

Indian Academy of Pediatrics (IAP)



GUIDELINES FOR PARENTS

Dealing with Adverse Events Following Immunization



Convener: Vipin M Vashishtha

**Members: Atul Kumar Agarwal,
Chetan G Trivedi, SG Kasi**

10 FAQs on DEALING WITH ADVERSE EVENTS FOLLOWING IMMUNIZATION

1. Why are vaccines necessary? Is it essential to vaccinate every child? Are vaccines safe?
2. What is an "adverse effect following immunization (AEFI)"? What are the common AEFIs? What are the "minor", "serious", and "severe" adverse events?
3. How can I know that an "adverse effect following immunization (AEFI)" is not minor and needs medical attention? What happens after I report an AEFI?
4. Is it true that natural infections provide more potent and longer lasting immunity? If natural disease provides lifelong immunity, what is the need of having a vaccine?
5. My child has been having a cold, cough, and fever for the last few days. His first booster dose of DTP-polio vaccines is due tomorrow. Shall I postpone it?
6. My child got swelling in the axilla after a month or so of birth dose vaccine. The doctor told me it is due to the Bacillus Calmette–Guérin (BCG) vaccine; do I need to worry about that?
7. The last time when I got my son vaccinated, he developed fever and a lot of pain at the injection site. His next dose is due after 2 days. Can I give paracetamol drops before going to hospital to avoid fever due to vaccine shots?
8. Does measles, mumps, and rubella (MMR) vaccination lead to autism? Does "Polio" vaccine cause impotence?
9. I saw on a TV news that five infants died after measles vaccine. Is it true? Why these incidents occur repeatedly? What Government is doing to prevent their occurrences? How are these incidents investigated?
10. A 5-month-old infant develops pneumonia 3 weeks after liquid pentavalent vaccine. Is this an "adverse events following immunization (AEFI)"?

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Deepak Ugra
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Dealing with Adverse Events Following Immunization



Q1

Why are vaccines necessary? Is it essential to vaccinate every child? Are vaccines safe?

Herd Immunity

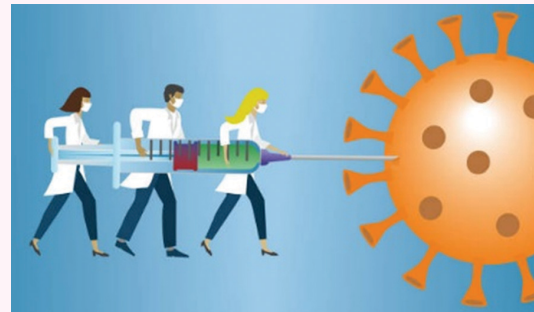


Vaccines are necessary to develop immunity against multiple diseases referred as “vaccine preventable diseases (VPDs)”. In fact, vaccines are the biggest gift that modern medicine has given to mankind. They provide protection to the vaccinated child and help in increasing the overall immunity of the susceptible population (community) against a particular disease, even when not all the children are vaccinated. This phenomenon is called as “herd immunity”.



Deadly diseases such as smallpox, polio, etc. were eliminated just because of large scale, mass vaccination.

The current pandemic of coronavirus disease (COVID-19) has once again highlighted the critical role of vaccines in controlling the ongoing lethal pandemic. Not only communicable diseases but also noncommunicable diseases such as cervical cancer and liver cancer can be controlled through immunization. If vaccination is stopped, the diseases which are prevented by vaccination return in the population. Diphtheria, pertussis (whooping cough), polio, and measles are such diseases which have potential to quickly reappear in a disease-free population.



Vaccinate Every Child

The higher the number of individuals vaccinated in a community, the higher is the population immunity and resistance to the infection and spread of a VPD. Hence, it is essential to vaccinate each child in a community.



Vaccines are safe: Vaccines undergo multiple rigorous tests in multiple phases of trials before they are approved and licenced for use. At every stage, assessment of safety takes precedence over the effectiveness of the vaccine. It usually takes about 5–10 years of research and development before a vaccine is considered for approval. Even after introduction in the market for individual use, it is mandatory to conduct surveillance for adverse effects. Constant monitoring is done through information from several sources for any sign that a vaccine may cause an adverse event.

**Vaccines are safe,
effective, and save lives**



#CelebrateVaccines

What should I inform my doctor before vaccinating my child?

- If your child is unwell.
- Your child has had any reaction to a previous dose of any vaccine.
- Your child has any known allergies.
- Your child is taking/had taken any medications that suppress the immune system.

Q2

What is an “adverse effect following immunization (AEFI)”? What are the common AEFIs? What are the “minor”, “serious”, and “severe” adverse events?

An adverse event following immunization (also known as an AEFI) is an unwanted or unexpected change in health that happens after someone receives a vaccine. An adverse event may or may not be caused by the vaccine.

The currently licensed vaccines in routine clinical usage in healthy infants and children are generally safe and elicit only minor reactions. Although all vaccines used in NIPs are safe and effective if used correctly, no vaccine is completely risk-free and adverse events will occasionally result after an immunization.

