COVID-19 Vaccination

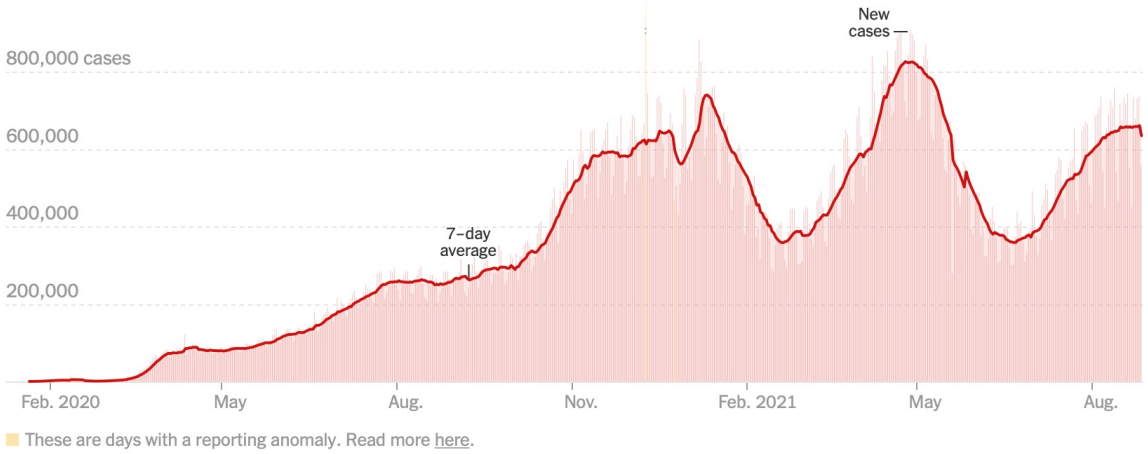
August / September 2021

Where We Are Today: Globally

- 215 million cases
- 4.5 million deaths

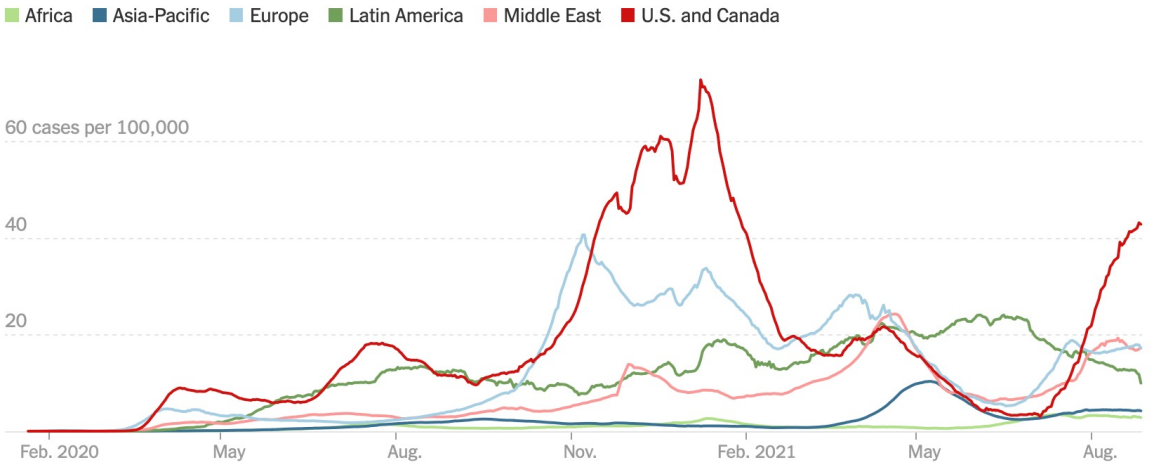
The US leads the world in the daily average number of new infections reported, accounting for **one in every 4 infections** reported worldwide each day
38 MM+ cases
638.5K+ deaths

New reported cases



These are days with a reporting anomaly. Read more here.

	DAILY AVG. ON AUG. 27	14-DAY CHANGE	TOTAL REPORTED
Cases	634,808	-2%	215,364,525
Deaths	9,694	Flat	4,483,014



Data accessed August 28, 2021 – source: NY Times

What Are We Seeing in This Surge?

- Low vaccination rates
- High prevalence of the delta variant
- Increase in children who are infected / hospitalized

VUMC has more patients in hospital with COVID-19 than at any other time in the pandemic.

The laboratory is testing more patients per day than at any other time in the pandemic.

Why is VUMC Requiring Vaccination?


Nashville's Largest Private Employer Decides To Require COVID Vaccinations, Starting With Leaders

BLAKE FARMER JULY 26, 2021

- We have high-risk patients and co-workers around us who won't be protected from the vaccine
- You could be infected and not feel sick
- Vaccines are very effective and safe
- Just like other vaccines, like the flu shot, VUMC expects all team members to get a COVID-19 vaccine (exemptions are allowed)


2 patients die in cancer ward at Sherbrooke hospital following COVID-19 outbreak

US Vaccination Coverage

Total Vaccine Doses

Delivered	437,567,285
Administered	366,838,484

Learn more about the distribution of vaccines.

172.6M
People fully vaccinated

732k
People received an additional dose since August 13th, 2021

People Vaccinated	At Least One Dose	Fully Vaccinated
Total	203,475,192	172,646,952
% of Total Population	61.3%	52%
Population ≥ 12 Years of Age	203,247,456	172,515,523
% of Population ≥ 12 Years of Age	71.7%	60.8%
Population ≥ 18 Years of Age	190,311,373	162,692,117
% of Population ≥ 18 Years of Age	73.7%	63%
Population ≥ 65 Years of Age	50,197,872	44,588,240
% of Population ≥ 65 Years of Age	91.8%	81.5%

About these data

CDC | Data as of: August 27, 2021 6:00am ET. Posted: Friday, August 27, 2021 2:58 PM ET

