THE IMMUNIZATION PARTNERSHIP

Simplifying Science Training Module Transcript

Slide 1: Hello and welcome to Simplifying Vaccine Science, an educational video presented by The Immunization Partnership.

Slide 2: The Immunization Partnership is a Texas-based non-profit dedicated to helping individuals, physicians, and others with an interest in immunizations protect their communities from vaccine-preventable diseases. All across Texas, The Immunization Partnership conducts educational community forums and researches immunization best practices.

Slide 3: This presentation is made possible through partnerships and funding from our listed supporters.

Slide 4: Before we get started, please note:

- The speakers and planning committee have disclosed no conflicts of interest

- This presentation is for educational use only and does not constitute medical or legal advice

Slide 5: This presentation will cover the following topics: Vaccine History, Vaccine Development, COVID-19 Vaccines Overview, Ingredients & Technology, and COVID-19 Vaccine Expectations.

Slide 6: To better understand the science behind vaccines, we'll start by briefly touching on the history of vaccines and how they were developed.

Slide 7: Vaccines are one of the greatest achievements in public health. This slide shows a variety of historical tidbits.

- French scientist, Louis Pasteur, best known for discovering the anthrax and rabies vaccines, pictured in his laboratory.
- A line chart showing the steady decline of Rubella cases in the US, 1966 – 1993.
- A UK immunization advocacy poster about diphtheria, 1960.
- And a nurse administering the polio vaccine to a child, Sweden 1957.

Let's discuss a few historical moments in vaccine history.

There is evidence that vaccines were first used as early as 1000 CE in China for smallpox. Smallpox inoculation was also practiced in Turkey and Africa at that time as well. In 1796, English scientist, Edward Jenner, innovated the use of cowpox material to create immunity against smallpox. Over the next 200 years his methods evolved as medicine and technology evolved. Eventually, smallpox was eradicated in the United States by 1949 and worldwide in 1980.[1]

In 1885, Louis Pasteur's rabies vaccine made a tremendous impact on protection against disease. From this time through the 1930s there was a boom in bacteriology and scientific advancements, in which a variety of vaccines including tetanus, anthrax, diphtheria, cholera, typhoid, tuberculosis, and more were developed.[1]

As vaccine research continued through the 20th century, laboratory methods for growing viruses led to more rapid discoveries. Researchers really focused on vaccines for common childhood diseases like measles, mumps, rubella, and polio. Today, wild polio virus is nearly eliminated.[1]

The benefits of vaccines far outweigh the risks. In the United States, the Food and Drug Administration (FDA) must be approved after scientists conduct extensive tests for safety and effectiveness. Vaccines are the best defense against infectious disease. As science and technology advances even more, we can expect safer and innovative techniques for vaccine development.[2]

In fact, some of these new advancements have allowed for the development of the COVID-19 vaccines that we know today.

Slide 8: We'll take a look at the stages of vaccine development, then delve into the science of the COVID-19 vaccines in particular.

Slide 9: Here you will see a simplified overview of the stages of vaccine development, starting with the initial Exploratory Stage and ending with Review and Licensure.

Every vaccine starts out in the Exploratory Stage and then moves into the Pre-Clinical Stage. Both the Exploratory and Pre-Clinical stages are focused on laboratory work and do not involve humans. After the Pre-Clinical Stage, vaccines enter Clinical Trials, where the vaccine candidate is studied in human participants. Each vaccine will go through Phase 1, 2, and 3 of clinical trials, with each phase growing in participant size. Finally, data from the clinical trials is reviewed as part of the Review & Licensure stages.

Every vaccine must go through each of these stages before it can be given approval by the FDA in the United States. Each stage is critical to the development of both safe and effective vaccines.

