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COVID-19 VACCINES COULD HELP US GET BACK TO NORMAL FASTER

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COVID-19 can have serious, life-threatening complications, and there is no way to know how COVID-19 will affect you. And if you get sick, you could spread the disease to friends, family, your patients, and others around you.

When you protect yourself, you protect your residents, friends, and family!

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The Current mRNA Vaccines Snapshot

Pfizer-BioNTech

Type of vaccine: mRNA
Number of shots: 2 shots, 21 days apart
Who can get it: Anyone 16 years or older
How given: Shot in the muscle of the upper arm
Efficacy after both doses: 95%
Does not contain:
•Eggs
•Preservatives
•Latex
Full ingredients list can be found here:
https://www.fda.gov/media/144414/download

Moderna

Type of vaccine: mRNA
Number of shots: 2 shots, 28 days apart
Who can get it: Anyone 18 years or older
How given: Shot in the muscle of the upper arm
Efficacy after both doses: 94.1%
Does not contain:
•Eggs
•Preservatives
•Latex
Full Ingredients list can be found here:
https://www.fda.gov/media/144638/download

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The Current Viral Vector Vaccine Snapshot

Janssen/Johnson & Johnson

Type of vaccine: viral vector
Number of shots: 1 shot
Who can get it: Anyone 18 years or older
How given: Shot in the muscle of the upper arm
Efficacy after dose: 66%
Does not contain:
•Eggs
•Preservatives
•Latex
Full ingredients list can be found here:
https://www.fda.gov/media/146304/download

AstraZeneca is likely to be assessed for EUA in April.

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The protection from the vaccine may take up to two weeks after the second dose for Moderna and Pfizer and two weeks after your single dose of Janssen/Johnson & Johnson.

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CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† • Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine†	**Among people without a contraindication, a history of:** • Any immediate allergic reaction* to other vaccines or injectable therapies‡ Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.#	**Among people without a contraindication or precaution, a history of:** • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies
Actions: • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative.†	**Actions:** • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated	**Actions:** • 30-minute observation period: people with history of anaphylaxis (due to any cause) • 15-minute observation period: all other people

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#Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur.

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Pfizer

Began phase 3 trials in July 2020 and received EUA from the FDA Dec. 11, 2020, based on clinical trials results:

Phase 3 Clinical Trial Data	
Study participants	> 43,000
Efficacy against mild-moderate COVID	95%
Efficacy against severe COVID-19 (hospitalization or death)	100%

Moderna

Began phase 3 trials in July 2020 and received EUA from the FDA Dec. 18, 2020, based on clinical trials results:

Phase 3 Clinical Trial Data	
Study participants	> 30,000
Efficacy against mild- moderate COVID	94% ** Efficacy drops to 84% in participants 65 or older
Efficacy against severe COVID-19 (hospitalizations or death)	89%

Janssen/J&J

Began phase 3 trials in December 2020 and received EUA from the FDA Feb. 27, 2021, based on clinical trials results:

Phase 3 Clinical Trial Data	
Study participants	> 44,000
Efficacy against moderate COVID	66% 72% efficacy for participants from the USA
Efficacy against severe COVID-19 (hospitalization or death)	85% Complete (100%) protection against COVID-19 related hospitalizations and death 28 days after vaccination

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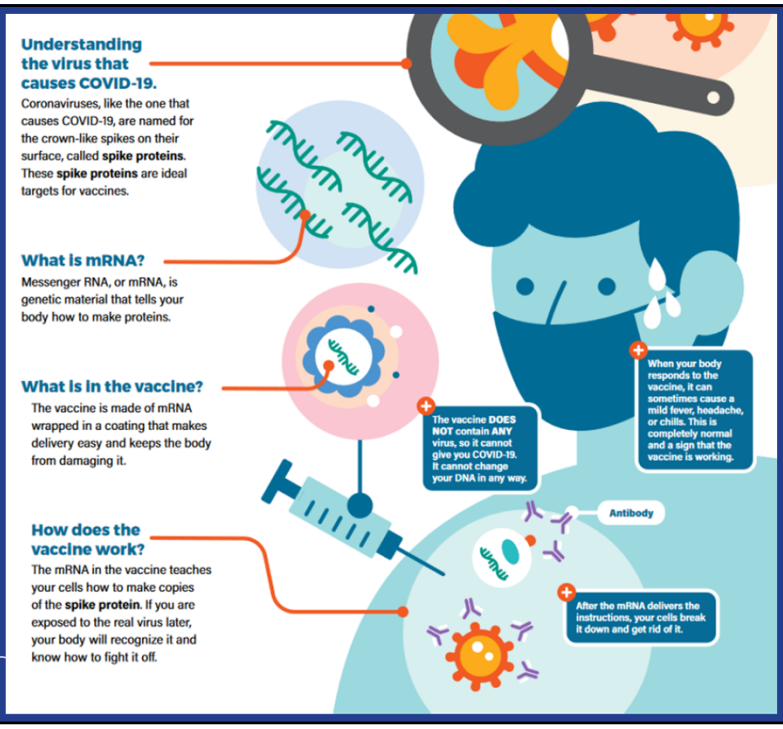
How do mRNA vaccines work?



