

OUR SPEAKERS



Dr. Jackie Eghrari-Sabet

Clinical Assistant Professor of Medicine, George Washington School of Medicine & Health Sciences

Medical Director, Telehealth, Allergy & Asthma Network



Dr. Purvi Parikh

Clinical Assistant Professor of Medicine NYU Langone School of Medicine & Director, Allergy and Asthma Association, Murray Hill

National Spokesperson, Allergy & Asthma Network



Tonya Winders

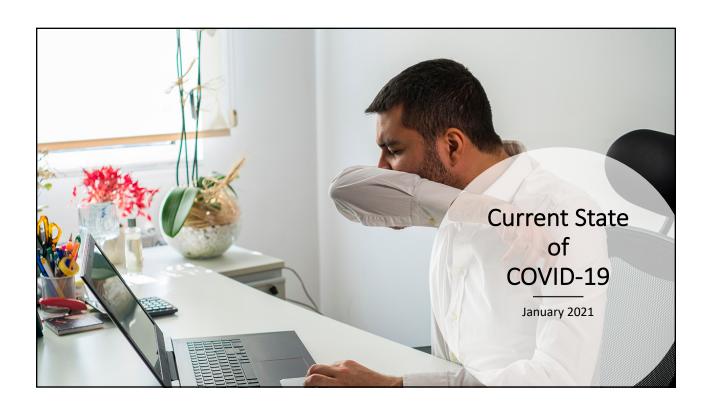
President & CEO, Allergy & Asthma Network

President, Global Allergy & Airways Patient Platform

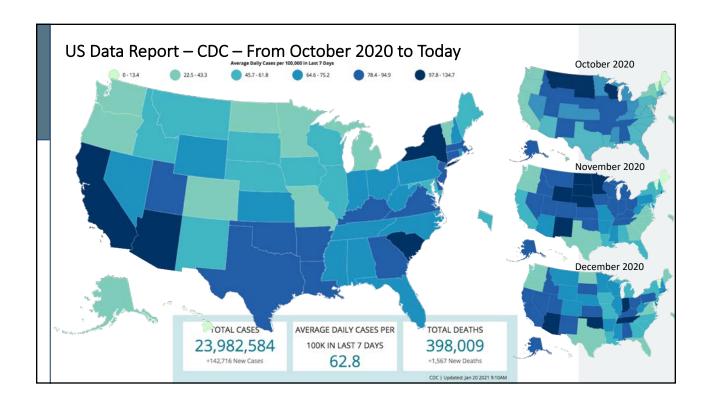
PROGRAM OUTLINE

- Current State of COVID-19
- Vaccine Overview
- Identification & Management of Anaphylaxis
- Allergy & Asthma Network Resources