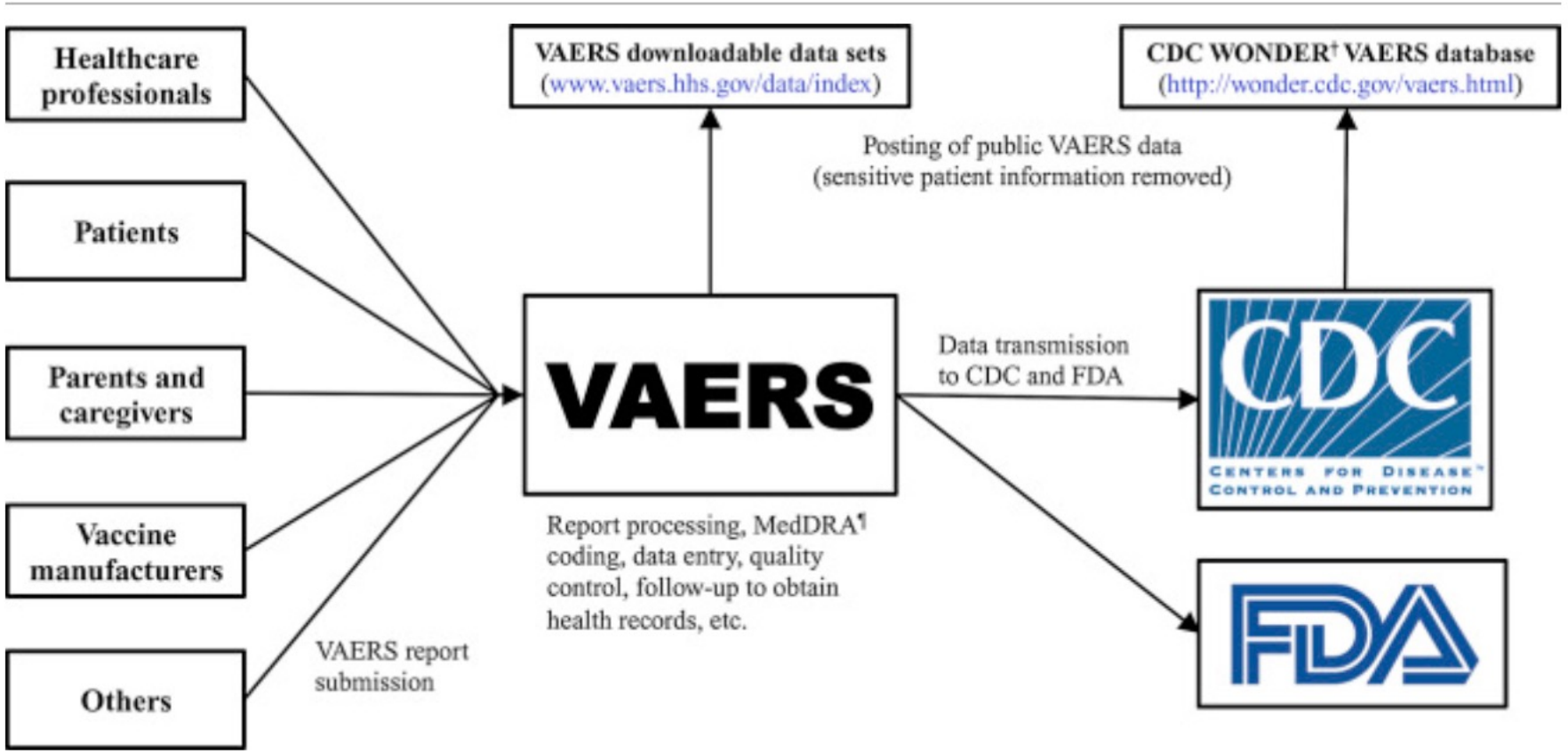
Location	Age < 18	Age 18-64	Age 65+
Tennessee	7.3%	44.8%	80.2%

Source link: CDC

(These data accessed on 08/28/2021)

VANDERBILT HEALTH

Understanding VAERS



- VAERS is not able to provide incidence
- Numerator-only surveillance system
- No info on total number of individuals vaccinated
- No info on incidence of adverse events in unvaccinated individuals

A report in VAERS does not necessarily mean causality! It may be a true adverse event, or coincidental.
>60% of adverse events for COVID-19 vaccines = not serious (headache, sore arm)

Shimabukuro TT et al. Vaccine. 2015. 33:4398-4405

Putting Data in Context: US Data

COVID-19 infections	COVID-19 Vaccines
• 38.7 MM infected • ? Adverse events • 1.6% deaths • 6.7% hospitalized	• 203 MM with 1 dose • 0.11% with adverse event* • 0.0012% serious AE* • 0.0019% death*

*reported through VAERS, but not confirmed, nor confirmed as causal

Data accessed 8/28/21
CDC.Gov
VAERS Website

Pfizer's COVID-19 vaccine now has full FDA approval. Here's what that means for

"the public can be very confident that this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product"
– FDA press release

Safety in Pregnancy

(Israeli Study)

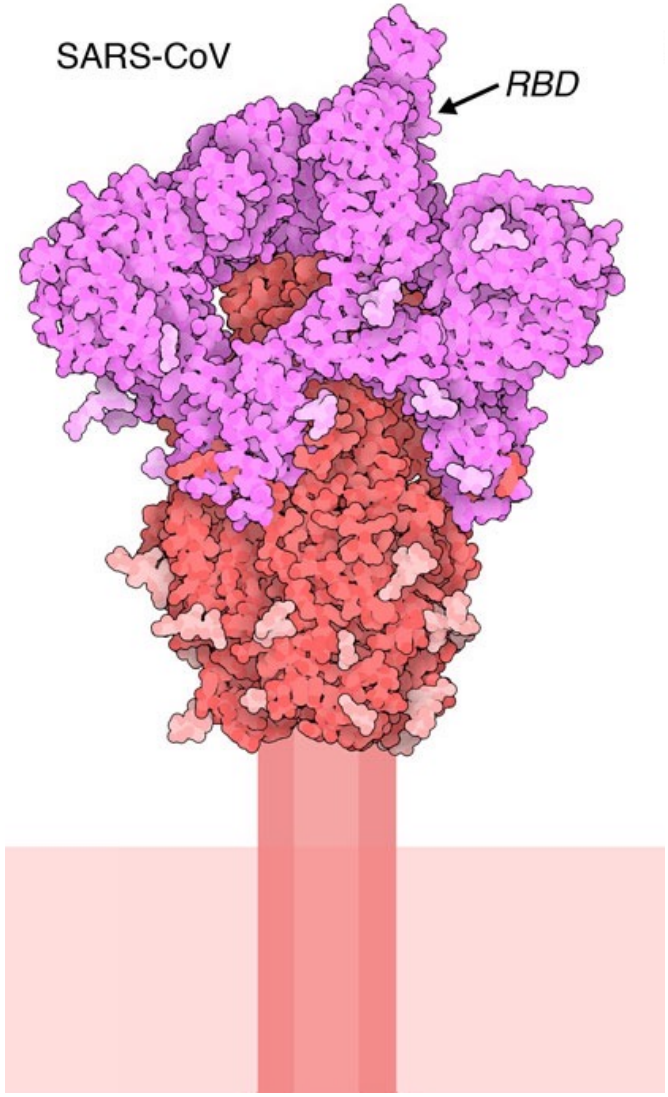
Vaccination with Pfizer mRNA vaccine appears to be effective & safe in pregnant woman, a demographic currently without published Phase 3 data

Outcomes	Vaccinated	Matched unvaccinated
No.	7530	7530
SARS-CoV-2 hospitalization, No. (%)	13 (0.2)	23 (0.3)
Abortion,[c] No. (%)	128 (1.7)	118 (1.6)
Intrauterine growth restriction, No. (%)	36 (0.5)	38 (0.5)
Preeclampsia, No. (%)	20 (0.3)	21 (0.3)
Stillbirth, No. (%)	1 (<0.1)	2 (<0.1)
Maternal death, No. (%)	0	0
Obstetric pulmonary embolism, No. (%)	0	0
Birth week, median (IQR)	39 (38-40)	39 (38-40)
Preterm birth (<37 wk), No. (%)	77/1387 (6.6)	85/1427 (6.0)
Infant weight, median (IQR), kg	3.2 (2.9-3.6)	3.2 (2.9-3.5)

Association between BNT162b2 vaccination and incidence of SARS-CoV-2 infection in pregnant women. Goldshtein *et al*. *JAMA* (July 12, 2021).

