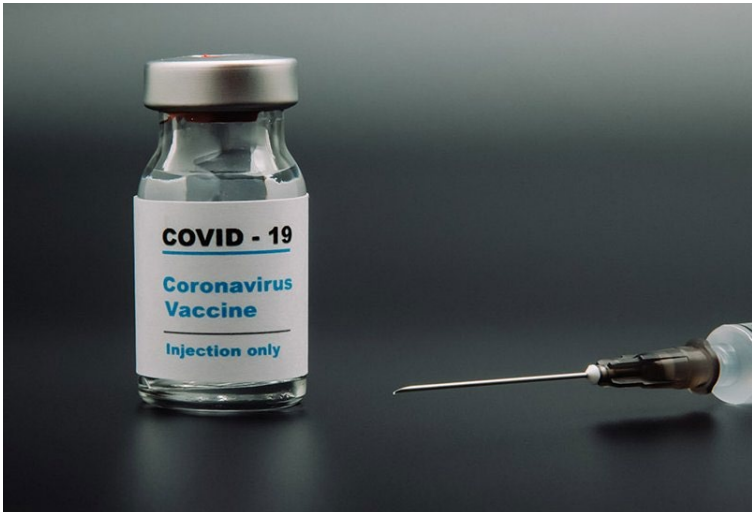


COVID-19 Vaccinations with an Update from 12/16/2020



Michael A. Kaufmann, MD, FACEP, FAEMS
State EMS Medical Director
Indiana Department of Homeland Security



Hot Off The Press



- 12/11/2020
- Vaccine advisers to the US Food and Drug Administration voted Thursday to recommend the agency grant emergency use authorization to Pfizer and BioNTech's coronavirus vaccine.
- Seventeen members of the Vaccines and Related Biological Products Advisory Committee voted yes, four voted no and one abstained.
- "The question is never when you know everything. It's when you know enough and I think we know enough now to say that this appears to be our way out of this awful, awful mess," Dr. Paul Offit, director of the Vaccine Education Center at Children's Hospital of Philadelphia and a member of the committee, told CNN's Wolf Blitzer after the vote.
- "That's why I voted yes."



FDA Concerns



- Several committee members expressed concern about reports of allergic reactions in two people who were vaccinated in Britain, which authorized Pfizer's vaccine ahead of the US.
- FDA staff said that, as with any vaccines, paperwork would accompany the Pfizer vaccine to warn against administering it to anyone with a history of severe allergic reactions to vaccines or allergies to any of the ingredients of the vaccine.
- The FDA will now decide whether to accept the recommendation, but has signaled that it will issue the EUA for the vaccine.
- ACIP has a meeting scheduled for Friday, and expects to vote during a meeting scheduled for Sunday.
- Operation Warp Speed officials say they will start shipping the vaccine within 24 hours of FDA authorization.



Public Safety Concerns



[HOME](#) | [SAFETY & HEALTH](#)

Poll: More than Half of FDNY Firefighters Will Refuse Vaccine

A recent internal survey by the FDNY's firefighters union polled 2,053 members, and around 55 percent of them said they wouldn't get the COVID-19 vaccine.

Source Firehouse.com News

Dec 6th, 2020

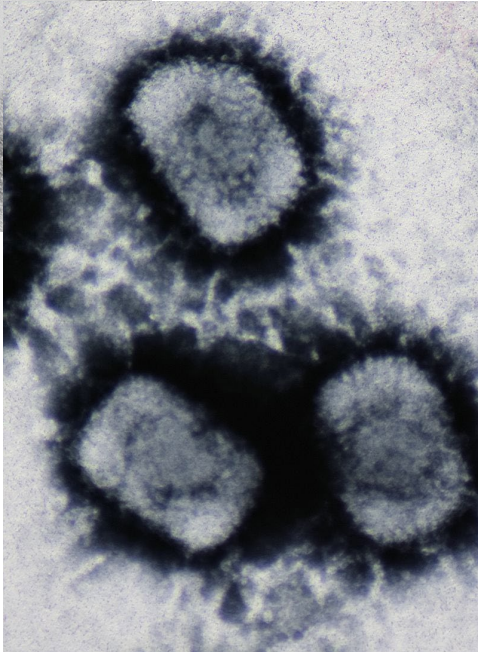
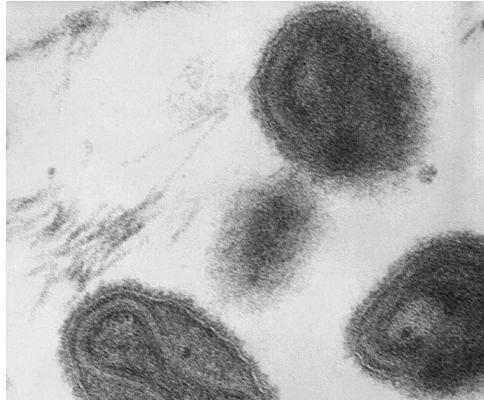


- In a joint statement last month, the International Association of Fire Chiefs, the International Association of Fire Fighters, the National Association of State Fire Marshals, and the National Volunteer Fire Council urged governors and state health officials to give top priority to firefighters and EMS workers when it came to receiving the vaccine. The National Fallen Firefighters Foundation announced Tuesday that at least 104 first responders have died from the virus this year.
- A Centers for Disease Control advisory panel, however, recommended last week that health care workers and long-term care facility workers and residents be placed in the 1a priority group for the vaccine.