Slide 10: The first step for any vaccine is the Exploratory Stage, which may also be referred to as the "Research" or Discovery Stage[3] . The exploratory stage involves basic laboratory research, often conducted at a research university, medical setting, or small biotech company by federally-funded academic or government researchers. During the Exploratory Stage, scientists work to create the beginnings of a vaccine by developing a method for the vaccine to prevent whatever disease they are working on.[3]

In order to develop a vaccine, scientists must understand how the disease affects the human body. Part of this work involves identifying an antigen from the virus or bacteria that can be used to develop a successful vaccine. Antigens are proteins that are found on the surface of a pathogen (either a virus or bacteria) that illicit the immune response when they "invade" the human body.[4] By identifying the antigen, researchers can begin to explore ways to use that antigen in the development of a vaccine. Antigens used in a vaccine may include virus-like particles, weakened viruses or bacteria, or other substances taken from the original bacteria or virus.[5]

Scientists may spend years testing their ideas to see if they will work and may have to adjust as they measure success. Many vaccines never make it beyond the Exploratory Stage. However, if the exploratory science that is performed reveals a practical solution in preventing a disease, a vaccine candidate may move forward into the Pre-Clinical stage.[6]

Photo from: https://phil.cdc.gov/Details.aspx?pid=23210

Slide 11: Once a vaccine candidate has shown promise in the Exploratory Stage, it moves into the Pre-Clinical stage, where it undergoes rigorous testing for both basic safety and efficacy.[5] During the Pre-Clinical stage, researchers perform additional laboratory tests using tissue and cell cultures, and finally move into testing the vaccine in animals, often mice and monkeys.[7] These tests help identify any concerns related to vaccine safety as well as help determine how effective the vaccine is at preventing disease. Testing the vaccine in animals helps researchers to understand how effective it is and may lead to adjustments of dosing.[4] Testing vaccine effectiveness during this stage may involve the animals being directly infected with the pathogen (virus or bacteria) to better understand how well the vaccine functions when it comes to preventing the disease.[6]

During the pre-clinical phase, the work of scientists is continually reported, shared, and reviewed by other scientists through peer-reviewed journal articles and presentations. At this time, scientists in the private sector working for pharmaceutical companies may approach researchers if they believe the vaccine candidate to be worthy and may partner to expand the research and work.[7] This leads into the IND Application, which is a requirement before moving into the Clinical Trials. A sponsor, generally a private pharmaceutical company, will submit an application for an Investigational New Drug or IND to the Food and Drug Administration (FDA).[6] This application includes details on the manufacturing and testing processes for the vaccine, summarizes the results of previous laboratory studies, and lays out the plan for the proposed vaccine study in the clinical trials. Finally, an institutional review board (IRB) must approve the clinical protocol for the proposed clinical studies. The FDA has 30 days to approve the IND application.[6] Once approved, the vaccine enters human clinical trials.

image from: https://www.smartmarketnews.com/news/2020-02-13/uk-scientists-uk-team-tests-coronavirus-vaccine-on-mice

Slide 12: Before we move into the phases of clinical trials, it's important to review how they are configured. Researchers use what is called "Placebo-controlled" trials when studying vaccines in human participants. In a placebo-controlled study, some participants receive the vaccine being tested – this is known as the "experimental group". Other participants receive a placebo, often a vaccine that is already approved, a saline-solution, or a portion of the vaccine being studied without its "active" ingredients that illicit an immune response. Individuals receiving the placebo are known as the "control group".[6]

It's important that researchers have a control group so they can have a comparison to determine what the true effects of the vaccine really are. The experimental group and the control group are made up of similar participants – meaning both groups have similar numbers of individuals of certain ages, race and ethnicity, health status or conditions, and sex. This is done to ensure that when researchers compare any differences between the two groups, they can attribute differences to the vaccine, and not to vast differences in the study participants themselves. This also helps ensure that the vaccine is safe and effective for a wide variety of people. Researchers will compare the differences between the control and experimental groups in terms of side effects, infection, and any development of disease which may result in sickness, hospitalization, or death.[7]