What About Protection from Natural Infection?

- People who had 2 doses of vaccine had a high enough level of antibodies to block the delta variant. 1 dose or just natural infection, **wasn't as protected**.[1]
- Vaccines **provide more "flavors" of antibody** that block the RBD.[1]
- The chance of **getting infected again** is **over 2-times higher** if you are not vaccinated.[2]
- One new study shows improved immunity post infection – but not yet peer reviewed.[3]



1. https://www.nature.com/articles/s41586-021-03777-9
2. Cavanaugh AM et al MMWR August 6, 2021
3. Gazit. Et al MedRx Preprint. Online August 25, 2021

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
August 6, 2021

Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021

Alyson M. Cavanaugh, DPT, PhD[1,2]; Kevin B. Spicer, MD, PhD[2,3]; Douglas Thoroughman, PhD[2,4]; Connor Glick, MS[2]; Kathleen Winter, PhD[2,5]

TABLE 2. Association of SARS-CoV-2 reinfection* with COVID-19 vaccination status — Kentucky, May–June 2021

	No. (%)		
Vaccination status	Case-patients	Control participants	OR (95% CI)†
Not vaccinated	179 (72.8)	284 (57.7)	2.34 (1.58–3.47)
Partially vaccinated¶	17 (6.9)	39 (7.9)	1.56 (0.81–3.01)
Fully vaccinated§	50 (20.3)	169 (34.3)	Ref
Total	**246 (100)**	**492 (100)**	—

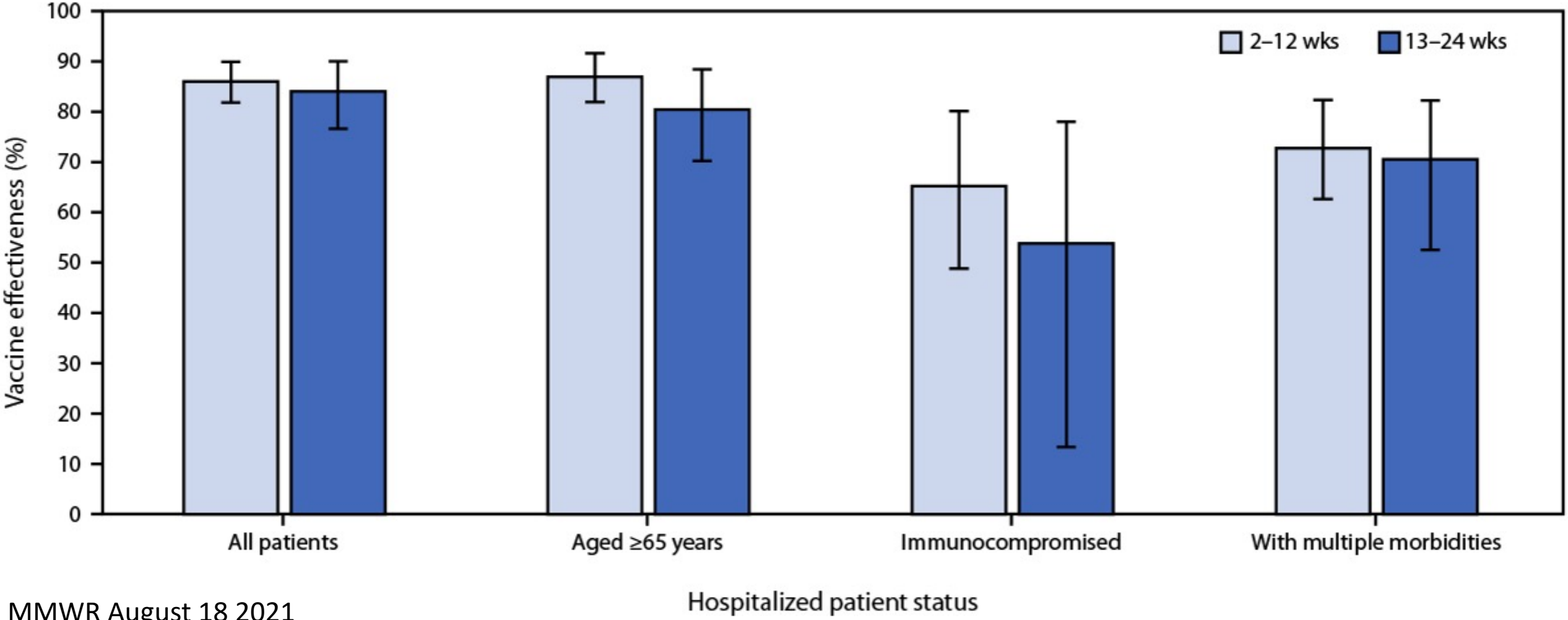
Abbreviations: CI = confidence interval; NAAT = nucleic acid amplification test; OR = odds ratio; Ref = referent group.