Vaccination technology through the years



Edward Jenner 1796

The Latin word for cow is vacca, and cowpox is vaccinia; Jenner decided to call this new procedure vaccination.





Advances in medical technology

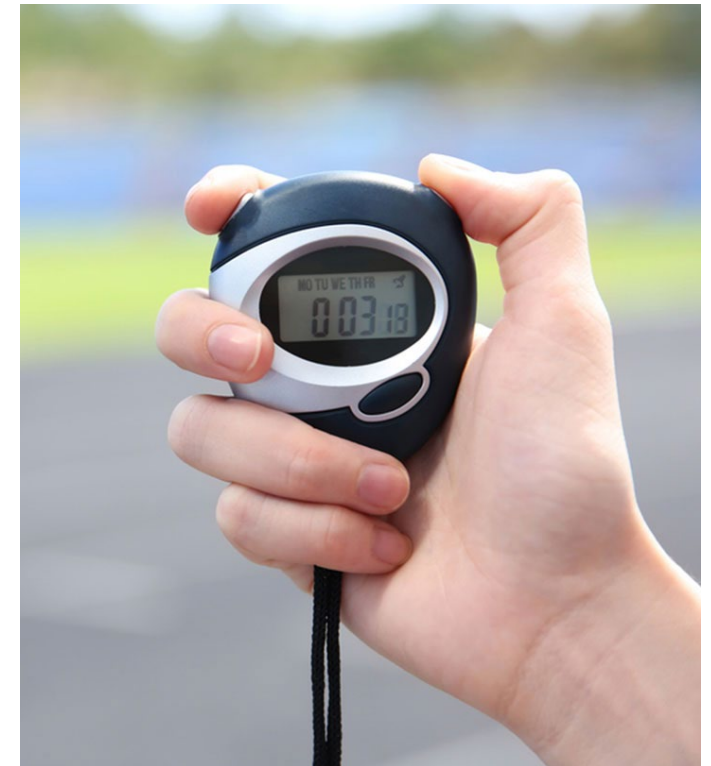
- Killed Virus: e.g. Hepatitis A
- Live Attenuated Virus: e.g. Measles – took 10 years to produce
- Genetic manipulation of a benign virus
 - Astra Zeneca
 - Johnson and Johnson
- Piece of a Virus: e.g. Novavax – Purified Spike Protein
- Messenger RNA in a man-made virus-like lipid nanoparticle
 - Pfizer
 - Moderna





How did we get a vaccine so fast?

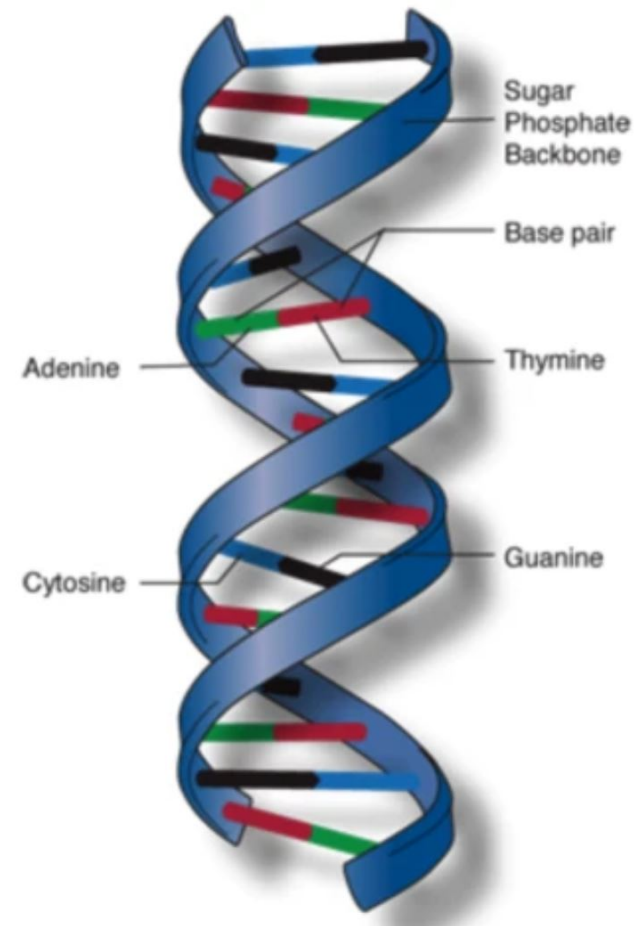
- Smallpox vaccine took thousands of years
- Next major advances took hundreds of years
- Measles live attenuated vaccine took a decade
- The Human Genome project was key for the next major advance



