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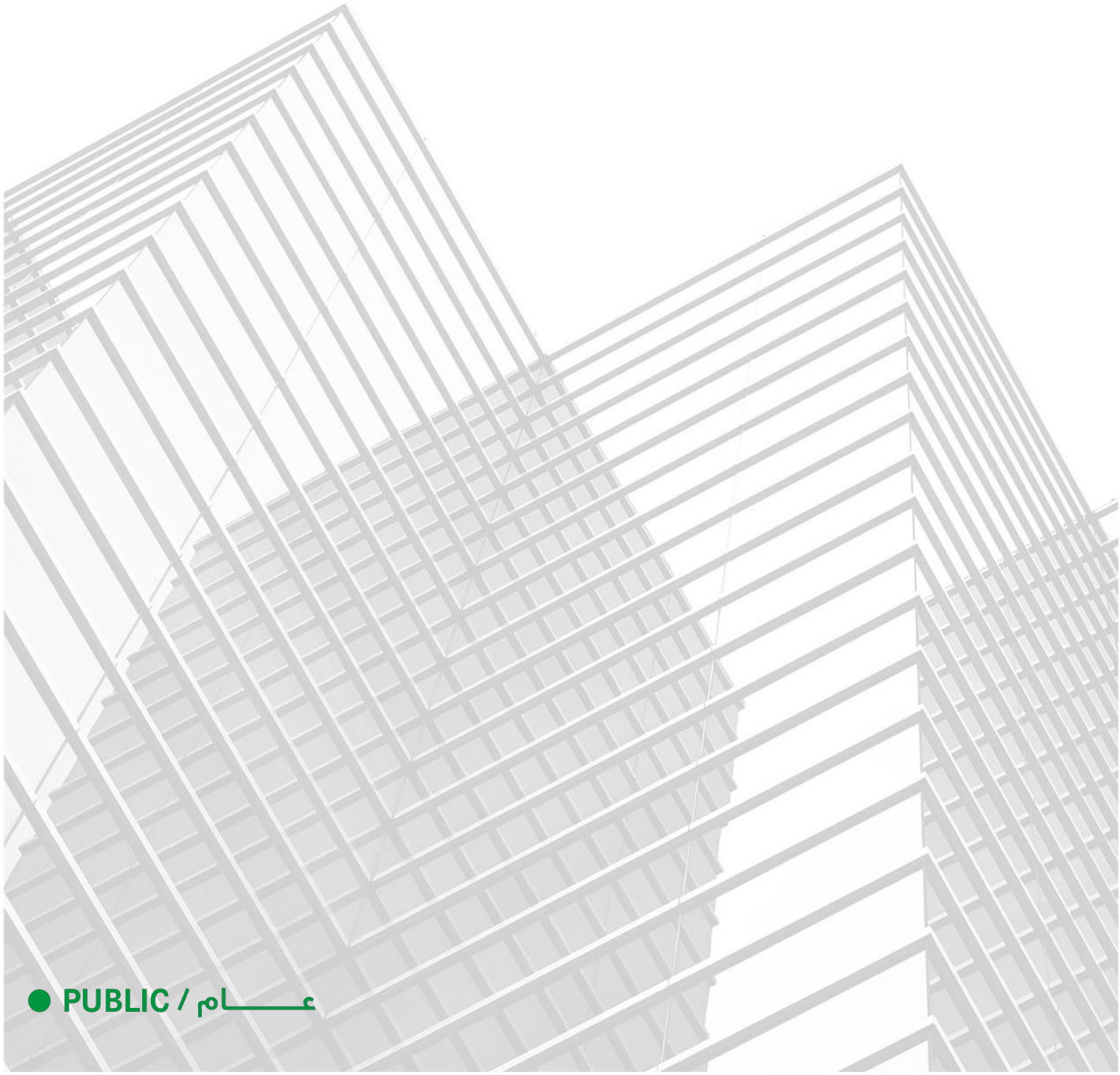
DEPARTMENT OF HEALTH

Surveillance of Adverse Events Following Immunization Guideline



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1.Guideline Purpose and Brief

The purpose of these guidelines is to provide a framework for implementing a comprehensive AEFI surveillance system that enhances vaccine safety monitoring and improves the efficiency and quality of surveillance activities, responds to potential safety signals, and maintains public confidence in vaccination programs. These guidelines strengthen immunization initiatives at both subnational (Emirate of Abu Dhabi), national and regional levels, ensuring the safety of all vaccine recipients.

This guideline was developed in line with the WHO's Global Manual on Surveillance of AEFI aligned with the Immunization Agenda 2030's Strategic Priority 1, Immunization programs for primary health care and universal health coverage with the objective of establishing and maintaining a well-functioning vaccine safety system involving all stakeholders. It is important to ensure that Abu Dhabi immunization programs can detect and respond to any concern about vaccine safety by continuous monitoring and coordination among relevant stakeholders.

2. Definitions and Abbreviations

No.	Term / Abbreviation	Definition
2.1	Active Vaccine Safety Surveillance (AVSS)	A proactive approach of a predefined data collection system that seeks to ascertain as completely as possible the number of adverse events following immunization (AEFIs) in a given population via a continuous organized process.
2.2	Adverse event following immunization (AEFI)	Any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.
2.3	Adverse Event of Special Interest (AESI)	An adverse event of special interest (serious or non-serious) is one of scientific and medical concern specific to a particular product or program, for which ongoing monitoring and rapid communication to the relevant authority (e.g. regulators) is needed. Such an event may require further investigation in order to characterize and understand it.
2.4	Causal association	A cause-and-effect relationship between a causative (risk) factor and an outcome. Causally associated events are also temporally associated (i.e. they occur after vaccine administration), but events which are temporally associated may not necessarily be causally associated.

2.5	Causality assessment	In the context of AEFI surveillance, it is a systematic review of data about AEFI case(s) to determine the likelihood of a causal association between the event and the vaccine(s) received.
2.6	Cluster	Two or more cases of the same or similar events related in time, geography (place), and/or vaccine administered AEFI clusters are usually associated with a particular supplier/provider, health facility, and/or a vial of vaccine or a batch of vaccines.
2.7	Coincidental events	An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety.
2.8	Contraindication	A situation where a particular treatment or procedure, such as vaccination with a particular vaccine, must not be administered for safety reasons. Contraindications can be permanent (absolute), such as known severe allergies to a vaccine component, or temporary (relative), such as an acute/ severe febrile illness.
2.9	Department of Health (DoH)	The regulative body of the Healthcare Sector in the Emirate of Abu Dhabi, Established based on law No. (10) of 2018.
2.10	Immunity	The ability of the human body to tolerate the presence of material 'indigenous' to the human "body" (self) and to eliminate "foreign" (non-self) material. This discriminatory ability provides protection from infectious diseases, since most microbes are identified as foreign by the immune system.

2.11	Immunization Stress Related Reaction (ISRR) - Previously “Immunization anxiety-related reaction”	A range of symptoms and signs that may arise around immunization that are related to “anxiety” or “stress” and not to the vaccine product, a defect in the quality of the vaccine or an error of the immunization program. They include vasovagal-mediated reactions, hyperventilation-mediated reactions and stress-related psychiatric reactions or disorders.
2.12	Immunization error-related reaction (formerly "programme error")	An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable.
2.13	Immunization safety	The process of ensuring the safety of all aspects of immunization, including vaccine quality, adverse events surveillance, vaccine storage and handling, vaccine administration, disposal of sharps and management of waste.
2.14	Immunization safety surveillance	A system for ensuring immunization safety through detecting, reporting, investigating, and responding to AEFI.
2.15	Injection safety	The public health practices and policies dealing with various aspects of the use of injections (including adequate supply, administration and waste disposal) so that the provider and recipient are not exposed to avoidable risks of adverse events (e.g. transmission of infective pathogens) and creation of dangerous waste is prevented. All injections, irrespective of their purpose, are covered by this term (see definition of safe injection practices).
2.16	Non-serious AEFI	An event that is not ‘serious’ and does not pose a potential risk to the health of the recipient. Non-serious AEFIs also should be carefully monitored because they may signal a potentially larger problem with the vaccine or immunization or have an impact on the acceptability of immunization in general.
2.17	Precaution	Events or conditions that should be considered in determining if the benefits of the vaccine outweigh the risks (especially if the would-be recipient is immunocompromised or pregnant).
2.18	Safe injection practice	Practices which ensure that the process of injection carries the minimum of risk, regardless of the reason for the injection or the product injected.

2.19	Serious AEFI	An event that results in death, life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Any medical event that requires intervention to prevent one of the outcomes above may also be considered as serious.
2.20	Severe vaccine reaction	It refers to the intensity of vaccine reactions. A severe reaction refers to the high-grade intensity of its grading such as mild moderate or severe. Severe reactions may include both serious and non-serious reactions.
2.21	Signal (safety signal)	Information (from one or multiple sources) which suggests a new and potentially causal association, or a new aspect of an own association, between an intervention and an adverse event or set of related adverse events, that is judged to be of sufficient likelihood to justify verificatory action.
2.22	Surveillance	The continuing, systematic collection of data which is analyzed and disseminated to enable decision-making and action to protect the health of populations.
2.23	Trigger event	A medical incident following immunization that stimulates a response, usually a case investigation.
2.24	Vaccine	A biological preparation that improves immunity to a particular disease. In addition to the antigen, it contains multiple components (excipients) and each component may have unique safety implications.
2.25	Vaccine pharmacovigilance	The science and activities relating to the detection, assessment, understanding and communication of AEFI and other vaccine- or immunization-related issues, and to the prevention of untoward effects of the vaccine or immunization.
2.26	Vaccine product-related reaction	An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product, whether the active component or one of the other components of the vaccine (e.g. adjuvant, preservative or stabilizer).

2.27	Vaccine quality defect related reaction	An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer.
2.28	Vaccination failure	Vaccination failure may be defined on the basis of clinical endpoints or immunological criteria where correlates or surrogate markers for disease protection exist. Primary failure (e.g. lack of sero-conversion or sero-protection) needs to be distinguished from secondary failure (waning immunity). Vaccination failure can be due to (i) failure to vaccinate, i.e. an indicated vaccine was not administered appropriately for any reason or (ii) because the vaccine did not produce its intended effect
2.29	Vaccine reaction	An event caused or precipitated by the active component or one of the other components of the vaccine. It may also relate to a vaccine quality defect.
2.30	Vaccine safety	The process, which maintains the highest efficacy of and lowest adverse reaction to a vaccine by addressing its production, storage and handling. Vaccine safety is a part of immunization safety.
2.31	ADRs	Adverse Drug Reactions
2.32	AEFI	Adverse Event Following Immunization
2.33	ADPHC	Abu Dhabi Public Health Center
2.34	AESI	Adverse Event of Special Interest
2.35	AVSS	Active Vaccine Safety Surveillance
2.36	BCG	Bacillus Calmette-Guerin vaccine
2.37	CIOMS	Council for International Organizations of Medical Sciences
2.38	CSF	Cerebrospinal fluid
2.39	DT	Diphtheria Tetanus Vaccine
2.40	DTaP	Diphtheria Tetanus Acellular Pertussis vaccine
2.41	DTwP	Diphtheria Tetanus Whole Cell Pertussis vaccine

2.42	DTPa-HepB-Hib	Diphtheria Tetanus Acellular Pertussis, Hepatitis B and Haemophilus influenza Type B vaccine (Pentavalent)
2.43	EPI	Expanded Program on Immunization
2.44	GVSB2.0	Global vaccine safety Blueprint 2.0
2.45	DoH	Department of Health
2.46	Hep B	Hepatitis B Vaccine
2.47	Hib	Haemophilus influenza type b vaccine
2.48	IPV	Inactivated Polio Vaccine
2.49	HNIP	Higher National Immunization Program
2.50	OPV	Oral Polio Vaccine
2.51	MMR	Measles Mumps Rubella Vaccine
2.52	MOHAP	Ministry of Health and Prevention
2.53	PV	Pharmacovigilance
2.54	SIDS	Sudden Infant Death Syndrome
2.55	VAPP	Vaccine Associated Paralytic Poliomyelitis
2.56	VPD	Vaccine Preventable Disease
2.57	WHO	World Health Organization

3.Guideline Content

3 Introduction

3.1 Vaccines are biological substances that are administered to individuals to elicit immunity (protection) against vaccine-preventable diseases but may cause adverse events in some individuals, highlighting the need for continuous monitoring and safety measures.

3.2 In the UAE, MOHAP authorizes vaccine marketing, while the DoH monitors their safety and oversees pharmacovigilance activities to detect and manage adverse events following immunizations (AEFIs).

3.3 The DoH uses spontaneous pharmacovigilance system to collect any suspected adverse drug reactions and Adverse Event Following Immunization experienced by patients.

3.4 All vaccine manufacturers are required by law to register their products before supplying and distributing them in Abu Dhabi.

3.5 Reporting of AEFI and subsequent investigation may trigger regulatory action including withdrawing the marketing authorization of a vaccine, instructing vaccine manufacturers to change their product labels, restricting the use of vaccines to specific patient groups or recalling defective vaccine batches from the market.

3.6 This guideline aligns with the principles enshrined in the Global vaccine safety Blueprint 2.0 (GVSB2.0) and with the Immunization Agenda 2030's core principles of being people-centered, country -owned, partnership-based, and data-driven.