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How Does Janssen Vaccine Work?

The Janssen COVID-19 vaccine is composed of a recombinant, replication-incompetent human adenovirus type 26 vector that, after entering human cells, expresses the SARS-CoV-2 spike (S) antigen without virus propagation. An immune response elicited to the S antigen protects against COVID-19.

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Vaccine Safety

ALL the COVID-19 vaccines that are being used have gone through the same safety tests as other vaccines produced and meet the same standards that ensure safety and efficacy!

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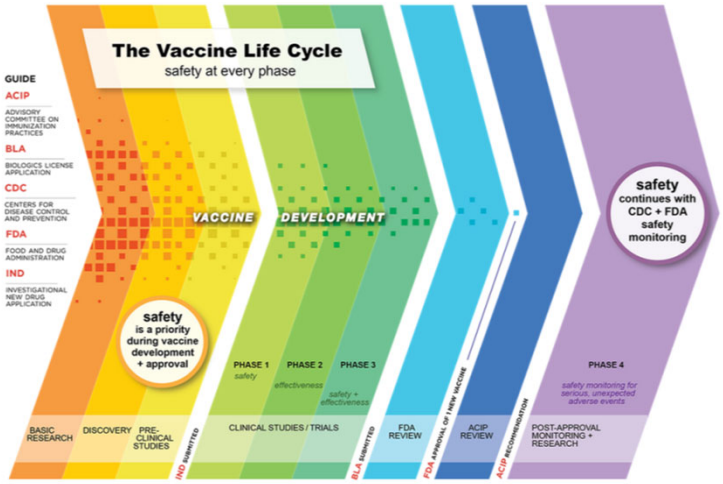
Vaccine Life Cycle: Safety at Every Phase



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Total vaccines administered throughout U.S.

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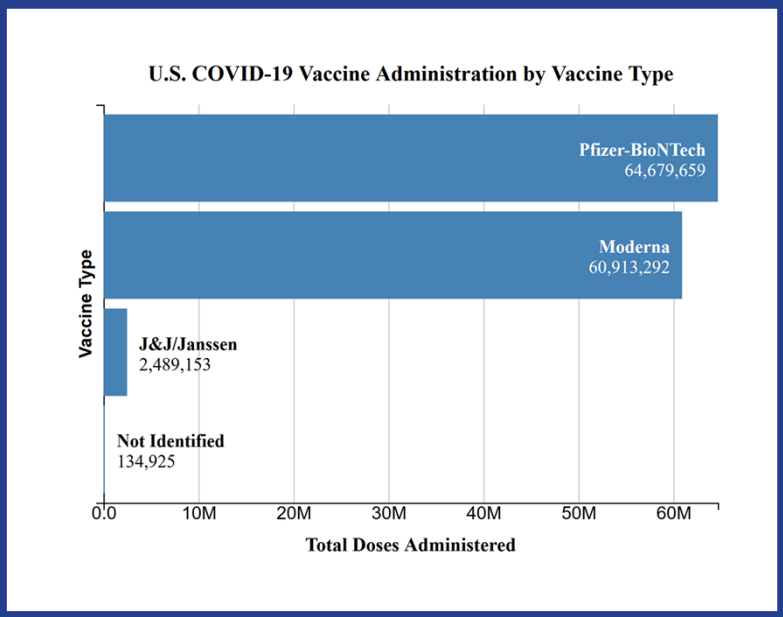
> 128,000,000 doses



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Number of fully vaccinated people in the U.S.

