



## RECOMMENDED IMMUNIZATION SCHEDULE: WHAT YOU SHOULD KNOW

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Although only one version of the immunization schedule is endorsed by the Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP), some parents prefer to be selective about which vaccines their children receive and when. Unfortunately, this approach can leave children susceptible to certain diseases at a time when they most need protection; worse, some children never catch up completely.

**Q. Who determines when vaccines are added to the immunization schedule?**

**A.** Before a vaccine can be added to the immunization schedule, it must be licensed by the Food and Drug Administration (FDA). Scientists at the FDA closely monitor and review vaccine trials; sometimes they request additional studies before making a decision. The FDA determines whether the vaccine is safe and whether it works (efficacy). Studies prior to licensure often last five to 10 years and are extensive. For example, if all of the paperwork from the pre-licensure studies of one of the rotavirus vaccines was piled up, the stack would be higher than the Empire State Building.

Once a vaccine is licensed, experts from the CDC, AAP and AAFP independently review data from scientific studies to determine whether or not a vaccine should be added to the immunization schedule. Not only will they look at the safety and efficacy of the vaccine, they will also look at disease rates and susceptible populations to determine if the vaccine is needed in the community and, if so, who should get it. Their recommendations are compiled to create the immunization schedule.

If a vaccine is recommended at an age when other vaccines are already given, *concomitant use studies* will be required to make sure the vaccine works and is safe when given as part of the existing schedule. If these studies reveal any negative consequences of giving certain vaccines together, restrictions will be placed on their use. For example, concomitant use studies have shown that if two live viral vaccines (for example, measles, mumps and rubella [MMR] and chickenpox vaccines) are given on the same day or separated by at least one month, no problems occur; however, if they are given between one and 28 days of each other, the immune response to the one administered later will be diminished. This is reflected on the schedule so that healthcare providers administer the vaccines correctly.

**Q. How are the amounts of immunological components in a vaccine determined?**

**A.** Vaccine doses are not chosen arbitrarily. During the four phases of vaccine development, different doses are tested to determine the lowest effective dose for the target group. For example, the rotavirus vaccine was tested at quantities as low as one-tenth the current dose and up to 10 times the current dose.

Vaccine developers must practice good medicine and good economics. Giving larger doses of active ingredients than required would increase the side effects and giving too little of the vaccine would lessen efficacy. It's a fine balance.

**Q. How can the recommended schedule be appropriate for all children?**

**A.** A common misconception is that the recommended immunization schedule is determined using a one-size-fits-all approach. These concerns are based on misconceptions about how vaccines work and misconceptions about the schedule itself:

- Vaccines and drugs aren't distributed in the body in the same manner. Medications must be distributed throughout the bloodstream to have the desired effect, so dosing is determined by body size. This is similar to the effects of a glass of alcohol on a large man compared with a small woman. In contrast, vaccines work by introducing cells of the immune system, known as B and T cells, to the parts of a virus or bacteria that cause disease. These cells are typically "educated" near the site the vaccine is given. Once they are equipped to recognize the agent that causes illness, they travel throughout the body. These educated patrol cells are known as memory cells; it typically takes about a week to 10 days after immunization for the memory response to develop completely. Memory cells allow for shorter infections and less severe symptoms if a person is exposed to the pathogen in the future.
- The immunization schedule is confusing. For this reason, it is often described more simply in terms of the age at which each vaccine is given. However, healthcare providers who administer vaccines know that many rules exist regarding when and if a vaccine can be given based on individual situations. Illnesses, allergies, age and health conditions all influence whether someone can get a vaccine. In fact, the published immunization schedule for children from birth through 18 years of age is eight pages long and is supported by a 195-page document on general recommendations as well as vaccine-specific recommendations. Documents describing specific vaccines are typically 25 to 40 pages long.

**Q. How do we know who should get a vaccine?**

**A.** A vaccine is added to the immunization schedule only after it has been studied in people who will receive it. Before a vaccine can be licensed, it must undergo rigorous scientific studies to make sure that it is safe and that it works in the age group for which it will be used.