2.3X

Risk of COVID-19 Reinfection 2.3-Fold Higher if Not Vaccinated

Cavanaugh AM et al MMWR August 6, 2021

Vaccines Continue to Prevent Hospitalization



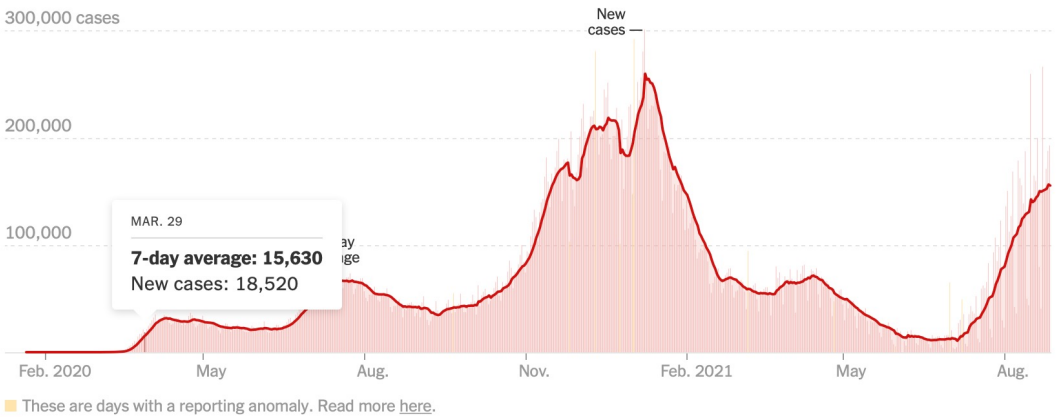
MMWR August 18 2021

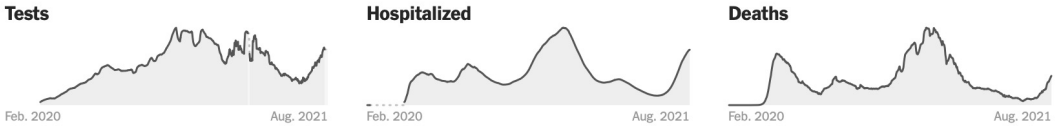
REFERENCE SLIDES

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

Updated April 22, 2021

New reported cases

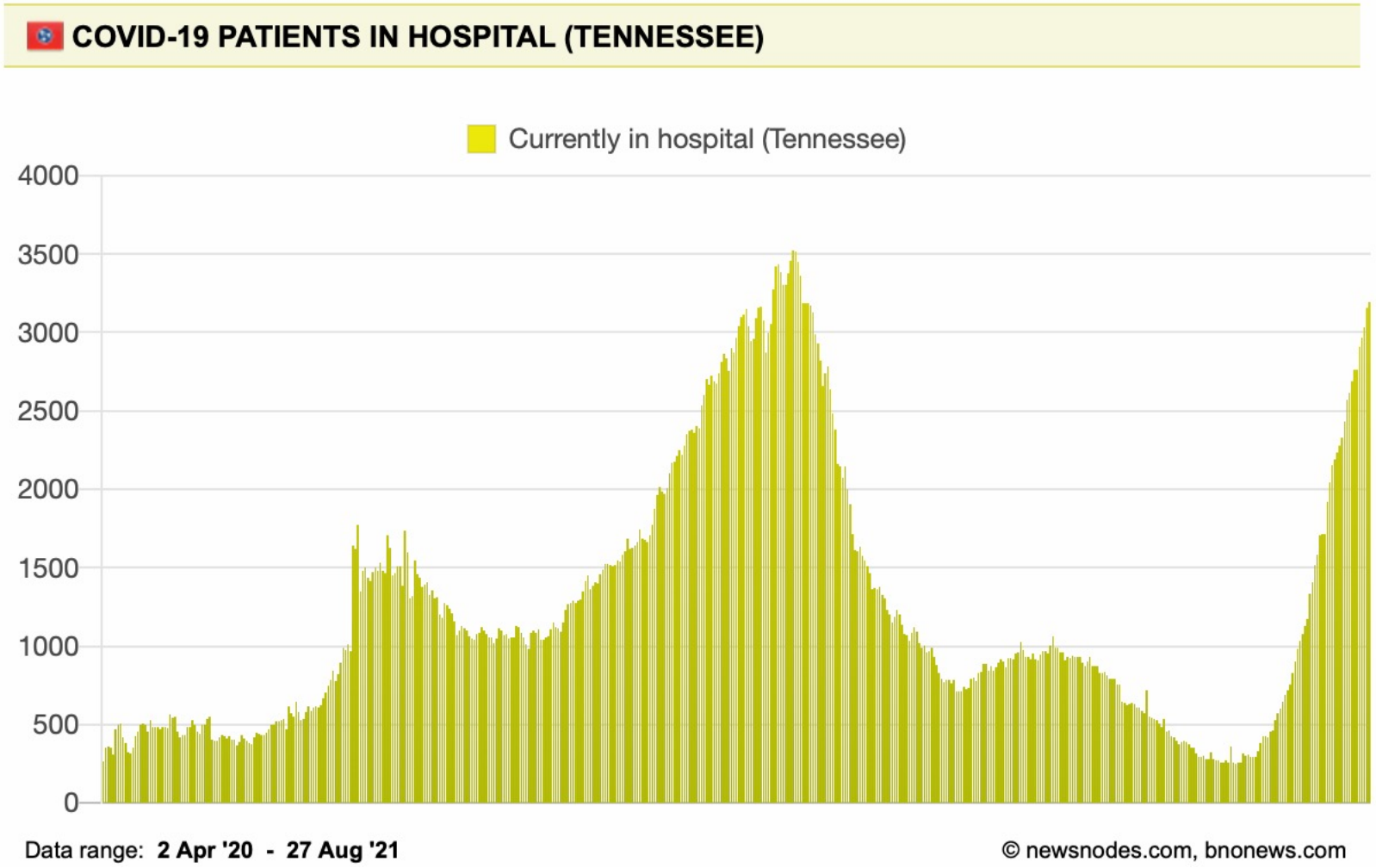




	DAILY AVG. ON AUG. 27	14-DAY CHANGE	TOTAL REPORTED
Cases	155,365	+21%	38,745,199
Tests	1,334,692	+33%	—
Hospitalized	98,337	+28%	—
Deaths	1,266	+95%	636,491

	CASES DAILY AVG.	PER 100,000	14-DAY CHANGE	HOSPITALIZED DAILY AVG.	PER 100,000	14-DAY CHANGE	DEATHS DAILY AVG.	PER 100,000	FULLY VACCINATED
United States	155,365	47	+21%	98,337	30	+28%	1,265.7	0.38	52%
Mississippi ›	3,056	103	−7%	1,714	58	+11%	41.1	1.38	38%
Florida ›	21,680	101	Flat	16,990	79	+11%	246.7	1.15	52%
Louisiana ›	4,269	92	−27%	2,543	55	Flat	63.0	1.36	41%
Kentucky ›	4,050	91	+65%	2,124	48	+56%	23.9	0.53	48%
South Carolina ›	4,658	90	+48%	2,088	41	+59%	34.1	0.66	43%
Tennessee ›	6,089	89	+60%	2,324	34	+16%	28.6	0.42	41%
Georgia ›	8,791	82	+53%	6,007	56	+46%	49.7	0.47	41%
Alabama ›	4,041	82	+15%	2,946	60	+22%	30.1	0.61	37%
Arkansas ›	2,132	71	−6%	1,363	45	+1%	31.7	1.05	41%
Alaska ›	512	70	+62%	133	18	+13%	3.4	0.47	47%

Where We Are Today: TN



(These data accessed on 08/28/2021)