Finally, placebo-controlled trials are randomized and double-blinded. This means that participants are placed into either the experimental or control group at random (through a data-driven process) and neither the study participants or researchers know who belongs to each group until the trial is complete. This is done to ensure that bias does not affect the results of the trials. For example, if an individual knows that they are in the experimental group and did receive the vaccine, they may be more likely to

report side effects such as a headache, than if they did not know which group they belonged to. This headache may be from the vaccine, or it may be coincidental. By keeping the groups hidden, researchers can compare side effect reports and rates between both the experimental and placebo groups and determine if there is a significant difference caused by the vaccine.[7]

In order to keep participant groups blinded throughout the study, while also tracking the outcomes of each individual, study participants are often assigned a code for tracking purposes as are the vials of the vaccine and placebo administered in the study. This is also done to ensure that there is no physical difference in the vials containing the vaccine or placebo. Individuals creating and managing the codes and vials are different from those administering the vaccines and placebo. Aside from the successful completion of the study, it is only in the event of serious side effects that the trial is paused, and the code is broken to reveal who received either the vaccine or placebo.[7]

Slide 13: Testing the vaccine in humans begins with Phase 1 of Clinical Trials. During Phase 1, the vaccine is administered to a small number of healthy adults to answer two main questions. First, and most importantly, is the vaccine safe? Second, is the vaccine effective – meaning, does it generate the expected immune response?[4,7]

Phase 1 clinical trials include the use of placebos and may be non-blinded, meaning that either researchers or participants know whether they have received either a placebo or the vaccine. Additionally, researchers may use the "challenge model" which involves infecting participants with the pathogen after receiving the vaccine.[6] This is not always ethically possible and is not a component of all vaccine clinical trials. For example, if the disease hoping to be prevented by the vaccine does not have an available treatment or isn't curable, researchers would not seek to actively infect participants as part of the study.

During Phase 1, researchers carefully monitor participants and control the study conditions. The immune response generated by the vaccine is studied so researchers can understand if differences in dosing are needed to improve how well the vaccine works in people. Additionally, any initial side effects observed in participants may alert researchers that modifications are needed to the vaccine.[7]

Another important part of vaccine development that occurs during Phase 1 Clinical Trials involves the pharmaceutical company studying the best ways to produce large enough amounts of the vaccine for later trial phases. Additionally, they must study and determine if the vaccine will need any preservatives or stabilizers so that it does not break down, as well as any adjuvants that may be necessary to help create a strong immune response. This step is very important because any preservatives, stabilizers, or adjuvants that will be used in the final vaccine must also be included and studied as part of the trials.[7]

Phase 1 clinical trials generally take one to two years to complete.

Image from: https://www.latimes.com/science/story/2020-07-14/clinical-trial-results-indicate-moderna-vaccine-is-on-the-right-track

Slide 14: When a vaccine candidate moves into Phase 2 of Clinical Trials, more participants, generally several hundred, are included in the study. A more diverse set of participants is recruited as the vaccine candidate moves into Phase 2, so researchers can study how the vaccine affects individual with different health statuses, different demographic backgrounds, and people who are likely to be at risk for acquihiring the disease in their day-to-day life.[4]

Participants in Phase 2 are included in randomized-controlled studies, where some participants will receive the vaccine and others will receive the placebo (referred to as the "control group").[6] Additionally, as researchers are working to identify the best dosage for a vaccine, participants may also receive different dosing for the vaccine. With this study set-up, researchers are then able to compare the data from individuals who did and didn't receive the vaccine, as well as any differences observed between dosing.[7]

During Phase 2, researchers continue to monitor safety and make note of any short-term side effects. How well the vaccine produces an immune response is a critical aspect of this trial stage, and researchers use standardized testing to validate the results comparing dosing between study participants. This helps researchers understand the relationship between the dose administered and the immune response generated by that dose amount.[7]

Manufacturing plans for the vaccine may occur concurrently with the human trials and at this stage, scientists and the pharmaceutical company continue to plan the methods for manufacturing the vaccine, stabilization of the product, and packaging and vials. During this stage, it is important to establish manufacturing consistency, so each lot of produced vaccines is the same.[7]

