



### **COVID-19 Vaccine**

What You Need to Know

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## Welcome to the System Office Vaccine Town Hall

- Thank you for joining!
- All lines are muted
- To ask a question, type it in the Q&A



- Questions that have not yet been answered will be published and answered
- This event is being recorded; the link will be shared following the meeting



### **Presenters**



Michael Slubowski
President and Chief
Executive Officer



**Dan Roth, M.D.**Executive Vice President and Chief Clinical Officer



Tammy Lundstrom, M.D., J.D.
Senior Vice President
and Chief Medical Officer



## Reflection

Dan Weiswasser, M.D.
Vice President and Chief Medical Officer, MGPS



### "The Light of You"

As we bring healing to those in need of strength, May our spirits be filled with the light of You. As we bring hope to a broken world. May our hearts be softened by the light of You. As we bring understanding to those who are suffering, May our arms be opened by the light of You. As we bring awareness to hatred, May our anger be lessened by the light of You. As we bring calm for inner peace, May our breath be deepened by the light of You. And may You guide us to those who seek our gifts, Leading them gently and lovingly, To the light of You. Amen.



**Our Mission, Vision and Values** inform our past, present and future and will endure

#### Our Mission

We, Trinity Health, serve together in the spirit of the Gospel as a compassionate and transforming healing presence within our communities.

#### Our **Vision**

As a mission-driven innovative health organization, we will become the national leader in improving the health of our communities and each person we serve. We will be the most trusted health partner for life.

#### Our Core Values

Commitment to Those Who are Poor Reverence Safety Justice | Stewardship

Integrity

### **Vaccination Milestones**

- More than 1.98 billion vaccine doses have been administered worldwide
- Nearly 315 million vaccine doses administered in the United States



In the United States:

% Vaccinated	At Least One Dose	Fully Vaccinated
Total Population	53%	44.5%
≥ 12 Years of Age	62%	52.1%
≥ 18 Years of Age	65%	55.2%
≥ 65 Years of Age	87.1%	76.8%



### What we've learned about vaccinations

#### Safe

- Nearly 300 million doses of COVID-19 vaccines have been given in U.S..
- No deaths attributed to vaccine
- Serious safety problems are extremely rare
- Most intense safety monitoring in U.S. history

#### **Effective**

- COVID-19 vaccines are extremely effective at preventing death, severe illness and hospitalization.
- Studies have shown COVID-19 vaccines to be effective against variants including:
  - Alpha (originating in the UK)
  - Beta (originating in South Africa)
  - Gamma (originating in Brazil)
  - Delta (originating in India)



### Rare serious health problems after vaccination

Safety systems in place have found two serious types of health problems after vaccination, which are extremely rare.

- Anaphylaxis (All vaccines)
  - A small number of people have had a severe allergic reaction (called "anaphylaxis") after vaccination
- Thrombosis with Thombocytopenia Syndrome (TTS)
   (Johnson & Johnson/Janssen)
  - Rare, but serious, event causing blood clots with low platelets.
     Women younger than 50 are at increased risk. Occurs at a rate of 7 per 1 million vaccinated women between 18 and 49 years old.



### Long-Term Side Effects are Unlikely

- Long-term side effects are extremely unlikely after any vaccination.
- Vaccine monitoring, and historical vaccine data has shown that side effects generally happen within six (6) weeks to eight (8) weeks of receiving a vaccine dose.
- More than six months of data is now available on COVID-19 vaccines since EUA approved, and even longer since clinical trials began.



