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## **REVIEW ARTICLE**

# Management of Adverse Events Following Immunization

Ulfat Amin

Faculty at Syed Mantaqui Memorial College of Nursing and Medical Technology, Islamic University of Science and Technology, Awantipora, Kashmir, India

\*Corresponding Author: cuteulfat@gmail.com

#### ABSTRACT

Immunization plays a vital role in big success of promotion of health over the last decade at least, enhancing and improving the livelihood of children around the world. National immunization programs employ vaccines that are both exceptionally safe and beneficial. The manufacturers have several empirical, moral, and legal responsibilities, as well as extensive field trials in terms of individual safety and security.

**Keywords--** Immunization, Adverse Events, Vaccines

Vaccines are tested before they could be approved for routine use. No vaccine, however, is completely risk-free. Furthermore, because vaccines are biological products, adverse events can occur after immunisation [1]. The entitle "adverse event following immunisation" (AEFI) allude to a negative reaction to immunisation that is imagined to be caused by immunisation [2]. There are total of five types of AEFIs (Table 1). Vaccination can cause unwanted events due to vaccine properties (vaccine reaction) or an immunisation erroneous procedure. The occurrence may be completely irrelevant to the immunisation but have a possible link with it [3].

Type of AEFI	Meaning
Reaction to a vaccine by- product	Adverse reaction originated or provoked by a vaccine due to inherent properties of the vaccine by-products.
Reaction associated to Vaccine quality	Adverse reaction originated or provoked by defect in quality of vaccine, including its administration products as supplied by suppliers.
Response to a vaccination fallacy	Adverse reaction caused by incorrect prescription, operation, or management and is preventable in nature.
Apprehensiveness caused by immunisation	Adverse reaction arising from concern associated with immunization.
A fortuitous occurrence	Adverse reaction caused by entity additional to vaccine by-product, immunization fallacy or immunization concern

 Table 1: Cause-specific categorizations of AEFIs (WHO/ CIOMS 2012)

The Adverse reaction that arises as a result of the immunisation could be expected, but not serious enough as to cause distress for an extended time span (e.g., discomfort or pyrexia following administration of DTP vaccine) [4], even though a critical or unusual event occurring as a result of the vaccine could be an unforeseen anaphylactic reaction or initiation of vigorous ailment after measles or OPV vaccination [5]. A hypothetical reaction could be linked to vaccine scares, which have a causal relationship with contentious issues occurring in vaccinations [6]. The most widespread vaccine responses are caused by the host's immune system response, and in some cases by vaccine components (for example, aluminium adjuvant and preservatives). These reactions are lessened [7]. A fruitful vaccine lowers these reactions to a

lowest level while likely to induce the highest level of immunity possible [8, 9].

Table 2 lists the expected reactions that occur within a day or two of immunisation.

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Vaccine	Adverse Vaccine reaction	Anticipated AVR	Prevalence
	$(\mathbf{AVK})$	%	category
BCG	• Site of injection reaction [papule, mild ulceration, or scar]	Almost all vaccines	• Very usual
	• Suppurative lymphadenitis	• 1 per 103 – 104	• Unusual to rare
	BCG osteitis	• 1 per 3333 -106	• Unusual to Extremely uncommon
	• Distributed BCG illness,	• 1per $23 - 64 \times 10^4$	• Extremely uncommon
	• Immune and inflammatory regeneration syndrome (IRIS)	• 1 per 64×10 <sup>4</sup>	• Extremely uncommon
Oral polio virus vaccine (OPV)	• VAPP (vaccine- associated paralytic poliomyelitis)	<ul> <li>1 per 6.4 ×10<sup>5</sup> doses</li> <li>1 per 2.9 ×10<sup>5</sup> doses</li> </ul>	<ul> <li>Extremely uncommon</li> <li>Extremely uncommon</li> </ul>
	<ul><li>recipient VAPP</li><li>total VAPP</li></ul>	<ul> <li>0.5-1.5%</li> <li>3-11%</li> <li>14-29%</li> </ul>	
Inactivated polio virus vaccine	• Erythema at site of injection		• Unusual to usual
(IPV)	• Inflammation at the injection site		• Usual to very usual
	• Tenderness at the injection site		• Very usual
Hepatitis B (Hep-	• Fever more than $37.7  {}^{\circ}\text{C}$	• 1-6%	• Usual
b) vaccine	<ul> <li>Headache</li> <li>Pain along the route of</li> </ul>	• 3%	<ul> <li>Usual</li> <li>Usual to vorv</li> </ul>
	administration	• 5-2970	
			• Usual
	• Location of injection redness	• 3%	• Usual
	• Intramammary site swelling	• 3%	• Extremely uncommon
TT'l	Hypersensitivity reaction	• 1.1 per 10°	<b>XX</b> 1
HID vaccine	<ul> <li>Pyrex1a</li> <li>Site of injection reaction</li> </ul>	• 2%	Usual     Vorw usual
Tetanus	Brachial nerve	• $5-10$ per $10^6$	<ul> <li>very usual</li> <li>Extremely</li> </ul>
vaccine	impingement	- J- 10 pci 10	uncommon
	Anaphylaxis	• $1 - 6 \text{ per } 10^6$	• Extremely
		~	uncommon
Measles	• Pyrexia	• 5-10%	• Usual to very