- Vaccine Product-related Reaction
- Vaccine Quality Defect-related Reaction
- Immunization Error-related Reaction
- Immunization Anxiety-related Reaction
- Coincidental Event

- *Minor/mild reactions are not uncommon after vaccination:* Minor reactions usually occur within a few hours of vaccination, resolve within a few hours or days and do not need specialized care or hospitalization. These include reactions at the site of the vaccination (local): pain, swelling, or redness at the site of injection. Symptoms involving the entire body include fever, malaise, muscle pain, headache, or loss of appetite. These reactions occur due to the response of the body’s immune response to the vaccine and are acceptable following any vaccination.
- *Severe reaction following vaccinations are very rare* and usually are enhanced minor reactions, generally due to a heightened immune response of the vaccinated individual. These include high fever (>40°C), redness/swelling at site >20 mm. They do not cause persistent disability and rarely need hospitalization.



- Serious reactions may need hospitalization, and may result in permanent disability or death. These include severe allergic reactions and convulsions. Any adverse reactions that occur in clusters (two or more cases occurring at one vaccination center or in a geographical area) are also considered as a serious AEFI.
- Most of the common adverse events after vaccination are *mild* and temporary like pain and swelling at injection site and mild fever.
- Rarely, some major, *serious* events may take place that require hospitalization or may lead to death or disability. Sometime, many such events occur in many (two or more cases) children at one vaccination center or occur in a geographical area which are termed as “clusters”. These clustering of adverse events also come under “serious” AEFI.
- All adverse effects which are not minor and not serious, fall under “*severe*” type of AEFI. These include convulsions or severe, potentially life-threatening allergic reactions. They are to be managed on emergency basis.

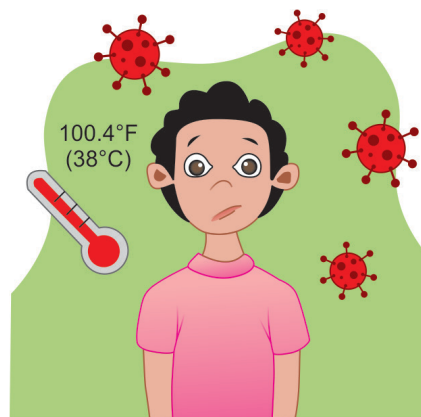
Q3

How can I know that an “adverse effect following immunization (AEFI)” is not minor and needs medical attention? What happens after I report an AEFI?

Stay in the vaccination center for at least 15 minutes after vaccination.

If your infant/child has:

- Fever higher than 40°C (104°F)
- Crying or fussing for more than a day
- Worsening swelling where the needle went in
- An allergic reaction (for example, a rash or hives)
- Unusual sleepiness
- Severe vomiting, diarrhea or blood in the stools
- Any other unusual or unexpected event please report to your doctor as soon as possible



If the AEFI comes under the category that must be reported, your doctor will fill up a form called case reporting form (CRF) and submit it to IdSurv/IAP or the District Health Officer (DHO), in charge of immunizations, who in turn will initiate proceeding to establish whether the vaccine has caused an AEFI. There are internationally accepted protocols for establishing the causality of an AEFI. The entire process may take up to 100 days.

Q4

**Is it true that natural infections provide more potent and longer lasting immunity?
If natural disease provides lifelong immunity,
what is the need of having a vaccine?**

Most viral infections generally confer lifelong immunity. However, bacterial infections generally do not confer long-lasting immunity, viz. typhoid, whooping cough, and tetanus. Some germs exist in multiple types called serotypes and infection with one serotype may not confer protection against the other serotypes, e.g., *Pneumococcus*, which is a major cause of pneumonia and brain infections.

Furthermore, it may be risky to acquire immunity through natural infection. Natural infections may also lead to complications or deaths. Death from complications due to measles, birth defects from maternal rubella, and liver cancer from hepatitis B virus are well-known in unimmunized individuals.

On the other hand, vaccines interact with the immune system to mimic an immune response similar to that produced by the natural infection, but they do not cause the disease or put the immunized person at risk of its potential complications. In short, vaccines will confer protection without the risk of complications that may happen after natural infections.

Q5

My child has been having a cold, cough, and fever for the last few days. His first booster dose of DTP-polio vaccines is due tomorrow. Shall I postpone it?

Children with a mild acute illness, such as a low-grade fever, or an upper respiratory infection such as common cold, ear infection, or mild diarrhea should be vaccinated on schedule. Low-grade fever is not a contraindication to vaccination. Measuring temperature is not necessary before vaccination, if the child does not appear ill and not report currently being ill. The decision to vaccinate is based on the overall evaluation of the child rather than an arbitrary body temperature.

However, if a child has a moderate or severe acute illness, vaccination with both live and inactivated vaccines should be delayed until the patient has recovered from the illness. There is no evidence that a concurrent acute illness reduces vaccine efficacy or increases vaccine adverse events. However, the concern is an adverse event (particularly fever) following vaccination could complicate the management of a moderate or severe illness.



Mild headaches



Pain or swelling at the injection site



Mild fever



Irritability

Q6

My child got swelling in the axilla after a month or so of birth dose vaccine. The doctor told me it is due to the Bacillus Calmette–Guérin (BCG) vaccine; do I need to worry about that?