Source link: Newsnodes

LATEST COVID-19 DATA

TOTAL CASES
1,021,578 *in total* (+6335) *daily average**

TOTAL DEATHS
13,345 *in total* (+29) *daily average**

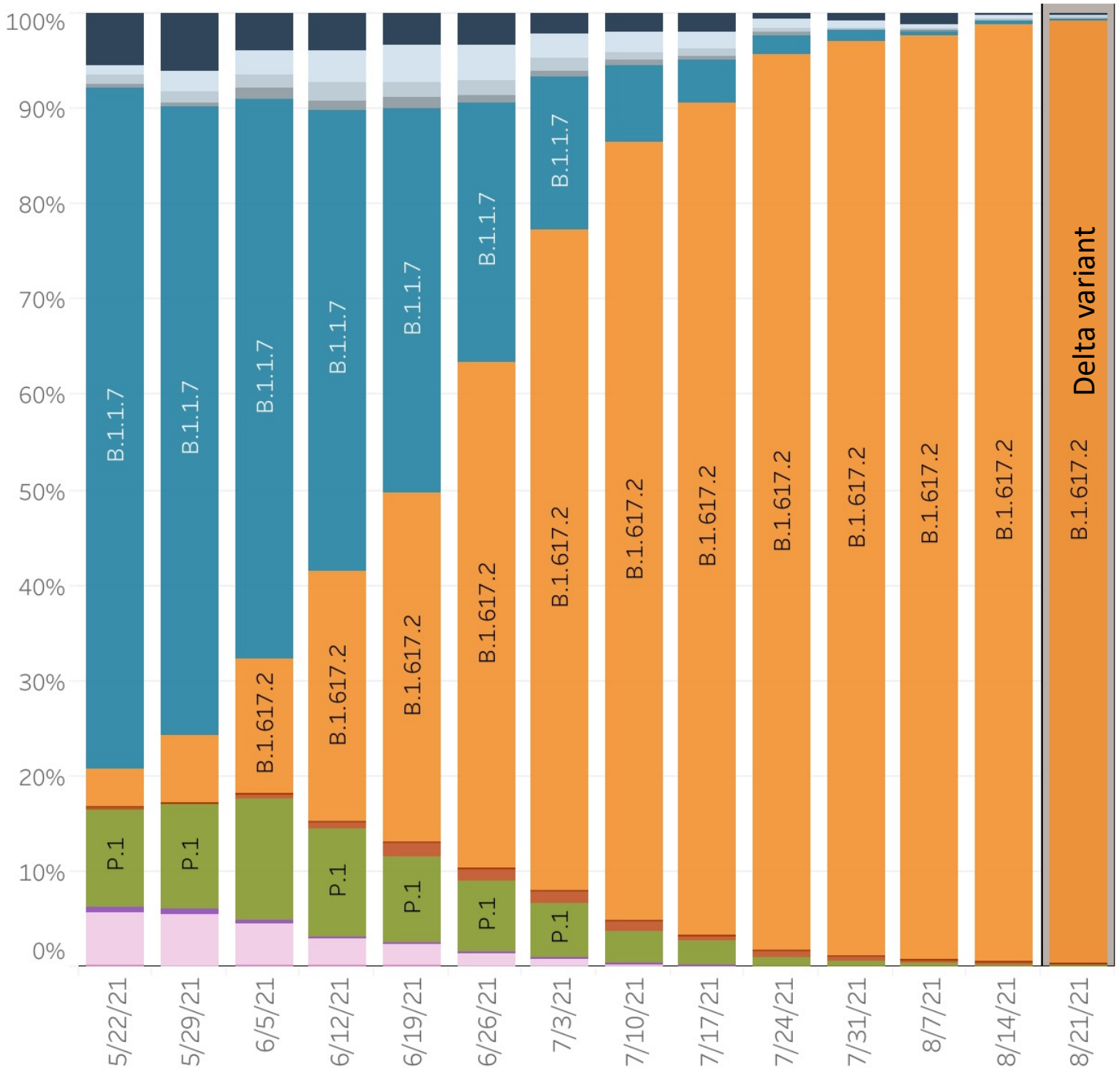
TOTAL TESTS
8,985,737 *in total* (+24963) *daily average**

CURRENTLY IN HOSPITAL
3,194 *in total* (+40)

CURRENTLY IN ICU
914 *in total* (+8)

VANDERBILT HEALTH

Slide courtesy Dr. Tom Talbot

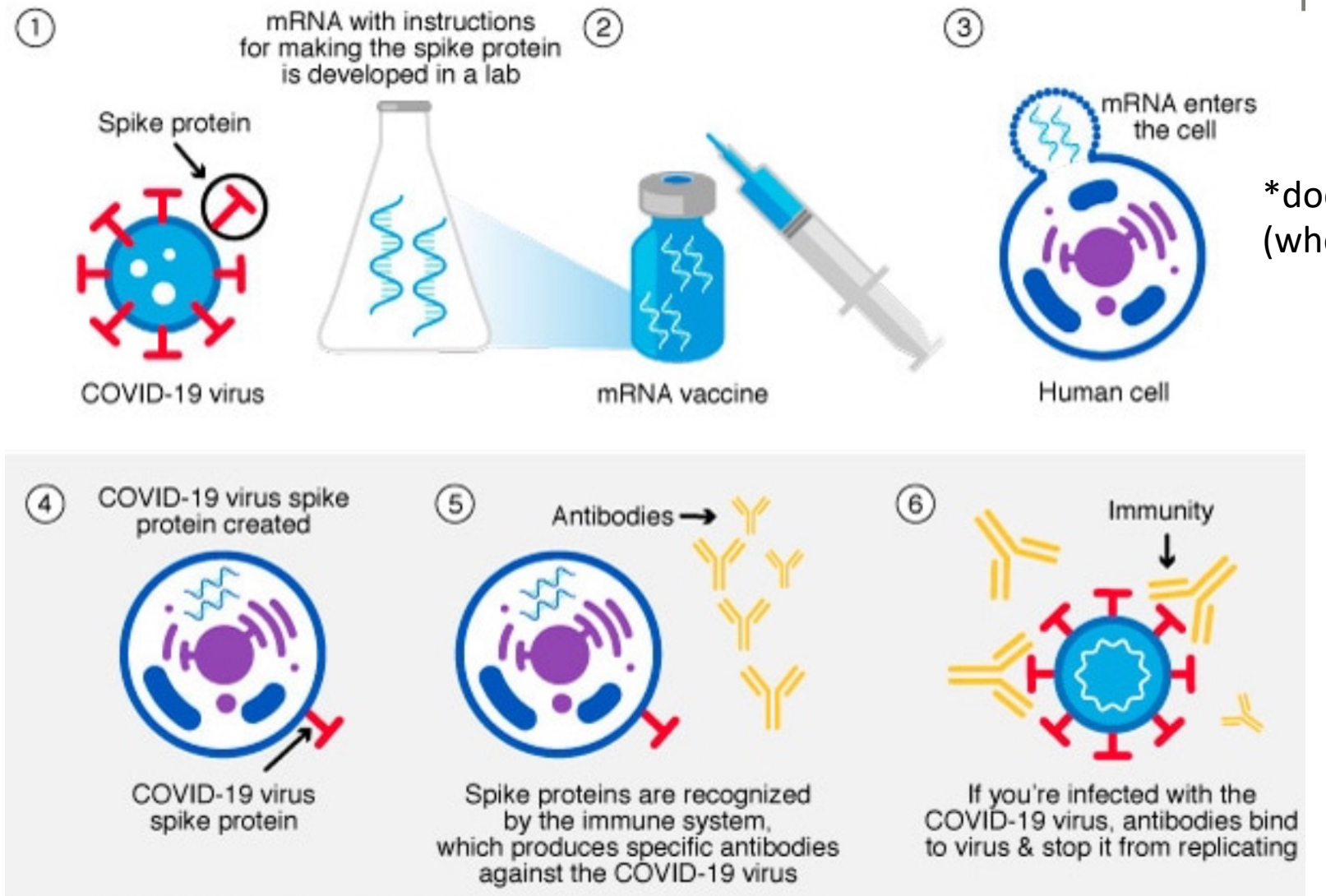


Delta Variant is Predominant

What We Know About the Delta Variant

- **Delta is more contagious than the other virus strains**
  - R_0 = 2.5 for original strain; R_0 = 5-10 for Delta
  - Shorter incubation period from infection-to-symptoms (4 vs 5 days)
  - Infected people shed much higher levels of virus (>1,000-fold more)
- **Unvaccinated people are at greatest risk, including younger people**
- **Delta could lead to 'hyperlocal outbreaks' where vaccine uptake is low**
  - This could be catastrophic in some communities
- **Breakthrough cases for vaccinated people are UNCOMMON, but do happen more than with other variants**
- **Even infected, vaccinated people can transmit virus**