Slide 15: Phase 3 is the final phase of development before a vaccine candidate can be reviewed and approved for licensure. Phase 3 studies include hundreds of thousands of people and are composed of study participants that are statistically similar to the population that will receive the vaccine.[4,7]

The size of the study during Phase 3 is calculated using factors of the frequency the disease occurs in the population, estimated dropout rates of study participants, and the ability of the different versions of the vaccine candidate to show differences. The final number of participants calculated for the study ensures that statistical differences between the experimental group receiving the vaccine, and the control group can be observed for comparison purposes.[6] Therefore, the study size of Phase 3 trials is different and unique to each vaccine candidate.

As with previous study phases, both vaccine safety and efficacy are monitored during Phase 3 trials. While researchers may have some understanding of common side effects from the vaccine after Phases 1 and 2, Phase 3 trials can help identify any rare side effects that may only appear among thousands and thousands of study participants. Additionally, greater sample size data helps researchers more fully understand how common and severe side effects of the vaccine will be.[6]

The double-blinded controlled study also allows researchers to compare the immune response outcomes of those who received the vaccine and those who received the placebo. Metrics like the number of confirmed cases of the illness in the vaccinated versus unvaccinated groups help researchers gauge how well the vaccine works at preventing illness.[7] Other factors such as hospitalizations or death (from the illness) can help researchers understand how well the vaccine protects against serious illness. This is the final stage of testing before vaccine data is reviewed for approval and generally takes three to four years to complete.

Slide 16: After the successful completion of Phase 3 clinical trials, the company developing the vaccine will spend months to years reviewing and analyzing their own data before submitting a Biologics License Application (BLA) to the U.S. Food & Drug Administration (FDA) for review. The BLA is the first step in a company seeking approval to distribute their vaccine in the United States.[4]

The FDA receives the data submitted to determine if the vaccine has been proven to be both safe and effective for the populations that it is intended to reach. Manufacturing processes are also an important factor in the BLA and review, as the FDA must ensure that the manufacturing processes and facility status will ensure product quality and consistency. [4]

At the heart of the FDA's consideration of approving a vaccine is whether the benefits of the vaccine outweigh any risks. Part of this risk analysis often involves how serious the disease is that is prevented by the vaccine. The scientific team of the FDA that is responsible for reviewing Biologics License Applications includes physicians, chemists, statisticians, pharmacologists/toxicologists, microbiologists, experts in post marketing safety, clinical study site inspectors, manufacturing and facility inspectors, and labeling and communications experts.[4]

Once the FDA gives approval to a company's BLA, the company is permitted to distribute and market the vaccine for the population in which it was approved. This is the typical route for approval of any vaccine in the United States. In instances of public health emergencies, some vaccines may be granted "Emergency Use Authorization" or EUA status, which is not quite the same as full approval.[4] This was the case of the COVID-19 vaccines, and we will talk further about the processes of an EUA in the next section.

Slide 17: Now we'll discuss the science behind the COVID-19 vaccines approved for emergency use as of March 19, 2021 – Pfizer/BioNTech, Moderna, and Johnson & Johnson.

Slide 18: Because of the pandemic, all three of the COVID-19 vaccines have been approved by the Food and Drug Administration (FDA) for Emergency Use Authorization (EUA). As part of the FDA's evaluation of COVID-19 vaccine Emergency Use Authorization requests, they analyzed the controls, chemistry, and manufacturing for each vaccine. To ensure good and current compliance in the vaccine manufacturing process, the FDA conducted site visits, reviewed records, and previous compliance history.[8]

In guidance released by the FDA in October 2020, entitled Emergency Use Authorization for Vaccines to Prevent COVID-19, it was made clear that OVERALL an EUA approval for the COVID-19 vaccine had to demonstrate two important rules:

1. There must have been "adequate manufacturing information to ensure it's quality and consistency."[8]
2. The FDA determined that "the vaccine's benefits outweigh its risks based on at least one well-designed Phase 3 clinical trial," demonstrating it's vaccine safety and efficacy in a "clear and compelling manner."[8]

In this slide you'll notice that Pfizer/ Biontech and Moderna received EUA approval within a week of one another in December, 2020, while the Johnson & Johnson vaccine was approved in the beginning of 2021.