Human Genome Project



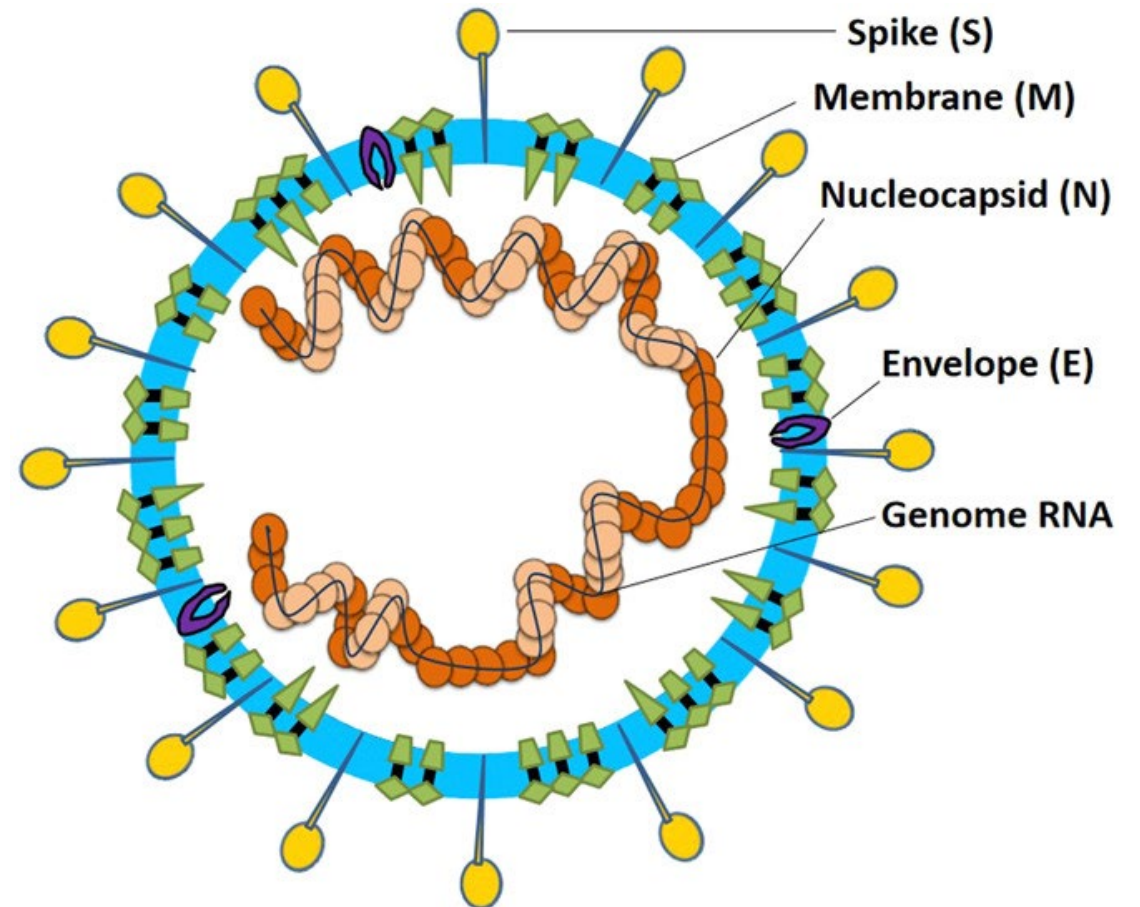
- 3 Billion Dollars
- Over 200 Labs in USA
- 18 other countries collaboration
- Took 13 years (1990 – 2003)
- Currently: Can decode entire human genome in 24 to 48 hours for less than \$1k





Comparative Size of Genetic Databases

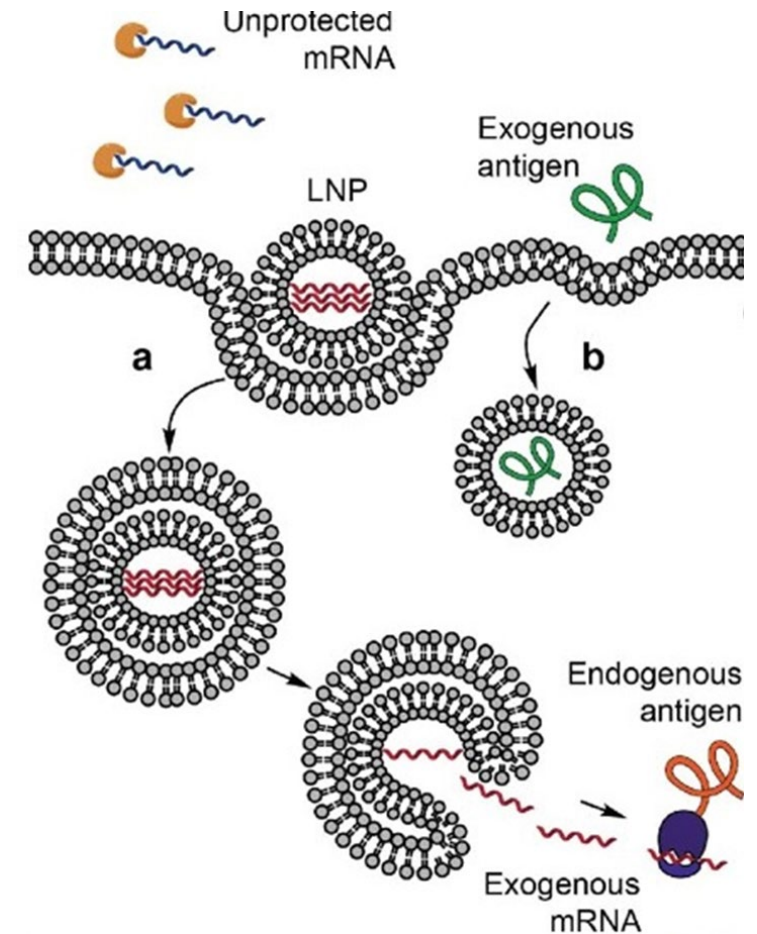
- Human: 6 Billion Bases
- Fruit Fly: 123 Million Bases
- E Coli: 5 Million Bases
- COVID: 30 Thousand Bases