https://www.globaltimes.cn/page/202107/1227847.shtml
https://www.yalemedicine.org/news/5-things-to-know-delta-variant-covid
https://health.ucdavis.edu/coronavirus/covid-19-information/delta-variant.html
https://www.medrxiv.org/content/10.1101/2021.07.19.21260808v1.full.pdf



*does not enter nucleus (where your DNA is)

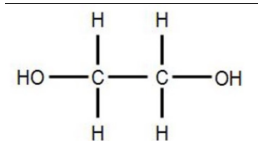
Source: Mayo Clinic

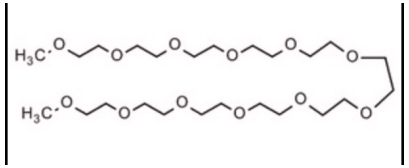
About the Vaccines: Ingredients

Description	Pfizer-BioNTech (mRNA)	Moderna (mRNA)	Janssen (viral vector)
Active ingredient	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
Inactive ingredients	2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Potassium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose	

- mRNA
- Fats
- Sugar
- Salt

- NOTE: ethylene glycol is different than polyethylene glycol

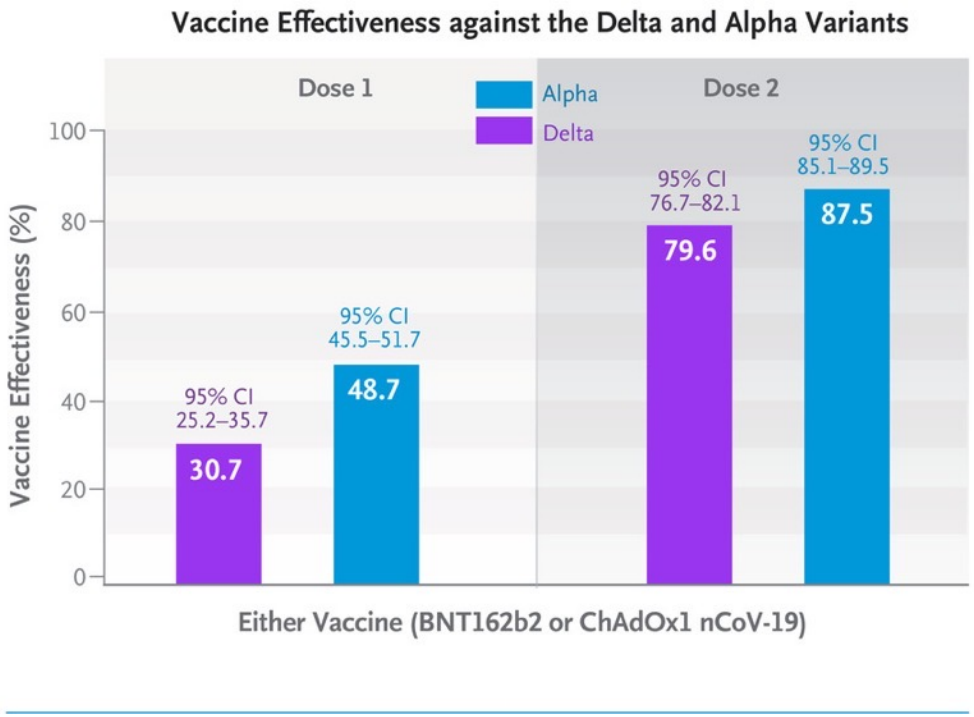