Let's take a look at the three EUA vaccines:

- Pfizer/Bio-n-Tech, EUA approval: Dec. 11, 2020, 2 dose regimen
- Moderna, EUA approval: Dec. 18, 2020, 2 dose regimen
- J&J, EUA approval: Feb. 11, 2021, only 1 dose needed

Slide 19: Factors of Vaccine Development Speed. Before the COVID-19 pandemic, vaccine development could take up to 10 years from concept to approval. However, the Pfizer and Moderna COVID-19 vaccines were both developed in less than a year. Why?

At the end of 2019, the SARS-Cov-2 virus posed an eminent threat to global public health. It was imperative that scientists moved quickly to provide immunization options to the public. The government established enough federal funding to help develop and mobilize approved vaccines as quickly as possible to American citizens, this was known as Operation Warp Speed. [9] To accelerate development while maintaining standards for safety and efficacy, Operation Warp Speed selected the most promising countermeasure candidates and providing coordinated government support. Protocols for the demonstration of safety and efficacy were aligned, which allowed the trials to proceed more quickly, and the protocols for the trials were overseen by the federal government, as opposed to traditional public-private partnerships, in which pharmaceutical companies decide on their own protocols. Rather than eliminating steps from traditional development timelines, steps proceeded simultaneously, such as starting manufacturing of the vaccine at industrial scale well before the demonstration of vaccine efficacy and safety as happens normally. [9] This increases the financial risk, but not the product risk.

Upon analysis of the virus' genome sequence, scientists realized that the coronavirus' genetic code was very similar to that of another coronavirus, Severe acute respiratory syndrome (SARS), which they had already encountered from the outbreak that took place in 2003. Although a SARS vaccine was never completed, scientists had a good idea of the vaccine strategy based on previous SARS vaccine research.[10] Think of it as a vaccine development cheat sheet. A combination of cutting edge technology and funding accelerated the vaccine development timeline and FDA review process.

Additionally, scientists had been working on developing mRNA technology to use in vaccines for over 10 years prior to COVID-19. Both the Pfizer/BioNTech and Moderna vaccines deliver the virus's spike protein via messenger RNA (mRNA), which is how the body's immune response is triggered. Researchers have been testing mRNA technology to develop vaccines for other viruses such as Zika, HIV, rabies, and influenza.[11] mRNA vaccines can be developed in a laboratory using a DNA template (that can be standardized and scaled up), lending to a faster vaccine development process than traditional methods. It is free from animal origin and synthesized without preservatives. Other benefits of using this technology includes use of a non-infectious element and the potential for targeting multiple diseases. [11] While some may hear mRNA referred to as "new technology", it has been around for more than a decade, is familiar to researchers, and has been studied in humans outside of COVID-19 vaccine clinical trials.

Despite rapid development, the results of a rigorous process involving clinical trials, efficacy, and safety prove that the vaccines are safe.

Slide 20: To better understand the science behind vaccines, we'll discuss the vaccine technologies associated with each.

Slide 21: You may be wondering…what's really inside of these vaccines? Let's take a look the Pfizer/BioNTech vaccine. It is comprised of four components:[12]

- **mRNA** – Provides instructions for our body on how to make a viral protein that triggers an immune response. It is the only active ingredient in the vaccine.

- **Lipids** – Protect the mRNA & have a “greasy” exterior that helps mRNA slide inside of the cell
- **Salts** – Help balance acidity in the body
- **Sugar (sucrose)** – Helps molecules maintain their shape during freezing

Next, we’ll discuss the list of ingredients in the vaccine.