3.7 The overall goal is the protection of the health and wellbeing of the entire population particularly infants, children and pregnant women and the general population who depend on vaccines to protect themselves from serious vaccine preventable diseases (VPD). By promptly detecting and analyzing adverse events, and responding swiftly and appropriately, we aim to mitigate the negative impact on individual health and the immunization program

3.8 This guideline outlines the processes and procedures to be followed by healthcare providers as a partnership in preventing, reporting and documenting AEFIs, as well as the roles, responsibilities and the accountabilities of stakeholders responsible for the planning and delivery of immunization programs in DoH. The guideline also outlines the surveillance system and provide tools and procedures needed to report and manage AEFIs.

3.9 An understanding of the profile of AEFI cases reported, data collection processes, investigation techniques, specimen collection, managing AEFIs and communication including communicating with the media is important.

3.10 This can be achieved through good governance and systems, coordination of activities and sharing of information between different stakeholders, ensuring a good regulatory framework, surveillance of adverse events following immunization (AEFI), enhanced vaccine safety communication and addressing the challenges of fragile areas in Abu Dhabi and during emergencies. These aspects are also described in this guideline.

3.11 It is anticipated that healthcare providers / professionals and their supervisors will read and use this guideline and thus appropriately prevent, manage and report AEFIs in Abu Dhabi. This guideline will also bring together stakeholders and allow for networking and improved collaboration in the process of detecting, analyzing and preventing AEFIs.

3.12 A brief introduction to causality assessment has been provided in this guideline. Advanced readers are encouraged to access the WHO website https://www.who.int/publications/i/item/9789241516990 for more information.

4 Basic concepts of vaccines and adverse events following immunization

4.1 Vaccines

4.1.1 A vaccine is a biological product that produces and enhances immunity to the particular Vaccine Preventable Disease (VPD) for which it is targeted. A vaccine contains the disease-causing microorganism or virus, or a portion of it (e.g. spike protein in COVID19 vaccines), in a form that is incapable of causing the actual disease. It is usually made from either live attenuated or inactivated (killed) forms of the microbe, or from its toxin or one of its surface proteins.

4.1.2 Primary classification of vaccines

4.1.2.1 Vaccines may be monovalent or multivalent (polyvalent):

4.1.2.1.1 A monovalent vaccine contains a single strain of a single antigen/immunogen (e.g. measles vaccine)

4.1.2.1.2 Polyvalent vaccine contains two or more strains/serotypes of the same antigen/immunogen (e.g. t OPV and IPV each of which contain three attenuated polio virus types).

4.1.2.2 Combination (or combined) vaccines contain two or more different antigens (e.g. DTwP, DTPa-HepB-Hib).

4.1.2.2.1 The potential advantages of combination vaccines include reduction in the cost and difficulty of shipping and storing and administering multiple vaccines, avoiding multiple injections, reducing the cost of extra health-care visits, improving timeliness of vaccination, and facilitating the addition of new vaccines into immunization programs.

4.1.2.3 There is no evidence that the administration of several antigens in combined vaccines increases the burden on the immune system, which is capable of responding to millions of antigens at a time. Combining antigens usually does not increase the risk of adverse reactions and can lead to an overall reduction in adverse reactions.

4.1.2.4 For instance, it can decrease the number of immunization stress related responses (ISRR) and the chances of immunization error-related reactions.

4.1.3 Other components of vaccines (Excipients)

4.1.3.1 In addition to the primary antigen(s), vaccines contain small quantities of other substances. Sometimes AEFI can result from one of the other substances. They include,

4.1.3.2 Adjuvants

4.1.3.3 Antibiotics

4.1.3.4 Preservative

4.1.3.5 Stabilizers

4.1.3.6 Residuals

4.1.4 Classification of vaccines

4.1.4.1 As alluded to above, there are several types of vaccines. The characteristics of these vaccines differ, and the characteristics determine how the vaccine works.

Table 1: Classification of vaccines	
Live attenuated vaccines (LAV)	Bacteria: BCG vaccine
	Virus: Live Japanese encephalitis vaccine, oral poliovirus vaccine, measles vaccine, mumps vaccine, rotavirus vaccine, rubella vaccine, yellow fever vaccine
Inactivated (killed antigen) vaccines	Bacteria: Whole -cell pertussis (wP)
	Virus: Inactivated Japanese encephalitis vaccine, inactivated poliovirus vaccine (IPV)
Subunit vaccines (purified antigens)	Protein-based: Hepatitis B vaccine Acellular pertussis vaccine(aP)
	Polysaccharide: Meningococcal polysaccharide vaccine Pneumococcal polysaccharide vaccine Typhoid Vi polysaccharide vaccine
	Conjugate vaccine: Haemophilus influenzae type b (Hib) conjugate vaccine, meningitis A and B conjugate vaccine Pneumococcal conjugate vaccines (PCV-7, PCV-10, PCV-13) Vi conjugate vaccine
Toxoids	Tetanus toxoid Diphtheria toxoid
Vectored vaccines	COVID-19 vaccine (Janssen and AstraZeneca), Ebola vaccine: Ad5-EBOV vaccine and rVSV/Ad5 vaccine
Nucleic acid vaccines	COVID19 vaccine (Pfizer-BioNTech Comirnaty COVID-19 vaccine, Moderna Spikevax COVID-19 vaccine)

4.1.5 Contraindications and precautions to vaccination

4.1.5.1 A contraindication to vaccination is a rare characteristic in a recipient that increases the risk of a serious adverse reaction if the vaccine is given.

4.1.5.2 Ignoring contraindications can lead to vaccine reactions that could be preventable.

4.1.5.3 One of the most serious reactions following vaccination is anaphylaxis which is the only contraindication applicable to subsequent doses of the same vaccine.

4.1.5.4 Most contraindications such as severe acute illnesses (e.g. acute respiratory tract infection) or treatment with steroids are temporary and the vaccination can be administered later. These are called temporary or relative contraindications.

4.1.5.5 Precautions, in contrast, are events or conditions that should be considered in determining if the benefits of the vaccine outweigh the risks (especially if the would-be recipient is immunocompromised or pregnant).

4.1.5.6 Precautions stated in the product labelling may sometimes be inappropriately interpreted as contraindications, resulting in missed opportunities to vaccinate.

4.1.5.7 Each vaccine may have specific considerations for specific populations and health conditions.

4.2 Adverse Events Following Immunization (AEFI)

4.2.1 An adverse event following immunization is any untoward medical occurrence (unfavorable or unintended sign, abnormal laboratory finding, symptom or disease) which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine.

4.2.2 Reported adverse events can either be true adverse events - i.e. resulting from the vaccine or immunization process - or coincidental events that are not due to the vaccine or immunization process but are temporally associated with immunization. The five categories of AEFI as defined by CIOMS and WHO are described in table 2

4.2.3 Table 2: Cause-specific categorization of AEFI (CIOMS/WHO 2012)

Table 2: Cause-specific categorization of AEFI (CIOMS/WHO 2012)

Cause-specific type of AEFI	Definition
Vaccine product-related reaction	An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product.
Vaccine quality defect-related reaction	An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer.
Immunization error-related reaction (formerly "program error")	An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable.
Immunization stress related response(formerly "Immunization anxiety-related reaction"	A range of symptoms and signs that may arise around immunization that are related to "anxiety" or "stress" and not to the vaccine product, a defect in the quality of the vaccine or an error of the immunization program. They include vasovagal-mediated reactions, hyperventilation-mediated reactions and stress-related psychiatric reactions or disorders.
Coincidental event	An AEFI that is caused by something other than the vaccine product, immunization error or immunization stress, but a temporal association with immunization exists.

4.2.4 Vaccine reactions

4.2.4.1 Based specifically on cause, seriousness and frequency, vaccine reactions may be grouped into two broad categories:

4.2.4.1.1 <u>Cause-specific vaccine reactions</u>:

4.2.4.1.1.1 vaccine product-related reaction

4.2.4.1.1.2 vaccine quality defect-related reaction

4.2.4.1.2 <u>Vaccine reactions by seriousness and frequency</u>:

4.2.4.1.2.1 Common or minor reactions

4.2.4.1.2.2 rare or serious reactions.

4.2.4.2 Cause-specific vaccine reactions

4.2.4.2.1 Vaccine product-related reaction (caused by the vaccine)

4.2.4.2.1.1 This is an individual's reaction to the inherent properties of the vaccine, even when the vaccine has been prepared, handled and administered correctly.

4.2.4.2.1.2 Most often the exact mechanism of a vaccine product-related reaction is poorly understood.

4.2.4.2.1.3 The reaction may be due to an idiosyncratic immune mediate reaction (e.g., anaphylaxis) or to replication of the vaccine-associated microbial agent (e.g. vaccine-associated paralytic poliomyelitis – VAPP following OPV which contains attenuated live virus).

4.2.4.2.2 Vaccine quality defect-related reaction (caused by the vaccine)

4.2.4.2.2.1 This is a due to a defect in a vaccine (or its administration device) that occurred during the manufacturing process.

4.2.4.2.2.2 Such a defect may have an impact on an individual's response and thus increase the risk of adverse vaccine reactions. Insufficient inactivation of wild-type vaccine agent (e.g. wild polio virus) during the manufacturing process or contamination introduced during the manufacturing process could cause such vaccine quality defect-related reactions.

4.2.4.3 Vaccine reactions by seriousness and frequency

4.2.4.3.1 Most vaccine reactions are minor and subside on their own.

4.2.4.3.2 Serious reactions are very rare and, in general, do not result in death or long-term disability.

4.2.4.3.3 Table 3: describes the frequency of occurrence of reported adverse events.

Table 3: Frequency of occurrence of reported adverse reactions

Frequency category	Frequency in rate	Frequency in %
Very common	≥ 1/10	≥ 10%
Common (frequent)	≥ 1/100 and < 1/10	≥ 1% and < 10%
Uncommon (infrequent)	≥ 1/1000 and < 1/100	≥ 0.1% and < 1%
Rare	≥ 1/10 000 and <1/1000	≥ 0.01% and < 0.1%
Very rare	< 1/10 000	< 0.01%

4.2.4.4 Common, minor vaccine reactions

4.2.4.4.1 They are caused when recipient's immune system reacts to antigens or the vaccine's components (e.g. aluminum adjuvant, stabilizers or preservatives) contained in the vaccine. Most AEFI are minor and settle on their own.

4.2.4.4.2 Minor AEFI could be local or systemic.

4.2.4.4.3 Local reactions include pain, swelling and redness at injection site.

4.2.4.4.4 Systemic reactions include (but not limited) fever, irritability, malaise and loss of appetite.

4.2.4.4.5 A successful vaccine reduces these reactions to a minimum while producing the best possible immunity.

4.2.4.4.6 Table 4 describes the common minor vaccine reactions by antigen and the treatment for the same.

Table 4: Common minor vaccine reactions by antigen and treatment1

Vaccine	Local adverse events (pain, swelling, redness)	Fever (> 380C)	Irritability, malaise and systemic symptoms
BCG[1]	90%-95%	-	-
Hepatitis B	Adults up to 15% Children up to 5%	1 – 6%	-
Hib	5-15%	2%-10%	
Measles/MR/MMR	~10%	5%-15%	5% (Rash)
OPV	None	Less than 1%	Less than 1%[2]
Pertussis (DTwP)[3]	up to 50%	up to 50%	up to 55%
†Pneumococcal conjugate	~20%	~20%	~20%
Tetanus/DT/aTd	~ 10%[4]	~ 10%	~ 25%
Treatment	Cold cloth at injection site and Paracetamol*	Give extra oral fluids, wear cool clothing, tepid sponge or bath and Paracetamol*	Supportive treatment

[1] Local reactogenicity varies from one vaccine brand to another, depending on the strain and the number of viable antigen in the vaccine.

[2] Diarrhoea, Headache and/or muscle pains

[3] When compared with whole cell pertussis (DTwP) vaccine, acellular pertussis (DTaP) vaccine rates are lower.

[4] Rate of local reactions are likely to increase with booster doses, up to 50 -85%.

* Paracetamol dose: up to 15mg/kg every 6-8 hours, maximum of 4 doses in 24 hours

4.2.4.5 Rare, more severe (and serious) vaccine reactions

4.2.4.5.1 They are caused by the body's reaction to a particular component in a vaccine. The term “severe” is used to describe the intensity of a specific event (as in mild, moderate or severe); the event itself, however, may be of relatively minor medical significance. Severe AEFI can be disabling but are rarely life threatening.Some examples are seizures, thrombocytopenia, Hypotonic Hyporesponsive Episodes (HHE), prolonged crying etc.

4.2.4.6 AEFI are considered serious by definition if they:

4.2.4.6.1 Result in death

4.2.4.6.2 Are life-threatening

4.2.4.6.3 Require in-patient hospitalization or prolongation of existing hospitalization

4.2.4.6.4 Result in persistent or significant disability/incapacity

4.2.4.6.5 Congenital anomaly/birth defect

4.2.4.6.6 Requires intervention to prevent permanent impairment or damage

4.2.4.7 All serious AEFI should be reported, investigated and assessed for causality.

4.2.4.8 The rate of occurrence of rare and more serious reactions has been summarized in table 5.

4.2.4.9 Note that children less than six months or over six years of age are unlikely to have febrile seizures. If this happens, a thorough investigation should be conducted to determine the underlying cause(s).