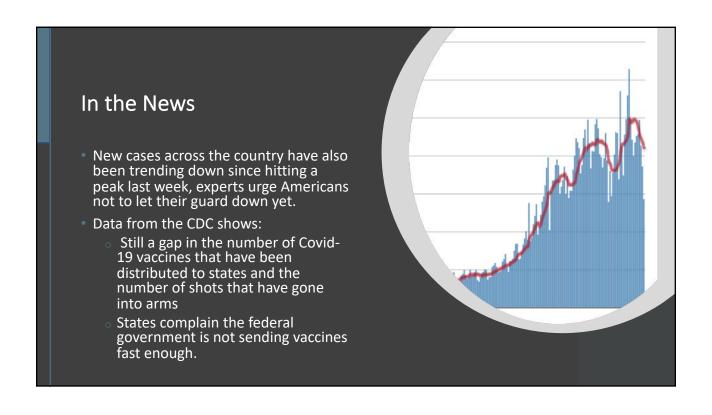


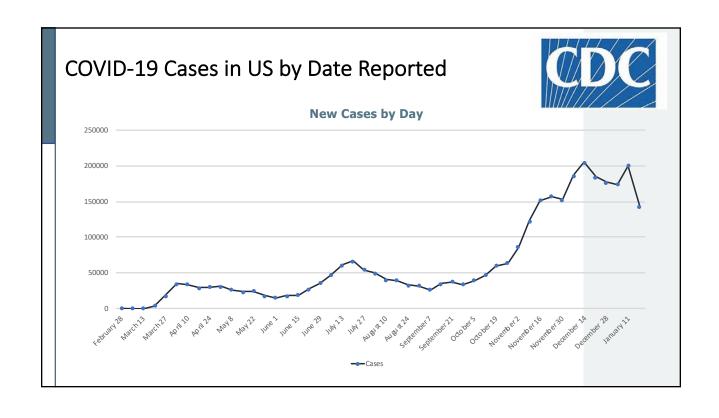




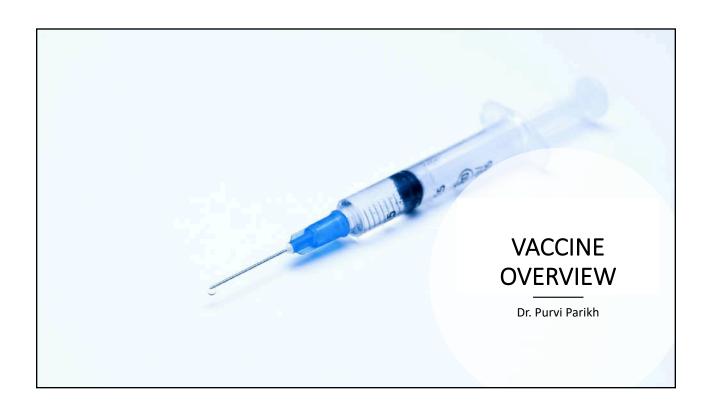


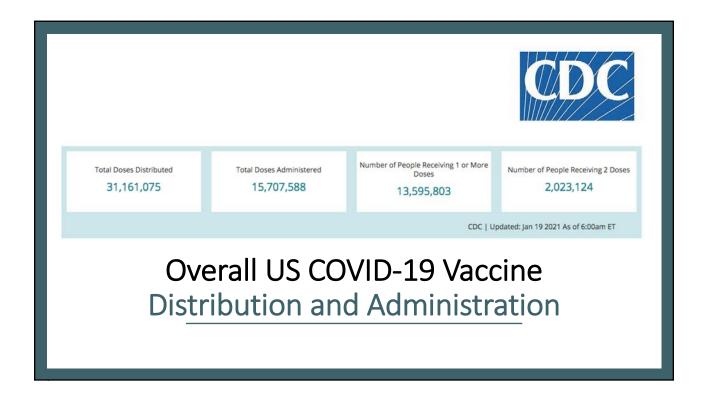






Poll Question • Are COVID-19 virus numbers going up in your area, staying the same or going down? • (Make it your best guess!)



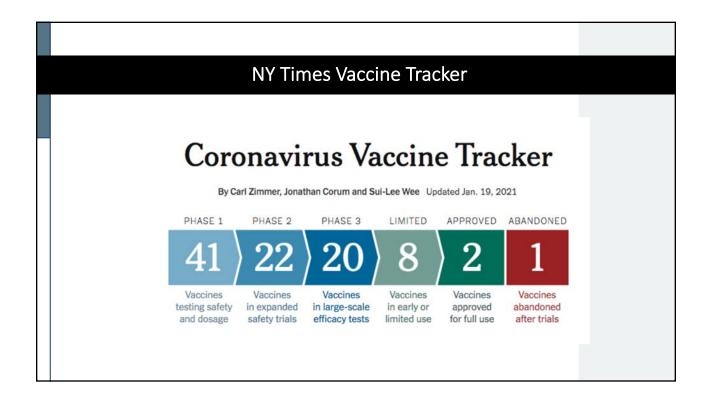


Are Vaccines Effective?

