## Among U.S. adults without immunocompromising conditions, vaccine effectiveness against COVID-19 hospitalization was:

93%

for the

Moderna vaccine

88%

for the Pfizer-BioNTech vaccine 71%

for the Johnson & Johnson vaccine



#### Let's discuss some of the Myths regarding COVID-19 Vaccines

- MYTH: The COVID-19 vaccine can make you infertile or affect your fertility.
- MYTH: If I've already had COVID-19, I don't need a vaccine.
- MYTH: Researchers rushed the development of the COVID-19 vaccine, so its effectiveness & safety can't be trusted.
- MYTH: The vaccines aren't safe because they were developed quickly.
- MYTH: Getting the COVID-19 vaccine means I can stop wearing my mask and taking coronavirus precautions.
- MYTH: You can get COVID-19 from the vaccines
- MYTH: The side effects of the COVID-19 vaccine are dangerous.
- MYTH: The COVID-19 vaccine changes your DNA.
- MYTH: The messenger RNA technology used to make the COVID-19 vaccine is brand new.
- MYTH: People with suppressed immune systems shouldn't get vaccinated.
- MYTH: If I'm pregnant or breastfeeding, I shouldn't get vaccinated.
- MYTH: The COVID-19 vaccine was developed with or contains controversial substances.
- MYTH: I don't need to get vaccinated because I'm young and healthy
- MYTH: The COVID-19 vaccine was developed to control the general population through microchips or "nanotransducers"

MYTH: If I've already had COVID-19, I don't need a vaccine. What is the benefit of getting vaccinated if I already had COVID-19 disease?

- FACT: People who have had COVID-19 disease benefit from getting vaccinated.
- We don't know how long people are protected from getting COVID after they have had disease, but evidence suggests protection may not last long.
- Previously infected individuals mount a robust immune response following receipt of COVID-19 vaccines
  - Vaccine offers better protection against the variants than natural infection
  - Vaccine after infection gives you higher, more predictable level of protection against the virus
  - Vaccination protects against reinfection
- Due to the severe health risks associated with COVID-19 disease and the fact that re-infection is possible, people are advised to get a COVID-19 vaccine even if they had COVID-19 disease.

### Why not just get COVID-19 disease and not worry about the Vaccine?

- COVID-19 vaccines are highly protective in preventing hospitalization and death
  - One is at risk for severe disease, hospitalization or death when you are infected with the coronavirus
- The risk of reinfection is low in the months after initial infection but increases with time due to waning immunity
- Sequelae from COVID-19 Disease, not seen with vaccination:
  - Many have residual symptoms 6 12 months after having COVID-19 disease
  - "Long COVID" can occur after disease, and symptoms include fatigue, shortness of breath, "brain fog," depression, and other symptoms
  - Children at risk for MIS-C after infection

Myth: The COVID-19 vaccine is not safe because it was rapidly developed and tested, so its effectiveness and safety cannot be trusted.

## Myth: The COVID-19 vaccine is not safe because it was rapidly developed and tested, so its effectiveness and safety cannot be trusted.

- **FACT:** The emergency situation warranted an emergency response but that does not mean companies bypassed safety protocols or didn't perform adequate testing.
- Studies demonstrated the 2 initial vaccines were both ~95% protective against severe disease from the original strain and reported no serious or life-threatening side effects. There are many reasons why the COVID-19 vaccines could be developed quickly. Here are a few:
- Many pharmaceutical companies invested significant resources into developing a COVID-19 vaccine because of the pandemic's world-wide impact
- The COVID-19 mRNA vaccines (Pfizer/BioNTech and Moderna) were created with a method that has been in development for years, so the companies could start the vaccine development process early in the pandemic.
- China shared genetic information about the SARS-CoV-2 virus, so scientists could work on vaccines.
- The vaccine developers didn't skip any testing steps, but conducted some of the steps on an overlapping schedule to gather data faster.
- Vaccine projects had plenty of resources, as governments invested in research and/or paid for vaccines in advance.
- Some COVID-19 vaccines were created using messenger RNA (mRNA), which allows a faster approach than the traditional way vaccines are made.
- Social media helped companies find study volunteers willing to help with COVID-19 vaccine research.
- Because COVID-19 is so contagious and widespread, it took less time to see if the vaccine worked for the vaccinated study volunteers.
- Companies began making vaccines early in the process, so some supplies were ready when EUA occurred.
- The FDA first gave emergency use authorization (EUA) to COVID-19 vaccines based on data that the vaccines are safe and effective
  - FDA continues to review trial results before approving or authorizing COVID-19 vaccines for use
- Gregory Poland, MD, an infectious diseases expert and head of Mayo Clinic's Vaccine Research Group, notes vaccines are saving lives, preserving health and preventing more infections. "This is a spectacular human accomplishment. Think of this from 18 months ago or so when this was identified to having hundreds of millions, billions when you look worldwide that have received a vaccine and the speed at which the science has been able to move. Amazing."