Table 5: Examples of severe vaccine reactions, onset interval and frequency

Vaccine	Reaction	~ Onset Interval	Rate per million (1,000,000) doses
BCG	Suppurative lymphadenitis	2-6 months	100-1000
	BCG osteitis	1-12 months	1 -700
	Disseminated BCG infection	1-12 months	~ 1-2
COVID19 (Viral vector vaccines)	Thrombosis Thrombocytopenia Syndrome (TTS)	28 days	10 to 20
Hib	None		
Hepatitis B	Anaphylaxis	0 – 1 hour	1 – 2
Measles/MMR/MR	Febrile seizures	6-12 days	330
	Thrombocytopenia	15-35 days	30
	Anaphylaxis	0-1 hour	~1
	Encephalopathy	6-12 days	< 1
Oral poliomyelitis	VAPP	4-30 days	0.4 - 3 million[2]
Tetanus Toxoid, DT	Brachial neuritis	2-28 days	5-10
	Anaphylaxis	0-1 hour	1 – 6
Pertussis (DTwP)	Persistent (>3 hours) inconsolable screaming	0-24 hours	1000-6000

	Seizures	0-3 days	80-570[3]
	Hypotonic, hypo responsive episode (HHE)	0-48 hours	30-990
	Anaphylaxis	0-1 hour	20
	Encephalopathy	0-2 days	0-1
1. Reactions (except anaphylaxis) do not occur if already immune (~90% of those receiving a second dose are immune): children over six years are unlikely to have febrile seizures 2. VAPP Risk is higher following the first dose (1 in 750,000 compared to 1 in 5.1 million for subsequent doses) and for adults and immunocompromised. 3. Seizures are mostly febrile and the risk depends on age, with much lower risk in infants under the age of 4 months.			

4.2.4.10 Immunization error-related reactions

4.2.4.10.1 The term "Immunization" as used here means the "use" of a vaccine for the purpose of immunizing individuals. "Use" includes all processes that occur after a vaccine product has left the manufacturing/packaging site – i.e. handling, prescribing and administration of the vaccine.

4.2.4.10.2 Immunization error-related reactions are usually preventable and they divert attention from the benefit of the immunization program. Some of them are described in Table 6 The identification and correction of these errors in a timely manner are, therefore, of great importance.

Table 6: Immunization error-related reactions

Immunization error		Related reaction
Error in vaccine handling:	Exposure to excess heat or cold as a result of inappropriate transport, storage or handling of the vaccine (and its diluents where applicable)	Systemic or local reactions due to changes in the physical nature of the vaccine, such as agglutination of aluminium-based excipients in freeze-sensitive vaccines
	Use of a product after the expiry date	Failure to protect as a result of loss of potency or no viability of an attenuated product
Error in vaccine prescribing or non-adherence to recommendations for use	Failure to adhere to a contraindication	Anaphylaxis, disseminated infection with a LAV e.g. Disseminated BCG
	Failure to adhere to vaccine indications or prescription (dose or schedule)	Systemic and/or local reactions, neurological, muscular, vascular or bony injury due to incorrect injection site, equipment or technique
Error in administration	Use of an incorrect diluent or injection of a product other than the intended vaccine	Failure to vaccinate due to incorrect diluent, reaction due to inherent properties of whatever was administered other than the intended vaccine or diluent
	Incorrect sterile technique or inappropriate procedure with a multidose vial	Infection at/beyond the site of injection

4.2.4.10.3 An immunization error-related reaction may sometimes lead to a cluster of events associated with immunization. These clusters are usually linked to a particular provider or health facility, or even to single or multiple vials of vaccine that have been contaminated or inappropriately prepared. For instance, freezing vaccine during transport may lead to an increase in local reactions. The details of an approach to investigating AEFI clusters are described later.

4.2.4.11 ISRR formerly known as immunization anxiety-related reactions

4.2.4.11.1 The term “immunization anxiety-related reaction” was previously used to describe a range of symptoms and signs that may arise around immunization that are related to “anxiety” and not to the vaccine product, a defect in the quality of the vaccine or an error of the immunization program.

4.2.4.11.2 These reactions are described as AEFI arising from anxiety about immunization and include vasovagal-mediated reactions (e.g. fainting), hyperventilation-mediated reactions and stress-related psychiatric reactions or disorders.

4.2.4.11.3 The term “anxiety” does not, however, adequately cover the presentation of all these AEFI and anxiety may not manifest during such events.

4.2.4.11.4 The term ISRR is used to cover the entire spectrum of manifestations (symptoms and signs) of a stress response rather than a single symptom, anxiety. Individual responses to stress vary from person to person or may change according to time or context.

4.2.4.11.5 In this cause-specific definition, stress results from the process of immunization. As for other AEFI, symptoms may occur during or after immunization; however, in contrast to other AEFI, the symptoms of an ISRR may also occur immediately before immunization.

4.2.4.11.6 When ISRR occur in a cluster, they may generate public concern, and, if they are linked to immunization, they may halt or undermine the immunization program.

4.2.4.11.7 Although the vaccine is not the underlying cause, the event may be wrongly attributed to it. Halting an immunization program in such situations will give the impression that the vaccine or the program is the cause.

4.2.4.11.8 Various terms have been used to describe such “outbreaks”, including “mass hysteria”, “epidemic hysteria” and “mass psychogenic illness” ISRR may spread by direct contact and via social media.

4.2.4.12 Coincidental events

4.2.4.12.1 An event may occur coincidentally with immunization and sometimes be falsely attributed to the vaccine i.e. a chance temporal association is falsely attributed to immunization.

4.2.4.12.2 Such temporal associations are inevitable especially in a mass immunization campaign.

4.2.4.12.3 Coincidental adverse events may be predictable. The number of events to be expected depends upon the size of the population and the incidence of disease or death in the community.

4.2.4.12.4 Vaccines are normally administered early in life when infections and other illnesses are common, including manifestations of underlying congenital or neurological conditions.

4.2.4.12.5 It is, therefore, possible to encounter many events, including deaths that can be falsely attributed to vaccine through a chance association.

4.2.4.12.6 For example, incidence of sudden infant death syndrome (SIDS or "cot death") peaks around the age of early childhood immunization. Consequently, many SIDS cases will occur in children who have recently been immunized. However, several well-designed studies have shown that the association of SIDS and immunization is coincidental and not causal.

4.2.5 Key AEFI terminology

4.2.5.2 Cluster of AEFI: A cluster is defined as two or more cases of the same or similar event, which is related in time and has occurred within the same district or geographical unit or associated with the same vaccine, same batch number administered or same vaccinator.

4.2.5.3 Signal: Information that arises from one or multiple sources which suggests a new potentially causal association or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.

4.2.5.4 Adverse Event of Special Interest (AESI): An adverse event of special interest (serious or non-serious) is one of scientific and medical concern specific to a particular product or program, for which ongoing monitoring and rapid communication to the relevant authority (e.g. regulators) is needed. Such an event may require further investigation in order to characterize and understand it.

4.2.5.5 Operational definition of an AESI: An AESI is a pre-specified medically significant event that has the potential to be causally associated with a vaccine product that needs to be carefully monitored and confirmed by further special studies.

5 Prevention and management of AEFI

5.2 General principles of prevention and management of AEFI

5.1.1 Vaccines are very rarely contraindicated. However, it is important to check for contraindications to avoid serious reactions. For example, a vaccine is contraindicated if there is a history of anaphylaxis to a given vaccine or its components in previous vaccinations.

5.1.2 Vaccine anaphylaxis is very rare. However, it is recommended that preparedness to provide emergency treatment for anaphylaxis is necessary in all clinic settings. All immunization providers / professionals need to be trained and develop competence in recognizing and managing anaphylaxis and have epinephrine (adrenaline) available.

5.1.3 For parents, advice should be given on managing the common minor reactions, in addition to instructions on seeking proper medical care if there are more severe symptoms. Such action will help to reassure parents about immunization and prepare them for common reactions.

5.1.4 Antipyretic drugs, in a recommended dosage and schedule, can be given as recommended by the prescriber (or manufacturer). For an example, paracetamol, at a dose of up to 15 mg per kg every 6-8 hours with a maximum of four doses in 24 hours, is useful for common minor reactions; it eases pain and reduces fever. However, it is important to advice against overuse of paracetamol or any other antipyretic drug as overdosing may harm the vaccinee. A febrile child can be cooled with a tepid sponging or a bath, and by wearing light cool clothing. Extra fluids need to be given to children with fever. For a local reaction, a cold cloth applied to the site may ease the pain

5.1.5 Using local remedies for any serious vaccine reaction can risk the health and life of the vaccinee and is strongly discouraged. Early medical care by a qualified clinician will minimize any unwanted outcome and ensure early recovery, and may also save lives.

5.2 Prevention and management immunization error-related reactions

5.2.1 Immunization error-related reactions are preventable and identification and correction of these errors in a timely manner are important.

5.2.2 Prior to the introduction of auto-disable syringes, the most common immunization error was an infection as a result of a non-sterile injection because of contamination of the vaccine or diluent vial or the injecting device (syringe and/or needle).

5.2.3 The infection could manifest as a local reaction (e.g. suppuration, abscess) or a severe systemic reaction (e.g. sepsis, toxic shock syndrome).

5.2.4 In addition, there was the perception of a risk linking immunization with blood borne infections. Nevertheless, one needs to consider infection that can occur in cases of mass vaccination or in disaster situations, particularly if there is a shortage of supplies or problems with logistics. This can be avoided by proper planning and preparedness of program managers.

5.2.5 The symptoms arising from an immunization error may help to identify the likely cause. For instance, children immunized with contaminated vaccine (usually the bacterium Staphylococcus aureus) become sick within a few hours with an injection site reaction (local tenderness, redness and swelling) and then develop systemic symptoms (vomiting, diarrhea, high temperature, rigors and circulatory collapse). Bacteriological examination of the vial, if still available, can confirm the source and type of infection.

5.2.6 Sterile abscesses, while rare (~1 per 100 000 doses) are local reactions from aluminium-containing vaccines, especially DTP. They, along with other local reactions, are more likely to occur if there is inadequate shaking of the vaccine before use, superficial injection and use of vaccine that had been frozen. Contamination of vaccine or injection equipment can lead to a bacterial abscess. For BCG vaccine, injection abscess can result from improper technique of injection (subcutaneous rather than intradermal injection).

5.2.7 Ignoring contraindications may lead to serious vaccine reactions and is considered an immunization error. The immunization team should be clearly aware of such contraindications and any precautions. Any uncertainty should be referred to a higher level – a program manager, pediatrician or physician. However, it is equally important not to overreact to concerns of false contraindications as this may lead to missed opportunities for vaccination, reducing coverage and thereby increasing the risk of disease in both individuals and the community.

5.2.8 Health-care workers also need a clear understanding of contraindications and precautions. As mentioned in the previous chapter, precautions are not contraindications, but a decision on whether to vaccinate requires a case-based assessment where the risk of the vaccine is balanced against the potential benefits. The use of live vaccines in pregnancy is a good example of this.

5.2.9 During vaccination, it is also important to ensure that the correct vaccine is used for the recipient. For example, the heterogenous storage conditions, presentation and dosage for age of the different types of COVID19 vaccines has resulted in recipients inadvertently receiving the wrong vaccine, wrong dosage and even vaccines administered in the wrong route.

5.2.10 To avoid/minimize immunization error, the following should be noted.

5.2.10.1 It is both important and necessary to maintain the cold chain at all levels.

5.2.10.2 Vaccines must be reconstituted only with the diluents supplied by the manufacturer.

5.2.10.3 Reconstituted vaccine should be maintained in the recommended cold chain and used within six hours after reconstitution or as per manufacturer recommendation; it must be discarded at the end of each immunization session and should never be retained.

5.2.10.4 Other than vaccines, no other drugs or substances should be stored in the refrigerator of the immunization center.

5.2.10.5 Immunization workers must be adequately trained and closely supervised to ensure that proper procedures are followed.

5.2.10.6 Careful epidemiological investigation of an AEFI is needed to pinpoint the cause and to correct immunization practices.

5.2.10.7 Prior to immunization,

5.2.10.7.1 The vaccine to be used need to be checked if appropriate/ suitable to the patient profile and

5.2.10.7.2 Verify with recipient to ensure that there are no contraindications.

5.2.11 Follow-up and corrective actions following immunization error-related reactions should be based on the findings of the investigation. Depending on the nature of the immunization error, these actions can be both general (e.g. training and awareness) and specific (e.g. strengthening cold chain maintenance if the problem found to be related to cold chain issues). Continued monitoring and supportive supervision can help to minimize these adverse events.

5.3 Prevention and management of ISRR

5.3.1 The immunization environment is important to prevent ISRR. When possible, vaccines should be administered in a calm, private, planned environment. This may be difficult when vaccines are provided during a short period for large groups of individuals, such as in mass campaigns or a school program

5.3.2 A rapid, targeted history before immunization can help to identify individuals with predisposing risk factors for an ISRR. The risk factors relevant to immunization include:

5.3.2.1 age 10–19 years (but can occur outside this age group)

5.3.2.2 history of vasovagal syncope

5.3.2.3 a previous negative experience (e.g., from pain or vasovagal syncope) and an expressed fear of injections, including blood–injection–injury phobia and

5.3.2.4 pre-existing conditions such as anxiety disorders and developmental disorders (particularly autism spectrum disorder).

5.3.3 If the responses to these questions suggest very strong needle fear (without avoidance), consideration should be given to treating the fear before future immunizations or at least taking time to manage the special needs of these individuals. If the fear leads to refusal (i.e., avoidance), additional measures may be required before immunization, such as counselling or behavioral interventions with appropriate health professionals. In selected circumstances of extreme fear and when the expertise is available, a patient might be referred for pharmacological anxiolytics and sedation. In some very rare instances, immunization could be done concurrently with a procedure that requires anesthesia.