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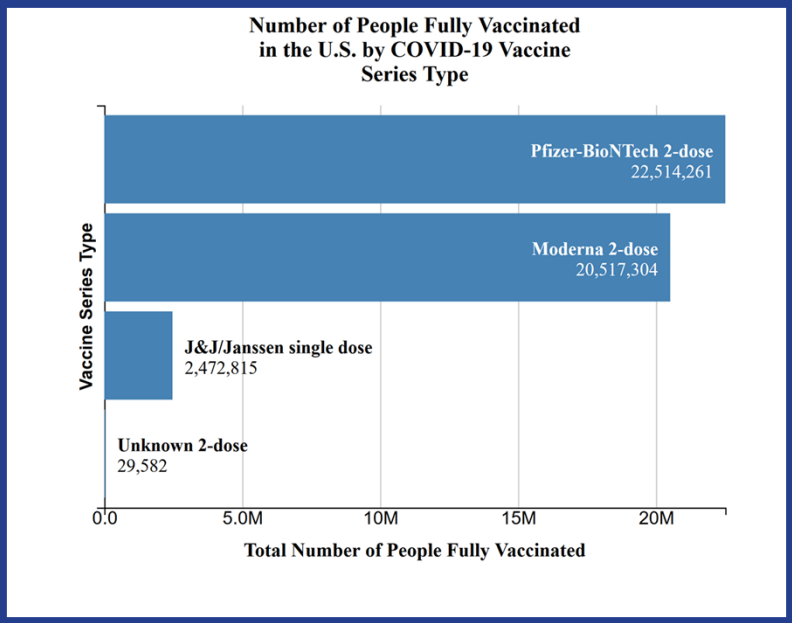
> 45,500,000 individuals



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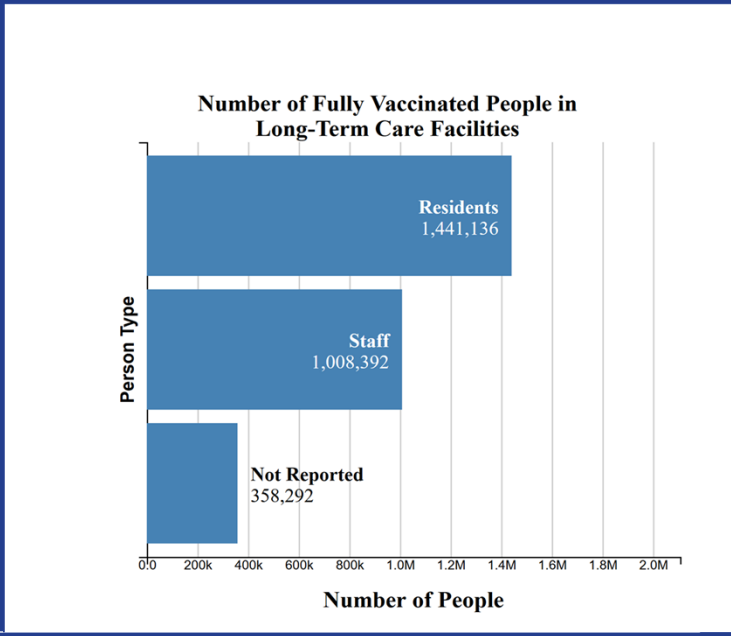
Number of fully vaccinated people in LTC facilities in the U.S.