#### Can the COVID-19 Vaccine cause Infertility /Sterility?

- No
- There is a false claim that the vaccine spike protein cross-reacts with another protein (syncytin-1) that is important for pregnancy.
- This is not true
- Claims linking COVID-19 vaccines to infertility are unfounded and have no scientific evidence supporting them. ACOG recommends vaccination for all eligible people who may consider future pregnancy and for those who are pregnant.

#### No evidence that COVID-19 vaccine results in sterilization

By BEATRICE DUPUY December 8, 2020

https://apnews.com/article/fact-checking-afs:Content:9856420671 https://www.nytimes.com/2020/12/10/technology/pfizer-vaccine-infertility-disinformation.html

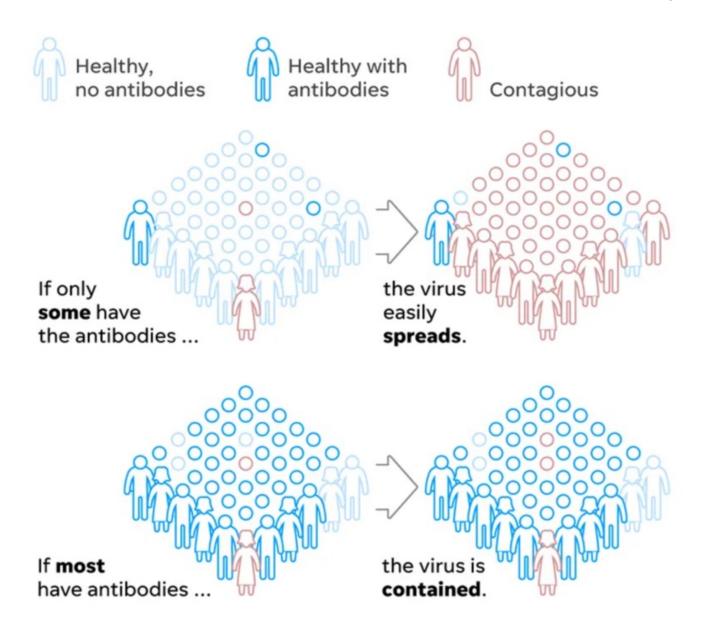
## Tracking Viral Misinformation No, there isn't evidence that Pfizer's vaccine causes infertility.

#### Can the Vaccine affect menstrual cycles?

- There have been anecdotal reports of temporary changes in menstruation patterns (eg, heavier menses, early or late onset, and dysmenorrhea) in individuals who have recently been vaccinated for COVID-19.
- Environmental stresses can temporarily impact menses, but prior vaccines have not been associated with menstrual disturbances.
- No evidence currently that the COVID-19 vaccine directly affects menstruation; however, this is being monitored.
- Vaccines can be given to women without regard to menstrual cycle timing

How does my not getting the vaccination hurt others?

#### How do vaccinations work to stop the spread of disease?



For this virus, especially the Delta variant, a high percent of the community needs protection to slow & stop pandemic.