5.3.4 Further details are available in the ISRR, A guideline for program managers and health professionals to prevent, identify and respond to stress-related responses following immunization[2].

5.4 Management of suspected anaphylaxis or collapse after vaccination

5.4.1 Every health facility providing vaccinations should have health staff trained in the practical steps for recognition and treatment of anaphylaxis. They should have immediate access to an emergency kit containing adrenaline. Once anaphylaxis is suspected consider the vaccine recipient as having a potentially life-threatening condition and begin treatment immediately and follow the treatment protocol below.

Table 7: Differentiation of anaphylaxis from an acute stress response of general and vasovagal reaction with syncope			
	Anaphylaxis	Acute stress response	
		General	Vasovagal reaction with syncope
Onset	Usually 5 min after immunization but may be delayed up to 60 min	Sudden, occurs before, during or shortly after (< 5 min) immunization	Sudden, occurs before, during or shortly after (< 5 min) immunization. May present after 5 min if the individual stands suddenly.
Clustering of cases	Uncommon	Can occur	Can occur
System			
Skin	Generalized urticaria (hives) or generalized erythema, angioedema, localized or generalized, generalized pruritus with or without skin rash, generalized prickle sensation, localized injection site urticaria, red and itchy eyes	Pale, sweaty, cold, clammy	Pale, sweaty, cold, clammy
Respiratory	Persistent cough, noisy breathing and airway constriction: wheeze, stridor. If very severe, respiratory arrest.	Hyperventilation (rapid, deep breathing)	Normal to deep breaths
Cardiovascular	↑ heart rate, ↓ blood pressure, circulatory arrest	↑heart rate, normal or ↑systolic blood pressure	↓ heart rate with or without transient ↓in blood pressure
Gastrointestinal	Nausea, vomiting, abdominal cramps	Nausea	Nausea, vomiting
Neurological and other symptoms	Uneasiness, restlessness, agitation, loss of consciousness, little response when supine or lying flat	Fearfulness, light-headedness dizziness, numbness, weakness, tingling around the lips, spasms in hands, feet	Transient loss of consciousness, good response once supine or lying flat, with or without tonic–clonic seizure

5.4.2 First aid response which includes;

5.4.2.1 Stop administering any further vaccine.

5.4.2.2 Call for help and never leave the vaccine recipient alone.

5.4.2.3 Place the vaccine recipient in the supine position (lying down flat on the back with head lower than the legs if patient is hypotensive). If the vaccine recipient has difficulty breathing, place him/her in a semi-supine (lying flat on the back but with bent knees/elevated legs)

position. Do not stand the vaccine recipient up or allow the vaccine recipient to walk. If already unconscious, place the vaccine recipient in the recovery position (on the left side) and ensure that airway is clear.

5.4.2.4 Assess airway, breathing and circulation (ABC). If necessary, begin cardiopulmonary resuscitation (CPR).

5.4.3 Diagnose anaphylaxis by doing a RAPD assessment by examining symptoms and signs involving the following body systems;

5.4.3.1 Rash and mucosa

5.4.3.2 Airway and respiratory

5.4.3.3 Pulse and cardiovascular

5.4.3.4 Diarrhea and gastrointestinal

5.4.3.5 Administer initial treatment – the first dose of Adrenaline

5.4.3.6 Draw up the correct dose of adrenaline 1:1000, according to age and/or weight.

5.4.3.7 Generally, the dose for individuals weighing more than 50 kg is 0.5 ml.

5.4.3.8 Using the appropriate needle size (length and gauge), administer adrenaline by deep intramuscular injection into the opposite limb to that in which the vaccine was given. For children, administer in the upper lateral thigh, and in adults in the upper arm (deltoid) or into the muscle of the upper lateral thigh.

5.4.3.9 Give oxygen by face mask (oral-nasal mask), if available.

5.4.4 Assess response and treat if ongoing respiratory and/or cardiovascular symptoms or signs

5.4.4.1 If needed, repeat same dose of adrenaline IM every 5-10 minutes up to TWO additional doses, give high flow oxygen, if available

5.4.5 Documentation and patient transfer

5.4.5.1 Call an ambulance (or arrange other means of transport) after the first injection of adrenaline, or sooner if there are sufficient people available to help you.

5.4.5.2 Record (or get someone to record), vital signs (pulse rate, respiratory rate and blood pressure) all other symptoms and signs, as well as time and exact dose of any medication given. Make sure the details accompany the vaccine recipient when s/he is transferred to the appropriate care center.

5.4.6 Further management is usually provided in a medical center /hospital

5.4.6.1 If shock (hypotension) IV Saline

5.4.6.2 If extrathoracic airway obstruction (stridor) – Nebulized adrenaline/airway intervention

5.4.6.3 If intrathoracic airway obstruction (wheeze) Nebulized salbutamol and airway intervention

5.5 Table AEFI Treatment Kit:

Table 8 : Contents of an AEFI treatment kit	
Injection adrenalin (1:1000) solution – 2 ampoules Disposable syringe (insulin type) having 0.1 ml graduations and IM needle (gauges and length adjusted to targeted recipients) – 2 sets Scalp vein set – 2 sets with medium bore needles. (gauges and length to be adjusted to targeted recipients) IV canula (various sizes, adjusted to targeted recipients) Paracetamol (500 mg) – 10 tabs IV fluids (Ringer lactate or normal saline): 1 unit in plastic bottle	IV fluid therapy: 1 unit in plastic bottle IV drip set: 1 set Cotton wool + adhesive tape: 1 each AEFI reporting forms Label showing: Date of inspection, expiry date of injectable adrenaline and shortest expiry date of any of the components Drug dosage tables for injecting adrenaline At hospital, oxygen support and airway intubation facility should be available.

6 AEFI surveillance in DoH

6.1 Vaccine Safety system in DoH

6.1.1 Surveillance for adverse events following immunization (AEFI) is an integral part of the Abu Dhabi Immunization Program and reinforces the safe use of all vaccines in Abu Dhabi while also helping to maintain public confidence in its immunization program. As shown in Figure 1, this is done systematically.

6.1.2 The objectives of AEFI surveillance are to:

6.1.2.1 Rapidly detect and respond on time to the occurrence of an AEFI

Figure 1: AEFI surveillance cycle

6.1.2.2 Identify, correct and prevent immunization error related reactions.

6.1.2.3 Facilitate AEFI causality assessment.

6.1.2.4 Recognize clustering or unusually high rates of AEFI, including those that are mild and/or “expected”.

6.1.2.5 Identify potential safety signals (including previously unknown vaccine reactions), and generate hypotheses that may require further investigation.

6.1.2.6 Generate information with which to effectively communicate with parents, the community, media and other stake holders, regarding the safety of vaccines used in Abu Dhabi.

6.1.3 Vaccine recipients themselves and/ or parents of immunized infants/children, health care providers / professionals at immunization facilities and staff in immunization facilities are most likely to recognize or detect AEFIs when they first occur. Any AEFI case that is therefore notified to any health care provider working within the health care system, should be reported to the DoH using the electronic reporting form available on: https://bpmweb.doh.gov.ae/UserManagement/MainPage.html
Path: DoH website/ Resources / Reporting

6.1.4 DoH pharmacovigilance should in fact be immediately informed of any Serious AEFI cases by telephone and this should be followed up by completion and submission of the reporting form.

6.1.5 The reportable AEFI include serious or suspected AEFI, AEFI as a result of potential immunization errors, clusters, AEFI causing parental or community concern, those that are unexpected, and any that are known but occur with unexpected frequency.

6.1.6 Table 9 below provides case definitions of commonly reportable AEFI. However, it needs to be stressed that health care providers / professionals should report all cases that are notified to them even if not listed in the table below.

Table 9 Case definitions of some of the important reportable adverse events.

AEFI	Case definition	Vaccine
Anaphylaxis	A clinical syndrome characterized by sudden onset (within one hour), rapid progression of signs and symptoms involving multiple (more than two) organ systems - Skin – urticaria (Hives), angioedema (swelling of face/body), Respiratory – persistent cough, wheeze, stridor, Cardiovascular – low blood pressure (hypotension) or reduced circulation (fast weak pulses), Gastrointestinal – vomiting, abdominal pain.	All
BCG Osteitis/ Osteomyelitis	Inflammation of the bone with isolation of Mycobacterium bovis BCG strain.	BCG
Disseminated BCG infections	Widespread infection occurring within 1 to 12 months after BCG vaccination and confirmed by isolation of Mycobacterium bovis BCG strain. Usually in immuno-compromised individuals.	BCG
Encephalopathy	Acute onset of major illness characterized by ▪ Depressed or altered level of consciousness and/or distinct change in behavior lasting for one day or more	Measles, Pertussis
Fever	The fever can be classified (based on rectal temperature) such as ▪ Mild fever: 100.4°F to 102°F (38 to 38.9°C), ▪ Moderate fever: 102°F to 104.7°F (39 to 40.4°C) and ▪ Severe fever: 104.7°F or higher (>40.5°C).	All
Hypotonic, Hyporesponsive Episode (HHE or shock-collapse)	Event of sudden onset occurring within 48 [usually less than 12] hours of vaccination and lasting from one minute to several hours, in children younger than 10 years of age. All of the following must be present: ▪ limpness (hypotonic) ▪ reduced responsiveness (hypo responsive) ▪ pallor or cyanosis – or failure to observe/ recall	Mainly DPT, rarely others
Injection site abscess	Fluctuant or draining fluid-filled lesion at the site of injection. Bacterial if evidence of infection (e.g. purulent, inflammatory signs, fever, positive bacterial culture),	All injectable vaccines

	Sterile abscess if no evidence of bacterial infection on culture. Sterile abscesses are usually due to the inherent properties of the vaccine.	
Lymphadenitis (includes suppurative lymphadenitis)	Either at least one lymph nodes enlarged to >1.5 cm in size (one adult finger width) or a draining sinus over a lymph node. Almost exclusively caused by BCG and then occurring within 2 to 6 months after receipt of BCG vaccine, on the same side as inoculation (mostly axillary).	BCG
Persistent inconsolable screaming	Inconsolable and continuous crying lasting 3 hours or longer accompanied by high-pitched screaming.	DPT, Pertussis
Seizures	Occurrence of generalized convulsions that are not accompanied by focal neurological signs or symptoms. Febrile seizures: if temperature elevated >100.4 0F or 38 0C (rectal) Afebrile seizures: if temperature is normal	All, especially Pertussis, Measles
Sepsis	Acute onset of severe generalized illness due to bacterial infection and confirmed (if possible) by positive blood culture.	All injectable vaccines
Severe local reaction	Redness and/or swelling centered at the site of injection and one or more of the following: ▪ Swelling beyond the nearest joint ▪ Pain, redness and swelling of more than 3 days and interfering with daily activities ▪ Requires hospitalization. Local reactions of lesser intensity occur commonly and are trivial and do not need to be reported.	All injectable vaccines
Toxic shock syndrome (TSS)	Abrupt onset of fever, vomiting and watery diarrhea within a few hours of immunization. Often leading to death within 24 to 48 hours.	All injectable vaccines
Vaccine Associated Paralytic Poliomyelitis (presenting as AFP)	Acute onset of flaccid paralysis and neurological deficits, compatible with diagnosis of poliomyelitis, with isolation of vaccine virus and absence of wild virus in stool.	OPV
Serious AEFI: Any AEFI causing • Death • Hospitalization • Disability, congenital anomaly • Other severe and unusual events	No time limit, if they are thought by health care providers / professionals or the public to be related to immunization	

6.1.7 All vaccination staff must be able to recognize AEFIs and report them. However, accurate diagnosis of AEFIs requires staff training and education. Health care providers / professionals also have the additional responsibility to manage AEFI and, if necessary, refer such patients for any required treatment.

6.2 Electronic tools for AEFI reporting in DoH

6.2.1 AEFI reports in DoH are received through electronic reporting system. The system is able to generate excel data outputs only by authorized users and is also capable of alerting the reporter for any duplicated report. For AEFI reporting, the critical data elements in the AEFI reporting form are captured as mandatory fields. All the submitted data at Abu Dhabi level are saved on DoH infrastructure that is accessed by DoH pharmacovigilance team. DoH pharmacovigilance section reviews the data to identify if there are "patterns" that are suggestive of signals and appropriate action is taken.

6.2.2 Tools and resources used in DoH:

6.2.2.1 The tool developed supports data collection for the DoH by assisting in the collection and analysis of data on Adverse Events Following Immunization (AEFI) at the Abu Dhabi level. Licensed healthcare professionals / healthcare provider from DoH are granted access to the DoH Pharmacovigilance electronic reporting systems. However, if access to the reporting system is unavailable, an email should be sent to PVE@doh.gov.ae

6.3 Stakeholders in AEFI reporting and investigation; their roles and responsibilities

6.3.1 Abu Dhabi stakeholders in AEFI reporting are:

6.3.1.1 Parents/ guardian

6.3.1.2 Licensed healthcare professionals

6.3.1.3 Licensed healthcare provider

6.3.1.4 The Immunization Officer

6.3.2 Abu Dhabi stakeholders in AEFI investigation are:

6.3.2.1 Pharmacovigilance Section.

6.3.2.2 Medication Safety Committee

6.3.2.3 ADPHC

6.4 Field investigation of serious AEFI

6.4.1 The ultimate goal of a serious AEFI field investigation is to arrive at a valid clinical diagnosis in the patient and correlate it with the circumstances around which the serious AEFI occurred so as to find the cause of the reported serious AEFI(s) and prevent recurrence. Remedial action needs to be taken promptly for immunization error related serious AEFI. Even if the cause cannot be identified or the cause of the event was due to some other reason, the fact that staff had investigated the incident itself will increase public confidence in the immunization program.

