

Eric J. Holcomb
Governor
Kristina M. Box, MD, FACOG
State Health Commissioner

Dear Clinical Providers at Long-Term Care Facilities:

Thank you for the care you are providing to the residents of the LTC Facilities. As you are aware, LTC residents are at higher risk for acquiring COVID-19 due to congregate living. They are also at risk for more severe illness, increased hospitalization rates, and increased mortality rates, when compared to the general population.

We would like you to be strong advocates for LTC residents COVID-19 vaccination and make your best efforts to get every eligible resident vaccinated.

We are starting to see an increase in outbreaks at nursing facilities. These cases are predominantly among the unvaccinated, with several requiring hospitalization. However, breakthrough cases in vaccinated individuals have resulted in infections ranging from asymptomatic infection to much lesser severity, when compared to infection in the unvaccinated. Although newer, more easily transmissible variants are emerging, vaccines still confer protection against severe COVID infection, so it is prudent to get all vulnerable to be fully vaccinated before fall.

Please take the time to show them data on vaccine safety, efficacy, and reduced incidence/severity of COVID among vaccinated individuals. I compiled several links for easy access for your conversations with residents. I am also attaching some data visualization tools to assist you in having these conversations.

Our IDOH LTC care team is available to assist you if you need additional materials or support.

We would like to thank you again for your vaccination efforts.

Sincerely,

A handwritten signature in blue ink, reading 'Shireesha Vuppalachchi'.

Shireesha Vuppalachchi, MD
Medical Director for Long-Term Care
svuppalachchi@isdh.in.gov

To promote, protect, and improve the health and safety of all Hoosiers.

Challenging Conversations

- Ask the reasons for their vaccine hesitancy.
- Acknowledge their concern, convey to them you see their viewpoint and ask them to give you an opportunity to explain your advice based on evidence and your expertise.
- Tell your reasons for why you took the vaccine.
- Find a compelling reason why the resident should take the vaccine — for resident's own self, his/her loved one, to protect others, to redeem lifestyle benefits etc.
- Encourage them to talk to other residents who took the vaccine six months ago, three months ago, and more recently.
- Encourage them to talk to their friends and family who took the vaccine.
- Encourage them to talk to the physician or provider they have known the longest.
- Encourage them to talk to the provider they trust the most (that may be you).

Other resources:

- [Tips for addressing vaccine hesitancy](#)
- [IDOH vaccine tools for providers](#)



COVID-19 Numbers

Access Current U.S. Case information:

<https://covid.cdc.gov/covid-data-tracker/#datatracker-home>

Access Current Worldwide Case Information:

<https://covid19.who.int/>

Clinical manifestations: Asymptomatic to severe

<https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>

Complications: Cardiac, stroke, thrombotic, pulmonary, renal hepatic, cognitive to name a few

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7927752/>

Long COVID: Fatigue, brain fog, mood changes, shortness of breath, cough, and headache are common for months after recovering from COVID-19. Some facilities started to have COVID-19 clinics to follow post COVID-19 symptoms.

Emotional and mental health symptoms are also common.

<https://www.cdc.gov/coronavirus/2019-ncov/long-term-effects.html>



COVID-19 Management

1. **Symptomatic, supportive for mild cases**
2. **Monoclonal antibody therapy (MAB):** Helpful to prevent clinical deterioration and hospitalization. MAB therapy is available under emergency use authorization for mild to moderate **confirmed** COVID infection, for cases with a symptom onset within the last 10 days, in the elderly or those at high risk for progression/hospitalization, and cases not needing oxygen OR no increase in oxygen requirement compared to baseline AND not hospitalized.

Long-term care facilities can directly order the monoclonal antibody therapeutics:

- Casirivimab/Imdevimab (Regeneron) - AmerisourceBergen Direct Ordering Link: <https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8>
- Sotrovimab (GlaxoSmithKline) - <https://www.sotrovimab.com/hcp/access/>
- For ordering through AmerisourceBergen, allow 1-2 days for the product to arrive following order placement. If a new customer to AmerisourceBergen, allow up to 2 days for the initial order following receipt of the required customer documentation.