Vaccines save lives.

Scientists widely consider immunization to be one of the greatest public health achievements of the 20th century

- Flu vaccination reduces the risk of flu illness by between 40% and 60% among the overall population. – CDC
- Two doses of inactivated polio vaccine (IPV) are 90% effective or more against polio; three doses are 99% to 100% effective. - CDC



Types of COVID-19 Vaccines

mRNA vaccine

- Synthetically produced RNA fragments of the virus are used to give the body those instructions that enable it to produce a protein that mimics a subset of the virus.
- This is recognized by the immune system, which reacts and produces antibodies and T cells. If the real coronavirus appears, the defence system is equipped and can prevent infection.

Vector vaccine

- Consists of a genetically modified chimpanzee cold virus, with which genetic material from Sars-CoV-2 is introduced into human cells as a vector.
- Same concept used in the Ebola vaccine

Vaccine Overview

Moderna

mRNA-1273

- First to fix formulation
- mRNA vaccine
- Two doses 4 weeks apart
- 94.5% effective
- Slightly more effective in younger groups than in elderly

- ✓ Caused side effects in more people
- Mainly included:
 - o Pain at the injection site
 - Flu-like symptoms
 - Subsided quickly
- ✓ Stored at -20 degrees for up to six months
 - Easier to store for non-hospital settings
- ✓ FDA factsheet:

https://www.fda.gov/media/144638/download

Vaccine Overview

BioNTech/Pfizer

NT162b2

- First to clear approval
- Already used on a massive scale
- mRNA vaccine
- Two doses 3 weeks apart
- 95% effective
- Gives protection to older population

- ✓ Side effects limited
- ✓ Mainly included:
 - Pain at the injection site
 - Flu-like symptoms
 - Subsided quickly 1 to 2 days
- Must be shipped and temporarily stored at -70 degrees
- √ At normal refrigerator temperatures has a shelf life of 5 days
- FDA factsheet: https://www.fda.gov/media/144414/download

Vaccine Overview

AstraZeneca

ChAdOx1 nCoV-19

- Can be produced in large quantities
- Does not require special cooling
- 90% effective when a ½ dose was administered followed by a full dose
- Two doses one month apart

- ✓ No serious side effects
- ✓ Approved in UK
- ✓ Booster at 3 months
- FDA factsheet not yet available

Vaccine Overview

Gamaleja-Institute Moskau

Sputnik V

- Vector vaccine
- Innovative process
- More than 95% effective
- Often requires multiple doses

✓ More information:

https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30923-3/fulltext

Vaccine Overview

Sinopharm China

CNBG-vaccine

- Does not use genetic engineering
- Classic method of triggering an immune response by killing the virus
- 79% effective in trials

- ✓ International confidence in Chinese vaccines is lacking
- √ Few test results have been published
- ✓ Approved in China and UAE

Vaccine Overview

Johnson & Johnson

Ensemble / Ensemble 2

- Not yet approved expected soon
- Viral vector vaccine
- 97% effective study participants developed antibodies
- Studied as single and twodose vaccine

- ✓ Booster shots may be required over time similarly to the pneumococcal vaccine
- ✓ Ongoing clinical trials
- FDA factsheet not yet available

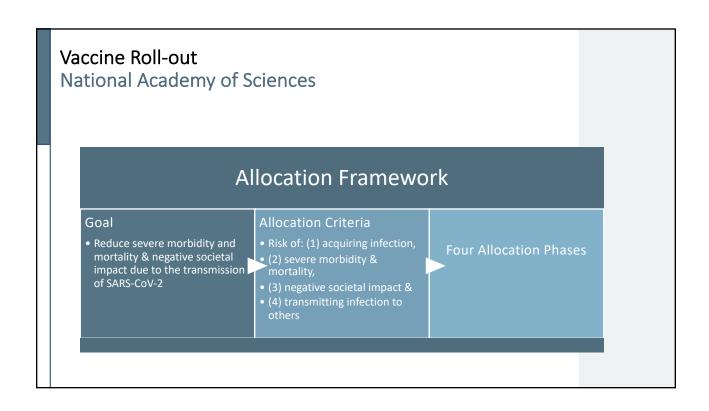
Key features of the COVID-19 Vaccine Frontrunners