6.4.2 The purpose of investigating serious AEFI cases are:

6.4.2.1 To confirm the reported diagnosis and/or propose other possible diagnoses as well as clarify the outcome of the medical incident comprising the serious AEFI.

6.4.2.2 To ascertain the particulars, circumstances and procedures around the vaccine used to immunize the affected recipient. Most importantly, identify any potential vaccine related link to the given serious AEFI.

6.4.2.3 To examine the operational aspects of the program. Even if an event seems to be vaccine product induced or coincidental.

6.4.2.4 To determine whether a reported event was a single incident or one of a cluster and if it is a cluster, confirm that the suspected immunizations were indeed given and the individual vaccines that were used.

6.4.2.5 To determine whether unimmunized people are experiencing the same medical incidents.

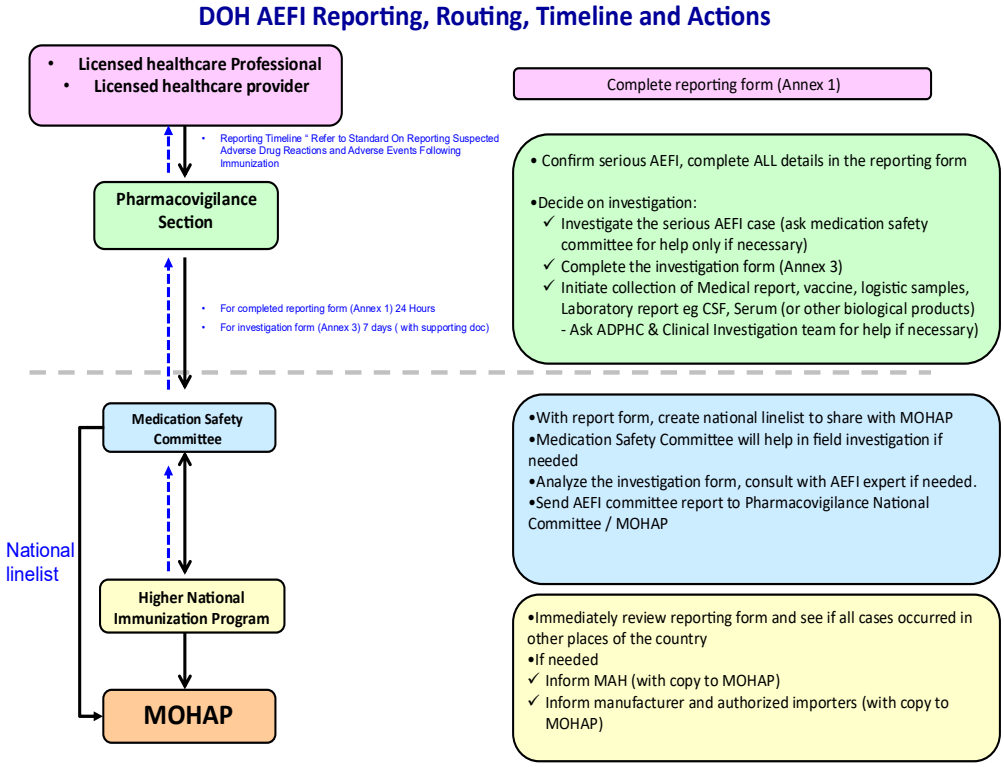

Figure 2: DoH AEFI Reporting, Routing, Timeline and Actions.

6.4.3 Role of the Abu Dhabi stakeholders

6.4.3.1 Role of the parent/ guardian

6.4.3.1.1 At the time of immunization, it is important for health care providers / professionals to sensitize the parents about expected events such as fever and pain at injection site etc. following immunization. Parents should be advised about simple home remedies (e.g., correct positioning of the child when sleeping, increasing intake of fluids, sponging, breast feeding, antipyretics etc.) should such events occur; however, at the same time, they should also be instructed to report severe expected events (e.g., very high fever, not responding to anti pyretic) or other unusual events to the health care provider if they occur.

6.4.3.2 Role of the healthcare provider/ professionals

6.4.3.2.1 If home remedies do not work, vaccine recipients themselves and/ or parents or guardians of immunized infants/children usually report the event to health care providers / professionals at immunization or other health care facilities. Sometimes staff in these facilities recognize or detect AEFIs when they first occur. All such AEFI cases brought to the notice of the health care worker or detected by the worker should be reported to the DoH using the standard reporting form (Annex 1).

6.4.3.2.2 In case of ineffectiveness of home remedies, vaccine recipients, or the parents/guardians of immunized infants and children, report adverse events following immunization (AEFIs) to healthcare providers / professionals at immunization or other healthcare facilities. Sometimes staff in these facilities recognize or detect AEFIs when they first occur. All such AEFI cases brought to the notice of the health care worker or detected by the worker should be reported using the electronic reporting form available on: https://bpmweb.doh.gov.ae/UserManagement/MainPage.html

6.4.3.2.3 Thus, the main role of the health care provider is to provide primary medical care and report the basic details about the notified adverse event to the DoH PV section

6.4.3.3 Role of stakeholders at medication safety committee:

6.4.3.3.1 When an AEFI report is received by the committee, they should review the report and determine if the reported AEFI case meets the criteria required for a detailed investigation. If necessary, they may suggest to contact the primary reporter and visit the locality of the event and interview relevant stakeholders for additional information. The case may be considered

6.4.3.3.1.1 Not warranting detailed investigation if it is a minor AEFI and NOT serious AEFI, they should indicate this on the reporting form

6.4.3.3.1.2 Warranting a detailed investigation if it is a Serious AEFI (death, hospitalization, significant disability, life threatening, or congenital anomaly/ birth defect)

6.4.3.3.1.3 or is a part of a cluster, or a part of a group of events above expected rate/ severity, or a suspected signal.

6.4.3.3.2 The committee should discuss the same with the local experts (or technical expert committee if available) and plan for a detailed field investigation.

6.4.3.3.3 All serious AEFI should be investigated and a completed AEFI investigation form (Annex 3) routed to the Abu Dhabi level. The details of each case should be included in the national line list.

6.4.3.3.4 Abu Dhabi investigations should be led by a team from the DoH team, AEFI pharmacovigilance team, supported by the ADPHC in DoH. During field investigations, the AEFI investigation form (Annex 3) should be used as a guide to collect suitable information.

6.4.3.3.5 The investigators should seek to document any deficiencies found in a generic way and suggest corrective measures, and not single out any individuals to blame. While an individual may have been at fault, it is more effective to focus on identifying the problems in the system and procedures leading to the event. This is

more effective in avoiding similar errors in the future, than blaming or punishing individuals. Such an approach is essential to ensure that AEFI reporting is encouraged for the ultimate benefit of all patients and the immunization program as a whole. It is also much more likely to improve system performance. Errors provide opportunity for learning and creating a system that encourages continued improvement. Hiding errors will only serve to form the basis for more errors.

6.4.3.3.6 The specific activities conducted at this point will include the following

6.4.3.3.6.1 Confirm the AEFI, assign a unique report identifying number, complete ALL details in the AEFI reporting form (in case any of them were missing when reporting) and initiate AEFI investigation.

6.4.3.3.6.2 Convene a local expert (or technical expert committee if available) planning meeting prior to the investigation.

6.4.3.3.6.3 With the experts, the auditors should visit as required the patient, the care provider(s) and the hospital; interview relevant stakeholders (parents, health care provider, treating doctor, vaccine supply focal person); and conduct the investigation of the AEFI case.

6.4.3.3.6.4 Complete the AEFI investigation form (Annex 3).

6.4.3.3.6.5 Initiate collection of medical reports, a post-mortem report (if available), vaccine vials (if necessary, and kept under recommended cold chain conditions), logistic samples, and laboratory reports e.g. CSF, Serum (or other biological products).

6.4.3.3.7 Generally, before the AEFI is attributed to any vaccine product related problems, the investigator should rule out any potential immunization errors and obvious coincidental events, as these are more common. Therefore, the investigation should first try to rule out immunization errors related to the storage, handling, reconstitution or administration of vaccines or contraindications ignored.

6.4.3.3.8 Attention can then focus on other events. Details of coincidental events can be determined by reviewing hospital admissions for similar conditions during the same period and verifying their vaccination status. A quick review of the morbidity pattern of similar conditions in the previous years can also indicate if the event is a part of a similar pattern observed in the previous years. The medical literature can also help, as the estimated background incidence of various conditions may be available in the published domain.

6.4.3.3.9 Once the investigation is initiated, the investigator should inform medication safety committee on the status and progress of the investigation. The completed case investigation form (annex 3) along with the supporting documents such as the medical report, vaccine, logistic samples, laboratory reports e.g., CSF, Serum (or other biological products) should be sent to the medication safety committee DoH within 7 days of initial case notification. If this is not possible, at least a progress report should be made with details on when the completed report can be expected.

6.4.3.3.10 It is important to remember that in case Abu Dhabi assistance for an investigation is requested, more accurate information can be obtained by a single coordinated investigation rather than a piecemeal investigation.

Table 10 Steps in an AEFI investigation

	Step	Actions
1	Confirm information in report	☐ Obtain patient's medical file (or other clinical record) ☐ Check details about patient and event from medical file and document the information. ☐ Obtain any details missing from AEFI Report Form.
2	Investigate and collect data: About the patient:	☐ Immunization history ☐ Previous medical history, including prior history of similar reaction or other allergies ☐ Family history of similar events.
	About the event:	☐ History, clinical description, any relevant laboratory results about the AEFI and diagnosis of the event ☐ Treatment, whether hospitalized and outcome.
	About the suspected vaccine(s):	☐ Conditions under which the vaccine was shipped, its present storage condition, state of vaccine vial monitor and temperature record of refrigerator ☐ Storage condition of vaccine at all levels before it arrived at health facility, Vaccine Vial Monitor. ☐ The date of manufacture, lot and batch numbers of vaccine and diluent
	About other people:	☐ Whether others received the same vaccine and developed illness and whether they need to be included in the investigation. ☐ Whether others had similar illness (may need working case definition); if so exposure of cases to suspect vaccine(s) ☐ Discuss with other immunization service providers / professionals to obtain an idea of the local standard practices
3	Assess the service provided by asking about:	☐ Vaccine storage (including open vials), distribution and disposal ☐ Diluents storage and distribution ☐ Reconstitution (process and time kept)

		☐ Use and sterilization of syringes and needles ☐ Number of immunizations (greater than normal?) ☐ Details of training in immunization practice, supervision and vaccinator(s)
	Observing the service in action:	☐ Refrigerator – what else is stored (note if similar containers stored next to vaccine vials which could be confused); which vaccines/diluents stored with other drugs; whether any vials have lost their label ☐ Immunization procedures (reconstitution, drawing up vaccine into the syringe, injection technique, safety of needles and syringes; disposal of opened vials) ☐ If any open vials look contaminated
4	Formulate a working hypothesis:	☐ On the likely/possible cause(s) of the event.
5	Test working hypothesis	☐ Does case distribution match working hypothesis? ☐ Laboratory tests may help (see text).
6	Conclude investigation	☐ Reach a conclusion on the cause. ☐ Complete AEFI Investigation Form ☐ Take corrective action and recommend further action.
To obtain further resources needed for any field investigation, AEFI investigator(s) may use the WHO AEFI investigation software bridge which can be accessed at https://investigation.gvsi-aefi-tools.org/#step-1 The "WHO Aide Memoire on AEFI Investigation" is available at https://cdn.who.int/media/docs/default-source/pvg/global-vaccine-safety/new-aide-memoire-aefi.pdf?sfvrsn=66340a11_4		

6.4.3.4 Role of the Abu Dhabi stakeholders

6.4.3.4.1 When DoH PV Section receives the AEFI reporting form, it is essential to review it in the context of other reported AEFI received from all parts of Abu Dhabi, particularly in the same period of time, to see if this report may constitute a signal. This can be done by appending data into an Abu Dhabi AEFI line list (Annex 2) with information from the reporting form and reviewing the data or running analyses as needed by authorized users.

6.4.3.4.2 If similar cases were reported earlier, it is essential to determine if an epidemiological linkage or other pattern can be identified if there is one.

6.4.3.4.3 The need for technical or operational assistance for the investigation must be assessed.

6.4.3.4.4 Expert advice can be sought from the Medication Safety Committee at this point.

6.4.3.4.5 The DoH and the Medication Safety Committee play a key role in supporting the immunization program for AEFI investigation and causality assessment. They also provide recommendations to the ADPHC.

6.4.3.4.6 Once ADPHC is notified, they will promptly initiate a comprehensive investigation by:

6.4.3.4.6.1 Tracing the reported vaccine: verify the batch number and identify the deviation

6.4.3.4.6.2 Review the cold chain: assess the cold chain management for any irregularity that was not reported during storage and transportation.

6.4.3.4.7 HNIP is responsible for providing all feedback to the relevant stakeholders within 7 days of causality assessment or potential signals determined by data review/analysis at the Abu Dhabi level. They are also responsible on following up on the program related actions recommended at the Abu Dhabi level (e.g. change in logistics, cold chain, training after program errors etc.) and ensuring that they are implemented.