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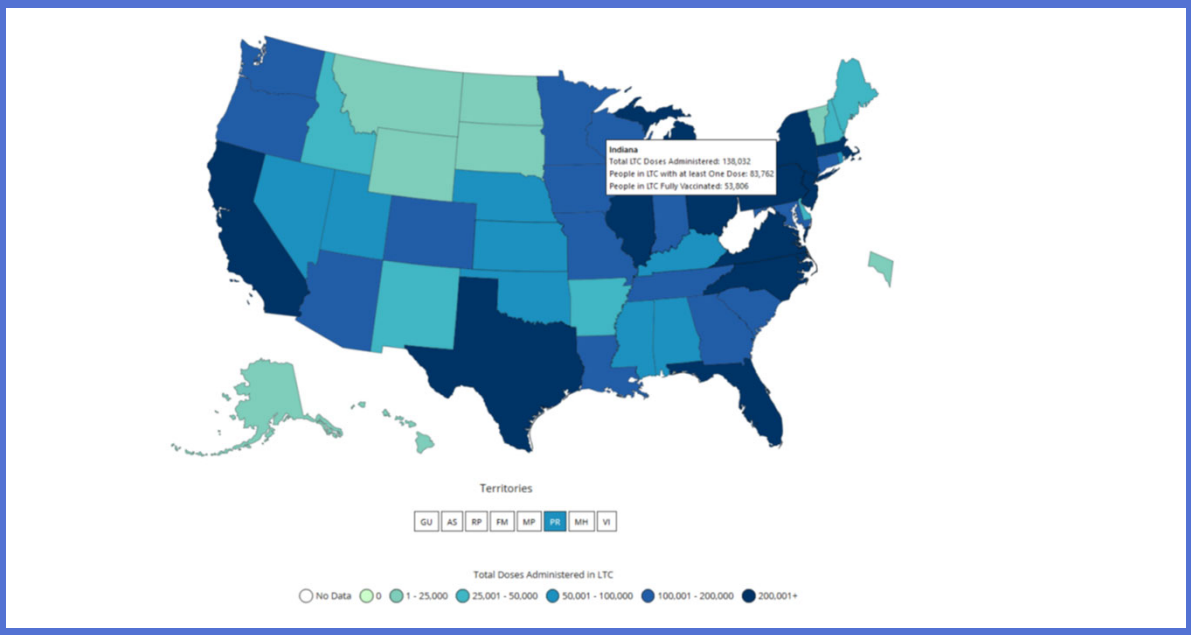

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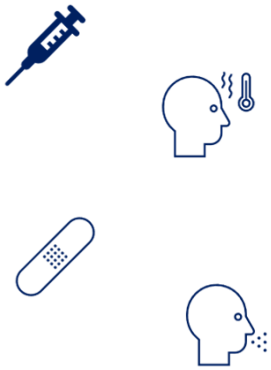

Normal vaccine side effects are to be expected and indicate an immune response. These side effects should not last longer than 24-48 hours:

- Mild fever
- Sore arm
- Headache
- Fatigue

If you develop symptoms aligned with COVID-19, you should not assume these are vaccine side effects and should be tested for COVID-19:

- Cough
- Shortness of breath
- Loss of taste or smell
- Diarrhea
- Nasal congestion
- High fevers or mild fevers lasting longer than 48 hours

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Monitoring Post EUA

- Vsafe: App-based self-reporting system
- Vaccine Adverse Event Reporting System (VAERS) is passive reporting system, meaning it relies on individuals to submit reports of their experiences. Anyone can submit a report to VAERS, including parents and patients.

- Vaccine Safety Datalink (VSD)

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VSD

- The VSD is a collaborative project between CDC's Immunization Safety Office and nine health care organizations. The VSD started in 1990 and continues today to monitor the safety of vaccines and conduct studies about rare and serious adverse events following immunization. Rapid Cycle Analysis (RCA) allows VSD to detect adverse events following vaccination in near real time so the public can be informed quickly of possible risks.
- Using VSD data that are updated each week, the rates of adverse events that occur in people who have received a particular vaccine are compared to the rate of adverse events that occurs in a similar group of people who have not received that vaccine. If the rate of adverse events among vaccinated people is higher than among the comparison group, the vaccine may be associated with an adverse event.

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Reported side effects from first month of vaccinations

(Pfizer and Moderna)

TABLE 1. Reports of adverse events after receipt of Pfizer–BioNTech and Moderna COVID–19 vaccines, by recipients' demographic characteristics and reported symptoms — Vaccine Adverse Event Reporting System, United States, December 14, 2020–January 13, 2021

Characteristic	No. (%) reporting adverse events			
		Pfizer-BioNTech vaccine		Moderna vaccine
	All COVID-19 vaccine doses (N = 6,994)	Dose 1 (N = 5,428)	Dose 2 (N = 193)	Dose 1 (N = 1,373)
Nonserious adverse event reports	6,354 (90.9)	5,087 (93.7)	152 (78.6)	1,115 (81.2)
Serious adverse event reports*†	640 (9.2)	341 (6.3)	41 (21.2)	258 (18.8)
Most frequently reported symptoms				
Headache	1,566 (22.4)	1,184 (21.8)	35 (18.1)	347 (25.3)
Fatigue	1,154 (16.5)	912 (16.8)	14 (7.3)	228 (16.6)
Dizziness	1,151 (16.5)	907 (16.7)	16 (8.3)	228 (16.6)
Chills	1,040 (14.9)	760 (14.0)	19 (9.8)	261 (19.0)
Nausea	1,037 (14,8)	790 (14.6)	18 (9.3)	229 (16.7)