Table 2: Frequency of Adverse Vaccine reaction (AVR) of Usually Given Vaccines

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vaccine	<ul> <li>Irritation</li> <li>Site of injection reaction</li> <li>Febrile convulsions</li> <li>Encephalomyelitis</li> <li>Leukopenia</li> <li>Anaphylaxis</li> </ul>	<ul> <li>5%</li> <li>17-30%</li> <li>1 in 2000 - 3000</li> <li>1 per 106</li> <li>1 per 30 000</li> <li>1 - 3.5 per 10<sup>6</sup></li> </ul>	usual Usual Very usual Rare Extremely uncommon Extremely uncommon Extremely uncommon
Rubella vaccine	<ul> <li>Pyrexia</li> <li>Site of injection reaction</li> <li>Acute arthralgia (adults)</li> <li>Acute arthritis (adults)</li> </ul>	<ul> <li>2%</li> <li>17-30%</li> <li>25%</li> <li>10%</li> </ul>	<ul> <li>Usual</li> <li>Very usual</li> <li>Very usual</li> <li>Very usual</li> </ul>
Mumps vaccine	<ul> <li>Site of injection reaction Parotid swelling</li> <li>Aseptic meningitis</li> </ul>		<ul><li>Very usual</li><li>Usual</li><li>Very usual</li></ul>
Pneumococcal Unconjugated Vaccine (PPSV) Conjugated vaccine (PCV)	<ul> <li>Fever &gt; 39 °C</li> <li>Site of injection reaction</li> <li>Fever &gt; 39 °C</li> <li>Site of injection reaction</li> </ul>	<ul> <li>&lt;1%</li> <li>50%</li> <li>&lt;1%</li> <li>10%</li> </ul>	<ul> <li>Unusual</li> <li>Very usual</li> <li>Unusual</li> <li>Very usual</li> </ul>
Rotavirus vaccine	• Intussusception	• 1-2 per 10 <sup>5</sup> [for first dose in some populations. No apparent increase identified	Extremely uncommon
Typhoid vaccine Ty21a	<ul><li>Fever</li><li>Vomiting</li><li>Diarrhoea</li></ul>	<ul> <li>0.3-4.8%</li> <li>0.5-2.3%</li> <li>1.2-3.9%</li> </ul>	<ul> <li>Unusual to usual</li> <li>Unusual to usual</li> <li>Usual</li> </ul>
ViCPS	<ul> <li>Low grade fever &lt; 39°C</li> <li>Local erythema</li> <li>Soreness</li> </ul>	<ul> <li>Up to 2%</li> <li>3-21%</li> <li>8-33%</li> </ul>	<ul> <li>Usual</li> <li>Usual to very usual</li> <li>Usual to very</li> </ul>
Vi-TT	<ul><li>Swelling</li><li>Injection site pain</li><li>Fever</li></ul>	<ul><li> 2-17%</li><li> Data not available</li><li> Data not available</li></ul>	usual • Usual to very usual
Varicella vaccine	<ul> <li>Febrile seizures</li> <li>Fever &gt; 39 °c</li> <li>Injection site reaction</li> <li>Skin rash (local/generalized)</li> </ul>	<ul> <li>4-9 per 10 000</li> <li>15-27%</li> <li>7-30%</li> <li>3-5%</li> </ul>	<ul> <li>Rare</li> <li>Very usual</li> <li>Usual to very usual</li> <li>Usual</li> </ul>

"Source: Fact sheets of WHO www.who.int/vaccine\_safety/initiative/tools/vaccinfosheets"

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### **Reactions to immunisation errors**

Another major part of adverse events following vaccination is due to system failures, which occurs as a result of mistakes/mishaps in vaccine readiness, dealing, or administration. Immunization-associated reactions (Table 3: Immunization error-related reactions) can be avoided and risk jeopardising the immunisation program's benefits This makes identifying and correcting errors easier. It is critical to correct these errors as soon as possible.

E	rror	Response
Error in handling Vaccines	• Excessive heat or cold exposure as a result of improper vaccine transport, storage, or handling.	• Local or systemic reactions induced by differences in the overall essence of the vaccine, like as agglutination of aluminum-based active ingredients in freeze- sensitive vaccines; and
	• Use of a product after its expiry date	• Inability to protect due to attenuated product potency damage or non-viability.
Vaccine prescribing error or noncompliance with recommendations for use	<ul> <li>Failure to follow a contraindication</li> <li>Failure to follow vaccine instructions or prescriptions (dose or schedule)</li> </ul>	<ul> <li>Anaphylaxis, disseminated LAV infection</li> <li>Systemic and/or local reactions, neurological, muscular, vascular, or bony injury as a result of the incorrect injection site, equipment, or technique</li> </ul>
Administrative blunder	<ul> <li>Injecting a product other than the intended vaccine or using an incorrect diluent</li> <li>Inadequate sterile technique or procedure when using a multi - dose vial</li> </ul>	• Inability to vaccinate due to insufficient diluent, reaction caused by the inherent characteristics of whatever was administered rather than the desired vaccine or diluent

Table 3: Vaccination error-linked response

One more essential element of adverse outcomes following immunisation is vaccine scares, which possess an extra tenuous association and are frequently theoretical, & are Tabulated here in Table 4.