6.4.4 Investigation of AEFI with fatal outcome

6.4.4.1 In the event of an identified death following immunization, the field investigation has to be initiated immediately. Within 24 hours the death should be notified to all administrative levels concerned, including member from ADPHC; who is representative HNIP.

6.4.4.2 Investigation of the case should be carried out by a team of experts from relevant areas, including clinicians. As a death causally linked to immunization is extremely rare (anaphylactic reactions being one of the only 2-3 known events), major programmatic errors may be involved and thus an investigation to rule those out has to be conducted without any delay to prevent additional cases.

6.4.4.3 As any fatality temporally linked to a vaccination can cause panic, the public will also demand an immediate explanation.

6.4.4.4 A post-mortem is preferred and recommended following all deaths suspected to be caused by a vaccine / immunization. However, the decision to conduct a post-mortem should be taken within the religious, cultural acceptance and legal framework of the local population.

6.4.5 Investigating AEFI clusters

6.4.5.1 A cluster of AEFI is defined as occurrence of two or more cases of the same adverse event related in time, place or vaccine administration. Apart from checking on these three factors, the investigator should look for AEFI occurring in similar age groups and populations with genetic predisposition or disease.

6.4.5.2 Cluster investigation begins by establishing a case definition for the AEFI and related circumstances and by identifying all cases that meet the case definition. The investigator should determine the cluster and identify common exposure factors within the cluster.

6.4.5.3 Cluster identification (i.e. cases with common characteristics) is done by gathering details (when and where) of vaccines administered. This can be achieved by collecting and recording

6.4.5.3.1 Detailed data on each patient;

6.4.5.3.2 Program-related data (storage and handling, etc.); and

6.4.5.3.3 Immunization practices and the relevant health care providers' practices.

6.4.5.4 Common exposures among the cases can be identified by reviewing:

6.4.5.4.1 All data on vaccine(s) used (name, lot number, etc.);

6.4.5.4.2 Data on other people in the area (also non-exposed); and

6.4.5.4.3 Any potentially coincidental factors in the community.

6.4.5.5 When an AEFI cluster has been identified, the cause-specific definitions provide a framework for investigation and causality assessment.

6.4.5.6 Usually, the key considerations will be to investigate the possibility of an immunization error vaccine or a quality defect. The possibility of immunization error must be considered when events cluster in one setting without a similar change in frequency in other settings using the same vaccine.

6.4.5.7 On the other hand, if an increased frequency of events is reported from multiple settings the possibility of a quality defect must be considered more strongly.

6.4.5.8 Clusters of fainting after immunization are well-recognized immunization stress-related response during immunization programs targeting adolescent girls.

6.4.5.9 They should be considered in all clusters except when product related events are confirmed.

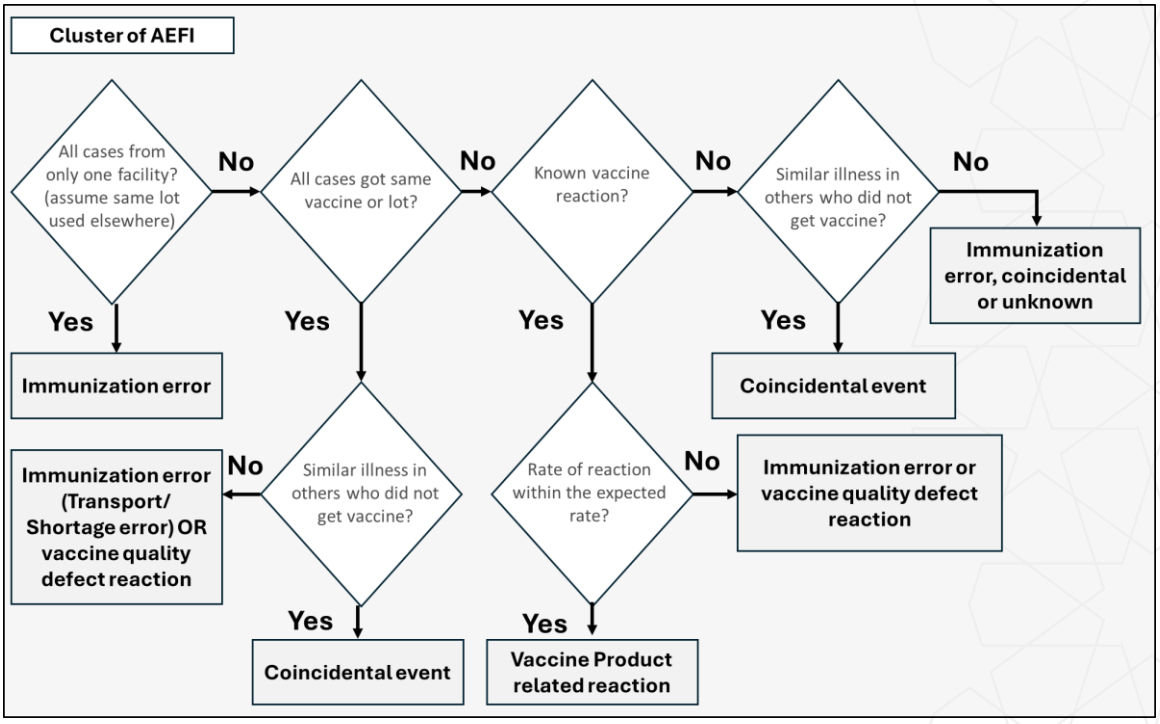

Figure 3: Identifying causes of AEFI cluster

6.4.5.10 For relatively new vaccines or established vaccines used in new target populations, a cluster may represent a previously unrecognized vaccine product-related reaction. Knowledge of the background incidence of events which may occur in causal relationship with a vaccine is therefore essential for assessing a cluster in terms of the strength of the signal it may provide.

6.4.6 Interpretation of results from AEFI clusters

6.4.6.1 If all cases received vaccines from the same health care provider/facility and there are no other cases, an immunization error is likely.

6.4.6.2 If all cases received the same vaccine or lot, and there are no similar cases in the community, a problem with the vaccine or the respective lot is likely.

6.4.6.3 If the event is a known vaccine reaction but is found to occur at an increased rate, an immunization error or a vaccine problem are likely causes.

6.4.6.4 Finally, if cases in the unvaccinated population are occurring at about the same rate/proportion as among the vaccinated from the same area in the same age group, the adverse event was probably coincidental (Figure 3).

6.4.7 Active Vaccine Safety Surveillance (AVSS) in DoH

6.4.7.1 In DoH, passive surveillance systems collect information on AEFIs as described above are useful for the identification of potential safety signals for adverse events that were unknown at the time of vaccine authorization or that are unexpected. However, these passive systems have challenges to differentiate between a reaction following immunization from a coincidental event.

6.4.7.2 DoH is developing systems for Active Vaccine Safety Surveillance (AVSS) that aims to collect complete, accurate information about adverse events following immunization (AEFIs) and their risk factors in a defined population via a continuous organized process. This information is collected with defined objectives which are to investigate one or more AEFIs that are pre-specified adverse events of special interest (AESI). AVSS, unlike passive surveillance systems, collect relevant data from all individuals within a well-defined population, thereby minimizing under-reporting.

6.4.7.3 AVSS system is planned to be used for signal detection (like passive surveillance systems) but they can also be used to determine:

6.4.7.3.1 the rate of an event, in a defined population.

6.4.7.3.2 the relative risk of the event:

6.4.7.3.2.1 the chance of the event occurring in those who were vaccinated with the specific vaccine, compared with those who were not or those who received a comparator vaccine.

6.4.7.3.2.2 the change in the event occurring over time.

6.4.7.4 The occurrence of events in both vaccinated and unvaccinated individuals in the defined population.

7 Laboratory testing of specimens:

7.1 Laboratories have an important role in AEFI case diagnosis and case management. They also have a key role in testing the quality of the samples of vaccines and the logistics used.

7.2 Laboratory tests for the purpose of AEFI case diagnosis and case management conducted on the patient (e.g. hematology, urine, radiology, CSF, ECG etc.) are based on the provisional case diagnosis and recommendations of the treating

physician. The results of these tests are important to confirm the clinical case diagnosis and arrive at the "valid diagnosis" for assessing causality as described in section 10.3

7.3 Laboratory testing of samples of vaccines and logistics are rarely necessary. It is not mandatory following an AEFI, particularly if the cause is evident such as a coincidental event or a program error. However, laboratory testing of vaccines and logistics are at times required to confirm or rule out the suspected cause.

7.4 In the context of AEFI, sometimes additional specific tests on the patient, vaccines and logistics as outlined below may also be necessary to confirm the cause. The testing of additional specimens includes:

7.5 Human specimens

- 7.5.1 Histopathology, body fluids etc. can be done at laboratories identified and approved by the DoH.
- 7.5.2 Autopsy specimens at approved and accredited government forensic laboratories as identified by DoH.

7.6 Vaccines and logistics

- 7.6.1 Vaccines and diluents for sterility and chemical composition.
- 7.6.2 Syringes and needles for sterility.

7.7 Only the appropriate specimen in the correct quantity required for the investigation should be collected. Laboratory specimens should be stored and transported as recommended and accompanied by clear supporting documents, reasons for specimen collection and any additional information required by the investigators. In case laboratory investigation is required, AEFI laboratory request form (Annex 4) should be completed and sent with any specimen collected.

7.8 Laboratory testing of vaccines is not a routine requirement but may be a part of an investigation.

7.9 Laboratory testing of vaccines is costly and is recommended only when it is necessary.

7.10 However, securing samples (vaccine vials, syringes, blood etc.) and storing them correctly is important because later investigations may require them.

7.11 Therefore, proper collection, storage and transport of suspected samples is recommended.

7.12 Human Specimens

- 7.12.1 It is difficult to generalize what specimens will be required in a given situation as it will depend on the symptoms and signs of the patient and the clinical decisions made by the doctor in charge of the case. Table 11 gives a general outline of some of the specimens that could be collected. The list is not exhaustive. It is necessary to record the specimen type, date and time of collection of each and every sample collected. Documents of clinical investigations and medical records related to the incident will support correct lab investigations. It is advised to consult the treating clinician(s) to make a decision on samples to be tested.

- 7.12.2 For biochemical, histo-pathological and microbiological examination, specimens should be handled and forwarded to the nearest laboratory, where facilities are available to carry out requested laboratory testing.
- 7.12.3 If facilities for essential laboratory testing are not available at Abu Dhabi, sending samples to laboratory outside Abu Dhabi or an accredited laboratory abroad need to be considered after discussing with HNIP.
- 7.12.4 In case of death suspected to be due to an AEFI, an autopsy needs to be performed as soon as possible (within 72 hours) to avoid tissue lysis (for e.g., in the adrenal glands), which can alter diagnosis. Samples for both toxicology and pathological examination should be sent to the reference laboratories identified by NIP as early as possible to avoid loss of

biological samples due to decomposition. It is essential to ensure that a detailed patient's history is included in the autopsy form and submitted to the autopsy team to help them look for any underlying pathologies.

7.12.5 Guide to human specimen sample collection

7.12.5.1 The details of the type of AEFI, the tests to be performed, the specimens to be collected, the process of storage and shipment and the labs are outlined in Table 11

Table 11: Type of AEFI, the tests to be performed, the specimens to be collected, storage and shipment procedures and the labs conducting tests

Suspected AEFI	Diagnostic Method	Specimen	When to collect	Preparation, Storage and shipment
Injection site abscesses	Microscopy and Culture/ sensitivity	Pus Swab	At contact	Use Transport media to transport Pus swabs to the next level
BCG lymphadenitis	Microscopy, Culture and serology	Blood, LN Aspirate or Biopsy and Suspected Vial Batch	At Contact	Wrap in leak proof and water proof container transport. Vaccine sample should be transported in reverse cold chain
Collapse or shock-like state	Microscopy, Culture and serology	Blood and Suspected Vial Batch	At Contact	▪ Blood smear ▪ Blood sugar tests at site ▪ Ensure asepsis for blood collection for culture
Convulsions or Seizures	Microscopy, Culture and antigen detection	Collect CSF from affected cases	At Contact	▪ Ensure aseptic techniques of lumbar puncture ▪ Never use vials that contained antibiotics ▪ Sugar and cell counts should be done at site ▪ Transport to referral laboratory immediately
Encephalitis	Microscopy, Culture and antigen detection	Collect CSF from affected cases	At Contact	▪ Ensure aseptic techniques of LP ▪ Never use vials that contained antibiotics ▪ Sugar and cell counts should be done at site Transport to referral laboratory immediately
Death	Serology	(1) Venous Blood (2) Vial Batch	Immediate	▪ Never use vials that contained antibiotics ▪ Transport to referral laboratory immediately ▪ Transport sampled vial batch in reverse cold chain

7.13 Vaccines and logistics

7.13.1 Vaccines and logistics samples from the site and the distribution point(s) should be collected as soon as possible and kept in cold chain. They should be sent to the laboratory for testing only on the recommendation of the local experts.

7.13.2 Testing of vaccines and logistics should be requested on a clear suspicion and not as routine and never before the working hypothesis has been formulated (Table 12). Determining which samples to send for testing (if any) depends on the working hypothesis for the cause of the event(s). If the used vial of suspect vaccine is available, it should be separately labelled and sent along with unused vials of the same lot.