One might reasonably ask then, how we know which age group might need to receive the vaccine. The answer is that scientists and public health officials perform "epidemiologic studies," which determine who gets a disease (susceptibility), when they get it (seasonality), how many people get it (morbidity), and how many people die from it (mortality). All of this information provides scientists and public health officials with a good understanding of how the disease is affecting communities and which individuals would benefit the most from a vaccine.

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# Q&A RECOMMENDED IMMUNIZATION SCHEDULE: WHAT YOU SHOULD KNOW

## Q. Why are multiple doses of some vaccines necessary?

A. Most vaccines require more than one dose. This happens for a few reasons, including the type of vaccine, the level of disease in the community, and the nature of immunity:

- Vaccines that are given as live, weakened versions of the virus (e.g., MMR and chickenpox) usually require fewer doses because they reproduce at low levels in the body. The advantages are that the resulting immune response will be more robust in terms of quantity and diversity of antibodies. In contrast, when the vaccine is made from polysaccharides, individual proteins or toxoids (e.g., *Haemophilus influenzae* type B, hepatitis B, tetanus and pertussis), the immune response is limited to the specific antigens and the levels of antibody tend to be lower, so additional doses are needed to boost the immune response.
- When a vaccine is first made available, levels of disease in the community are typically high, so a child who was immunized will come in contact with the organism (i.e., virus or bacteria), but does not get sick. Even though as parents and healthcare providers, we often do not know about these encounters, they serve to boost the child's immunity to that organism. However, after the vaccine has been available for several years, the levels of disease in the community are often reduced making these anonymous encounters less frequent. As a result, immunity may wane making a second dose of vaccine necessary. This is what happened following introduction of the measles and chickenpox vaccines, so children are now recommended to get one dose around 12 to 15 months of age and a second dose before starting school around 4 to 6 years of age.
- As people get older, their immune systems may not be able to fend off bacterial and viral encounters as readily as they once did. For example, most of us have the virus that causes chickenpox living silently in cells of our nervous system. This virus can also cause shingles, but shingles only occurs if our immune system fails to keep the virus "in check," such as during times of high stress, compromised immunity or with increasing age. For this reason, people 50 years and older are recommended to get two doses of shingles vaccine.

## Q. When is it OK to use a different vaccine schedule?

A. Children who have certain health conditions or acute illnesses may not be able to get vaccines according to the routine schedule. **Contraindications** are reasons not to get one or more vaccines; they include things like having an allergic reaction to a previous dose of vaccine or not getting a live virus vaccine, such as MMR or chickenpox, when receiving chemotherapy. **Precautions** are reasons to delay getting one or more vaccines either because of an increased chance of experiencing a severe side effect or a situation that may compromise the ability of the vaccine to work. Examples of precautions can include situations such as moderate or severe illness, recent blood transfusion, uncontrolled seizures or unstable neurological condition. If you are concerned about conditions that might delay or prevent getting vaccines, talk to your healthcare provider or contact your local health department.

## Q. Why are so many vaccines necessary?

A. While it may seem like a lot of vaccines when you are watching your baby get multiple shots during the course of several office visits, the reality is that vaccines only protect babies from a small fraction of the potential disease-causing agents in the environment. The good news is that vaccines have been developed for the most deadly diseases, increasing life expectancy and decreasing infant mortality rates in the countries that use them.



## Q. Wouldn't it be better for children to get some of these diseases naturally?

A. For each virus or bacteria, a specific level of immunity is needed to avoid getting sick. Once this protective level is reached, any additional protection doesn't make much difference. Vaccines are designed to introduce enough viral or bacterial antigens to induce protective immunity but not enough to cause symptoms of disease. So, while getting the disease usually creates better immune responses, not much is gained in terms of protection as compared with vaccination, and the price paid for natural infection can be great in terms of suffering and, sometimes, death.

## Selected resources and references

Immunization schedules are available on the CDC website at [cdc.gov/vaccines/schedules/index.html](http://cdc.gov/vaccines/schedules/index.html).

Immunization recommendations are available on the CDC website at [cdc.gov/vaccines/hcp/acip-recs/index.html](http://cdc.gov/vaccines/hcp/acip-recs/index.html).

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