<b>Lucie</b> in the entricities been es	Table 4:	Vaccination	scares
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Vaccine	Aside from the vaccine scare, an adverse event has occurred as a result of the vaccine scare.
Hepatitis B	Multiple sclerosis, lupus, and type 2 diabetes
Whole cell pertussis	Encephalopathy, epilepsy, learning disorders
Diphtheria, tetanus and pertussis	HIV infection, sudden infant death syndrome (SIDS)
Inactivated polio vaccine	Type I diabetes
Influenza	Type I diabetes
Haemophilus	Irritable bowel syndrome, and early life arthropathy, Autistic spectrum
influenza type b	disorder
Measles, mumps and	Concerns about ethics because it was grown in cells from an aborted
rubella: Rubella	foetus, neuro-developmental disorder, and autism.

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Aluminium- containing vaccines	Illness of hidden or incompletely understood aetiology, e.g., autism and asthma
Various vaccines,	Chronic fatigue syndrome, Irritable bowel disease, cradle death, autoimmune disease, lymphoma, learning disabilities, an increase in

Source: Vaccines—Children and Practice 2003, Vol. 5 No. 2 (3).

The detection and correction of these errors is critical, as they would otherwise result in a cascade of other immunization-related events. Iatrogenic infection caused by unsterilized injection, such as sterilised abscess, that can have adverse effects, or blood-borne disease is the most usual programme error (e.g. Hepatitis B & HIV). For every vaccine used in the immunisation programme has its own set of comorbidities, the majority of which are expected and minor. Some of them are grave negative responses that must always be anticipated, and immediate corrective measures must be implemented.

## Prevention and Treatment of Vaccine Reaction

Adequate knowledge of vaccines, expected side effects, and better informing parents is required for the person administering the vaccine. Moreover, in order to be prepared for the rare adverse effects, each vaccination site should have a 'kit' of life-saving medicine and devices Parents are provided advice on dealing with common responses, as well as directions to revert back to the clinic if more severe conditions arise. This will doubtlessly forewarn parents about vaccination and help them prepare for common reactions. Errors in programmes can be easily avoided. The detection and correction of these errors are critical. The following are WHO guidelines for avoiding programme errors:

- Dilute Vaccines only with the dilution provided by the supplier.
- Reconstituted vaccines should be discarded at the final moment of each vaccination session and never saved.
- Do not keep any other medications or substances in the immunisation centre's refrigerator.
- Immunization personal should be properly trained and meticulously monitored to make that the proper practices are implemented.

- A thorough epidemiological enquiry of an AFEI is required to determine the cause and correct vaccination processes.
- It is critical to preserve the temperature of cold chain at all stages.
- Adequate consideration should be given to the potential contraindications.

# **Guidelines for Safe Vaccination**

- Always use non-reusable syringes to ensure safe injection procedures for your health.
- Choose the right vaccine and follow the recommended guidelines. (Indications/dosage/route/administration)
- Control the cold chain.
- Advise parents about the benefits and anticipated reactions.
- Prior to vaccination, obtain written or verbal consent.
- Observe children for 15 minutes following vaccination. Prepare to treat any unfavourable responses.
- Always keep resuscitation equipment on hand.
- Use the preferred injection technique, such as loading the vaccine into the appropriate syringe size. For drawing and injection, use a separate needle (single Syringe and two needles for every vaccine). Throw away the used needle.
- Until the vaccine is approved, do not mix multiple vaccines in a single syringe.
- Use separate hypodermic needles for each vaccine.
- Inject at various locations.
- During puberty, always use the outer part of the thigh. Infants and older children should be injected in the deltoid region. In children, never use the gluteal area.
- After vaccination, avoid compressing or vigorous massage. A few minutes of intense pressure is all that is required.
- Record each vaccine in a vaccine card and keep a copy.

• Follow the vaccine Calendar to complete the vaccination schedule. Remind parents of the upcoming date.

#### CONCLUSION

The WHO's vaccination focus seeks to eradicate vaccine mortality and morbidity from vaccine-preventable diseases by developing strong, self-sustaining National Immunization Programs capable of providing high-quality vaccines in a safe and efficient manner to all children. Safe and effective vaccine training, including in-depth vaccine knowledge, a wellmanaged cold chain, Best parental education, effective resuscitation equipment's etc are critical components in making immunisation the most customer-friendly public health medium in child survival programmes.

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