7.13.3 ADPHC will be responsible to communicate with service provider/storage facility for required actions.

7.13.4 ALL specimens sent to the lab should be accompanied by a laboratory request form (Annex 4).

7.13.5 The laboratory will process the specimens and send the laboratory results to ADPHC. Laboratories will also send a copy of the laboratory results to all persons with contact details (complete address with postal code, phone and fax numbers and email address) mentioned in the lab request form.

Table 12: Laboratory testing to investigate AEFI by working hypothesis

Working hypothesis	Specimens to send	Laboratory test
Vaccine transportation or storage	Vaccine vial	Visual test for clarity, presence of foreign matter, turbulence, discoloration or flocculation (examine under magnification)
Reconstitution error	Vaccine vial and/or diluents	Chemical composition analysis for abnormal components (e.g. suspect drug used instead of vaccine or diluent), or microbiological culture for bacterial contamination
Non-sterile injection	Needle, syringe, vaccine vial and diluents	Sterility, if an infectious cause is suspected
Vaccine problem	Vaccine vial	Chemical composition analysis: preservatives, adjuvant level, etc. (e.g. aluminium content) or biological tests for foreign substances or toxins if abnormal toxicity is suspected

8 Falsified vaccines

8.1 It is important to have increased vigilance within the supply chains within DoH and regions likely to be affected by falsified vaccines. Increased vigilance should include hospitals, clinics, health centers, wholesalers, distributors, pharmacies, and any other suppliers of medical products.

8.2 Some indicators that a vial is falsified and may have been illicitly refilled may include:

8.2.1 Vials have scratches or signs of tampering

8.2.2 Labels show signs of damage

8.2.3 The metal cap is dented, scratched or broken

8.2.4 Rubber seals are scratched or punctured

8.2.5 Foreign materials/particles visible inside the vial

8.2.6 Visible signs that the expiry date has been changed or tampered with

8.2.7 The expiry date does not match the authentic batch number

8.2.8 The product is available for private sale outside of authorized immunization programs.

8.3 All vaccines and medical products must be obtained from authorized/licensed suppliers and authorized immunization programs. The products' authenticity and physical condition should be carefully checked.

8.4 If the vaccinator suspects a falsified vaccine, it is important not to use them. It is important to seek advice from a healthcare professional or supervisor in case of doubt. If these vaccines were used, or an adverse reaction/event occurred after having used these vaccines, it is important to seek immediate medical advice from a qualified healthcare professional and to report the incident to the Abu Dhabi Pharmacovigilance Section and report the same using the standard AEFI reporting form and investigations and testing are carried out by the authorities.

8.5 HNIP should immediately notify WHO of these falsified vaccines at rapidalert@who.int .

9 Data and performance analysis

9.1 Sources of AEFI data

9.1.1 Information on vaccine safety and the possible occurrence of AEFIs can be obtained from clinical examinations, interviews of health care provider, parents and community leaders, review of registers (Malaffi and Immunization), Vaccine and Injection logbooks, observation of immunization administration, vaccine handling and storage and laboratory reports. Analysis of data on AEFIs consists of reviewing data from the following sources

9.1.1.1 Data collated into a line list

9.1.1.2 Case investigation forms for each reported AEFI case,

9.1.1.3 Laboratory information (Human and vaccine related)

9.1.1.4 Records about similar events in the community

9.1.1.5 Records of the implicated vaccine

9.2 Analysis of AEFI reports

9.2.1 It is essential that all notified cases are reported (serious and non-serious AEFI) using the AEFI electronic reporting form available on: https://bpmweb.doh.gov.ae/UserManagement/MainPage.html.
Path: DoH website / Resources / Reporting

9.2.2 All serious reported AEFI cases should be line listed at all levels using the AEFI line list (Annex 2). The use of electronic tools for the same is very helpful. This is the first step of data management. Before the analysis, verify and reassure the data for accuracy and validity. In addition to basic time, place and person analysis that should be done by the PV section, other key analysis related to the performance of the surveillance system, include

9.2.2.1 Timeliness and completeness of receiving AEFI forms.

9.2.2.2 Identifying health institutions where AEFIs are not reported by checking on "zero reporting" or "nil reporting". Determine whether it is due to failure of reporting or whether there are no AEFIs to be reported.

9.2.2.3 Assessing AEFI case reports received during stipulated time period.

9.2.2.4 Assessing number of events and reporting rate per 1,000 or 10,000 or 100,000 doses of vaccine used.

9.2.2.5 Analyses by the type of AEFI and the types of vaccines

9.2.2.6 Analyzing program errors by number and rates per 100 or 1,000 doses of relevant vaccines used.

9.2.2.7 Compare the rates with available or known background rates.

9.3 Data analysis at DoH

9.3.1 Data analysis could be carried out by the responsible and authorized focal persons at DoH PV section at DoH and may request further assistance from ADPHC

9.3.2 Analysis of data at Abu Dhabi level is important to identify the program errors. This helps to carry out local corrective action in a timely manner.

Table 13 Types and purpose of data analysis at different levels

Program implementation level	Suggested Analysis	Purpose of analysis at this level
Local Level	Number of reports by local level Number of reports by clinics, hospitals, villages by a given time Reported AEFIs by Place (clinics, hospitals), Persons and time Cluster analysis Reported AEFIs by antigen	These are program operation indicators such as timeliness and completeness Identify immunization errors that will lead to corrective local action Cluster analysis too lead to identify immunization errors, but also coincidence and vaccine reactions too. Will identify vaccine reactions and coincidental events?
HNIP level	Number of reports by local levels Reported AEFIs by Place (clinics, hospitals), Persons and time Cluster analysis Reported AEFIs by antigen	These are program operation indicators (timeliness, completeness) at intermediate level Identify immunization (program) errors and thereby will lead to corrective action. Cluster analysis too lead to identify immunization errors, but also coincidental events and vaccine reactions. Will identify vaccine reactions including signal detection lead to take operational and policy decisions at national level

9.4 Data analysis process

9.4.1 Before analysis of the line list at the Abu Dhabi level, it is important to re-check the case definitions adopted by the reporting sources. The case should fit into a case definition such as the Brighton collaboration case definitions https://brightoncollaboration.us/category/pubs-tools/case-definitions/ or any definition selected by the Medication Safety Committee or HNIP.

9.4.2 Line lists should be used to sort data by place, person and time. Analysis should be done by antigens by type of reported adverse events (e.g., high fever, abscess) after stratifying data. Number of doses administered for each antigen is the best denominator for calculating reported AEFI rates for each antigen in a given time period (by month, quarter or year). Various denominators and their limitations are described in table 14. Analysis can be expanded to AEFI rates by first or second or third dose, when the antigen is administered more than once. For this, the number of doses administered of the given antigen by first, second or third need to be used as the denominator.

Table 14 Selection of denominators and their limitations

Denominator	Limitations
Administered doses of vaccines	Most reliable, but not often available
Distributed doses	Greater than administered doses, thus may reduce rate (underestimate)
Coverage x Population	May be less accurate because of variability in coverage estimates
Target population	Proxy measure for vaccine population (may also underestimate)

9.4.3 Multiplier: Use of proper multiplier in data analysis is important and also varied by purpose and level of analysis. At Abu Dhabi, percentage (x100= %) is the best choice, whereas at UAE level, one may use 1000, 100,000 or million as multiplier. For common, minor vaccine reactions, percentage is recommended and for rare serious reactions, 10,000, 100,000 or 1,000,000 (million) can be used.

9.5 Interpretation of data

9.5.1 Available expected rates for each type of AEFI for a given antigen is provided at https://www.who.int/groups/global-advisory-committee-on-vaccine-safety/topics/pharmacovigilance/rates-of-reactions#cms

9.5.2 This can help to make decisions on corrective action to be taken on reported AEFIs.

9.5.3 It is also important to know about background rates of reported medical events in Abu Dhabi. Comparison of background rates with reported rates of AEFI will guide to a possible hypothesis of a coincidental event. For example, febrile seizures with bacterial or viral infection aetiologies are common among young children and may also occur following some vaccines such as DTwP. Therefore, it is important to know the rate of febrile seizures due to other reasons and expected rates following a given antigen.

9.5.4 If the values exceed the expected background rates, then one should consider true increase or a coincidence due to other ongoing diseases.

9.6 Monitoring and Evaluating the performance of the AEFI surveillance system

9.6.1 The AEFI surveillance system performance needs to be regularly reviewed to ensure that the system is sensitive enough to identify and respond to serious AEFI rapidly. The "standard overall" indicator proposed to determine the quality of AEFI surveillance, "Individual serious AEFI** reporting rate in million total population from a country/ sub-Abu Dhabi area per year". This is calculated as

Number of individually documented serious AEFI cases reported from a country/ Abu Dhabi area per year (Rate) per million population	=	Individual serious AEFI reporting rate in million total population per year / Total population in the same country/ Abu Dhabi area per year X 1,000,000

9.6.2 Notes: The initial target***proposed is at least 1 serious report cases per 1,000,000 population per year. The Abu Dhabi /country is defined according to the functional requirements and setup of the Abu Dhabi AEFI surveillance system.

9.6.3 **An event that results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/ incapacity, or is a congenital anomaly/birth defect. Any medical event that requires intervention to prevent one of the outcomes above may also be considered serious.

9.6.4 ***This will be revised based on periodic reviews

9.6.5 Some of the other key indicators that help to monitor the performance of the system include

9.6.5.1 Timeliness and completeness of AEFI reporting

9.6.5.1.1 Percentage of serious AEFI cases reported on time (no later than 24 hours of notification) to the Abu Dhabi level

9.6.5.1.2 Percentage of serious AEFI cases investigated on time (7 days of onset) using standard formats.

9.6.5.2 Number (%) of AEFI investigation conclusions supported by findings of special tests (clinical specimens, Post-mortem findings (among AEFI deaths), lab findings for vaccine samples)

9.6.5.3 Number (%) AEFI cases where final classification including causality assessment and raised to medication safety committee is completed within 30 days of receipt of all documentation/

9.6.5.4 Number (%) AEFI cases reviewed by HNIP following receipt of reported AEFI cases.

9.6.5.5 Number (%) AEFI cases reviewed by medication safety committee and not assessable due to lack of information.

9.6.5.6 Response to AEFI particularly those related to vaccination program error

9.6.6 WHO has developed an AEFI data management e-Learning course that can be accessed here https://who.csod.com/selfreg/register.aspx?c=aefi%20causality%20assessment

10 Brief overview of AEFI causality assessment

10.1 This section is a short introduction and practical overview of the purpose, process and classification of AEFI cases after causality assessment A comprehensive guide and background to causality assessment has been published by WHO and can be accessed online at https://www.who.int/publications/i/item/9789241516990

10.2 Causality assessment is the systematic evaluation of the information obtained about an AEFI to determine the likelihood that the event might have been caused by the vaccine/s received. Causality assessment does not necessarily establish whether or not a definite relationship exists, but generally ascertains a degree of association between the reported adverse events and the vaccine/vaccination. Nevertheless, causality assessment is a critical part of AEFI monitoring and enhances confidence in the immunization program. Causality assessment is important for:

- 10.2.1 identification of vaccine-related problems;
- 10.2.2 identification of immunization error-related problems;
- 10.2.3 excluding coincidental events;
- 10.2.4 detection of signals for potential follow-up, testing of hypothesis and research; and
- 10.2.5 validation of pre-licensure safety data with comparison of post-marketing surveillance safety data.

10.3 Case selection for causality assessment

- 10.3.1 The cases for which causality is ascertained include:
  - 10.3.1.1 Serious AEFI
  - 10.3.1.2 Clusters & events above expected rate/ severity
  - 10.3.1.3 Evaluation of suspected Signals
  - 10.3.1.4 Other AEFI (if required) as decided by reviewing team / committee including
    - 10.3.1.4.1 If immunization error is suspected
    - 10.3.1.4.2 Significant events of unexplained cause within 30 days of vaccination
    - 10.3.1.4.3 Events causing significant parental or community concern (e.g. Hypotonic Hyporesponsive Episode (HHE), febrile seizures etc.)
- 10.3.2 Preparation for causality assessment
  - 10.3.3 Prior to causality assessment, The AEFI case investigation should have been completed
  - 10.3.4 It is important that high quality AEFI investigation is conducted and a clinical case diagnosis/ differential diagnosis is available and the vaccines that were received by the recipient clearly identified
  - 10.3.5 All details of the case should be placed into a dossier and presented to the committee for causality assessment. This includes the case report form, case investigation form (annex 3), completed clinical case record, lab reports, autopsy report, details of field investigations (including occurrence of similar events among non-vaccinated) etc. should be available at the time of assessment
  - 10.3.6 There must be a “valid diagnosis” which is which the extent to which the unfavorable or unintended sign, abnormal laboratory finding, symptom or disease is defined.
  - 10.3.7 With inadequate or incomplete case information, a proper causality assessment cannot be performed. Such AEFI cases will be considered “ineligible” for causality assessment and the investigators will be asked to revisit the sites and collect additional information.

10.3.8 Even with complete information the AEFI may be categorized indeterminate due to the lack of clear evidence of a causal link (e.g., a new event), or conflicting external evidence or other inconsistencies. Sometimes even with adequate information, AEFI may be deemed unclassifiable or not assessable due to inability to proceed with the assessment. Nevertheless, these assessments should be recorded because the reporting of more cases may lead to a stronger signal and a plausible hypothesis, or stronger refutation of any link.