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Data that includes reported side effects of J&J after EUA have not yet been released, but clinical trial study data shows similar side effects as those noted above for Pfizer and Moderna

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Preliminary results of the VSD **unvaccinated concurrent comparator** analysis for COVID-19 vaccine safety after either dose of any mRNA vaccine as of February 13, 2021

VSD Rapid Cycle Analysis prespecified outcomes for COVID-19 vaccines	Concurrent comparator analysis	Risk interval	Events in vaccinated	Adjusted expected events in risk interval
Acute disseminated encephalomyelitis	Unvaccinated	1-21 days	0	0
Acute myocardial infarction	Unvaccinated	1-21 days	23	26.0
Acute respiratory distress syndrome	Unvaccinated	N/A	0	N/A
Anaphylaxis	Unvaccinated	0-1 days	20	N/A
Appendicitis	Unvaccinated	1-21 days	31	23.6
Bell's palsy	Unvaccinated	1-21 days	21	20.3
Convulsions/seizures	Unvaccinated	1-21 days	10	9.6
Disseminated intravascular coagulation	Unvaccinated	1-21 days	1	1.1
Encephalitis/myelitis/encephalomyelitis	Unvaccinated	1-21 days	1	.1
Guillain-Barré syndrome	Unvaccinated	1-21 days	1	.6
Thrombotic thrombocytopenic purpura	Unvaccinated	1-21 days	0	0
Immune thrombocytopenia	Unvaccinated	1-21 days	1	1
Kawasaki disease	Unvaccinated	1-21 days	0	0
MIS-C and MIS-A	Unvaccinated	N/A	0	N/A
Myocarditis/pericarditis	Unvaccinated	1-21 days	2	2.1
Narcolepsy and cataplexy	Unvaccinated	N/A	2	N/A
Stroke, hemorrhagic	Unvaccinated	1-21 days	8	10
Stroke, ischemic	Unvaccinated	1-21 days	41	38.8
Transverse myelitis	Unvaccinated	1-21 days	0	0
Venous thromboembolism	Unvaccinated	1-21 days	26	26.3
Pulmonary embolism (subset of VTE)	Unvaccinated	1-21 days	20	21.0

- No statistically significant increased risks detected for any prespecified outcomes

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Preliminary results of the VSD **sequential vaccinated concurrent comparator** analysis for COVID-19 vaccine safety after either dose of any mRNA vaccine as of February 13, 2021

- No statistical signals detected

VSD Rapid Cycle Analysis prespecified outcomes for COVID-19 vaccines*	Concurrent comparator analysis	Risk interval	Events in risk Interval	Adjusted expected events in risk interval	Statistical signal (Y/N)
Acute myocardial infarction	Vaccinated	1-21 days	21	30.8	N
Appendicitis	Vaccinated	1-21 days	25	53.5	N
Bell's palsy	Vaccinated	1-21 days	17	23.1	N
Convulsions/seizures	Vaccinated	1-21 days	10	9.4	N
Disseminated intravascular coagulation	Vaccinated	1-21 days	1	0	N
Immune thrombocytopenia	Vaccinated	1-21 days	1	0	N
Myocarditis/pericarditis	Vaccinated	1-21 days	2	0	N
Stroke, hemorrhagic	Vaccinated	1-21 days	7	0	N
Stroke, ischemic	Vaccinated	1-21 days	37	43.5	N
Venous thromboembolism	Vaccinated	1-21 days	23	12.4	N
Pulmonary embolism (subset of VTE)	Vaccinated	1-21 days	19	0	N

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* Only includes outcomes with events in the risk window

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Variants

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Variants

- Currently there is no indication that the B.1.1.7 UK variant reduces the effectiveness of the Moderna, Pfizer, or J&J COVID-19 vaccines.
- Pfizer and Moderna may be less effective against South African(B1.351) and Brazil(P1/P2) variants, but more studies need to be conducted.
- J&J clinical trials were conducted in South Africa and Brazil, where B.1.351 and P1/P2 variants were present. Trials found efficacy of 61-67% in these regions (for mild-moderate illness).
- Pfizer and Moderna are already working on developing booster shots for their vaccines to improve their effectiveness against the B.1.351 strain.
- Studies are continuing to determine variant effectiveness for all three vaccines.