Messenger RNA vaccines



- NOT A VIRUS!!
- mRNA codes for the target protein
- Can be used for infectious diseases and even cancer therapy
- Ultra rapid development process compared to prior vaccination technology
- 62 Days from SARS-CoV-2 genetic decoding to first human vaccine test injection
- Pandemic causes rapid exposure of treatment groups

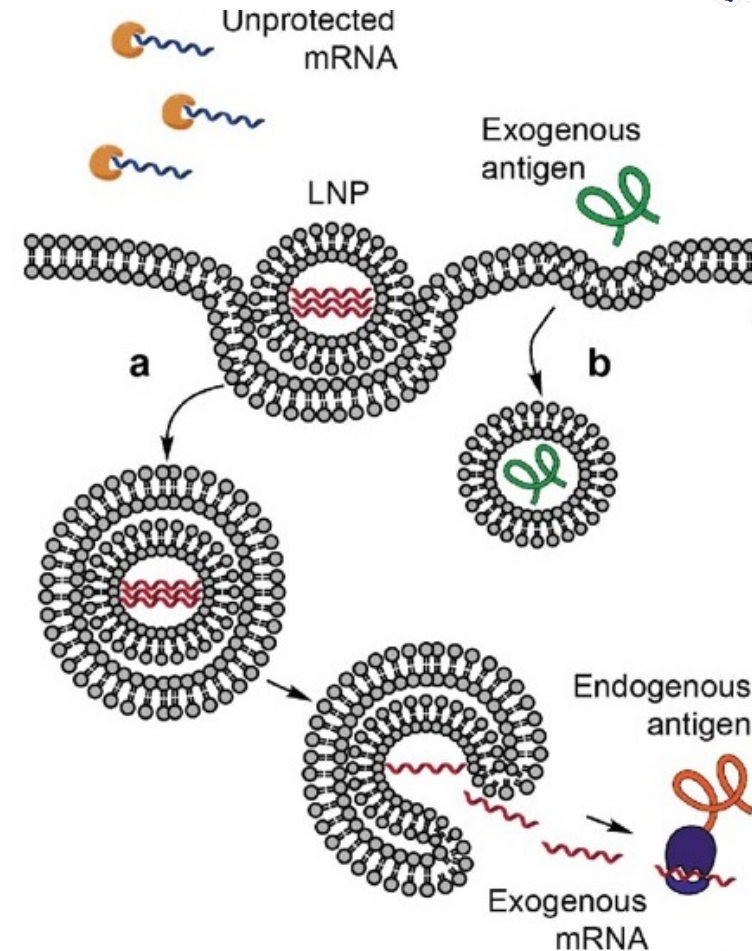




Pfizer-Biontech



- mRNA Vaccine
- Ultracold storage -80C: 6 months
- Refrigerator storage: 5 days
- Room Temperature: 6 Hours
- 44k Study Participants, Diverse background
- Zero safety concerns
- 95% Effective
- Both Antibody and T Cell Immunity
- Possibly 30M Doses by end of 2020 ?