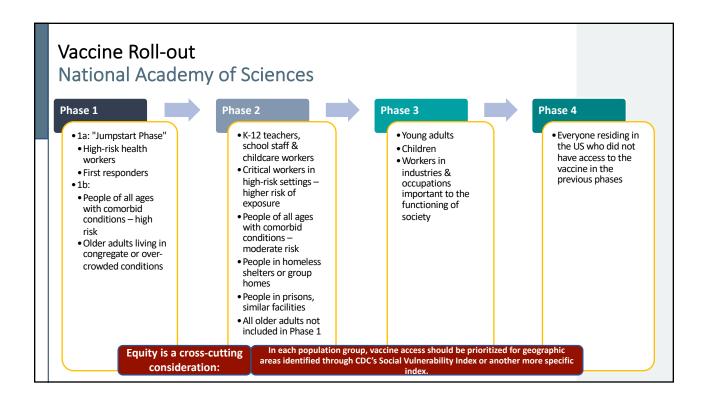
	Pfizer/BioNTech BNT162b2	Moderna mRNA-1273	AstraZeneca/ Oxford ChAdOx1-S/AZD1222	Janssen (Johnson & Johnson) Ad26COVS1
Type of vaccine	mRNA in lipid nanoparticles	mRNA in lipid nanoparticles	Non-replicating adenovirus vector	Non-replicating adenovirus vector
Dosage	2 doses 21 days apart	2 doses 28 days apart	2 doses 28 days apart	1 or 2 doses 56 days apart
Antibody detection	7 days after booster	14 days after booster	14 days after booster	14 days after booster
Efficacy	95%	95%	70%	N.A.

Key features of the COVID-19 Vaccine Frontrunners

	Pfizer/BioNTech BNT162b2	Moderna mRNA-1273	AstraZeneca/ Oxford ChAdOx1-S/AZD1222	Janssen (Johnson & Johnson) Ad26COVS1
Planned Production Volume	50M (2020) 1.3B (2021)	20M (2020) 0.5 – 1B (2021)	3B (2021)	1B (2021)
Storage Requirement	-70°C <u>+</u> 10°C	-20°C	2 - 8°C	2 - 8°C
Shelf life once thawed	5 days	30 days	180 days	180 days
Phase III Trial Enrollment	43,000 (ages 16-85)	30,000 (age 18+)	11,500 (age 18+)	Single dose – 60,000 Two dose – 30,000 (age 18+)
Percentage high-risk population in phase III trial	40.90%	42%	N.A.	N.A.

Company	Type	Doses	How effective*	Storage	Cost per dose
Oxford Uni- AstraZeneca	Viral vector (genetically modified virus)	x2 /	62-90%	Regular fridge temperature	£3 (\$4)
Moderna	RNA (part of virus genetic code)	x2	95%	-20C up to 6 months	£25 (\$33)
Pfizer- BioNTech	RNA	x2 /	95%	-70C	£15 (\$20)
Gamaleya (Sputnik V)	Viral vector	x2 /	92%	Regular fridge temperature (in dry form)	£7.50 (\$10)





COVID-19 Vaccine

- Landmark in the pandemic response for Americans
- Appears to be equally protective across age groups
- Appears to be equally protective across racial & ethnic groups
- Severe systemic events were reported in less than 2%

Banerji A, Wickner PG, Saff R, Stone CA Jr, Robinson LB, Long AA, Wolfson AR, Williams P, Khan DA, Phillips E, Blumenthal KG, mRNA Vaccines to Prevent COVID-19 Disease and Reported Allergic Reactions: Current Evidence and Approach, The Journal of Allergy and Clinical Immunology: In Practice (2021), doi: https://doi.org/10.1016/j.jaip.2020.12.047.

