# COVID-19 Series for Free & Charitable Clinics

July 15, 2021









**CDC's Strategy: Empower Healthcare Personnel**: Promote confidence among healthcare personnel in their decisions to get vaccinated and recommend the vaccination to their patients.

**Project Goal:** Build and reinforce COVID-19 vaccine confidence among healthcare personnel in the safety net sector and, in turn, the patients they serve.

Partnerships: The National Association of Free and Charitable Clinics and 15 State Associations and Federally Qualified Health Centers (FQHCs) in Puerto Rico and the U.S. Virgin Islands.

**How:** Provide tailored COVID-19 vaccine information to the free and charitable clinic sector through various channels and give the FCC sector a direct line of communication to CDC.

### **Reminders:**

- Please use your first name and clinic name when you join the session
- Use the "chat" feature to ask questions



• Please remember to <u>mute your microphone</u>



- If you can't connect audio via computer or you lose computer audio at anytime, you can call in to session at (408) 638-0968, Meeting ID 961-0597-7825##
- This activity has been approved for AMA PRA Category 1.25 Credit™ & Nursing CEUs







## Disclosures

• We have no relevant financial interests to disclose.

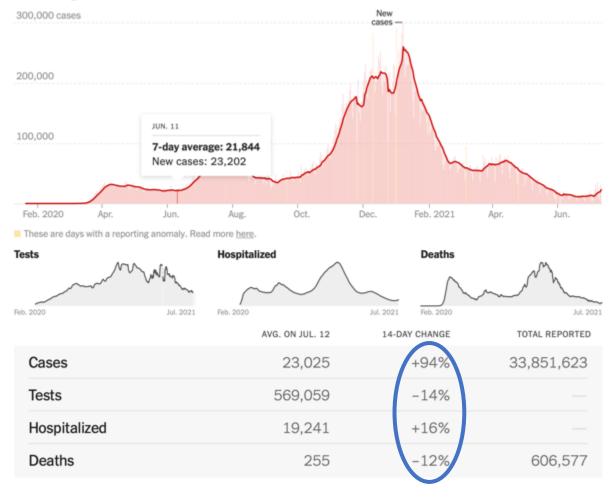


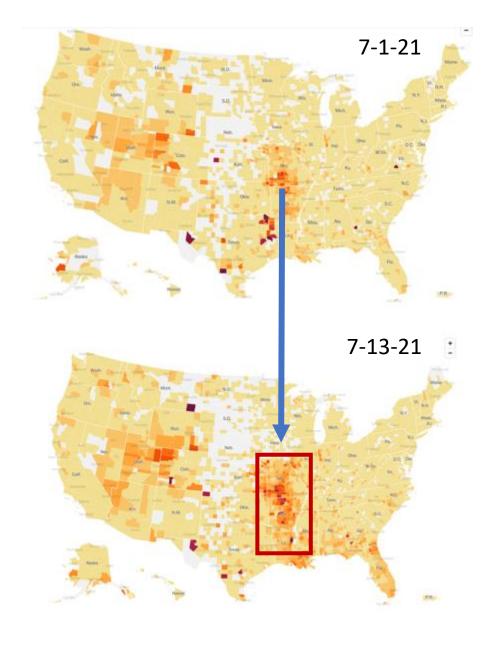




## Coronavirus in the U.S.: Latest Map and Case Count

#### New reported cases





https://www.nytimes.com/interactive/2021/us/covid-cases.html?action=click&module=Top%20Stories&pgtype=Homepage

## What's a variant?

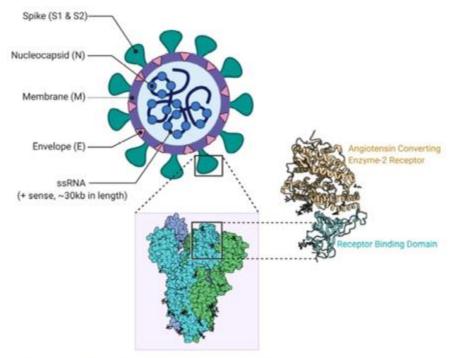
• During replication, a virus often undergoes genetic changes that may create what are called variants. Some mutations weaken the virus; others may yield an advantage that enables it to proliferate. If changes produce a version with distinctly different physical characteristics, the variant may be co-termed a strain. A variant that deviates significantly from its viral ancestors may be identified as a new lineage, or branch on the evolutionary tree. In general discourse, however, the terms are often used interchangeably.

