PARENTS PACK

MONTHLY UPDATES ABOUT VACCINES ACROSS THE LIFESPAN

COVID-19 VACCINE: WHAT'S IN THE VIAL?

June 2023

Although the COVID-19 public health emergency came to an end in May 2023, the COVID-19 vaccine continues to be recommended for virtually everyone. At this point in time, three groups are of particular focus when it comes to getting vaccinated against COVID-19:

1. Infants turning 6 months of age
2. People in high-risk groups who have not received a current booster
3. Those who remain unvaccinated

Often those in this third group have concerns about the safety of the vaccine or their need for it. Regarding the need for COVID-19 vaccine, two points are important. First, although the numbers of people getting hospitalized or dying from COVID-19 have decreased dramatically, most of those who are severely affected (i.e., hospitalized or die) are previously unvaccinated. Second, even if someone has had COVID-19 infection, the vaccine is still beneficial. Indeed, those among us with the most robust protection appear to be individuals who were both infected and vaccinated.

TRIVIA CORNER

During which U.S. president's term was the first childhood vaccination program launched?

A. Harry S. Truman
B. James "Jimmy" Carter
C. Lyndon B. Johnson
D. George H. W. Bush

With regard to COVID-19 vaccine safety, while many rumors continue to circulate, the reality is that globally more than 13 billion people have been vaccinated, and we know how the vaccine works, so we are not expecting any long-term consequences that have yet to be "discovered."

However, we also realize that people still have questions, so this month we thought we would address one of those. Specifically, what is contained in COVID-19 vaccines? And, related to this, what is NOT contained in COVID-19 vaccines. Since J&J/Janssen vaccines are no longer available in the U.S. (as of mid-May 2023), information about that vaccine will not be included. Instead, we will focus on the mRNA vaccines (Pfizer and Moderna) and the protein-based vaccine (Novavax). Continue reading to find out more.

COVID-19 vaccines: What's in the vial?

Vaccines, including those for COVID-19, typically contain specific categories of ingredients, including antigens, adjuvants, stabilizers, preservatives, and residual manufacturing byproducts. However, not all vaccines contain all five of these categories. So, let's take a look related to COVID-19 vaccines.

Antigens: All vaccines will contain an antigenic component because this is the part of the vaccine to which we make an immune response. For the vaccine to work, our immune system has to be introduced to some part of the pathogen that it will come into contact with during an infection. Historically, viral vaccines have included:

- Whole, weakened viruses (like chickenpox and measles vaccines)
- Whole viruses that have been treated, so they can't reproduce (like hepatitis A and polio vaccines)
- Single proteins important to the infection and subsequent immune response (like hepatitis B, HPV and shingles vaccines)

The protein-based COVID-19 vaccine (Novavax) is also in this latter category (single protein) as its antigenic component is the spike protein from SARS-CoV-2 virus, the virus that causes COVID-19.

The other category of COVID-19 vaccines, commonly referred to as "mRNA" vaccines, used a new approach. One that, although it had been in development for about 20 years prior to the COVID-19 pandemic, had never previously been used in an approved vaccine. The reasons that no previous mRNA vaccines were approved had to do with the pathogens and circumstances, not the safety of the mRNA approach. For example, Zika vaccines could not finish being tested because the outbreak receded. HIV and influenza mRNA vaccines did not work, meaning that people who got the vaccine were not better protected than those in the placebo group. mRNA technology has also been explored for treating cancer; however, clinical trials for treatments are different than those for preventions, and often if a patient has the choice of taking a proven treatment or one that is "in development," they will opt for the former (for obvious reasons). As a result, these trials tend to take much longer to complete. So, after decades of studying the potential of mRNA technology, COVID-19 vaccines became the first of their kind. We suspect, they won't be the last, given how clearly they demonstrated that this technology can be highly effective and safe.

With this said, however, it is understandable that in the situation we found ourselves — one of angst, fear and concern over a novel infection and the shortest timeline ever to develop a vaccine — using a new type of vaccine stood to compound the concerns some people had about their safety. Indeed, the use of mRNA is one of the most asked about aspects of these vaccines. Two considerations are important though:

1. *To our cells, mRNA processing was not new.* mRNA stands for **m**essenger **r**ibo**n**ucleic **a**cid, which is a blueprint for protein production. mRNA is found in every cell, and every day, machinery in our cells reads mRNA to produce proteins that our cells or our body need to survive. As such, when the vaccine delivers mRNA for the spike protein of SARS-CoV-2, the cell does not treat it differently. It reads the mRNA blueprint and produces the protein. When that protein starts "milling around" the inside of the cell, it is recognized as foreign, and chemical signals alert nearby immune system cells, which descend on the affected cells and activate a cascade of immune system steps that lead to production of antibodies and memory cells. Watch this animation for more details.
2. *As a society, we were extremely fortunate on two fronts.* First, the 20 years of experience with mRNA technology positioned us to have this option to try at the start of Operation Warp Speed. Second, this technology allows for significantly faster production of a vaccine. The protein-based vaccine, indeed all the historic vaccine technologies, take much longer to produce. The Novavax vaccine was not approved until almost seven months after the mRNA vaccines were approved. If we had to wait for the protein-based vaccine, hundreds of thousands of more people would have likely died during the first six or seven months of 2021 while we continued to wait for a vaccine.