Slide 22: Here is a detailed list of ingredients in the Pfizer/BioNTech vaccine, including active ingredients, lipids, salts, and others.[13] If you'd like to learn more about the molecular structure of any of the ingredients listed above, the National Library of Medicine's, PubChem, website is a great resource. The site allows you to search chemicals by name, molecular formula, structure, and other identifiers. The link to PubChem is listed in the Helpful Resource section at the end of this presentation.

Slide 23: What's in the Moderna vaccine? The Moderna vaccine has very similar components to the Pfizer/BioNTech vaccine, as they are both mRNA vaccines:[12]

- **mRNA** – again, it is the only active ingredient in the vaccine. Provides instructions for our body on how to make a viral protein that triggers an immune response.
- **Lipids** – The “greasy” exterior helps mRNA slide inside of the cell and serves as protection to the mRNA
- **Acids, Acid Stabilizers, & Salts** – work together to maintain the stability of the vaccine after production
- **Sugar (sucrose)** – Allows molecules to maintain their shape during the freezing process

Slide 24: A more in depth look in to the ingredients list for the Moderna vaccine.[13] Feel free to search any ingredient on the PubChem website, as previously mentioned.

Slide 25: The Pfizer and Moderna vaccines use messenger RNA (mRNA) technology. Despite the myths and misinformation surrounding it, mRNA technology isn’t anything new. In fact, talks of using mRNA technology as a vaccine platform actually began in the early 90s, so scientists have been researching mRNA vaccines for decades. For example, in 2015 scientists who conducted early stage clinical trials of vaccines for Zika explored using mRNA. At the time, it was unsuccessful because of modest immune responses and unintended inflammatory outcomes. However, recent technological advancements in RNA biology and chemistry drastically improved mRNA safety and effectiveness.[14] These improvements have allowed for the development of the Pfizer and Moderna vaccines.

There are a few benefits associated with mRNA technology as well: [15]

- It does not generate infectious particles
- It is a shorter manufacturing time compared to other vaccines
- And it has the potential for targeting multiple diseases with one vaccine

Here is how mRNA vaccines work: [16]

1. mRNA from the virus’s genetic code is injected into the patient

2. The mRNA instructs human cells to create part of the SARS-COV-2 virus called the “spike” protein. The cell gets rid of the protein once it breaks down the mRNA instructions.

3. Our immune system reacts to the protein (because it doesn’t belong) by producing antibodies and activating T-cells to destroy the spike proteins.

4. Lastly, the t-cells and antibodies will remember how to fight the virus, and protect you from getting sick if you are exposed in the future.

Slide 26: What's in the J&J vaccine? The J&J vaccine differs from the other two. It is an vector vaccine, which is a more traditional virus-based technology. The J&J vaccine is specifically called an adenovirus vector vaccine. Adenovirus is a group of very common viruses that can cause cold or flu-like symptoms. The adenovirus in the vaccine is disabled (meaning it cannot replicate in the body), and is not at all related to the coronavirus. In fact, the disabled adenovirus is used to simply deliver instructions to cells on how to defeat coronavirus. It does not result in any sort of viral infection.[17]

Here’s what it comprised of:

- **Adenovirus vector** – is used as the vehicle to introduce the vaccine (virus cannot replicate)
- **Acid & acid stabilizers –** work together to maintain the stability of the vaccine after production
- **Salt –** help balance acidity in the body

Slide 27: We need to review an important update that occurred with the J&J vaccine in April of 2021.

In early April, several reports of a rare blood clot condition, thrombosis with thrombocytopenia syndrome, referred to as TTS, were detected via VAERS, the Vaccine Adverse Event Reporting System. All reported cases of TTS occurred within 2 weeks of individuals receiving the J&J COVID-19 vaccine. All reported cases occurred among women ages 18 – 59 years. [18]

Out of an abundance of caution, the CDC and FDA recommended a temporary pause of the J&J vaccine on April 13th while experts worked to review the data. On April 23rd, after reviewing all available data, the pause was listed by the CDC and FDA after determining that the vaccine’s known and potential benefits outweigh its known and potential risks. [19]

