PARENTS PACK

MONTHLY UPDATES ABOUT
VACCINES ACROSS THE LIFESPAN

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FEATURE ARTICLE — VACCINES DURING PREGNANCY: THE HISTORY AND REASONS BEHIND THE RECOMMENDATIONS

Probably more than any other time in life, people monitor what they are putting into their bodies during pregnancy. This focus is one of the earliest forms of parenting that an individual feels they can do. Everything is aimed toward protecting the developing baby — foods, drinks and medications all come under scrutiny. Historically, this also meant avoiding most vaccines. But in recent years, some vaccines have become staples of pregnancy, leading to confusion, questions and, sometimes, angst. So, let's take a closer look.

Why would anyone recommend a vaccine during pregnancy? Two main reasons.

1. To protect mom
2. To protect baby

For mom. During pregnancy, the body undergoes changes to accommodate the growth of the fetus. For example, because the fetus is not genetically identical, the pregnant person's immune system would view it as foreign and try to rid the body of it without special accommodations. So, during pregnancy, the mother's immune system is to some extent dampened. Several physical changes can also make pregnant people more susceptible to infections, particularly some respiratory infections. First, blood volume increases because the blood is also circulating through the placenta to the developing fetus. This results in more fluids, which in an area like the lungs can make the local environment more friendly than it normally would be for the bacteria and viruses that cause pneumonia. Second, as the fetus grows, the enlarged uterus can exert physical pressure on organs in the chest cavity, like the heart and lungs. This can lead to breathing that is not as deep, allowing for these pathogens to "settle in" more comfortably in the lungs. Likewise, the heart needs to work harder to circulate blood throughout the body. As a result of these and other changes during pregnancy, infections can be more severe than they would be expected to be normally. Influenza and COVID-19 have both been shown to be more severe during pregnancy. For this reason, pregnant people are recommended to get both of these vaccines to decrease the chance that they will be infected and go on to experience more severe disease.

For baby. When babies are first born, their immune systems are remarkably developed and immediately begin protecting them against potential pathogens, but their immune systems are not completely matured yet. So, newborns benefit from maternal antibodies that they receive before birth through the placenta and after birth in breast milk. This type of "passive immunity," meaning immunity generated by one person that is protecting another, helps protect babies while their immune systems mature and before they get vaccines given in the first year of life. This is important for some diseases that can be particularly detrimental to young babies, such as pertussis (whooping cough). In this case, giving the Tdap vaccine (the "p" in Tdap stands for pertussis) during pregnancy boosts the quantity of pertussis antibodies that are passively transferred to the baby, thereby offering better protection. This is also why the Tdap vaccine is recommended during a specific interval during pregnancy (i.e., 27 to 36 weeks of gestation) — to allow for the greatest quantity of antibodies to be transferred to the baby.

When did this change? The evidence.

*"The time has passed where we say we have to protect pregnant women **from** research. We have to say we need to protect them **through** research."*
– Dr. Marion Gruber in "Paving the way for maternal vaccination," Medical History Pictures, 2023.

Historically, vaccines were to be avoided during pregnancy, and, indeed, some vaccines continue to be deferred during pregnancy in most situations, particularly those that are given in the form of live, weakened viruses, like measles, mumps, rubella and chickenpox vaccines. In nature, each of these viruses can harm a developing fetus if the pregnant person is infected, so people are recommended to be immune before becoming pregnant. However, if they are not immune, they are suggested to wait until after delivery to get the vaccines unless particular circumstances prevail, such as during an outbreak. The reason for this divergence between pregnancy and non-pregnancy is rooted in a theoretical risk that because the viruses, in their natural form, can damage a developing fetus, the weakened versions may be able to as well. None of these vaccines, however, have ever been shown to cause damage to a developing fetus. Although the risks from these weakened viruses are largely theoretical, the recommendations take this theoretical risk into account.

According to Dr. Marion Gruber, Director of the Food and Drug Administration's (FDA's) Office of Vaccines Research & Review (OVRR) from 2012-2021, the importance of preventing some infections during pregnancy started to come into focus during the 2009 H1N1 influenza pandemic. Prior to that time, pregnant people were generally excluded from participating in clinical trials because of the theoretical risk of harm to the developing fetus. However, during the 2009 pandemic, pregnancy increased the chance of experiencing severe influenza and death. So, it became important to try to prevent this group from ever becoming infected. The 2014-2016 Ebola outbreak also provided evidence of the importance of preventing some infections in pregnant women as infants born to women who were infected during pregnancy had smaller than average heads and brains, a condition known as microcephaly.

During Dr. Gruber's time at the FDA, she worked to understand the risks associated with clinical trial participation during pregnancy as well as to promote the study of potential risks and benefits in these scenarios.

Watch Dr. Gruber discuss these developments in this short video. [vimeo.com/836001301]

TRIVIA CORNER

How many types of HPV have been identified?

A. About 50
B. More than 100
C. About 75
D. Less than 10

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What does this mean for pregnant people? The vaccines.

Because of the work of many scientists and clinicians like Dr. Gruber, we are now at a place where we can test vaccines in pregnant people and better protect them and their unborn babies. For these reasons, the following vaccines are recommended during pregnancy:

COVID-19 vaccine is recommended during pregnancy to protect the mom. It is likely that the virus that causes COVID-19 will continue to circulate for decades. Antibodies will also pass to the baby, and data indicate that the presence of maternal COVID-19-specific antibodies can protect the baby during the first few months of life.

