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

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?

- 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)
## US Vaccination Coverage

These data accessed on 08/28/2021

Source link: CDC

(These data accessed on 08/28/2021)

### Total Vaccine Doses
- Delivered: 437,567,285
- Administered: 366,838,484

Learn more about the distribution of vaccines.

### People Vaccinated

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

172.6M People fully vaccinated

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

Location

<table>
<thead>
<tr>
<th>Location</th>
<th>Age &lt; 18</th>
<th>Age 18-64</th>
<th>Age 65+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tennessee</td>
<td>7.3%</td>
<td>44.8%</td>
<td>80.2%</td>
</tr>
</tbody>
</table>

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

VANDERBILT HEALTH
Understanding VAERS

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)

- 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

Shimabukuro TT et al. Vaccine. 2015. 33:4398-4405
## Putting Data in Context: US Data

### COVID-19 infections
- 38.7 MM infected
- ? Adverse events
- 1.6% deaths
- 6.7% hospitalized

### COVID-19 Vaccines
- 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: 

“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.

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

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

Alyson M. Cavanaugh, DPT, PhD1,2,5; Kevin B. Spicer, MD, PhD2,3; Douglas Thoroughman, PhD2,4; Connor Glick, MS5; Kathleen Winter, PhD2,3


<table>
<thead>
<tr>
<th>Vaccination status</th>
<th>Case-patients</th>
<th>Control participants</th>
<th>OR (95% CI)†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not vaccinated</td>
<td>179 (72.8)</td>
<td>284 (57.7)</td>
<td>2.34 (1.58–3.47)</td>
</tr>
<tr>
<td>Partially vaccinated</td>
<td>17 (6.9)</td>
<td>39 (7.9)</td>
<td>1.56 (0.81–3.01)</td>
</tr>
<tr>
<td>Fully vaccinated</td>
<td>50 (20.3)</td>
<td>169 (34.3)</td>
<td>Ref</td>
</tr>
<tr>
<td>Total</td>
<td>246 (100)</td>
<td>492 (100)</td>
<td>—</td>
</tr>
</tbody>
</table>

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

**Risk of COVID-19 Reinfection 2.3-Fold Higher if Not Vaccinated**
Vaccines Continue to Prevent Hospitalization

- All patients
- Aged ≥65 years
- Immunocompromised
- With multiple morbidities

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

**Updated April 22, 2021**

## New reported cases

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

**Tests**

- **Cases**: 155,365 (+21%)
- **Tests**: 1,334,692 (+33%)
- **Hospitalized**: 98,337 (+28%)
- **Deaths**: 1,266 (+95%)
Where We Are Today: TN

COVID-19 PATIENTS IN HOSPITAL (TENNESSEE)

Currently in hospital (Tennessee)

Data range: 2 Apr '20 - 27 Aug '21

© newsnodes.com, bnonews.com

(These data accessed on 08/28/2021)

Source link: Newsnodes
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**

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https://www.globaltimes.cn/page/202107/1227847.shtml
https://www.yalemedicine.org/news/5-things-to-know-delta-variant-covid
How does the mRNA vaccine work?

*mRNA with instructions for making the spike protein is developed in a lab*

*Spike protein

COVID-19 virus

*mRNA vaccine

Human cell

*mRNA enters the cell

*does not enter nucleus (where your DNA is)

*COVID-19 virus spike protein created

*Spike proteins are recognized by the immune system, which produces specific antibodies against the COVID-19 virus

*If you’re infected with the COVID-19 virus, antibodies bind to virus & stop it from replicating*

Source: Mayo Clinic
## About the Vaccines: Ingredients

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

- **mRNA**
- **Fats**
- **Sugar**
- **Salt**

**NOTE:** ethylene glycol is different than polyethylene glycol

![Diagram of ethylene glycol and polyethylene glycol](image-url)
Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant

BNT162b2 = Pfizer/BioNtech ChAdOx1 nCOV-19 = Astra-Zeneca Vaccine
Breakthrough cases are not driving the US Covid-19 surge

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

All adults aged ≥18 years

- Cases per 100,000: fully vaccinated
- Cases per 100,000: unvaccinated
- Cases per 100,000: all persons
- Fully vaccinated coverage
- Estimated vaccine effectiveness

New hospitalizations: all adults aged ≥18 years

- Hospitalizations per 100,000: fully vaccinated
- Hospitalizations per 100,000: unvaccinated
- Hospitalizations per 100,000: all persons
- Fully vaccinated coverage
- Estimated vaccine effectiveness

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>
<thead>
<tr>
<th>Participant-Reported Outcome</th>
<th>Published Incidence*</th>
<th>V-safe Pregnancy Registry†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>no./total no. (%)</td>
</tr>
<tr>
<td>Pregnancy loss among participants with a completed pregnancy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spontaneous abortion: &lt;20 wk¹⁵-¹⁷</td>
<td>10–26%</td>
<td>104/827 (12.6)%</td>
</tr>
<tr>
<td>Stillbirth: ≥ 20 wk¹⁸-²⁰</td>
<td>&lt;1%</td>
<td>1/725 (0.1)%</td>
</tr>
<tr>
<td>Neonatal outcome among live-born infants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preterm birth: &lt;37 wk²¹,²²</td>
<td>8–15%</td>
<td>60/636 (9.4)%</td>
</tr>
<tr>
<td>Small size for gestational age²³,²⁴</td>
<td>3.5%</td>
<td>23/724 (3.2%)</td>
</tr>
<tr>
<td>Congenital anomalies²⁵,²⁶</td>
<td>3%</td>
<td>16/724 (2.2%)</td>
</tr>
<tr>
<td>Neonatal death²⁶,²⁷</td>
<td>&lt;1%</td>
<td>0/724</td>
</tr>
</tbody>
</table>

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 1\textsuperscript{st} dose
  - 2\textsuperscript{nd} study: 1,000 reported getting pregnant after 2\textsuperscript{nd} 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.

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.
The Swiss Cheese Respiratory Virus Pandemic Defence

Recognising that no single intervention is perfect at preventing spread

Personal Responsibilities

Shared Responsibilities

Each intervention (layer) has imperfections (holes). Multiple layers improve success.

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