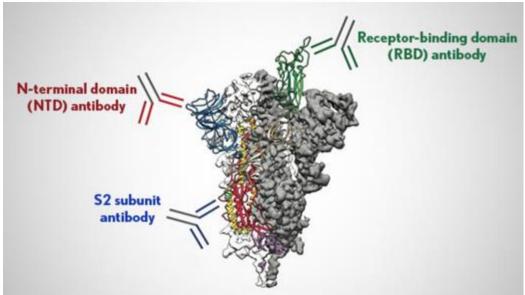
#### • For example:

- D614G mutation appears to position its receptor binding domain to interact more efficiently with the ACE2 receptor, and it is associated with higher nasopharyngeal loads
- In October 2020, sequencing analysis in the UK detected an emerging variant, later termed B.1.1.7 or 20I/501Y.V1, contains 8 mutations in the spike protein and maintains the D614G mutation. One of these, N501Y, appears to further increase the spike protein interaction with the ACE2 receptor

#### **SARS-CoV 2 Structure**

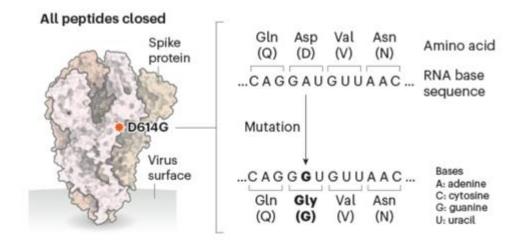


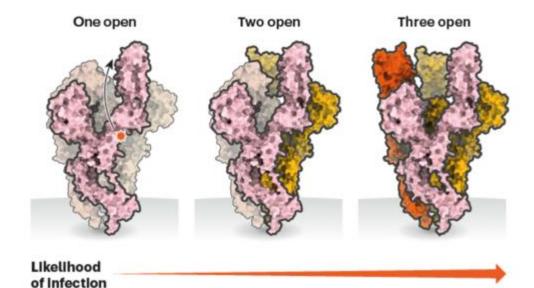




#### THE MUTATION THAT LOOSENS THE SPIKE PROTEIN

Spike proteins on SARS-CoV-2 bind to receptors on human cells, helping the virus to enter. A spike protein is made up of three smaller peptides in 'open' or 'closed' orientations; when more are open, it's easier for the protein to bind. The D614G mutation — the result of a single-letter change to the viral RNA code — seems to relax connections between peptides. This makes open conformations more likely and might increase the chance of infection.





#### WHO renames SARS-CoV-2 variants

From alpha to lambda

Variants of concern





			C. Carrier
WHO	label	Lineage	First documented samples
α	Alpha	B.1.1.7	UK Sep. 2020
β	Beta	B.1.351	South Africa May 2020
γ	Gamma	P.1	Brazil Nov. 2020
δ	Delta	B.1.617.2	India Oct. 2020

### Variants of interest

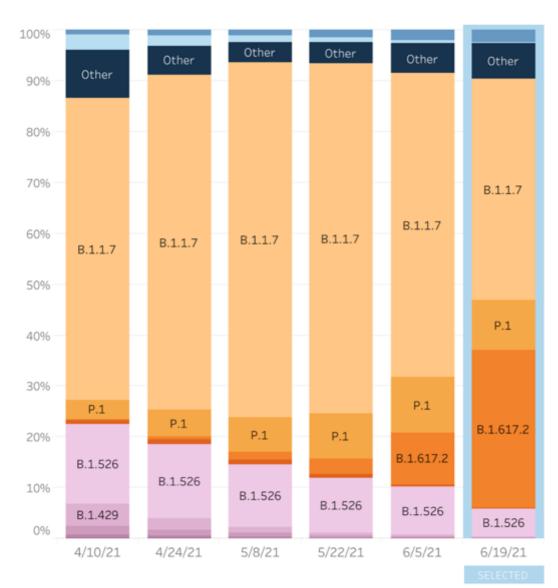






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3	Epsilon	B.1.427/ B.1.429	USA Mar. 2020
ζ	Zeta	P.2	Brazil Apr. 2020
η	Eta	B.1.525	<i>Multiple</i> Dec. 2020
θ	Theta	P.3	Philippines Jan. 2021
1	Iota	B.1.526	USA Nov. 2020
K	Карра	B.1.617.1	India Oct. 2020
λ	Lambda	C.37	Peru Aug. 2020
			Aug. 2020