If you would like to find a center that can provide the MAB therapy near you:

<https://protect-public.hhs.gov/pages/therapeutics-distribution#distribution-locations>. This is based on current shipment locations from AmerisourceBergen.

Guides for providers:

- [sotrovimab-infusion-guide.pdf](#)
- [Regeron- covid19-eua-guide-book.pdf](#)

Other resources:

- National Infusion Center Association (NICA) – <http://infusioncenter.org/healthcare-providers-monoclonal-antibody-therapies/>
- HHS Combat COVID-19: <https://combatcovid.hhs.gov/hcp/resources-clinicians#>
- ASPR: <https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/default.aspx>

3. **Hospitalization:** for severe or complicated infection



Prevention

- Masks for source control
- Social distancing: 6 feet distance between individuals
- Frequent hand hygiene
- CDC Guidance to [Prevent Getting Sick](#)
- Monoclonal antibodies:

The new authorization is for post-exposure prophylaxis use:

- **In adult and pediatric individuals** (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis of COVID-19 in individuals who are at **high risk for progression to severe COVID-19**, including hospitalization or death; **AND**
- **Are not fully vaccinated or who are not expected to mount an adequate immune response** to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications); **AND**
 - Have been **exposed to an individual infected with SARS-CoV-2** consistent with close contact criteria per CDC **or**
 - Who are at **high risk of exposure to an individual infected with SARS-CoV-2** because of occurrence of COVID-19 infection in other individuals in the same institutional setting (for example, nursing homes or prisons)
 - [FDA EUA REGEN-COV monoclonal antibody therapy for post-exposure prophylaxis \(prevention\) for COVID-19 _ FDA](#)
 - [Fact sheet for HCP-EUA post exposure prophylaxis REGEN-COV](#)
 - [Fact sheet for patients- EUA Post Exposure Prophylaxis](#)
 - [Frequently Asked Questions REGN mAb EUA 7 30 2021 final](#)

COVID-19 vaccines:

All three authorized vaccines were studied just like any other vaccine that has come to market in the past. No steps were skipped. Large phase 3 studies (study population 30,000 to 43,000) were done for all three authorized vaccines. Vaccines have gone through review by the U.S. FDA and independent groups of scientists and clinicians. Vaccine doses were manufactured simultaneously while they were being studied, so they could be rolled out for distribution when safety and efficacy were confirmed. If the studies did not show efficacy, those doses would have been discarded. It was a risk taken to save time on manufacturing doses waiting to start until after authorization. If vaccine manufactures had waited for authorization before manufacturing the doses, it would have delayed the availability of the vaccine significantly.





Vaccine ingredients

Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines

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[(poly ethylene glycol (PEG)2000)-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-distearoyl-sn-glycero-3-methoxy poly ethylene glycol	Poly sorbate-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)azanediylbis(hexane-6,1-diyl)bis(2-hexyldcanoate)	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	

<https://www.cdc.gov/vaccines/covid19/clinical-considerations/covid-19-vaccines-us.html>

Emergency Use Authorization vs. FDA Approval

<https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>

Emergency use authorization (EUA)

EUA is issued when:

- A vaccine is shown to be effective in preventing a serious or life-threatening condition
- Known and potential side effects outweigh the known and potential risks
- For use in the setting of public health emergency.
- No other product already is available for this use.
- Has completed phase 3 study with thousands of participants and have at least three months of safety data

Vaccine can be manufactured while under study but cannot be distributed until after authorization.

FDA approval

The vaccine must have at least six months of safety data and months of review by FDA. Pfizer and Moderna have submitted data for FDA approval.

NOTE: Please share with patients that we have seen real world effects of 334 million doses.



Monitoring Post Authorization

After the vaccines have been authorized, robust monitoring is continued to monitor safety and efficacy.