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Why Should I Get the Vaccine?

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COVID-19 Has Known Long-Term Effects

The worst-case scenario from COVID-19 is obviously **death;** however, numerous **short-term and long-term effects are** associated with the disease:

- Fatigue
- Shortness of breath
- Join and muscle pain
- Rash and hair loss
- Concentration and memory problems
- Blood clots
- Organ damage: brain, lungs, and heart

As of March 2021, over **29 million** Americans have had COVID-19 and over **535,000** have died from the disease in the U.S alone. Over **2.7 million** people have died worldwide.

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- Healthcare personnel are at high risk of exposure to COVID-19.
- Vaccinating healthcare personnel protects healthcare capacity.
- Vaccinating healthcare personnel helps prevent patients from getting COVID-19.
- The benefits of vaccination are believed to outweigh the possible risks.
- Based on what we know about vaccines for other diseases and early data from clinical trials, experts believe that getting a COVID-19 vaccine will also help keep you from getting seriously ill even if you do get COVID-19.
- The vaccine is FREE.
- Vaccinating long-term care staff and residents WILL save lives!

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Vaccination Has Significant Benefits.

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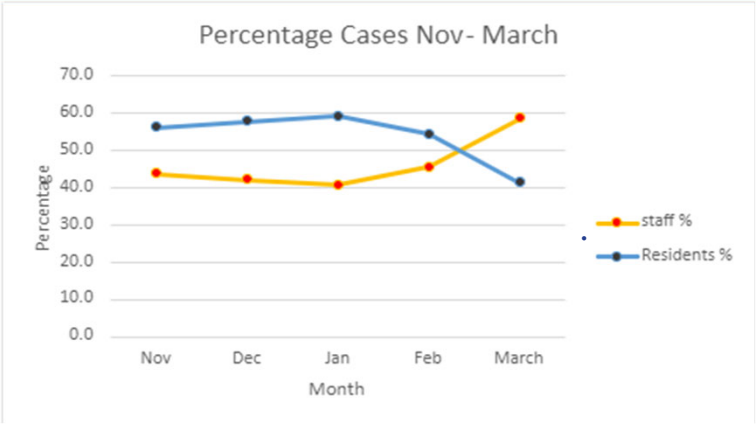
Staff Cases vs Residents (Indiana LTC)



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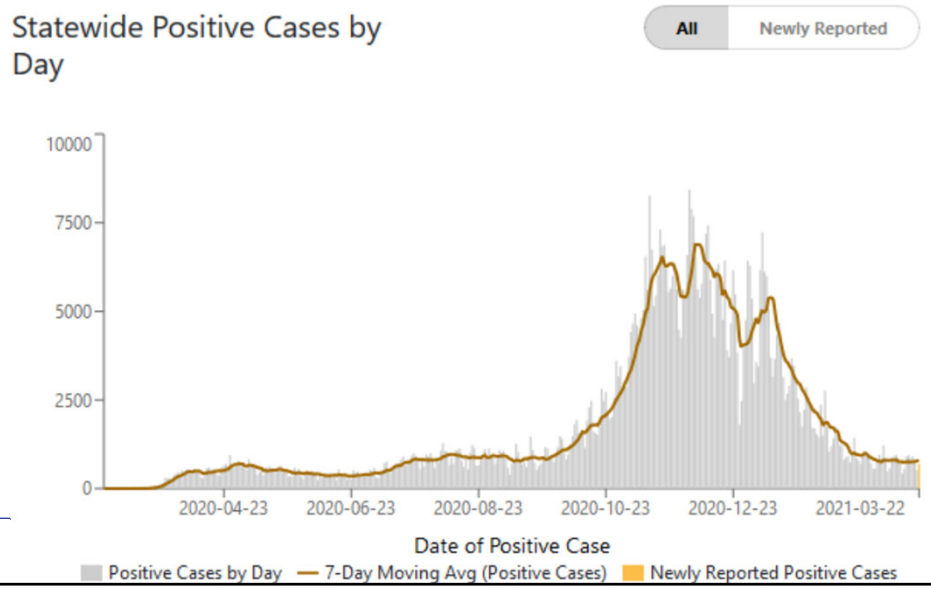
Positive Cases in Indiana