Pfizer / biontech



PfizerThermalShipper_9_23

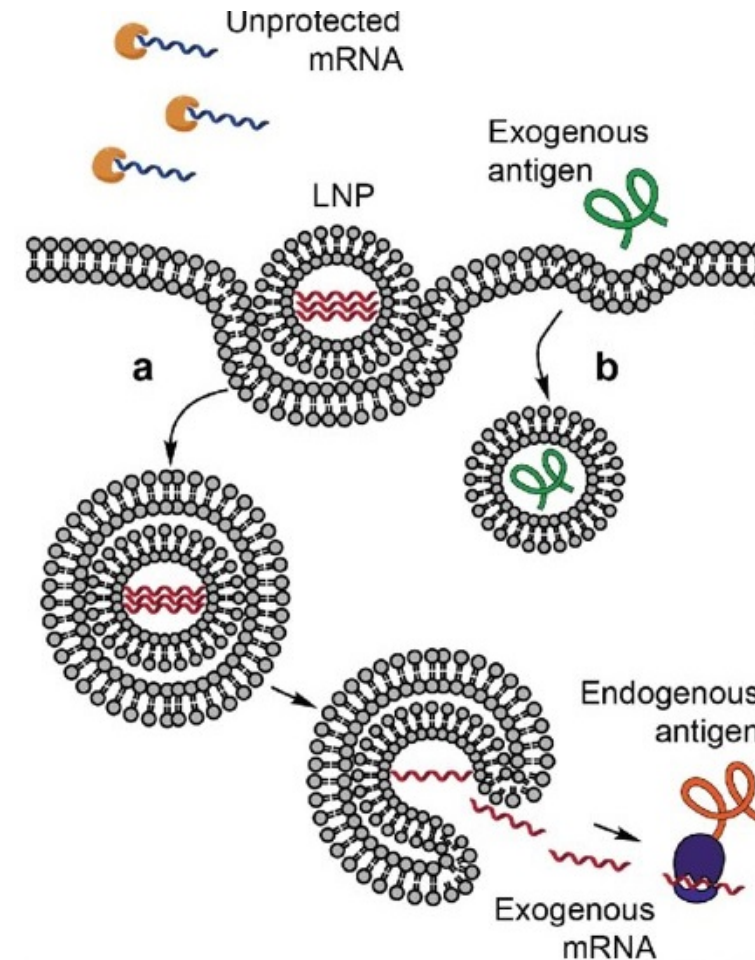




Moderna



- mRNA Vaccine
- Normal Freezer storage: 6 months
- Refrigerator storage: 7 days (Maybe 30 days)
- Once opened: 6 Hours
- 30k Study Participants, Diverse background
- Zero safety concerns
- Greater than 94% Effective
- Both Antibody and T Cell Immunity
- Possibly 20M Doses by end of 2020 ?





Vaccine supplies included?

For centrally distributed vaccines, each kit will contain supplies to administer 100 doses of vaccine, including:

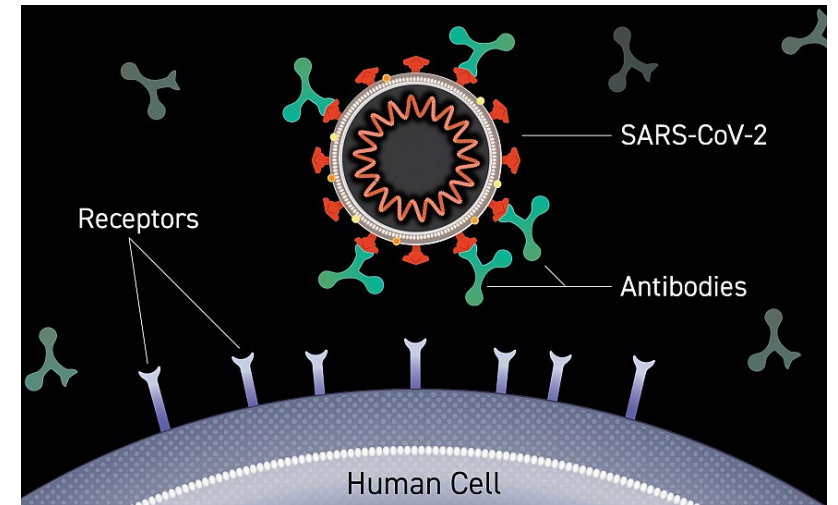
- Needles: 25G 1 – 1.5 Inch 105 per kit
- Syringes: 1 to 3 mL 105 per kit
- Alcohol Prep Pads 210 per kit
- 4 Surgical Masks per kit
- 2 Face Shields per kit
- Gloves?



Astra Zeneca



- AZD1222 Vaccine: Chimpanzee Adenovirus
- Unable to replicate
- Genetically modified to carry the COVID-19 Spike Protein
- Early Results show both Antibody and T-Cell Immune Response
- May be ready for EUA early 2021





Johnson and Johnson



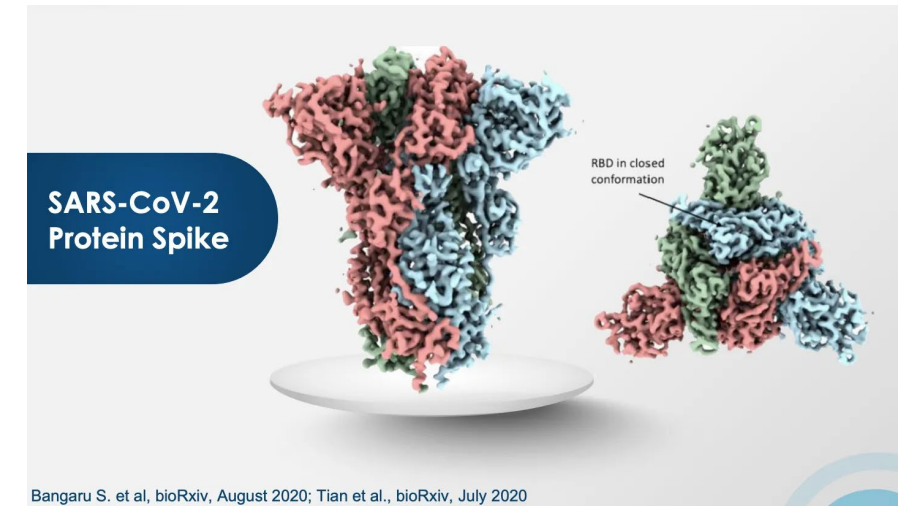
- Ad26 Single Shot Vaccine: Adenovirus Vector similar to AZ
- Unable to replicate
- Genetically modified to carry the COVID-19 Spike Protein
- Early Results show both Antibody and T-Cell Immune Response
- May be ready for EUA early 2021
- Plan to study 60,000 adults 18 years old and older