Summary of Allergic Reactions

Following release of Pfizer Vaccine (published January 6th)

104 cases of allergic reactions

21 cases of anaphylaxis after administration of 1,893,360 first doses

- 10 times the anaphylaxis rate of the flu vaccine
- 17 cases occurred in persons with a documented history of allergies or allergic reactions
 - 7 of these had a history of anaphylaxis

Summary of Allergic Reactions

Following release of Pfizer Vaccine (published January 6th)

Allergic symptoms onset after vaccine

- Median of 13 minutes (2-150 minutes)
- 71% onset within 15 minutes

Non-anaphylaxis symptoms:

- Pruritis
- Rash
- Itchy & scratchy throat
- Mild respiratory symptoms

Reports of Possible Allergic Reactions

- Very strong safety profiles
- Reports of possible allergic reactions
 - Raised public concern
- Recommendations:
 - All patients be observed for 15 minutes after injection
 - Staff must be able to identify and manage anaphylaxis



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Allergic Reactions

Confirmed allergic reactions to vaccines are not frequently attributed to active ingredients

- But to inactive ingredients:
 - Includes egg protein, gelatin, formaldehyde, thimerosal or neomycin
 - PEG polyethylene glycol, polysorbate

Current vaccines are not formulated with any food, drugs or latex



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Risk Stratifying Patients for Allergies Before Vaccination

Followed by skin allergy testing if deemed to be at "higher risk"

4 Screening Questions: Do you have a history of a *severe* allergic reaction to an injectable medication?

Do you have a history of a *severe* allergic reaction to a prior vaccine?

Do you have a history of a *severe* allergic reaction to another allergen (e.g. food, venom or latex)?

Do you have a history of a *severe* allergic reaction to polyethylene glycol (PEG) a polysorbate or polyoxyl 35 castor oil containing injectable or vaccine?

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FDA

Emergency Use Authorization

Pfizer-BioNTech

Moderna

Guidance:

Do not administer vaccine to individuals with a known history of a severe allergic reaction to any component of the COVID-19 vaccine.

Management of Possible Reaction to COVID-19 Vaccine

- Should the second dose be administered?
- Need to verify that an allergic reaction occurred
 - Follow up with an allergist
 - Pre-treatment with antihistamine not recommended – masks symptoms, doesn't treat anaphylaxis
- If allergy testing is positive, avoid the second dose
- Vaccines have good efficacy with one dose but approved based on two doses

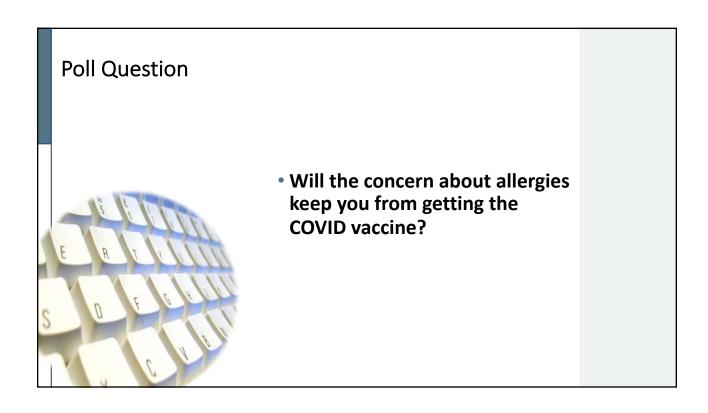


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Need to Support Patients

We need to understand the safety issues surrounding these vaccines, because the success of this mRNA platform is foundational to the flexibility of the COVID-19 response and our response to other viruses with similar vaccines in phase I and II trials.