No, there is no need to worry about this swelling which is usually due to BCG vaccination. It usually heals spontaneously without any treatment over a period of few weeks. But, if there is a large swelling with soft consistency and redness of the overlying skin, it may need minor surgical intervention-like needle aspiration (Removal of liquid or semisolid content of soft swelling with the help of needle).



Q7

The last time when I got my son vaccinated, he developed fever and a lot of pain at the injection site. His next dose is due after 2 days. Can I give paracetamol drops before going to hospital to avoid fever due to vaccine shots?



There is no evidence that prophylactic use of antipyretics or pain killer before or at the time of vaccination will decrease the pain associated with an injection. These medications might suppress the immune response to some vaccine antigens, or in other words may affect the proper “take” of the vaccine. It is a better policy to wait for these events to occur, and only then take measures to reduce fever or pain.

How can I reduce the pain associated with vaccination?

- *Breastfeeding:* Mothers who are breastfeeding should be encouraged to breastfeed children before, during, and after vaccination. It is thought to

- decrease pain by multiple mechanisms: being held by the parent, feeling skin-to-skin contact, suckling, being distracted, and ingesting breastmilk.
- Keeping the infant in the mother’s lap during vaccination.
- Older children can be distracted with books or media devices during the vaccination.
- *Local agents*: Topical anesthetic sprays or gels or coolants can be used according to age appropriate recommendations (this is the doctor’s choice).

I heard that my cousin’s daughter fainted after receiving her cervical cancer vaccine shot. Was it due to a vaccine?

No, this has nothing to do with the cervical cancer vaccine but may occur with any injection. This is referred to as “immunization anxiety-related reaction”. Usually, this kind of event can happen in adolescent girls aged 11–18 years after vaccination due to stress or fear of vaccination itself.

To prevent fainting episodes after vaccination, the child should be informed and reassured about the vaccination procedure, the vaccine should be administered with the child in the sitting or supine position, and the child should be made to sit in one place for 15 minutes after vaccination.



Q8

Does measles, mumps, and rubella (MMR) vaccination lead to autism? Does “Polio” vaccine cause impotence?

No, there is no link between vaccines and autism.

Autism is a specific condition of young and growing kids with unknown etiology. The affected children find it difficult to communicate and interact with other people. The cause(s) of autism is(are) unknown. But some believe that genetics, differences in brain anatomy, and toxic substances in the environment may contribute to its development.



The link between vaccines (measles/MMR) and autism was postulated in a study published in the year 1998. Later, it was found that the study had many

flaws, the lead author had conflict of interests, and the results were manipulated. The research paper was retracted by the journal that published it after confirming the flaws and manipulations. Numerous large and well-planned scientific studies have shown that there is no link between vaccines—or any of their ingredients—and autism.

There is absolutely no evidence that the polio vaccine (either oral or parenteral) leads to impotency or erectile dysfunction. The vaccine contains live-attenuated strains (“oral poliovirus” vaccine) and killed strains (inactivated poliovirus vaccine). It does not contain any antifertility agents. The vaccine has played very vital role in eliminating the disease from all the countries in the world.



Q9

I saw on a TV news that five infants died after measles vaccine. Is it true? Why these incidents occur repeatedly? What Government is doing to prevent their occurrences? How are these incidents investigated?

There is no direct link between measles vaccination and death of children. These reactions are usually caused by improper vaccine storage and administration. In this case, partially used vials of measles vaccine, with perforated rubber lids, were kept immersed in cold water, resulting in contamination with deadly disease-causing germs. Such “adverse events following immunization (AEFI)” comes under the category of AEFI due to immunization errors.

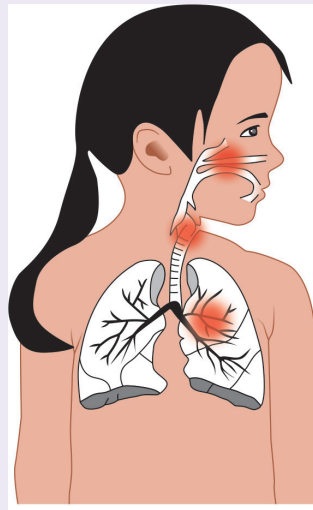
In such cases, the local health authority immediately starts a thorough investigation with sophisticated tests and medical history. These cases are further studied by members of AEFI committees at state and national levels, causality assessment is done, and if indicated, remedial actions are taken.



Q10

A 5-month-old infant develops pneumonia 3 weeks after liquid pentavalent vaccine. Is this an “adverse events following immunization (AEFI)”?

This illness is not related to the administration of pentavalent vaccine and may have been caused by a bacterial or viral infection contracted later. This type of event is referred as a *coincidental type* since the adverse event is caused by something other than the vaccine product, immunization error, or immunization anxiety.



On further analysis, it is evident that the disease course does not fit in the causation since pneumonia is an acute illness and results in disease within a few days of exposure. There is a significant gap in the administration of the vaccine and appearance of symptoms, hence, there is no association between vaccine and pneumonia.