- Over 334 million doses of COVID-19 vaccine have been given in the United States from December 14, 2020, through July 12, 2021.
- Monitoring is being done by various methods: Vsafe, VAERS, VSD, CISA and others.
- **Vsafe:** Text based questionnaire for individuals to fill out what they are feeling
- **VAERS:** Anyone can submit symptoms or illness experienced post vaccine. Does not mean vaccine caused it. If a significant number of reports of a side effect or serious effects are submitted, they are analyzed in the context of full review of the clinical situation and studied for causal linkage. Then benefit-risk analysis is performed.
- <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/reporting-systems.html>

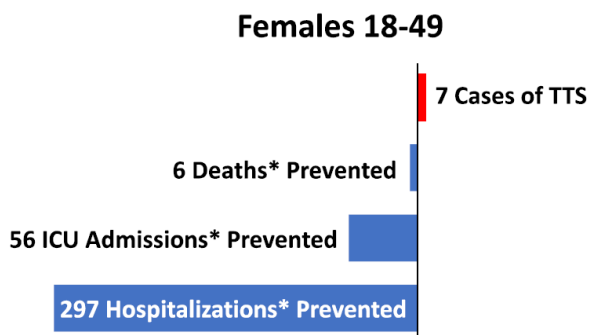
TTS, myocarditis, and Guillian-Barré syndrome cases were reported in similar fashion in some subgroups of individuals.

Thrombotic Thrombocytopenic syndrome (TTS)-CVST (cerebral venous sinus thrombosis with thrombocytopenia) risk vs. benefit from the vaccine in females 18-49

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-04-23/06-COVID-Oliver-508.pdf>

Risks and benefits by for females, by age group

For every **1 million** doses of vaccine given with current US exposure risk¹

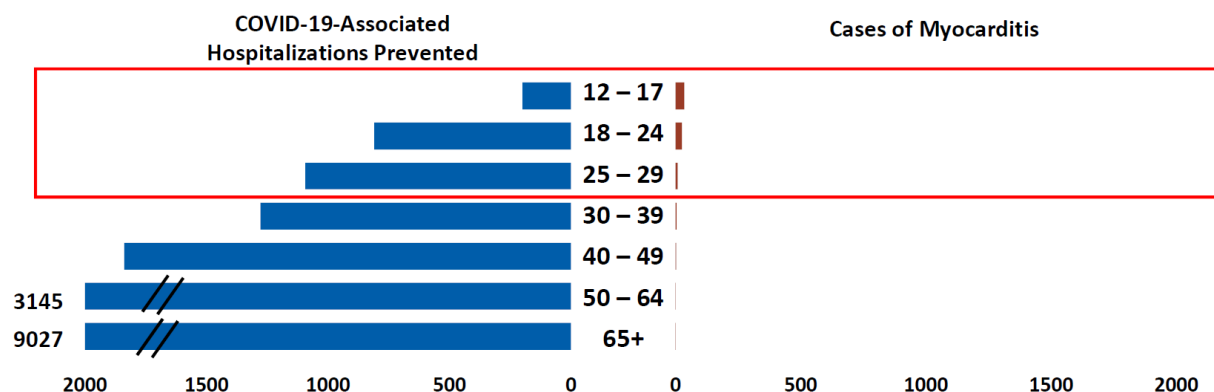


Myocarditis risk vs. benefit from mRNA vaccines

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/05-COVID-Wallace-508.pdf>

Benefits and risks after dose 2, by age group

For every **million** doses of mRNA vaccine given with current US exposure risk¹



¹ Based on hospitalization rates from COVID-NET as of May 22nd. Benefit/Risk calculated over 120 days.

TABLE 2. Individual-level estimated number of COVID-19 cases and COVID-19-associated hospitalizations, intensive care unit admissions, and deaths prevented after use of 2-dose mRNA COVID-19 vaccine for 120 days and number of myocarditis cases expected per million second mRNA vaccine doses administered, by sex and age group* — United States, 2021

Sex/Benefits and harms from mRNA vaccination	No. per million vaccine doses administered in each age group (yrs) [†]				
	12–29	12–17	18–24	25–29	≥30
Male					
Benefit					
COVID-19 cases prevented [§]	11,000	5,700	12,100	15,200	15,300
Hospitalizations prevented	560	215	530	936	4,598
ICU admissions prevented	138	71	127	215	1,242
Deaths prevented	6	2	3	13	700
Harms					
Myocarditis cases expected [¶]	39–47	56–69	45–56	15–18	3–4
Female					
Benefit					
COVID-19 cases prevented [§]	12,500	8,500	14,300	14,700	14,900
Hospitalizations prevented	922	183	1,127	1,459	3,484
ICU admissions prevented	73	38	93	87	707
Deaths prevented	6	1	13	4	347
Harm					
Myocarditis cases expected [¶]	4–5	8–10	4–5	2	1

Abbreviations: ICU = intensive care unit; VAERS = Vaccine Adverse Event Reporting System.