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Adjuvants: An adjuvant is added to some vaccines to enhance the recipient's immune response to the vaccine. The mRNA COVID-19 vaccines (Pfizer and Moderna) do not contain an adjuvant. The protein-based vaccine (Novavax) contains the same adjuvant used in the shingles vaccine. It is made from the soapbark tree, *Quillaja saponaria*. None of the COVID-19 vaccines contain aluminum salts, the most common adjuvant used in vaccines.

Stabilizers: Stabilizers ensure that a vaccine can be transported and stored without losing its effectiveness. Typical stabilizers include salts and other chemicals that maintain the integrity of the antigen. Because stabilizers are present in low quantities, they generally do not present any safety issues.

For the mRNA to remain stable, the two vaccines of this type (Pfizer and Moderna) include lipids, which are fat-based molecules, that protect the mRNA. Cholesterol is one such lipid that is in both versions. The Pfizer vaccine contains three additional lipids, and the Moderna vaccine contains two additional lipids. Sugar, the same kind you put in your coffee, is also added to both vaccines; it keeps the fat molecules from sticking to each other or to the sides of the vials. Both mRNA vaccines also contain chemicals to help keep them at a pH conducive for cells. The Pfizer version contains four salts in this role, one of which is table salt. The Moderna version also uses four ingredients in this role: acetic acid (the main ingredient in vinegar other than water); the salt form of acetic acid, called sodium acetate; and two chemicals in a class known as amines.

The protein-based vaccine (Novavax) contains salts, cholesterol, hydrochloric acid and polysorbate 80. Polysorbate 80 is a chemical commonly used as an emulsifier, meaning it helps compounds with different qualities that don't normally mix stay in solution together. Common examples of where polysorbate 80 is used in this way are ice cream, salad dressings and chocolate. Because of the polysorbate in this vaccine, individuals with known allergies to that compound should avoid getting the Novavax vaccine. They can get the mRNA vaccines though as long as they do not have a contraindication, or medical reason to forgo receipt of a vaccine, such as having had a severe allergic reaction to a previous dose or any ingredients contained in the vaccine.

Preservatives: Preservatives ensure that vaccine doses don't become contaminated with other agents. Historically, a common preservative was thimerosal, a mercury-containing chemical; however, companies have moved away from using this preservative due to unfounded safety concerns. None of the COVID-19 vaccines (Pfizer, Moderna, or Novavax) contain a preservative.

Residual manufacturing byproducts: The mRNA vaccine antigen can be manufactured without the need to grow the virus. This means that these types of vaccines do not have residual manufacturing byproducts like more traditional vaccines tend to have.

On the other hand, the antigen (spike protein) in the protein-based vaccine (Novavax) was produced by inserting the spike protein gene into a virus that infects insect cells, so that as the cells make the virus, the spike protein is also manufactured. The spike protein is then purified for use in the vaccine. As a result of this process, the Novavax vaccine contains small amount of viral and cellular proteins and DNA as well as some other materials that were used as nutrients during the growth process. The proteins and DNA are not in sufficient quantities or form to cause any adverse cellular effects, and they are not of human origin. Likewise, the extremely tiny quantities of any residual growth nutrients would not be expected to cause any safety concerns.

COVID-19 vaccines: What's NOT in the vial?

COVID-19 vaccines have been the subject of several conspiracy theories and an abundance of misinformation. Some of these falsehoods involve vaccine ingredients. As such, it is important to also be aware of what is not in the vaccine.

The following ingredients are not contained in COVID-19 vaccines distributed in the U.S. (Pfizer, Moderna, and Novavax):

- Aluminum
- Animal products
- Antibiotics
- Blood products
- Egg proteins
- Fetal material
- Gluten
- Human DNA
- Latex*
- Microchips
- Pork products
- Soy
- Thimerosal

*Although people with latex allergies sometimes need to avoid vaccines with latex-based packaging, none of the COVID-19 vaccines currently distributed in the U.S. contain latex in the vial or its packaging.

Summary

Hopefully, with more understanding of what is and is not in COVID-19 vaccines, some people who have previously been hesitant to get vaccinated against COVID-19 will feel more comfortable to do so.

Check out the infographic related to this article, "COVID-19 Vaccines: What's in the vial?".

For more information about COVID-19, including answers to dozens of questions submitted by the public, visit our dedicated webpage at COVIDVaccineAnswers.org.

For links to resources, check out the online version, *bit.ly/June2023FA*.

DR. HANDY'S CORNER – Antibiotics: How they work and when to use them

Watch Dr. Handy's latest video to find out when to use antibiotics, how they work, and what side effects may occur.

Watch the video: *bit.ly/AntibioticsInfo*.

NEWS & NOTES

Information covered in this section include:

- Preparing for vaccine visits at any age
- Comic book series about vaccines for 9- to 12-year-olds
- In the absence of Twitter's blue check mark

Visit News & Notes online, *bit.ly/June2023NN*.

TRIVIA ANSWER

The correct answer is B. During his presidency, Jimmy Carter established a national energy policy, expanded the national park system, fought inflation, and many other things. At the urging of Betty Bumpers and his wife, Rosalyn, the first childhood vaccination program was also started during Jimmy Carter's presidency.

Go to vaccine.chop.edu/trivia to play Just the Vax, the Vaccine Education Center's trivia game, where you can find this question and others like it.

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