#### United States: 3/28/2021 - 6/19/2021



#### United States: 6/6/2021 - 6/19/2021

#### USA

	Lineage			Туре	%Total	95%CI	
Most	B.1.1.7	Alpha		VOC	43.4%	39.1-47.9%	
common	B.1.617.2	Delta		VOC	31.1%	24.6-38.3%	
lineages#	P.1	Gamma		VOC	9.9%	7.5-12.9%	
	B.1.526	lota		VOI	5.5%	4.4-6.8%	
	B.1				2.3%	1.5-3.6%	
	B.1.1.519				0.2%	0.1-0.3%	
Additional	B.1.351	Beta		VOC	0.2%	0.1-0.4%	
VOI/VOC	B.1.525	Eta		VOI	0.1%	0.1-0.4%	
lineages#	B.1.429	Epsilon		VOI	0.1%	0.0-0.4%	
	B.1.427	Epsilon		VOI	0.1%	0.0-0.3%	
	B.1.617.1	Карра	†	VOI	0.0%	0.0-0.1%	
	B.1.617.3		†	VOI	0.0%	NA	
	P.2	Zeta	†	VOI	0.0%	NA	
Other*	Other				7.1%	5.6-9.1%	

Collection date, two weeks ending

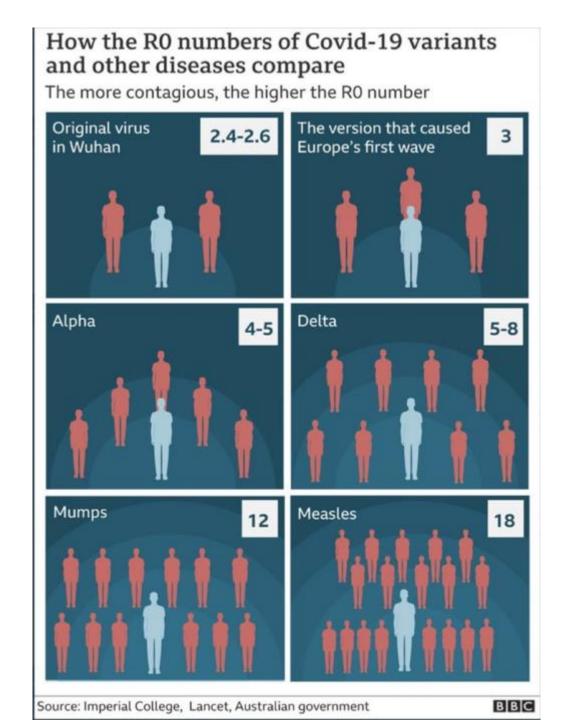
# Delta accounts for nearly all virus cases in southwestern Missouri, where a hospital recently ran out of ventilators.

Missouri has been averaging about 1,000 new cases per day, a 44
 percent increase over the past two weeks, though a fraction of the
 state's November peak when its average topped 5,000, according to a
 New York Times database. Hospitalizations are up 25 percent from two
 weeks ago.