* This analysis evaluated direct benefits and harms, per million second doses of mRNA COVID-19 vaccine given in each age group, over 120 days. The numbers of events per million persons aged 12–29 years are the averages of numbers per million persons aged 12–17 years, 18–24 years, and 25–29 years.

[†] Receipt of 2 doses of mRNA COVID-19 vaccine, compared with no vaccination.

[§] Case numbers have been rounded to the nearest hundred.

[¶] Ranges calculated as ±10% of crude VAERS reporting rates. Estimates include cases of myocarditis, pericarditis, and myopericarditis.

Guillain-Barré Syndrome: approximately 100 cases after over 12 million Johnson and Johnson vaccinations: risk benefit analysis like above is awaited, but vaccines clearly prevent far more deaths and complications.



Crude comparison with mRNA vaccines

COVID-19 Vaccine	VAERS reports with GBS screening*	Doses administered	Crude** VAERS GBS reporting rate per million doses administered
Janssen	100	12,235,978	8.1
Moderna	162	134,076,668	1.21
Pfizer-BioNTech	190	181,347,436	1.05

VAERS reports processed through June 30, 2021

Notes:

Doses administered data per CDC Vaccination Report as of 7/1/2021

*GBS screening definition is any one of the following encoded MedDRA preferred terms: DEMYELINATING POLYNEUROPATHY;GUILLAIN-BARRE SYNDROME; MILLER FISHER SYNDROME. Include reports processed through 7/1/2021.

**Counts of VAERS reports meeting GBS screening definition divided by doses administered; counts are based on encoded terms

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[ACIP-Guillain-Barre Syndrome \(GBS\) after Janssen COVID-19 Vaccine VAERS \(cdc.gov\)](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html)

Otherwise, side effects reported were generally mild and vaccines were well tolerated:

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html>

Mythbusters Related to Vaccine Hesitancy

- The vaccines do not make you magnetic.
- The vaccines do not cause COVID.
- The vaccines do not contain live virus.
- They do not have a tracking device.
- They do not change your DNA.
- There is no current evidence that COVID vaccines cause problems with pregnancy.
- No evidence that they cause fertility problems.
- Those who had COVID-19 in the past should still take the vaccine.
- There are no fetal cells in the vaccine.

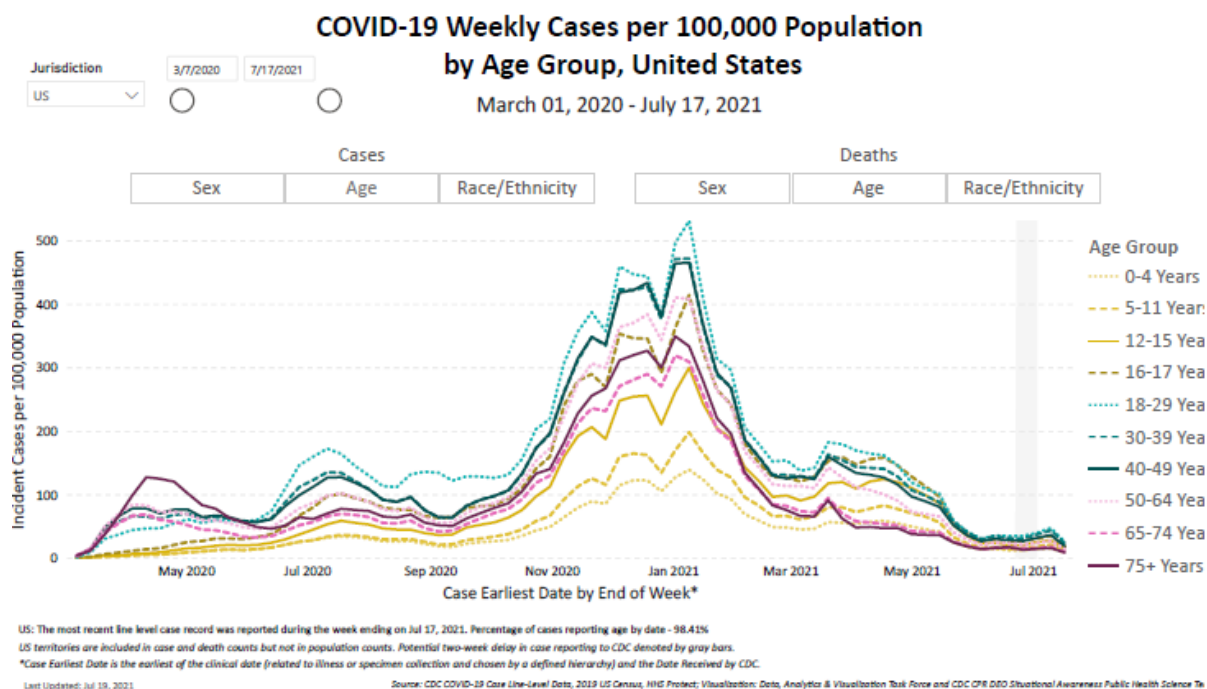
Other resources:

- <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html>
- <https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/covid-19-vaccines-myth-versus-fact>
- <https://www.mayoclinichealthsystem.org/hometown-health/featured-topic/covid-19-vaccine-myths-debunked>



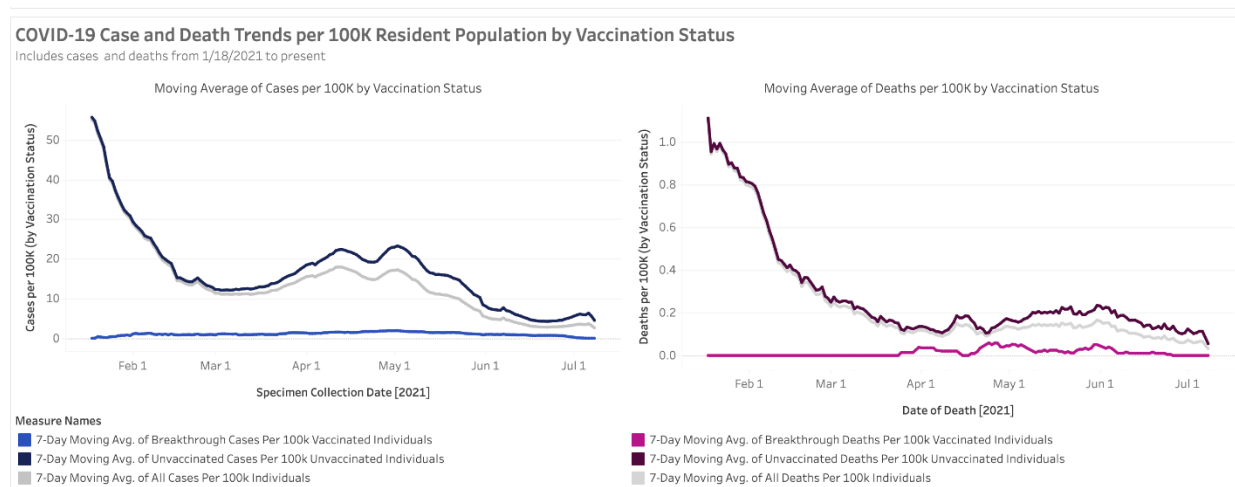
Cases and Deaths Trends

Clear downward trend since vaccinations have become available



Vaccinated vs. Unvaccinated

- **Breakthrough cases are not common, and when they occur, they are much less severe.**
- **In June 2021, 95 % of cases and 97% of COVID-related deaths were in unvaccinated individuals.**
- Clear difference in numbers when you compare vaccinated vs. unvaccinated:
<https://www.coronavirus.in.gov/vaccine/2680.htm> (click on breakthrough tab in top right corner)
 Vaccination rates by county are available here:
<https://www.coronavirus.in.gov/vaccine/2680.htm> (click on population tab in top right corner)



Current rates vs. Targets

Nearly 50% of the total U.S. population is now fully vaccinated, while the goal is 70-85% of the total population (that includes ages not yet eligible for vaccination): <https://covid.cdc.gov/covid-data-tracker/#vaccinations>

LTC resident target vaccination nearly 100%, as we want to protect as many residents as we can.