As of June 21, 2021, more than 12 million doses of Johnson & Johnson’s COVID-19 vaccine have been administered in the United States. Through continuous safety monitoring, 36 total cases of TTS have been identified among individuals who had received the J&J COVID-19 vaccine, the majority of whom were women between ages 18 – 59. [20]

Currently, women 50 years and younger may still receive the J&J vaccine but should be aware of this rare but adverse event risk. [19]

While media reports of the pause may have created fear and hesitancy among the general public, the J&J pause was a wonderful example of our vaccine safety monitoring systems working exactly as they should. VAERS, the system that detected the original cases of TTS, is available to medical professionals and the general public alike, and accepts any adverse event reports following vaccination, whether they are ultimately related or not. It is a great tool to first detect any initial concerns that then may warrant further investigation, such as the reports of TTS following the J&J vaccine.

Slide 28: Here is the detailed ingredients list for the J&J vaccine. Again, PubChem is a very helpful tool for gaining a better understanding of each ingredient.

Slide 29: The Johnson & Johnson COVID-19 vaccine uses Janssen's AdVac Viral Vector Technology. The AdVac Technology is fairly new. It was first used in the Johnson & Johnson vaccine for Ebola, which was approved by the European Commission in July 2020. We touched on this earlier, but just as a reminder…the AdVac vectors are made of adenovirus – a group of viruses that cause the **common cold**. These vectors are based on a modified adenovirus that cannot replicate and cause disease.[17]

Here is how the AdVac Viral Vector Technology works: [21]

- A piece of coronavirus DNA is placed inside of the vector. A vector carries genetic materials into cells. In this vaccine, an adenovirus vector (which is a carrier made from a modified version of a virus that causes the common cold) from an antigen's genetic code, used to mimic the virus, is injected into the patient.
- Our immune system reacts to the antigen (because it doesn't belong) by producing antibodies and activating t-cells.
- The t-cells and antibodies will remember how to fight the virus and help you from getting sick if you are exposed to the virus in the future.

Slide 30: Novavax is a protein-based, or protein subunit coronavirus vaccine that has yet to be approved for an EUA. There was a 96% efficacy rate against the original coronavirus strain in their United Kingdom trial. There were strong results for the vaccine against the B.1.1.7 variant at 89% efficacy. But in the South Africa trial (where volunteers were exposed to B.1.351 variant) there was only 49% efficacy. The company is working on a new version of the vaccine that is designed to protect against the new B.1.351 variant.[22] As of June 14, 2021, results from a Phase 3 clinical trial that included nearly 30,000 adult volunteers in the United States demonstrated a 90.4% efficacy in preventing symptomatic COVID-19 disease. If approved, this would be the fourth EUA vaccine on the market by Summer 2021. [23]

Slide 31: Let's discuss the Novavax vaccine in more detail. This protein-based vaccine, or protein subunit vaccine, includes harmless proteins of the virus that cause COVID-19. When the vaccine enters the body, it recognizes that the protein does not belong and builds T cells and antibodies that remember how to fight the virus that causes COVID-19 in the future.[24] The vaccine is 2 doses, where the second dose should be administered a month from the first dose. Unlike the Pfizer and Moderna vaccines, but similar to the J&J vaccine….the Novavax vaccine requires basic refrigeration. [25]

Slide 32: The Novavax COVID-19 vaccine uses Protein-Based, or Protein Subunit Technology. As of June 28, 2021, Novavax has not yet been approved for use, although it is predicted to be ready by Summer 2021.

Here is a simplified explanation on how the Protein-Based Technology works:[22]

- A modified spike gene is inserted into a baculovirus, and infects moth cells. (A baculovirus is an insect pathogenic virus.) Those infected cells then produce spike proteins.
- The spike proteins are harvested from moth cells and assembled into nanoparticles. Nanoparticles mimic the molecular structure of coronavirus, but do not replicate or cause COVID-19.