## Delta Variant (B.1.617.2)

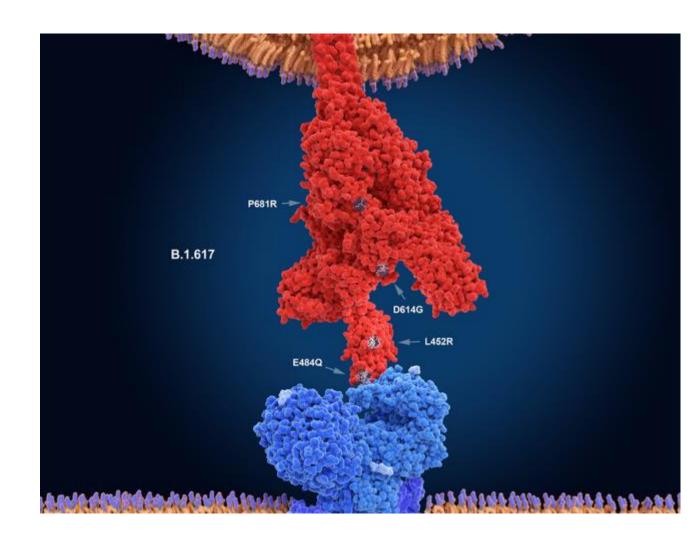
- Initially identified in India in December 2020
- Associated with increased transmissibility and more severe disease
- 20.6% of new cases in the U.S. are due to the Delta variant
- Now, the dominant virus variant in the U.S.
- All the vaccines authorized for use in the U.S. appear to provide powerful protection against all variants, including Delta

# SARS CoV2 is Evolving to be More Contagious



## Delta Variant

- The delta variant is the most contagious version of the coronavirus worldwide. It spreads about 225% faster than the original version of the virus
- The variant grows more rapidly inside people's respiratory tracts and to much higher levels
- On average, people infected with the delta variant had about 1,000 times more copies of the virus in their respiratory tracts than those infected with the original strain of the coronavirus
- In addition, after someone catches the delta variant, the person likely becomes infectious sooner. On average, it took about four days for the delta variant to reach detectable levels inside a person, compared with six days for the original coronavirus variant.



# Decline in Vaccine Effectiveness Against Infection and Symptomatic Illness?

- Israeli Ministry of Health:
  - It is evident that since June 6th there was marked decline in the effectiveness of the vaccine in preventing infection (64%) and symptomatic illness (64%). This decline has been observed simultaneously with the spread of the Delta variant in Israel.
  - Nevertheless, the vaccine maintains an effectiveness rate of about 93% in preventing serious illness and hospitalization cases.
- In UK, researchers reported in May that two doses of the Pfizer-BioNTech vaccine had an effectiveness of 88% protecting against symptomatic disease from Delta. A June study from Scotland concluded that the vaccine was 79 % effective against the variant.

## Will the Current Vaccines work?

Table 1. Summary of evidence on vaccine effectiveness against different outcomes (data relate to period when the Alpha variant dominated)

	Vaccine effectiveness					
Outcome	Pfizer-BioN	Tech	Oxford-AstraZeneca			
	1 dose	2 doses	1 dose	2 doses		
Symptomatic disease	55-70%	85-90%	55-70%	65-90%		
Hospitalisation	75-85%	90-95%	75-85%	80-95%		
Mortality	75-80%	95-99%	75-80%	No data		
Infection	55-70%	70-90%	60-70%	No data		
Transmission (secondary cases)*	45-50%	No data	35-50%	No data		

Table 2. Vaccine effectiveness against symptomatic disease for Alpha and Delta variants

Vaccine Status	Vaccine Effectiveness		
	Alpha	Delta	
Dose 1	49 (46 to 52)	35 (32 to 38)	
Dose 2	89 (87 to 90)	79 (78 to 80)	

Table 3. Vaccine effectiveness against hospitalisation for Alpha and Delta variants

Vaccine Status	Vaccine Effectiveness			
	Alpha	Delta		
Dose 1	78 (64 to 87)	80 (69 to 88)		
Dose 2	93 (80 to 97)	96 (91 to 98)		

## Real-World Data from UK

06-Jun-21	Symptomatic	S Gene Positive (Delta Variant)				
	Vaccine					
Vaccine	Status	N	R	VE	LCL	UCL
	Unvaccinated	40504	2439	0	0	0
Pfizer-	V1_0-27	1942	203	18	4	31
BioNTech	V1_28+	2376	92	33	15	47
	V2_0-7	883	5	84	61	93
	V2_14+	4401	75	83	78	87
	Unvaccinated	40504	2439	0	0	0
Oxford-	V1_0-27	4422	186	23	7	36
AstraZeneca	V1_28+	10242	511	33	23	41
	V2_0-7	1877	160	37	23	48
	V2_14+	2089	126	61	51	70