Novavax



- NVX-CoV2373: Adjuvanted, recombinant, full-length spike protein manmade nanoparticle vaccine
- No virus, no viral nuclear material, just purified viral spike protein
- Early studies showed both antibody and T cell immunity
- Phase 3 results won't be ready till 2021
- Normal Refrigerator Storage





Two Shots – Same Flavor

- Most vaccine candidates require a 2-shot series
- Second shot must be from same manufacturer
- Only J and J is single shot candidate



COVID Vaccine for EMS



- IDOH has prepared a COVID vaccine distribution plan that is detailed in the linked document. https://www.coronavirus.in.gov/files/Indiana%20COVID-19%20Vaccination%20Plan_%20Interim%20Draft.pdf
- EMS providers have been included in vaccine prioritization group 1A (meaning they will be in the first group to receive the vaccine.)
- The initial allotment of vaccine (Pfizer Vaccine) should be arriving in the next few days.
- After EUA approval, 50 hospitals will receive the vaccine in anticipation for ACIP administration recommendations
- This first round of vaccine is allocated to healthcare personnel who in their line of work have the potential for exposure to COVID-19 patients or infectious material.
- You will be notified that vaccine is available and you have met criteria for prioritization
- You will receive a letter with a link to the registration and scheduling platform. This may be distributed from your employer, professional licensing agency, or an association. You will be asked to bring an ID or some form of verification that you work in healthcare. If you work at one of the 50 hospitals that will initially be administering the vaccine, you must choose that location to get vaccinated.



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

Dec. 1, 2020

Dear Healthcare Professional:

First of all, thank you for everything that you have done to care for Hoosiers during these unprecedented times. I'd like to update you on the latest information about COVID-19 vaccination.

Pfizer and Moderna have applied for an Emergency Use Authorization (EUA) from the FDA. If approved, we could have vaccine ready to administer in Indiana before the end of the year.

The Indiana Department of Health put together a group of internal and external stakeholders, experts in immunology, infectious disease, ethicists and others to develop an allocation prioritization list. The committee agreed with other national leaders, such as the National Institutes of Science, that healthcare personnel should be the first to receive the vaccine. The goal is to protect those with the most risk of exposure, prevent them from giving it to vulnerable populations, and to reinforce our healthcare workforce by preventing illness.

After EUA approval, Advisory Committee on Immunization Practices (ACIP) recommendations, and review by the Indiana-specific vaccine review committee, the Indiana Department of Health will begin a phased-in vaccination schedule. You will receive an email with a link to schedule your appointment when you are eligible to receive the vaccine. Vaccine will be distributed based on the quantity received.

Here are several important considerations to keep in mind:

1. This first round of vaccine is allocated to healthcare personnel who in their line of work have the potential for exposure to COVID-19 patients or infectious material. We are anticipating that we will not initially have enough vaccine available to vaccinate everyone who meets the criteria. Therefore, the Indiana Vaccine Advisory Committee has further prioritized healthcare personnel based on individuals who provide direct care to the most vulnerable populations and in their line of work have a high likelihood of contact with COVID-positive patients and who are integral to healthcare structure and the response to the pandemic.
2. You will be notified that vaccine is available and you have met criteria for prioritization

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



Letter From ISDH – Dr. Weaver



- This first round of vaccine is allocated to healthcare personnel who in their line of work have the potential for exposure to COVID-19 patients- Dr or infectious material. We are anticipating that we will not initially have enough vaccine available to vaccinate everyone who meets the criteria. Therefore, the Indiana Vaccine Advisory Committee has further prioritized healthcare personnel based on individuals who provide direct care to the most vulnerable populations and in their line of work have a high likelihood of contact with COVID-positive patients and who are integral to healthcare structure and the response to the pandemic.
- You will be notified when you receive a letter with a link to the registration and scheduling platform. a. This may be distributed from your employer, professional licensing agency, or an association. b. We anticipate moving through the prioritizations tiers quickly, but there maybe a delay from when Indiana initially receives a vaccine to when you qualify.



EMS Participation in Vaccine Administration



- There are three ways that Indiana EMS Provider Agencies can get involved in administering vaccinations.
 - Individuals
 - Agency partnership with local health departments and other vaccine administering entities
 - Registering with IDOH to become a vaccine providing entity
- Numerous programs are spinning up across the State.

