Allergy & Asthma Network
Upcoming Webinars

Webinar: Vaccines & Vaccine Hesitancy – How to Improve Respiratory Outcomes
January 26th – 4:00 PM ET

Webinar: The Long-haul Consequences of COVID-19: Asthma, Allergies and All Conditions
February 4 – 4:00 PM

Webinar: Sleep Issues: The Effect of Allergies, Asthma & Related Conditions
February 25 – 4:00 PM ET

Look for more information at Allergyasthmanetwork.org

COVID-19 Vaccine:
Allergies, Anaphylaxis & Answers
January 20, 2021
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
In the News

- At least 20 states are reporting new cases of the more-contagious COVID variant first found overseas
  - May be new “California Variant”
- Biden won’t end pandemic travel restrictions
  - Plans to “strengthen public health measures around international travel”
- Residents and staff at long-term care facilities starting to get 2nd dose of vaccine
In the News

- New cases across the country have also been trending down since hitting a peak last week, experts urge Americans not to let their guard down yet.
- Data from the CDC shows:
  - Still a gap in the number of Covid-19 vaccines that have been distributed to states and the number of shots that have gone into arms
  - States complain the federal government is not sending vaccines fast enough.
Poll Question

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

VACCINE OVERVIEW

Dr. Purvi Parikh
Overall US COVID-19 Vaccine Distribution and Administration

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
NY Times Vaccine Tracker

Coronavirus Vaccine Tracker

By Carl Zimmer, Jonathan Corum and Sui-Lee Wee  Updated Jan. 19, 2021

<table>
<thead>
<tr>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
<th>LIMITED</th>
<th>APPROVED</th>
<th>ABANDONED</th>
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<td>22</td>
<td>20</td>
<td>8</td>
<td>2</td>
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Vaccines testing safety and dosage  Vaccines in expanded safety trials  Vaccines in limited use  Vaccines in large-scale efficacy tests  Vaccines approved for full use  Vaccines abandoned after trials

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:
  - 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](https://www.fda.gov/media/144638/download)

**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](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

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 two-dose 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

<table>
<thead>
<tr>
<th></th>
<th>Pfizer/BioNTech BNT162b2</th>
<th>Moderna mRNA-1273</th>
<th>AstraZeneca/Oxford ChAdOx1-S/AZD1222</th>
<th>Janssen (Johnson &amp; Johnson) Ad26COV1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of vaccine</strong></td>
<td>mRNA in lipid nanoparticles</td>
<td>mRNA in lipid nanoparticles</td>
<td>Non-replicating adenovirus vector</td>
<td>Non-replicating adenovirus vector</td>
</tr>
<tr>
<td><strong>Dosage</strong></td>
<td>2 doses 21 days apart</td>
<td>2 doses 28 days apart</td>
<td>2 doses 28 days apart</td>
<td>1 or 2 doses 56 days apart</td>
</tr>
<tr>
<td><strong>Antibody detection</strong></td>
<td>7 days after booster</td>
<td>14 days after booster</td>
<td>14 days after booster</td>
<td>14 days after booster</td>
</tr>
<tr>
<td><strong>Efficacy</strong></td>
<td>95%</td>
<td>95%</td>
<td>70%</td>
<td>N.A.</td>
</tr>
</tbody>
</table>

### Planned Production Volume

- **Pfizer/BioNTech BNT162b2**: 50M (2020), 1.3B (2021)
- **Moderna mRNA-1273**: 20M (2020), 0.5 – 1B (2021)
- **AstraZeneca/Oxford ChAdOx1-S/AZD1222**: 3B (2021)
- **Janssen (Johnson & Johnson) Ad26COV1**: 1B (2021)

### Storage Requirement

- **Pfizer/BioNTech BNT162b2**: -70°C+10°C
- **Moderna mRNA-1273**: -20°C
- **AstraZeneca/Oxford ChAdOx1-S/AZD1222**: 2 - 8°C
- **Janssen (Johnson & Johnson) Ad26COV1**: 2 - 8°C

### Shelf life once thawed

- **Pfizer/BioNTech BNT162b2**: 5 days
- **Moderna mRNA-1273**: 30 days
- **AstraZeneca/Oxford ChAdOx1-S/AZD1222**: 180 days
- **Janssen (Johnson & Johnson) Ad26COV1**: 180 days

### Phase III Trial Enrollment

- **Pfizer/BioNTech BNT162b2**: 43,000 (ages 16-85)
- **Moderna mRNA-1273**: 30,000 (age 18+)
- **AstraZeneca/Oxford ChAdOx1-S/AZD1222**: 11,500 (age 18+)
- **Janssen (Johnson & Johnson) Ad26COV1**: Single dose – 60,000, Two dose – 30,000 (age 18+)

### Percentage high-risk population in phase III trial

- **Pfizer/BioNTech BNT162b2**: 40.90%
- **Moderna mRNA-1273**: 42%
- **AstraZeneca/Oxford ChAdOx1-S/AZD1222**: N.A.
- **Janssen (Johnson & Johnson) Ad26COV1**: N.A.
Vaccine Roll-out
National Academy of Sciences

Allocation Framework

Goal
• Reduce severe morbidity and mortality & negative societal impact due to the transmission of SARS-CoV-2

Allocation Criteria
• Risk of: (1) acquiring infection,
• (2) severe morbidity & mortality,
• (3) negative societal impact &
• (4) transmitting infection to others

Four Allocation Phases
Vaccine Roll-out
National Academy of Sciences

Phase 1
• 1a: "Jumpstart Phase"
  • High-risk health workers
  • First responders
  • 1b: People of all ages with comorbid conditions – high risk
  • Older adults living in congregate or overcrowded conditions

Equity is a cross-cutting consideration:
In each population group, vaccine access should be prioritized for geographic areas identified through CDC’s Social Vulnerability Index or another more specific index.