#### Why should I get vaccinated?

- To avoid getting SARS-CoV2 infection or COVID-19 disease
- Decrease risk of severe disease, hospitalization or death
- Avoid 'Long COVID' and prolonged symptoms, seen in some 6-12

months after infection

- Less anxiety in indoor and outdoor crowds
- Decrease quarantine and disrupting your life
- Decrease spreading viral infection to others
  - Avoid exposing immunocompromised people, those at risk for severe disease, and those ineligible for vaccine, including children under 12 yo
- The more people vaccinated, less spread and less risk of new variants

#### **Update:** Booster Vaccine Doses for Select Groups

- Friday, 9/17/21, the FDA Advisory Panel recommended a 3<sup>rd</sup> dose of the Pfizer mRNA vaccine ("booster" dose) to the following groups:
  - Those 65 years and older
  - Those at high risk for severe COVID-19 disease
  - Those at high risk of occupational Coronavirus exposure (incl healthcare workers)
  - Two factors cited in decision:
    - Rise of the highly infectious delta variant and some evidence the Pfizer vaccine's protection against infection wanes with time, especially in elderly
- The CDC's Advisory Committee on Immunization Practices (ACIP) will weigh in on the 3<sup>rd</sup> dose this week
- Of note, a 3<sup>rd</sup> dose is already recommended for immunocompromised individuals

### When will Children under 12 yrs of age be able to receive the COVID Vaccination?

- We all want our younger children to be protected from COVID-19 disease via vaccination.
- The FDA will take the same precautions it did for adolescents & adults and will study all the data before approval in younger children.
- Press release today: Pfizer-BioNTech Announced Positive Topline Results From Pivotal Trial of COVID-19 Vaccine in Children 5 to 11 Years
  - In 5 to 11 year olds, the vaccine was safe, well tolerated and showed robust neutralizing antibody responses
  - Two-dose regimen using a smaller dose than that used for people 12 and older
- They will be submitting the data to the FDA and other regulatory agencies around the world shortly
  - Please don't vaccinate your younger children with the adult vaccine dose a lower dose is being used in younger children
- For children 6 months to 5 years of age, data and subsequent EUA approval expected in late 2021 or early 2022
- In the meantime, if we surround children with vaccinated people and everyone wears a mask at school, the children will be safe in school

#### Why vaccinate children?

- Vaccines are safe in adults.
- Important to protect children also
  - Children comprise 23% of the population but have accounted for ~29% of cases in recent weeks
  - Since July, pediatric cases of COVID-19 have risen by around 240% in the US
- To prevent disease and possible severe disease in children
  - Children less likely to develop serious illness with COVID-19 but serious disease can occur
- Long-term sequelae may follow COVID-19 infection
- Children can develop MIS-C (Multisystem Inflammatory Syndrome in Children) after COVID-19 infection
- Infected children may transmit SARS-CoV-2 to adults
  - Including those at high risk for serious disease, such as older adults, pregnant women, and immunocompromised persons
- Decreases need to quarantine and increase safety when participating in sports
- "We've seen the harm done to children's mental and emotional health as they've missed out on so many experiences during the pandemic. "Vaccinating children will protect them and allow them to fully engage in all of the activities— school, sports, socializing with friends and family— that are so important to their health and development." AAP President, Lee Savio Beers, MD
- Public Health rationale: Data suggest vaccinating adults can significantly decrease case numbers, but to obtain sweeping immunity and get control of the pandemic, need to vaccinate children

#### If you are eligible for the vaccine, please get vaccinated

- The U.S. Food and Drug Administration fully approved the Pfizer-BioNTech COVID-19 vaccine for ages 16 and older on 8/23/21
- Pfizer vaccine is available under an EUA for ages 12-15





#### Two solutions for schools: Vaccination & Masking

#### Vaccinations

- Safe and effective for adults and children
   12 years old (Pfizer)
- Save lives, prevent illness, and reduce SARS-CoV2 spread
- Reduce risk of new variants emerging

#### Vaccine effectiveness

	Alpha	Delta
	Vaccine effectiveness vs hospitalization	Vaccine effectiveness vs hospitalization
Any vaccine		
One dose	78% (65-86)	75% (57-85)
Two doses	92% (78-97)	94% (85-98)
Pfizer		
One dose	83% (62-93)	94% (46-99)
Two doses	95% (75-99)	96% (86-99)



#### "A Needle Today Helps Keep COVID Away", CDC

Stick to it!





#### **Summary:**

- SARS-CoV2 is not going away any time soon
- Schools are a safe environment for children and staff, if mitigation strategies followed
- Delta variant is highly transmissible
- Increasing COVID-19 cases being seen in children
  - Increased hospitalizations and ICU admissions
- COVID Vaccinations are safe and effective
  - Vaccination is important to decrease spread locally and globally



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# Thank you.