EMS ROLE AND GUIDANCE IN COMMUNITY VACCINATIONS





IHCP will reimburse EMS provider agencies for administration of vaccines

Effective for dates of service on or after **October 7, 2020**, the Indiana Health Coverage Programs (IHCP) will reimburse Emergency Medical Services (EMS) provider agencies for administering vaccines. This policy applies to both fee-for-service (FFS) and managed care delivery systems.

To receive reimbursement, the EMS provider agencies must be EMS-certified provider organizations and enrolled with the IHCP under provider specialty 260 – *Ambulance*. EMS provider agencies will be reimbursed only for the administration of the vaccine and only when provided by a paramedic or advanced emergency medical technician (EMT).



Billing guidance

For vaccine administration, EMS provider agencies should bill using diagnosis code Z23 – *Encounter for immunization* and applicable procedure codes in Table 1.

Table 1 – Vaccine administration procedure codes allowed for EMS providers

Procedure code	Description
90471	Immunization admin
90472	Immunization admin each add
90473	Immunization admin oral/nasal
90474	Immunization admin oral/nasal add

*Note: When billing vaccine administration for IHCP members 18 years of age or younger, EMS providers must include the **SL** modifier as described in the following section.*

These procedure codes will be added to the *Covered Procedure Codes for Ambulance* in *Transportation Services Codes*, accessible from the [Code Sets](#) page.

Special requirements for members under age 19

For members age 18 or younger, the IHCP reimburses for vaccine administration through the Vaccines for Children (VFC) program. When a vaccine is administered through the VFC program, the provider must bill using the appropriate VFC code.

Reimbursement
Available for
Medicaid
Members





Will it/Can it Be Made Mandatory

- No, this is not allowed under an EUA.

<https://www.law.cornell.edu/uscode/text/21/360bbb-3>

21 U.S. Code § 360bbb–3 - Authorization for medical products for use in emergencies

(a) In general

(1) Emergency uses

Notwithstanding any provision of this chapter and section 351 of the [Public Health Service Act](#) [42 U.S.C. 262], and subject to the provisions of this section, the [Secretary](#) may authorize the introduction into [interstate commerce](#), during the effective period of a declaration under subsection (b), of a [drug, device](#), or [biological product](#) intended for use in an actual or potential emergency (referred to in this section as an “[emergency use](#)”).

(2) **Approval status of product** An authorization under paragraph (1) may authorize an [emergency use](#) of a [product](#) that—

(A)

is not approved, licensed, or cleared for commercial distribution under section [355](#), [360\(k\)](#), [360b](#), or [360e](#) of this title or section 351 of the [Public Health Service Act](#) [42 U.S.C. 262] or conditionally approved under [section 360ccc of this title](#) (referred to in this section as an “[unapproved product](#)”); or

(B)

is approved, conditionally approved under [section 360ccc of this title](#), licensed, or cleared under such a provision, but which use is not under such provision an approved, conditionally approved under [section 360ccc of this title](#), licensed, or cleared use of the [product](#) (referred to in this section as an “[unapproved use of an approved product](#)”).

(3) Relation to other uses

An [emergency use](#) authorized under paragraph (1) for a [product](#) is in addition to any other use that is authorized for the [product](#)



Other FAQs



The safety and efficacy of this has been studied across the globe in people over the age of 12 with lots of different characteristics. There are things researchers are still studying and learning that will help us over time. A couple of quick highlights:

- We aren't sure how long immunity lasts. At least three months for sure.
- We don't know about safety in kids or pregnant women yet. Coming soon.
- We don't know everything there is to know about side effects. That will require VERY close monitoring. What we DO know is that side effects so far have been minor and short lived like: redness where the shot goes in, a low grade fever, headache, muscle aches and feeling tired. These are indicators that your body is revving up for an immune response. It looks like this occurs in about 5-15% of people and goes away in about three days.
- If you've had COVID, you will still likely benefit from getting the vaccine.





Additional FAQs from the CDC

- The mRNA disintegrates rapidly – I think this is important since some persons will worry about producing viral proteins for the rest of their life or some other prolonged period of time. These do not stick around that long. They did not say for how long they are able to produce proteins (obviously long enough to elicit an immune response) but their word is it disintegrates rapidly.
- What happens if someone accidentally mixes vaccines (e.g., gets Pfizer for shot one and Moderna for shot two) – The short answer is they don't know. They just haven't studied it. There is no reason to assume it would have some untoward effect though. If that happens the persons should not get a third shot. They are done after two regardless.
- What happens if someone gets the second shot before the 21 (Pfizer) or 28 (Moderna) time frame – the short answer is it will probably add to your immunity but maybe not as much. They have evidence from other vaccines that having a longer period of time between doses improves immunity. The Pfizer study is 21 days and we know that spacing results in 95% efficacy. So if someone gets a shot at 14 days it will probably add to their immunity but perhaps not as much as waiting that additional week. If that does happen they should not get a third shot. They are done after the second dose.
- Is it safe to give in people who are asymptomatic carriers? – Yes, at least to the best of our knowledge there is no reason to think the vaccine would not work or would have untoward effects if given to someone who has the virus but no symptoms. I would think the biggest risk is if they develop symptoms from their infection a few days after the shot they may falsely attribute the shot to giving them COVID-19. We see this every year with the flu.