Influenza vaccine is recommended if an individual is pregnant during a time of the year when influenza virus is circulating. Influenza viruses have continued circulating around the globe since the mid-1300s. Indeed, when people travel, sometimes they are surprised to learn that influenza is circulating at their destination. So, if traveling during pregnancy, it is good to check whether influenza is circulating in your travel destination. The goal of influenza vaccination during pregnancy is to protect mom. Vaccine-induced antibodies can also afford the baby some protection before they can get vaccinated against influenza, starting at 6 months of age.

Tdap vaccine is recommended between 27 and 36 weeks of gestation during every pregnancy. The goal is to protect the baby with passive antibodies.

RSV vaccine (Abrysvo™) is recommended between 32 and 36 weeks of gestation if the baby will be born during RSV season. The goal is to protect the baby. Unlike influenza and COVID-19, pregnant women are not more likely to experience severe RSV compared with their non-pregnant counterparts. The decision to get the RSV vaccine during pregnancy should be guided by two important points:

- Because RSV season can vary by location and somewhat by year, not all pregnant people will need this vaccine. The estimated delivery date and whether that falls during RSV season in the area where the individual lives will determine when that vaccine is administered.

  In the clinical trials, there was some evidence that vaccinated people were more likely to deliver early compared with those who got the placebo. The numbers were small, so we need to monitor this as more vaccine doses are given. Because of this potential problem, the recommendation was limited to the four-week period between 32 and 36 weeks of gestation to decrease the chance of the infant having any untoward effects should delivery occur early.
- Further, a product is now available to protect babies during their first RSV season. Called Beyfortus™, this product is not a vaccine. Like maternal immunization, this product leverages passive immunization. The product, given as an injection, is a long-lasting monoclonal antibody; it has been shown to be safe and effective. However, since it is new, supplies have been extremely limited, and some insurers are not yet covering it. As such, maternal immunization may be the more available option during the 2023-2024 RSV season. In future years, the supply will likely increase and insurance coverage will be in place, enabling more families to opt for this form of RSV protection for their infants. This option will be particularly important if the maternal vaccination is found to be causally associated with early delivery.

For other vaccines, the general rule of thumb remains:

Live, weakened viral vaccines — People should wait until after delivery if possible (based on assessing the potential risks and benefits in discussion with their healthcare provider).

Inactivated or subunit vaccines (vaccines made of only a part of a virus or bacteria) — People can usually get these types of vaccines during pregnancy, with the exception of the HPV vaccine.

What does this mean for the baby? The relatives.

Cocooning. Several years ago, the Tdap vaccine was recommended for any adults who were going to be around an infant. This included the non-pregnant parent, grandparents, older siblings, and any other adults who would be spending significant time with the new baby. The concept was known as cocooning, meaning to surround the baby with a wall of immune people to decrease the chance of being infected with pertussis in the first few months f life. While this sounds like it should work, the data showed otherwise. In fact, the best way to protect the baby from pertussis was via passive immunity garnered by maternal antibodies. As such, the recommendation for other adults to get the Tdap vaccine was removed, and more focus was placed on vaccination during pregnancy. Unfortunately, some people, including clinicians, still promote vaccination to cocoon the baby, and while this dose of vaccine is not likely to harm the adult who receives it, and it may indirectly help protect the baby, the reality is that this approach offers a false sense of protection.

Likewise, now that there is an RSV vaccine for the elderly, some providers are suggesting that grandparents or grandparents-to-be get the vaccine to protect their grandbabies. This, too, will only indirectly protect the baby and offer a false sense of security. The RSV vaccine has not been recommended as a means for protecting babies through cocooning; therefore, grandparents should decide whether to be vaccinated based on the risks and benefits for themselves.

Vaccines to avoid. Sometimes people wonder whether they need to keep recently vaccinated people away from babies. However, people can rest assured that grandparents, other adults, and other children in the home can get any vaccines they need without worry about being around the new baby.

Other considerations for protecting baby. In addition to getting the vaccines offered to protect the baby during pregnancy, parents should seek to protect their newborns by establishing rules related to decreasing the spread of any transmissible infection, such as:

- Limiting the number of people around the baby during the first weeks and months after delivery
- Encouraging handwashing before holding the baby
- Discouraging touching or kissing the baby's hands or face
- Asking anyone with cold-like symptoms (or other illnesses) to delay their visit until they are feeling better

In sum, we all want to protect our babies in every way possible. Sometimes this means avoiding certain things. Other times, it means doing certain things, like getting vaccines as recommended during pregnancy or limiting the chance for the baby to be exposed to an infectious disease. Regardless of what we decide, protecting our babies from infectious diseases relies on some of the earliest decisions we make as parents.

For links to resources in the Feature Article, please visit bit.ly/Jan2024FA.

TRIVIA ANSWER

The correct answer is B. More than 100 types of HPV have been identified. Some have been found to cause disease. Types 16 and 18 are the most common causes of cervical cancer and types 6 and 11 are the most common causes of anal and genital warts.

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.