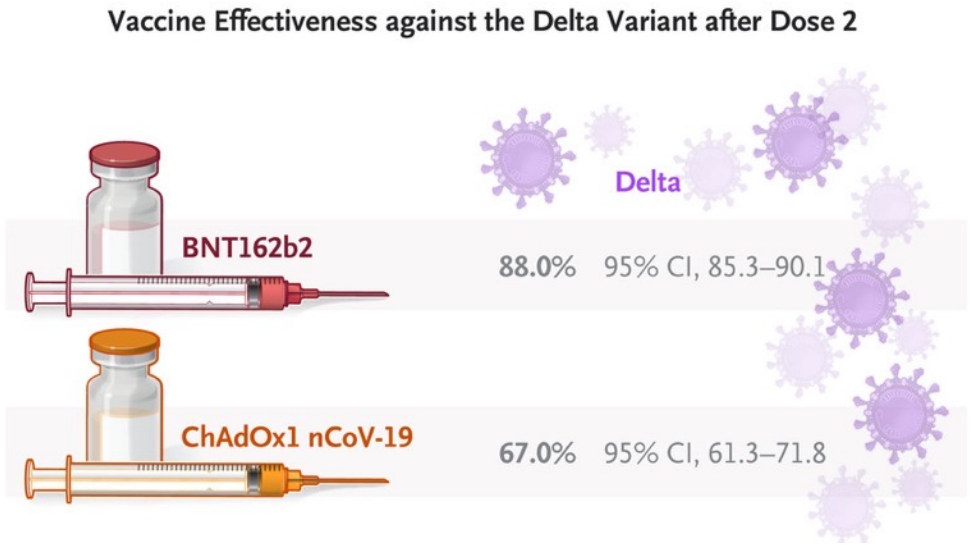


ORIGINAL ARTICLE

Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant

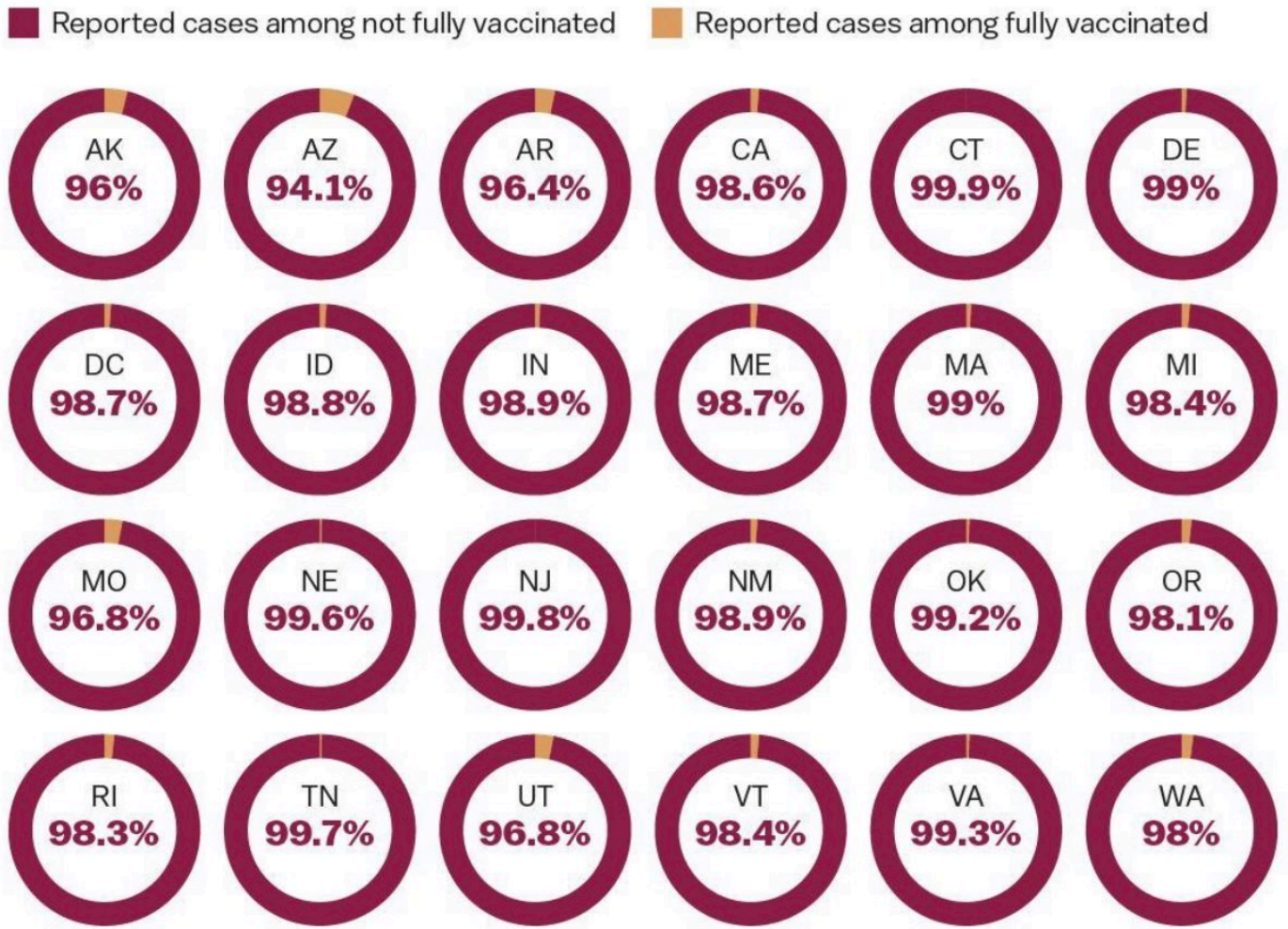
Jamie Lopez Bernal, F.F.P.H., Ph.D., Nick Andrews, Ph.D., Charlotte Gower, D.Phil., Eileen Gallagher, Ph.D., Ruth Simmons, Ph.D., Simon Thelwall, Ph.D., Julia Stowe, Ph.D., Elise Tessier, M.Sc., Natalie Groves, M.Sc., Gavin Dabrera, M.B., B.S., F.F.P.H., Richard Myers, Ph.D., Colin N.J. Campbell, M.P.H., F.F.P.H., Gayatri Amirthalingam, M.F.P.H., Matt Edmunds, M.Sc., Maria Zambon, Ph.D., F.R.C.Path., Kevin E. Brown, M.R.C.P., F.R.C.Path., Susan Hopkins, F.R.C.P., F.F.P.H., Meera Chand, M.R.C.P., F.R.C.Path., and Mary Ramsay, M.B., B.S., F.F.P.H.





BNT162b2 = Pfizer/BioNtech ChAdOx1 nCOV-19 = Astra-Zeneca Vaccine

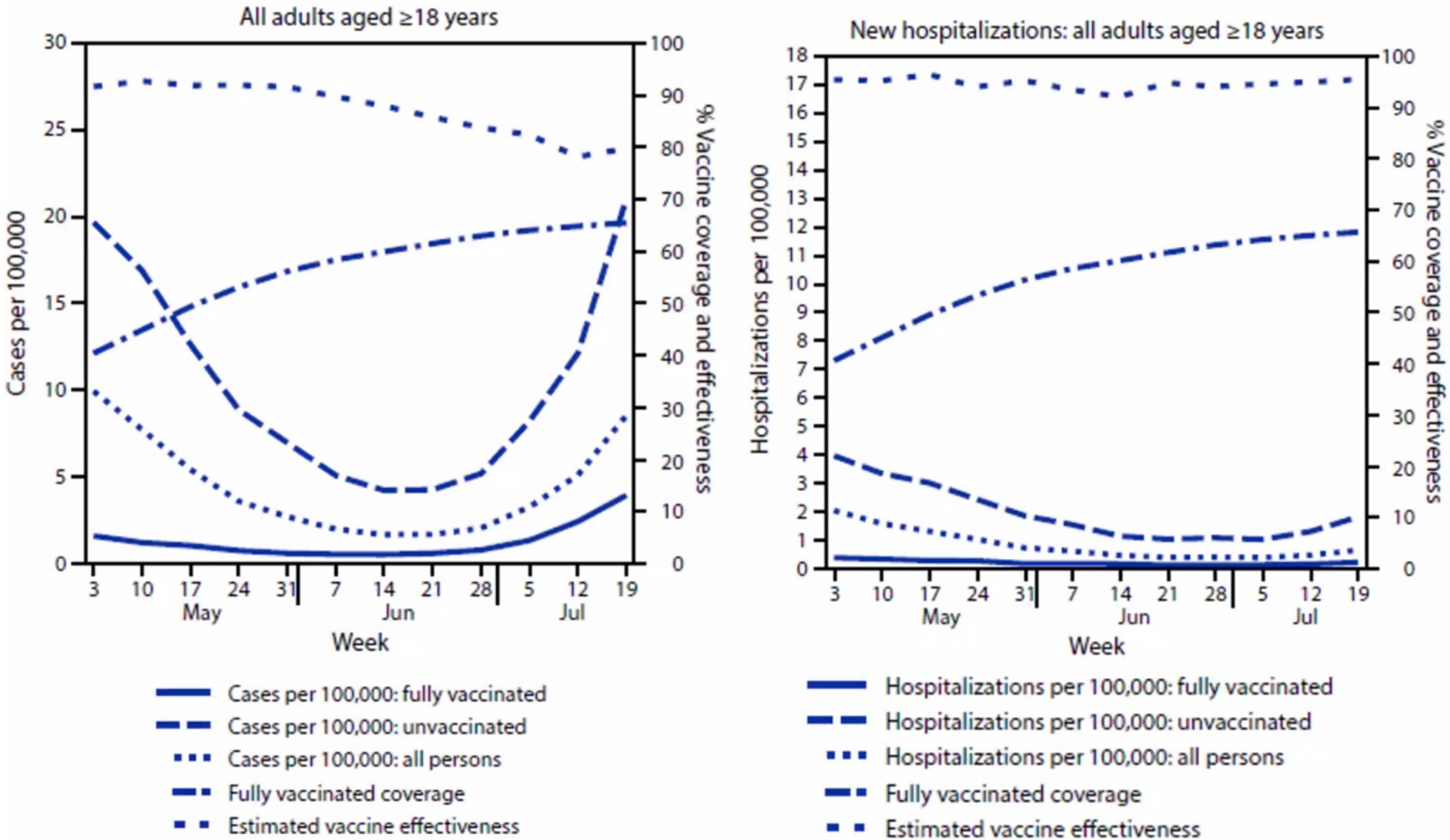
Breakthrough cases are not driving the US Covid-19 surge