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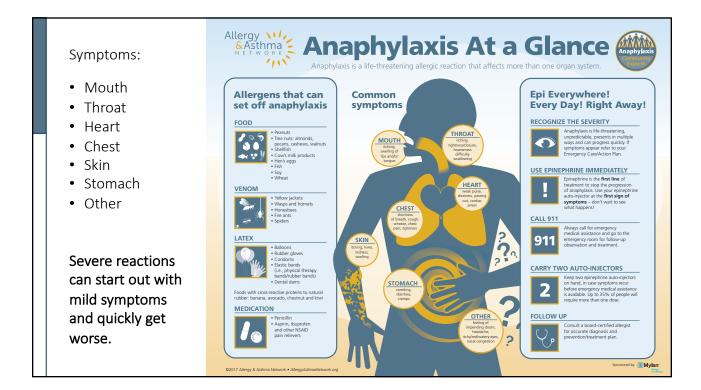


Anaphylaxis

"A life-threatening allergic reaction that affects more than one body system."

Anaphylaxis and anaphylactic shock are terms that are usually used for the same thing.

A drop in blood pressure and narrowing of the airways in response to the exposure to an allergen can officially be called anaphylactic shock, while most people refer to it as anaphylaxis.



Treatment

- The first line treatment for anaphylaxis is epinephrine.
- It's the ONLY medication proven to stop a life-threatening allergic reaction.
- Epinephrine needs to be given as soon as anaphylaxis symptoms occur.

Epinephrine FIRST. Epinephrine FAST.

Epinephrine

- Epinephrine is a form of adrenaline, a hormone that naturally occurs in the body.
- Epinephrine is given using an autoinjector or injection into the muscle in the outer thigh.
- When epinephrine is given by injection
 - Increases your heart rate and blood pressure
 - Relaxes the muscles in the airways
 - Reverses swelling and suppresses the body's immune system's response to allergens.
 - Reverses the symptoms of anaphylactic shock and temporarily halts the allergic reaction.



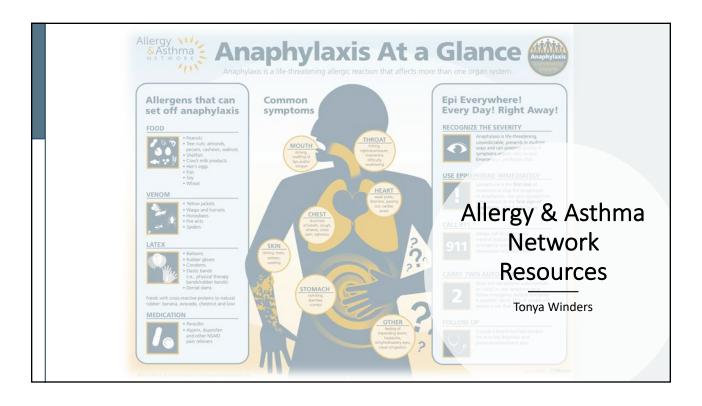


Epinephrine

- Epinephrine is the ONLY drug that will reverse anaphylaxis and should be given as soon as symptoms appear.
- Any delay in giving epinephrine greatly increases the chance of hospitalization.
- Deaths due to anaphylaxis are often associated with either delaying the use of epinephrine or not using it at all.

Antihistamine or Epinephrine?

- Antihistamines will not reverse anaphylaxis. Doctors recommend using an epinephrine auto-injector as the first treatment at the sign of any severe allergic reaction. Epinephrine will not harm a patient.
- Antihistamines only treat a few minor symptoms of anaphylaxis like hives. Antihistamines take about 30 or more minutes to take effect, which is far too long to treat an urgent medical condition.
- Don't wait. Don't delay giving epinephrine.
- One more time: epinephrine will treat a life-threatening allergic reaction antihistamines will not.