# Fully Vaccinated People Can Resume Normal Life

### Full vaccinated people can:

- Stop wearing masks (except in places where healthcare delivered)
- Gather with other vaccinated people
- Travel safely

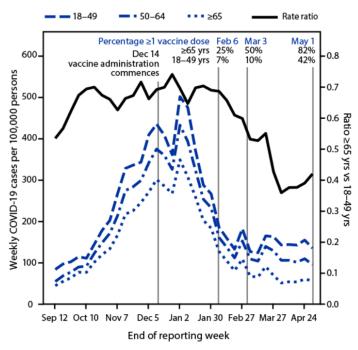
### Fully vaccinated people are:

- Unlikely to transmit the virus, even if they become infected
- Unlikely to have symptomatic infection, if they get COVID-19
- Unlikely to be hospitalized or die from COVID-19

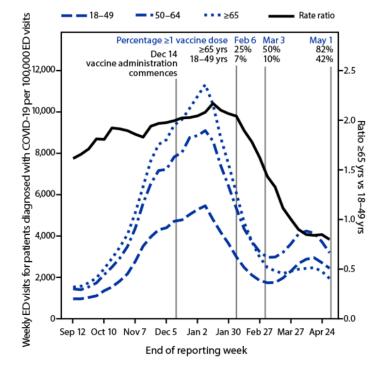


# The COVID-19 situation in the U.S. has improved drastically due to effective vaccines

A. Weekly rate of COVID-19 cases, by age group, and rate ratio for persons aged  $\geq$ 65 yrs vs those aged 18–49 yrs



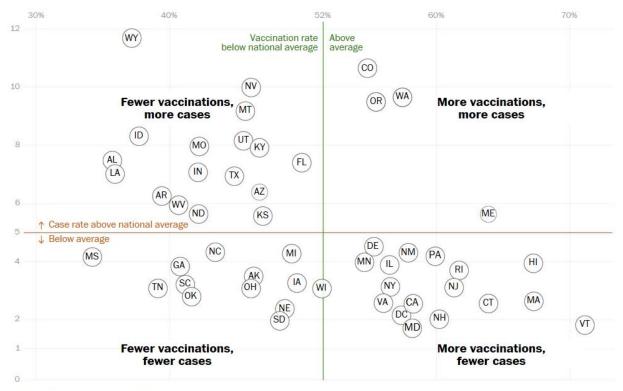
B. Weekly ED visits for patients diagnosed with COVID-19 per 100,000 ED visits, by age group, and rate ratio for persons aged ≥65 yrs vs those aged 18–49 yrs





Source: CDC

# States with greater share of population vaccinated have lower current case rates





# Variants or mutations to the COVID-19 virus are expected

- Viruses mutate over time, some more easily than others, that's why we sometimes need booster vaccines (example: flu vaccine)
- There have been and will continue to be mutations in the COVID-19 virus; the concerning mutations are around the spike protein, against which the vaccines prompt us to make antibodies (variants)
- The mutations have made some of these strains more transmissible, but, at this point, the vaccines still work
- Concern is that over time enough changes could occur so that the virus can evade the antibodies we get from the vaccine
- The good news is that the mRNA technology allows scientists to quickly respond with changes to the vaccine
- It is still unknown if booster doses will be required for the COVID-19 vaccine



### **Vaccination at Trinity Health**

- Trinity Health has administered nearly
   1.1 Million doses of vaccine
- An estimated 72% of Trinity Health colleagues have received at least one dose of the COVID-19 vaccine, with 64% fully vaccinated
  - 159,020 doses administered to colleagues
  - 84,322 colleagues with at least the first dose
  - 74,698 colleagues fully vaccinated

Data as of 6/7/21







# How well does the vaccine work?



#### **Effectiveness in clinical trials:**

- Pfizer vaccine: Almost 95%
- Moderna vaccine: Almost 95%
- Johnson and Johnson: 72%
- NovaVax: 90%
- AstraZeneca: TBD

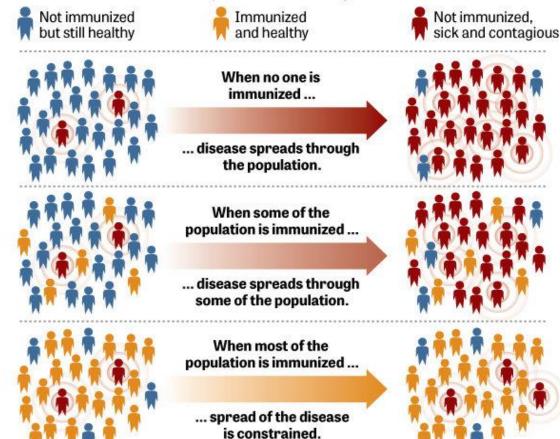
In a good year, the flu shot has 60% efficacy.