- Vaccine includes spike nanoparticles and a compound. The compound attracts immune cells to site of injection, which causes a strong response to nanoparticles.
- Our immune system reacts to nanoparticles by producing T-cells and antibodies. They will remember how to fight the virus upon future exposure.

Slide 33: COVID-19 Vaccine Expectations... In this next section, we'll explain how to manage expectations and go over helpful tips after receiving the vaccine.

Slide 34: There are some common side effects associated with the COVID-19 vaccines. There may be pain, redness, and/or swelling at the site of injection on your arm. Also, there is a chance you may experience tiredness, headaches, muscle pain, chills, fever, or nausea. [26]

If you experience any side effects it is a normal sign that your body is just having an immune response and building protection. Be sure to contact your health care provider if redness or tenderness gets worse after 24 hours or if your side effects don't go away or get worse after a few days.[26]

Although experiencing side effects can be bothersome, they aren't nearly as severe as the symptoms associated with COVID.

Slide 35: The CDC does not recommend that you take over-the-counter pain relief medicines before vaccination for the purpose of trying to prevent side effects. It is best to take these medications POST-vaccination if necessary.[26]

To reduce pain and discomfort where you got the shot you can apply a clean, cool wet washcloth over the area and use or exercise your arm. If you happen to get a fever post-vaccination, be sure to drink plenty of fluids and dress lightly. [26]

Slide 36: A few things to remember upon receiving a COVID-19 vaccine:

- You are considered fully vaccinated after 2 weeks upon receiving either your second dose for Pfizer and Moderna or 2 weeks after the single dose of the J&J vaccine. It takes time for your body to build immunity after receiving a vaccine. [26]
- Once you are fully vaccinated, you may be able to continue to do things that had to stop because of pandemic. For example, you can gather indoors with other fully vaccinated people without wearing a mask. [27]
- The most important thing to remember is researchers are still learning about effects of vaccines and the spread of COVID-19. Keep taking precautions after being fully vaccinated. Wash your hands often, stay 6 feet apart from others, wear a mask, and avoid very crowded places. [27]

Slide 37: Here are some helpful resources for understanding COVID vaccine science.

Slide 38: The resources listed on this slide are helpful in breaking down vaccine science.

- First… Understanding How COVID-19 Vaccines Work is a section on the CDC website that explains how vaccines work, our immune systems, and different types of vaccines.

- PubChem, which has the world's largest collection of freely accessible chemical information...is a wonderful resource if you are looking for more detailed chemical information about vaccine ingredients.
- The Children's Hospital of Philadelphia, Vaccine Science section on their website is a great resource for addressing questions about how vaccines work in general.
- World Health Organization's, Science in 5 is a great series of 5 minute videos that address a variety of public health topics around the world.

Slide 39: Be sure to follow us on Twitter, Facebook, Instagram, and LinkedIn.

Also, if you'd like to stay updated on the latest information from The Immunization Partnership sign up for our alerts at www.immunizeusa.org.

Slide 40: People like you are vital in helping promote the importance about how to eliminate vaccine-preventable diseases from spreading in your communities. We hope you will take the tools, strategies, and resources you've learned about to help you navigate situations where you may encounter vaccine myths and misinformation. The work is ongoing as organizations like The Immunization Partnership and healthcare professionals like yourselves work to push the message that vaccines are safe and effective.

Immunize. Prevent what's preventable.

Slide 41:

1. https://www.historyofvaccines.org/timeline/all
2. https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html
3. https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101
4. https://microbiologysociety.org/why-microbiology-matters/what-is-microbiology/microbes-and-the-human-body/immune-system.html
5. https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation
6. https://www.chop.edu/centers-programs/vaccine-education-center/making-vaccines/process-vaccine-development
7. https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html
8. https://www.fda.gov/media/143890/download
9. https://news.uchicago.edu/story/how-were-researchers-able-develop-covid-19-vaccines-so-quickly
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Slide 42: If you have any questions about this presentation please reach out to Ashley Beale or Rachel Walker at The Immunization Partnership. Thank you for listening.