Vox

Source: Kaiser Family Foundation
Note: Case data in recent months, as of July

New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021



MMWR August 18, 2021

Vaccines and Pregnancy

- v-safe COVID-19 Vaccine Pregnancy Registry tracks patients who were pregnant when they got the vaccine and in periconception period
- 147,147 patients reported being pregnant when they received the vaccine
- June 2021, initial results reported in NEJM
- 35,691 participants, age 16-54 identified as pregnant; 827 had completed pregnancy

Table 4. Pregnancy Loss and Neonatal Outcomes in Published Studies and V-safe Pregnancy Registry Participants.

Participant-Reported Outcome	Published Incidence*	V-safe Pregnancy Registry†
	%	*no./total no. (%)*
Pregnancy loss among participants with a completed pregnancy		
Spontaneous abortion: <20 wk[15-17]	10–26	104/827 (12.6)‡
Stillbirth: ≥ 20 wk[18-20]	<1	1/725 (0.1)§
Neonatal outcome among live-born infants		
Preterm birth: <37 wk[21,22]	8–15	60/636 (9.4)¶
Small size for gestational age[23,24]‖	3.5	23/724 (3.2)
Congenital anomalies[25]**	3	16/724 (2.2)
Neonatal death[26]††	<1	0/724

Shimabukuro TT, et al. NEJM, 2021

Vaccines and Fertility

- No link shown between vaccines and infertility
  - v-safe: 4,800 people reported a positive pregnancy test after 1st dose
  - 2nd study: 1,000 reported getting pregnant after 2nd dose
  - pregnancy rates among never been infected / vaccinated, infected/ not vaccinated, and vaccinated= no difference in pregnancy success rates
- Several studies have linked SARS-CoV2 infection with potential male infertility
  - ACE2 is produced in testicular cells. COVID-19 which uses ACE2 pathway may cause infertility through dysregulation of pathway and increased expression.
  - Inflammation caused by the virus is considered a risk factor for healthy reproduction
  - Preliminary studies have shown hormonal imbalances associated with lower fertility in men.

1.Shimabukuro TT, et al., N Engl J Med.
2.Razzaghi H, et al. MMWR Morb Mortal Wkly Rep 2021
3.Morris RS. F&S Reports. 2021.
4.Renu K., et al. J Reproductive Immunology, 2020.
5.Shen Q., et al. J Cell Mol Med, 2020.;
6.Ma L., et al. medRxiv, 2020

When will Vaccinations be Available to Children?

NOW

Ages 12 – 17 years

Pfizer

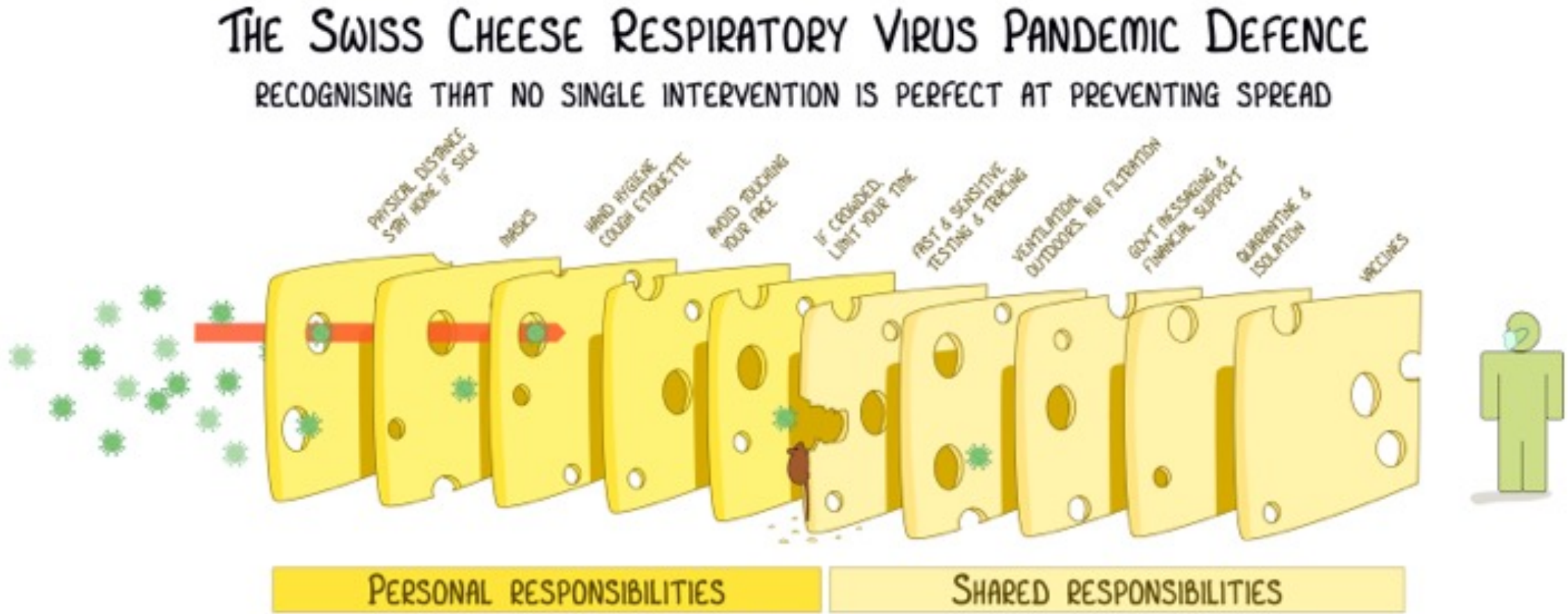
? DEC 2021

Ages 6 mo - 11 years

At the F.D.A.'s urging, Pfizer-BioNTech and Moderna are expanding their trials for children 5 to 11.

At the urging of federal regulators, two coronavirus vaccine makers are expanding the size of their clinical trials for children ages 5 to 11 — a precautionary measure designed to detect rare side effects including heart inflammation problems that turned up in vaccinated people younger than 30.

VANDERBILT HEALTH



https://virologydownunder.com/the-swiss-cheese-infographic-that-went-viral/