Phase 2
• K-12 teachers, school staff & childcare workers
• Critical workers in high-risk settings – higher risk of exposure
• People of all ages with comorbid conditions – moderate risk
• People in homeless shelters or group homes
• People in prisons, similar facilities
• All older adults not included in Phase 1

Phase 3
• Young adults
• Children
• Workers in industries & occupations important to the functioning of society

Phase 4
• Everyone residing in the US who did not have access to the vaccine in the previous phases

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%

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

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
# Risk Stratifying Patients for Allergies Before Vaccination

*Followed by skin allergy testing if deemed to be at “higher risk”*

## 4 Screening Questions:

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>Do you have a history of a <em>severe</em> allergic reaction to an injectable medication?</td>
<td></td>
</tr>
<tr>
<td>Do you have a history of a <em>severe</em> allergic reaction to a prior vaccine?</td>
<td></td>
</tr>
<tr>
<td>Do you have a history of a <em>severe</em> allergic reaction to another allergen (e.g. food, venom or latex)?</td>
<td></td>
</tr>
<tr>
<td>Do you have a history of a <em>severe</em> allergic reaction to polyethylene glycol (PEG) a polysorbate or polyoxyl 35 castor oil containing injectable or vaccine?</td>
<td></td>
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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

“...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...”

Poll Question

- Will the concern about allergies keep you from getting the COVID vaccine?
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.

Symptoms:
- Mouth
- Throat
- Heart
- Chest
- Skin
- Stomach
- Other

Severe reactions can start out with mild symptoms and quickly get worse.

Anaphylaxis At a Glance

Anaphylaxis is a life-threatening allergic reaction that affects more than one organ system.

Common symptoms
- Mouth
  - Itching, swelling of lips and/or tongue
- Throat
  - Throat itching, tightness/closure, hoarseness, difficulty swallowing
- Heart
  - Chest pain, tightness
- Skin
  - Itching, hives, redness, swelling
- Stomach
  - Vomiting, diarrhea, cramps
- Other
  - Feeling of impending doom, headache, itchy/red/watery eyes, nasal congestion

Allergens that can set off anaphylaxis

- Food
  - Peanuts
  - Tree nuts: almonds, pecans, cashews, walnuts
  - Shellfish
  - Cow’s milk products
  - Hen’s eggs
  - Fish
  - Soy
  - Wheat
- Venom
  - Yellow jackets
  - Bees, hornets
  - Honeybees
  - Fire ants
  - Spiders
- Latex
  - Balloons
  - Rubber gloves
  - Condoms
  - Elastic bands (i.e., physical therapy bands/rubber bands)
  - Dental dams
- Medication
  - Penicillin
  - Aspirin, ibuprofen and other NSAID pain relievers

Epi Everywhere! Every Day! Right Away!

Recognize the severity
Anaphylaxis is life-threatening, unpredictable, presents in multiple ways and can progress quickly. If symptoms appear refer to your Emergency Care/Action Plan.

Use epinephrine immediately
Epinephrine is the first line of treatment to stop the progression of anaphylaxis. Use your epinephrine auto-injector at the first sign of symptoms—don’t wait to see what happens!

Call 911
Always call for emergency medical assistance and go to the emergency room for follow-up observation and treatment.

Carry two auto-injectors
Keep two epinephrine auto-injectors on hand, in case symptoms recur before emergency medical assistance is available. Up to 35% of people will require more than one dose.

Follow up
Consult a board-certified allergist for accurate diagnosis and prevention/treatment plan.

Severe reactions can start out with mild symptoms and quickly get worse.
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

- Epinephrine is a form of adrenaline, a hormone that naturally occurs in the body.
- Epinephrine is given using an auto-injector 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.
Allergy & Asthma Network Resources
Tonya Winders

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
- Mental Health Impact of COVID-19
- COVID-19 Myths Busted
- Asthma and Covid-19
- Mental Health Tools
- Distinguishing between COVID-19 vs Allergies vs Flu
- Latex allergy and COVID-19
- COVID-19 Webinars & Videos
- COVID-19 School Resources for Allergies & Asthma
- 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.
Poll Question

• Have you visited the Allergy & Asthma Network COVID-19 Information Center?

Publications

Understanding Anaphylaxis
• a "101 Guide" to allergies & anaphylaxis

Epinephrine Treatments Poster
• A guide to the available epinephrine auto-injectors for all ages

Anaphylaxis at a Glance Poster
• Signs, symptoms and recommended treatment
Videos

- Patient Learning Pathways –
  - Short videos explaining anaphylaxis in easy to understand terms

TIME FOR QUESTIONS

Record your questions in the question box
We’ll get to as many as we can!
JOIN US FOR OUR
NEXT COVID-19 WEBINAR

• The Long-Haul Consequences of COVID-19: Asthma, Allergies and All Conditions

• Thursday, February 4th
• 4:00 PM ET

A Moment for Providers from the CDC

• The COVID-19 Vaccine

• https://youtu.be/oErqI0ZdWo
COVID-19 Vaccine:
Allergies, Anaphylaxis & Answers
Allergyasthmanetwork.org