COVID-19 Information Center

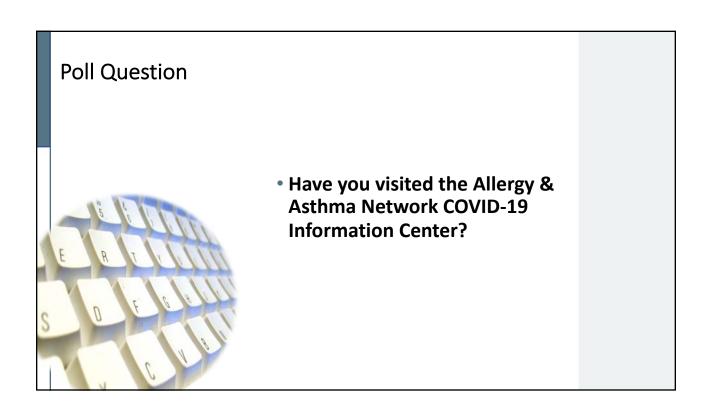
Coronavirus: What You Need to Know

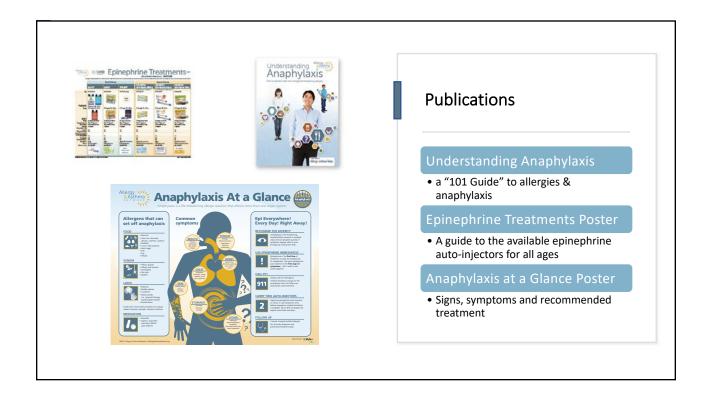
Check here weekly for updated information and news webinars, fact sheets, podcasts and infographics to help you.

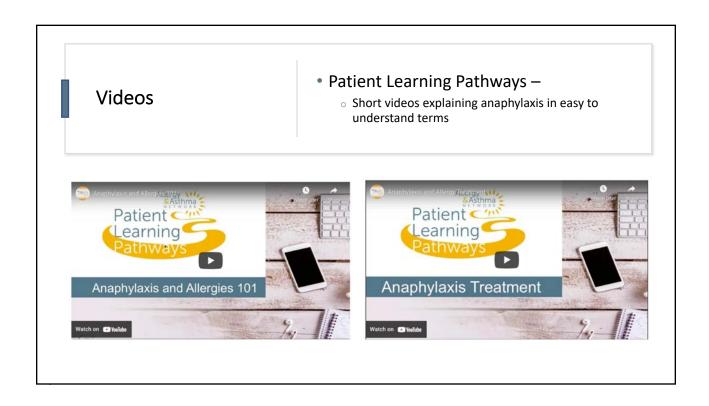
- · COVID-19 FAQs →
- Distinguishing between COVID-19 vs Allergies vs Flu →
- Mental Health Impact of COVID-19 →
 - Latex allergy and COVID-19 →
- COVID-19 Myths Busted →
- COVID-19 Webinars & Videos →
- Asthma and Covid-19 →
- COVID-19 School Resources for Allergies & Asthma →
- Mental Health Tools →
- AERD and COVID-19 →

For People with Asthma, Allergies and Related Diseases We're here for you!

We know COVID-19 is a serious concern for you if you have asthma, allergies or related diseases. Right now, experts are learning more about the coronavirus every week. We want to make sure you have the most current, accurate and trustworthy information to manage your health.















COVID-19 Vaccine:

Allergies, Anaphylaxis & Answers

Allergyasthmanetwork.org