Additional FAQs from the CDC

- Is it safe to give in people who have had COVID-19? Yes, in the trials they did serology on participants and know that some of the people who got the COVID-19 vaccine had antibodies suggesting a prior infection. The CDC recommends persons who have had COVID-19 get the vaccine. It makes sense that in those with active infection wait till they recover (to not expose persons giving the vaccine) and for those with infections in the last 90 days perhaps let their colleagues get ahead of them in line since they will have some immunity.
- Can you give the vaccine to persons who have received monoclonal antibodies or convalescent plasma? – They don't have any data on that. Since the mRNA makes spike proteins and the antibodies are generated against spike proteins, it makes sense to say anyone who has received a monoclonal antibody or convalescent plasma wait 90 days until they receive the vaccine.
- Can you give the vaccine to someone in quarantine? There is nothing about quarantine that would prevent the vaccine from working or cause an untoward effect, but since individuals may be carrying COVID (either asymptomatic or pre-symptomatic) they should not get the vaccine till out of quarantine to protect those working at vaccine sites. There is one important exception to this rule. ***Those in long-term care facilities (LTCs) in quarantine can get the vaccine.*** Because persons in LTCs are often exposed and re-exposed to persons with COVID and they are high risk, the recommendation is to vaccinate them regardless of being in quarantine.
- Will the vaccine work in persons with HIV or those immunosuppressed? They do not have data on this population at this time. They would recommend offering the vaccine but explaining to anyone who fits this description that there is little data on its use in this population. Just so they are informed.

Additional FAQs from the CDC



- After you are vaccinated, can you stop wearing masks and not have to quarantine if exposed? No. They were pretty firm on this. They mentioned that the studies only looked at whether someone who received the vaccine developed COVID-19 (symptoms and Positive test). They did not study whether receiving the vaccine decreased the chance that someone who was exposed to virus might not be able to carry it and pass it on. They did mention that Pfizer is conducting these studies right now and they hoped in several months to have an answer to this. But till then, wear your damn mask, wash your damn hands, and yes, quarantine if you are exposed to someone with COVID.
- What about this anaphylaxis business? Important to note. The studies did exclude people with prior vaccine allergic reactions. But, in a tribute to the adverse monitoring system in place, two person in the initial rollout in England developed anaphylaxis. The real deal. Not the I feel queezy or syncope from being vagal but real anaphylaxis. It is important to not that only TWO cases have been observed. This is an incredible low number. And in both cases they had had prior anaphylactic reactions to injections. They don't know exactly what the ingredient in the vaccine that caused it but believe it is the lipid nanoparticles. Although not yet proven, they suspect persons with allergies to polyethylene glycol injections would be at risk.
- What about other causes of anaphylaxis? CDC was clear the only caution at this time is in giving this vaccine to someone who has had anaphylaxis to **an injectable** (IV, IM, SQ) medication or vaccine.
 - What about shellfish? Not a problem they can get the vaccine?
 - What about other food allergies? Not a problem they can get the vaccine?
 - What about bee stings or insect allergies? Not a problem they can get the vaccine?
 - What about oral medication allergies? Not a problem they can get the vaccine?
 - **The only contraindication at this time is if the have had an anaphylactic reaction to an injectable medication or vaccine**



Additional FAQs from the CDC

- If someone has had anaphylaxis to an injectable medication or allergy, can they still get the vaccine? Short answer is yes, but the provider needs to let them know of the risk. (My commentary – The provider must be able to manage anaphylaxis. They did not mention this but I would consider pretreating someone with Benadryl and having an epi shot at the bedside. We would run into this with antivenom for snake bites [lots of people, well lots of men, are bitten by snakes more than once and have severe anaphylaxis to the antivenom]. We would pretreat them with Benadryl and have epi ready to give in case they developed symptoms. We were usually still able to treat them though.)
- How long to watch someone after the vaccine shot? 15 minutes if they have no history of anaphylaxis or allergic reactions to injectables. 30 minutes if they have a history of allergic reactions or anaphylaxis to injectables.
- Will the vaccine make antibody tests positive? Yes and No. Some antibody tests are to the spike protein. These new vaccines will, hopefully, make antibodies to spike proteins so the antibody tests will be positive after someone is vaccinated. There are antibody tests, however, to the nucleocapsid protein. These tests will not be positive after the vaccine and would be able to diagnosis someone has having had a prior infection.
- Will the vaccine cause an autoimmune flair in individuals with autoimmune disorders? It makes sense to worry about this, but fortunately to date this had not been seen. There were individuals with autoimmune disorders in the Pfizer and Moderna trials. They did not see flairs of disease form the vaccine. No doubt this will continue to be looked at but right now it appears safe.
- What are the components of the Pfizer vaccine? Only the mRNA and lipid nanoparticles. There is no preservative. This is why they think the lipids are the cause of the very rare case of anaphylaxis.

Thank you.



- You may now close this presentation.