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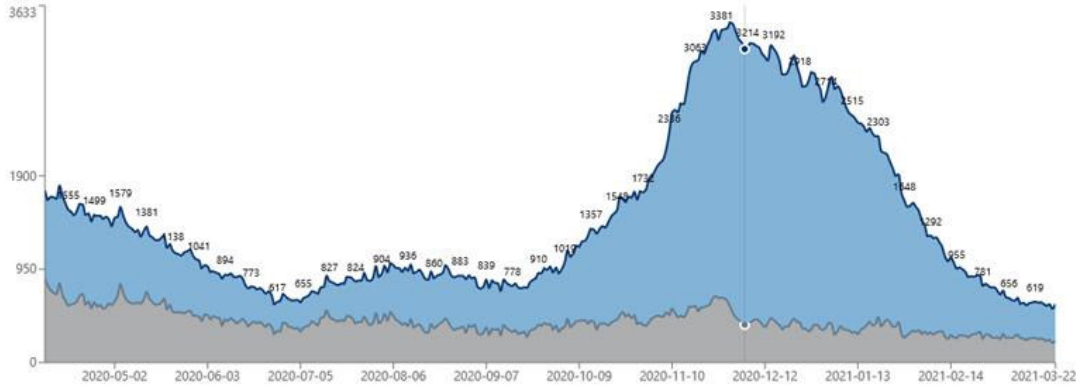
Hospitalizations in Indiana



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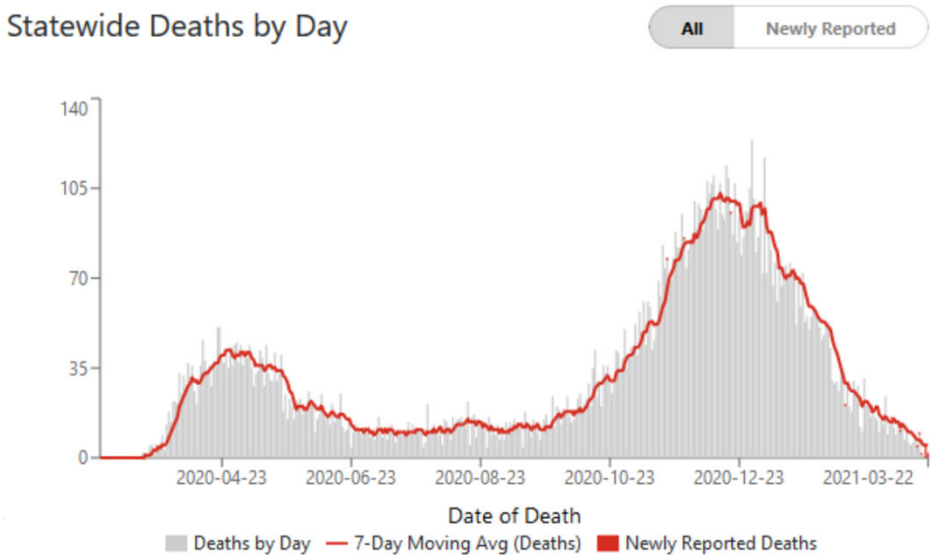
Deaths in Indiana



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Benefits>>>>Risks of Vaccination

- Less chance of getting COVID-19 infection
- Much reduced risk of severe illness, hospitalization, and death
- Less chance of emergence of new variants if more and more are vaccinated
- According to CDC, fully vaccinated can meet other fully vaccinated without masks or social distancing
- No need to quarantine if asymptomatic after being exposed to COVID-19
- Hope for normal life as we knew it quicker as more are vaccinated.

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Travel

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Spring Break is Upon Us!

Please don't let your guard down!

When you plan this spring break, do not forget best infection control practices.

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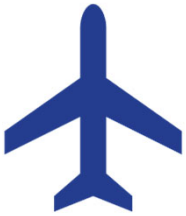
Recommendations

If you do travel, please be responsible:

- Keep gatherings outdoor.
- Limit to small size if participating in group activities.
- Stick to the same group of people.
  - Always follow basic infection control practices: hand hygiene, social distancing, masking if not your group.
- Even if fully vaccinated, get tested and quarantine if you feel ill.
- Even if fully vaccinated, if you came across high-risk situations even with precautions, get tested 3-5 days after possible exposure.



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You will still need to take precautions!

Socially distance
Mask up
Avoid crowds
Stay home if you are sick
Hand hygiene

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Thank you!

Consumer Services and Health Care Regulation Commission

Shireesha Vuppalanchi, MD
Medical Director for Long-term Care

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