LTC vaccination dashboard will be available soon on the [IDOH website](#) and will include data on resident and staff vaccination rates, separated by facility.



Variants

Current vaccines are highly effective against severe disease caused by current variants in circulation. Vaccinated individuals are less likely to develop infection and even less likely to transmit infection. Variants develop when virus is transmitted. The only way to stop this is by stopping transmission, which is possible only by vaccinating all eligible individuals.

Top 5 things to know about Delta:

- 1. Getting vaccinated prevents severe illness, hospitalization, and death; it also helps reduce the spread of the virus in communities.**

Unvaccinated individuals should get vaccinated and continue masking until they are fully vaccinated.

With the Delta variant, this is more urgent than ever. The highest spread of cases and severe outcomes is happening in places with low vaccination rates.

- 2. Data show Delta is different than past versions of the virus: it is much more contagious.**

Some vaccinated people can get Delta in a breakthrough infection and may be contagious. Even so, vaccinated individuals represent a very small amount of transmission occurring around the country. Virtually all hospitalizations and deaths continue to be among the unvaccinated.

- 3. In areas with substantial and high transmission, CDC recommends that everyone (including fully vaccinated individuals) wear a mask in public indoor settings to help prevent spread of Delta and protect others.**

- 4. CDC recommends that community leaders encourage vaccination and masking to prevent further outbreaks in areas of substantial and high transmission.**

- 5. CDC recommends universal indoor masking for all teachers, staff, students, and visitors to K-12 schools, regardless of vaccination status. Children should return to full-time in-person learning in the fall with layered prevention strategies in place.**



Benefits of Vaccination

[IDOH Vaccine Provider Resources](#)

Lifestyle benefits of vaccination:

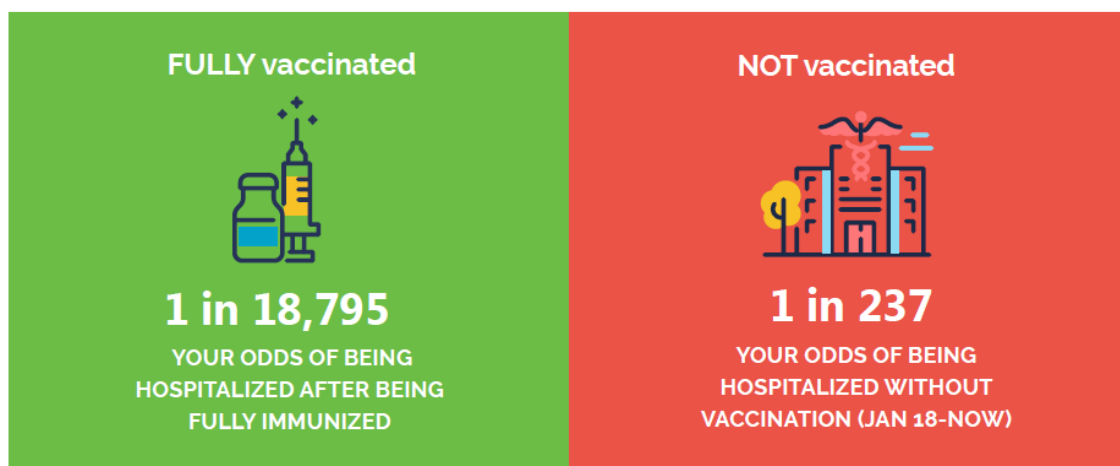
Traveling requirements, masking requirements, and quarantine related requirements:

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html>

Health benefits of vaccination:

- Less chance of acquiring COVID-19
- Even lesser chance of contracting a severe COVID-19 infection
- Less chance of transmission to others

Know the risks of hospitalization if you are infected with COVID-19:



Community benefits of vaccination: Less chance for variants to develop

Other Medical Issues to Address

With COVID-19 as the primary concern for the last 16 or so months, some other things were less priority. As we now have powerful tools to prevent COVID, it is time to look at those other issues.

- Routine vaccination: Tetanus, shingles, pneumovax etc.
- Mental health screening
- Primary prevention
- A1C, BP goals
- Dental care
- Review medications
- Physical conditioning