- Analysis of cases in Scotland from April 1 to June 6, 2021
- 19 543 confirmed infections
- 377 were admitted to hospital
  - 134 (35.5%) hospital admissions were in those with delta variant
- Vaccine Efficacy (VE) increased substantially with completion of both Pfizer and AZ series



### Moderna Provides a Clinical Update on the Neutralizing Activity of its COVID-19 Vaccine on Emerging Variants Including the Delta Variant First Identified in India

June 29, 2021

Serum samples from eight participants obtained one week after second dose of the primary series in the Phase 1 clinical trial of the Moderna COVID-19 Vaccine

Serum neutralization assays performed on emerging variants including 2 additional versions of the Beta variant (B.1.351) and 3 lineage variants of B.1.617, including the Kappa (B.1.617.1) and Delta (B.1.617.2) variants

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 29, 2021-- Moderna, Inc. (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced new results from in vitro neutralization studies of sera from individuals vaccinated with the Moderna COVID-19 Vaccine showing activity against variants of SARS-CoV-2. Vaccination with the Moderna COVID-19 Vaccine produced neutralizing titers against all variants tested, including additional versions of the Beta variant (B.1.351, first identified in South Africa), three lineage variants of B.1.617 (first identified in India), including the Kappa (B.1.617.1) and the Delta variants (B.1.617.2); the Eta variant (B.1.525, first identified in Nigeria); and the A.23.1 and A.VOI.V2 variants first identified in Uganda and Angola, respectively. These data were submitted as a preprint to bioRxiv.

## Will we need Boosters?

- It's too soon to know whether we will need a booster modified to target the Delta variant—or any other variant.
- Nor do experts know with certainty yet if vaccinated people will need an additional shot at some point to boost the overall immunity they got from their first shots.
- Pfizer has announced that it is planning clinical trials in August for a booster shot that would potentially be used against Delta
  - CDC, FDA asked Pfizer to report more data before making any recommendations regarding authorization of 3<sup>rd</sup> dose, etc.

# F.D.A. Attaches Warning of Rare Nerve Syndrome to Johnson & Johnson Vaccine

- Federal officials have identified 100 suspected cases of Guillain-Barré among recipients of Johnson & Johnson's one-dose shot through VAERS
  - Causation is not clear, but there is an uptick above the baseline rate
  - GBS is a known complication from other vaccines
- 95% of those cases were considered serious and required hospitalization
- Warning label now placed on vaccine
- Will this decrease use of this vaccine further?

## And, now there's Delta Plus...

- Delta Plus—a subvariant of Delta, that has been found in the U.S., the U.K., and other countries.
- Delta Plus has one additional mutation to what the Delta variant has
- This mutation, called K417N, (previously seen in the Beta variant)
  affects the spike protein that the virus needs to infect cells, and that is
  the main target for the mRNA and other vaccines
- More data is needed to determine the actual rate of spread and impact of this new variant on disease burden and outcome. Also, more data is needed on effectiveness of vaccines against this variant.

## What does the Delta variant mean for FCCs?

- "Prepare for delta as you would prepare for a hurricane." Amber Schmidtke
- What does preparation mean?
  - Infection control
  - Sufficient supplies
  - Testing and management
  - Increasing vaccinations

## **Conflicting Needs**

### **Current Reality**

- Need for primary care appointments
- Staff are tired
- Patient concern has ebbed
- Funding for treatment, testing, and staffing has moved to vaccination
- Resource prioritization

### **Possible Upcoming Needs**

- Possible COVID surges
- Triage and rapid identification
- Expanding vaccine age limits
- Increased requests for testing
- Renewed emphasis on symptom identification and infection control

## Questions?

## Thank you!

Next Session: Thursday, July 29th

Topic: TBD

Resources & recording of the session

https://www.echo-chicago.org/resources/covid19/

This project was funded in part by a cooperative agreement with the Centers for Disease Control and Prevention grant number 1 NU50CK000588-01-00. The Centers for Disease Control and Prevention is an agency within the Department of Health and Human Services (HHS). The contents of this resource center do not necessarily represent the policy of CDC or HHS and should not be considered an endorsement by the Federal Government.









#### **QUESTIONS & CONTACT**

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