# What is herd immunity?

It occurs when most of a community members become immune to a disease.

#### WHY DOES MY CHOICE MATTER TO OTHERS?

It matters because of the concept of "herd immunity." Here's how it works:



(MLive.com)



### A second dose for mRNA vaccines is necessary



- A single dose offers some protection
- All study participants received a second dose in the recommended time frames, so it is unknown how long immunity lasts with only one dose
- The efficacy after the first dose is <u>less</u> <u>than half</u> the 95% efficacy shown after two doses



- The second dose significantly improves your immune system's memory of how to fight the virus
- 95% efficacy—one of the best levels ever seen in a vaccine



# FDA EUA vs. FDA Approval: What You Need to Know

#### **FDA Emergency Use Authorization**

Under an EUA, in an emergency, the FDA makes a product available to the public based on the best available evidence, without waiting for all the evidence that would be needed for FDA approval or clearance.

When evaluating an EUA, we carefully balance the potential risks and benefits of the products based on the data currently available.

- Clinical Trials (Phases 1, 2, 3)
- Two months of safety data
- Thorough review of all non-clinical, clinical and manufacturing data

#### **FDA Biologic License Application**

Before the FDA can approve a drug, the agency must determine whether the clinical data and other information show that the drug is safe and effective for its intended use (for example, to prevent or treat a certain disease), and that the product can be made according to federal quality standards.

When the FDA approves a drug, it means the agency has determined, based on substantial evidence, that the drug is effective for its intended use, and that the benefits of the drug outweigh its risks when used according to the product's approved labeling.

- Clinical Trials (Phases 1, 2, 3)
- Six months of safety data
- Thorough review of all non-clinical, clinical and manufacturing data



# Vaccinating children has more benefits than risks

- Children ages 12 and up are eligible for vaccination
- While most children are at lower risk for severe illness, there are still many unknown long-term effects of COVID-19
- Vaccinating children will:
  - Prevent risk of multisystem inflammatory syndrome (MIS-C)
  - Eliminate need to quarantine after exposure
  - Keep child from missing sporting events or activities and allow safe in-person school attendance
  - Avoid passing COVID-19 infection to family members and others at high-risk for severe illness



### Vaccinating children is safe and effective

- Clinical trials show COVID-19 vaccines are even more effective in children than adults
- Children experienced similar side effects
- While adults have been authorized first, it is only because adults were most severely affected and first to be involved in clinical trials
- Clinical trials underway for ages 6 months to 11 and data could be available as early as mid-July



# Rare heart complication in young males following vaccination

- Small number of mostly male adolescents age 16 and older experienced myocarditis (heart inflammation) after receiving mRNA vaccine
- Very rare occurs 12 cases per million
- More CDC information forthcoming



### Why should you get vaccinated?

- Protect yourself, our patients and residents and our communities—especially the most vulnerable
- Most deaths from COVID-19 are now preventable due to effective and safe vaccines
- To prevent transmission
- To get back to normal and doing what you love
- To protect those who can't protect themselves
  - Children
  - Immunocompromised individuals



# We continue to experience misinformation about vaccine side effects

- Microchip
- Infertility
- Metal in vaccine causes you to be magnetized
- FDA EUA means it is experimental
- Needle stays in arm (retractable needles)
- Using fake needles on leaders (retractable needles)
- Can't get life insurance if you're vaccinated
- All vaccinated people will die in next two years



### More information

- Common questions are answered in our vaccine FAQs
- Visit our <u>COVID-19 Vaccine page</u> for the latest information
- CDC COVID-19 vaccine information page
- Support for colleagues and their families: <u>Trinity-Health.org/Colleague-Care</u>