10.4 Causality assessment team

10.4.1 Causality assessment " Refer to Annex 3 AEFI INVESTIGATION FORM: Step 4" in DoH is done by a PVE section and discuss the assessment through medication safety committee, to be:

10.4.1.1 Independent

10.4.1.2 free of real or perceived government, industry conflicts of interest

10.4.1.3 Can call for broad range of expertise in the areas of 'infectious diseases, epidemiology, microbiology, pathology, immunology, neurology, pediatrics, obstetrics and gynecology, geriatrics, vaccine program.

10.4.1.4 The committee has written terms of reference (ToRs)

10.4.2 In summary, causality assessment of serious cases needs high levels of expertise and is done by an expert committee. For sensitive high-profile cases it is done preferably at the Abu Dhabi level. A causality assessment usually will not prove or disprove an association between an adverse event and the immunization. It is meant to assist in determining the level of certainty of such an association. A definite causal association or absence of association often cannot be established for an individual event.

11 Action and response to AEFI

11.1 Responding to serious AEFI may involve immediate short-term activities or/and long-term follow-up activities. Follow-up activities should be based on findings of investigations, causality assessments and recommendations by the investigation/expert committees.

11.2 Proper and early treatment should be immediately provided to patients regardless of the diagnosis. Case management and referral will vary depending on the seriousness. Mild symptoms such as mild fever and pain are likely to be of short duration and can be managed by assuring and educating parents during immunization. If parents return to seek medical attention, these cases should be documented and reported in the standard form. In case patients need hospitalization, a clear system for referral should be in place.

Table 15: Actions to be taken upon completion of the investigation/causality assessment	
Type of AEFI	Follow-up action
Vaccine-related reaction	If there is a higher reaction rate than expected from a specific vaccine or lot, obtain information from the manufacturer and consult with the WHO state office to consider: If vaccine product related reaction is confirmed • Inform HNIP, marketing authorization holder, the procuring agency and the WHO • Alert healthcare workers on possible serious reactions with guidance on clinical diagnosis and management • Assess risk of specific vaccine product-related reaction and adapt vaccination and communication strategies If vaccine quality defect related reaction is confirmed • If related to a particular lot / batch: may have to withdraw specific lot(s) • Inform the HNIP/MOHAP, marketing authorization holder, the procuring agency and the WHO • Periodically review & supervise on the maintenance of a database of lot numbers, expiry dates, distribution & administration-related data
Immunization error related	Correct the cause of the error. This may mean one or more of the following: • Improve and ensure the safety of logistics for supply, store or handle • Review vaccination service procedures at the health facility and do needful changes to ensure immunization safety • Training of health workers • Intensified supervision • Measure outcome of corrective action: short- and long-term Whatever action is taken, it is important to review later to check that the immunization error related events have been corrected.
ISRR	• Conduct periodical risk communications to the public and healthcare Provider/ professional on potential anxiety-related reactions, particularly in children/adolescents • Ensure that vaccine program managers and healthcare workers can prevent, identify and respond to anxiety-related responses following immunization
Coincidental	The main objective is to present the evidence showing that there is no indication that the AEFI is a vaccine-related reaction or immunization-related error and, that the most likely explanation is a temporal association between the event and vaccine/vaccination. This communication can be challenging when there is widespread belief that the event was caused by immunization. Sometimes, it may be useful to enlist further expert investigation to ensure that the event was truly coincidental. The potential for coincidental events to harm the immunization program through false attribution is immense.

11.3 Depending on the nature of the event(s), the number of people affected, and community perceptions, an investigation may be conducted. In general, it is not advisable to discontinue the immunization program while awaiting the completion of the investigation. If AEFI causality is not established – depending on the nature of the event, its extent and whether it is ongoing – a further investigation or epidemiological study may be warranted. However, it must be accepted that in some cases the relationship to vaccine will never be clear.

11.4 Communication, capacity building and training are key follow-up actions that have long term implications.

12 Communication and media management

12.1 Risk communication

12.1.1 Communication makes stakeholders aware of the process at each stage of the Investigation. The identification of particular interest groups and their representatives should comprise a part of an overall communication strategy. Decisions including what, whom and how, should be part of an overall communication strategy.

12.1.2 Need for improved communication

12.1.2.1 Concerns are frequently raised about vaccines and immunization programs by members of the general public and in the media. These concerns can be serious and are often misplaced. The graphic below (Fig 9.1) illustrates some of the factors that may trigger public concerns; hence the need for improved quantity, quality and targeted communication about vaccine safety.

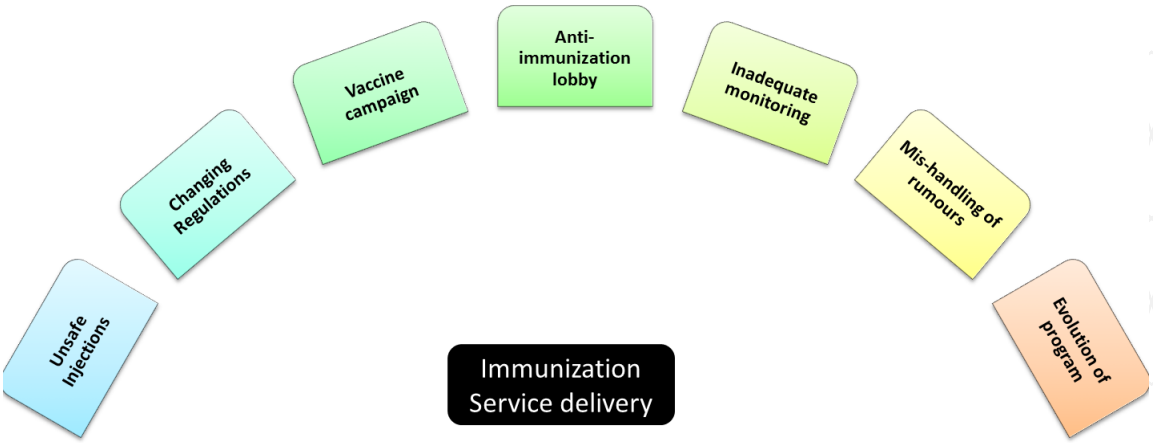

Figure 4: Factors triggering public concerns to immunization

12.1.3 Challenges to effective communication

12.1.3.1 Challenges that need to be overcome with effective communication include among others:

12.1.3.1.1 Communicating the decline of childhood infections and deaths from VPD

12.1.3.1.2 Parents view that infectious disease is a thing of the past

12.1.3.1.3 Introduction of new vaccines and related information gaps

12.1.3.1.4 Mass campaigns or Supplemental Immunization Activities (SIAs)

12.1.3.1.5 Need for transparency and accountability

12.2 Communication with clients, parents or guardian and community

12.2.1 Communication with parents, other members of the community, health staff and media need to be carried out under all circumstances. They should be kept informed about the investigation, results and action taken already or going to be taken regarding the AEFI. It is crucial to highlight the benefits of immunization while communicating on AEFI with the public and stakeholders.

12.2.2 Key points to consider when communicating with the vaccine recipient (patient or client) or parents and guardians of the patient, community and health staff are;

12.2.2.1 Listen to the client, parents or guardian and their concerns empathetically.
12.2.2.2 Reassure and support the client, parent or guardian but do not make false promises.
12.2.2.3 Assist the client, parents and guardian for hospitalization if necessary.
12.2.2.4 Frequent communication with the client, parents or guardian regarding the progress of the patient.
12.2.2.5 Prepare a fact sheet on adverse event for the client, parents or guardian, community, health staff and media.
12.2.2.6 Build up and maintain relationship among health staff, community and media.
12.2.2.7 Inform the individual client, parent or guardian about possible common adverse events and how to handle them.
12.2.2.8 Continuously communicate with the client, parent or guardian and community during the investigation period to assure understanding the risk-benefit of vaccination.

12.3 Role of health professionals in community communication on AEFI

12.3.1 AEFI can have repercussions on the entire routine immunization program as well as campaigns. Where medical interventions are necessary, they should be carried out as rapidly as possible. Suppressing reports of serious AEFI or slow reaction can cause considerable damage to the immunization program in the long-term. Messages relating to adverse events must be disseminated rapidly to prevent rumors spreading.

12.3.2 Once a serious AEFI has occurred, responses should include the following communication elements:

12.3.2.1 Communicate immediately with the medication safety committee, HNIP, ADPHC and MoHAP.
12.3.2.2 Provide the parents with factual information. Remember that some parents may seek information elsewhere and you may lose credibility if you do not provide a trustworthy and technically sound response. The public and the other stakeholders have a right to know exactly what happened.
12.3.2.3 Reassure parents, caregivers and adults that necessary measures are being taken so that the members of the community and caregivers are informed of what is happening.
12.3.2.4 Communicate the results of the investigation to DoH PVE section, the Medication safety committee, HNIP, ADPHC and MoHAP.
12.3.2.5 If the AEFI was caused by immunization error, tell the public what steps are being taken to prevent similar events in the future.
12.3.2.6 Broadcast an official statement about the event on radio and television and publish a statement in newspapers.
12.3.2.7 Repeat the message to dispel all fears.
12.3.2.8 Constantly reassure the public of the safety of vaccines.

12.4 Communication with other health care staff

12.4.1 Communicate among all levels of health authorities involved.
12.4.2 Reinforce their knowledge, ability, skills and performances.
12.4.3 Update them on investigation process, progress and findings.
12.4.4 Reassure the staff of ongoing confidence in the immunization program; quality of the vaccine and their services provided
12.4.5 Create blame free culture and focus on the correction and quality of the NIP program.

12.5 Communicating with stakeholders

12.5.1 Vaccine safety information needs to be shared with other stakeholders in order to ensure dissemination of correct information and thereby ensuring the smooth functioning of Abu Dhabi immunization program. Depending on the need stakeholders mentioned below will be given preliminary information at initial stage and final report after completion of investigation and causality assessment at a later stage.

12.5.1.1 ADPHC

12.5.1.2 Medication safety committee.

12.5.1.3 HNIP

12.6 Communicating with media

12.6.1 The media is an important gateway to inform the public and shapes their view and attitudes towards vaccines and immunization, especially including the occasional mass campaign. In the long-term, building partnerships with the media is key to keep the public regularly informed about immunization, its benefits and to motivate families and communities to make use of immunization services.

12.6.2 Advance preparedness

12.6.2.1 Effective communication with the media includes efficient coordination with the field staff, a plan, trained personnel, budget and practiced responses to potential issues around AEFI. Effective communication should be in place before an immunization campaign starts and as part of the on-going communication to support routine immunization programs.

12.6.3 A database of journalists

12.6.3.1 It is essential to maintain a database of print and electronic media journalists covering health with contact information. They need to be contacted and informed about the circumstances of the serious AEFI.

12.6.4 Information packages:

12.6.4.1 Keep media informed through email or hardcopy by sending regular updates on any plans, programs and decisions. Sensitize media about health benefits of immunization and its impact globally and locally. Prepare monthly or quarterly updates. Provide an updated information package with documents including Frequently Asked Questions (FAQs) on immunization in general, for specific disease and AEFI (Factsheet or a technical brief on a specific vaccine preventable disease etc.).

12.6.5 Draft media release:

12.6.5.1 The draft media release must specifically answer the W's for journalists:

12.6.5.1.1 Who is affected/is responsible?

12.6.5.1.2 What has happened?

12.6.5.1.3 What is being done?

12.6.5.1.4 Where has it happened?

12.6.5.1.5 When did it happen?

12.6.5.1.6 Why did it happen?

12.6.5.1.7 Will it happen again?

12.6.5.2 In the media release, mention the name and contact details of the AEFI focal person(s) and the name and contact details of the official spokesperson for further details should journalists have additional questions (at the end).

12.6.6 A spokesperson system:

12.6.6.1 The assign person from the Federal level shall be the first source in releasing the information to the media. For this purpose, this person will be responsible for communicating the AEFI to media, public and stakeholders. This limits the possibility of conflicting messages coming from different sources. Ensure spokesperson has the important information.

12.6.7 Orientation workshops and field visits for media:

12.6.7.1 Regular orientation workshops and field visits for journalists will help them achieve a better understanding of immunization advantages as well as the complexities of an immunization program. This will also help to identify in advance the kind of questions or concerns that journalists specifically have.

12.6.8 Media Management during an AEFI crisis

12.6.8.1 While every single serious AEFI must be investigated in detail, all serious AEFI cases may not be a crisis situation. A crisis often occurs from inaction rather than from taking appropriate action on AEFI.

12.6.9 Monitoring of media:

12.6.9.1 When a serious AEFI occurs, media should be monitored for authenticity of their reporting. The HNIP should move very quickly to correct any inaccuracies. The HNIP could take the following immediate actions:

- 12.6.9.1.1 Analyze rumor, its level and potential to cause damage.
- 12.6.9.1.2 Anticipate how situations might evolve following response; prepare before responding.
- 12.6.9.1.3 Deal with a simple mistake in reporting with a simple solution. If it is an isolated error, make a polite call to the reporter and offer to help the reporter with correct data and facts then and in the future.
- 12.6.9.1.4 If the rumor is confined to a small audience, correct it within that group only. If the error is widely reported, it may be necessary to call a media conference to present the correct facts before it leads to further damage.
- 12.6.9.1.5 Plan how to prevent future rumors.

12.6.9.2 Prepare a media release:

12.6.9.3 An effective media release should include a complete account of the event, framed in its context (e.g., an isolated event or a cluster of AEFI or coincidental event or serious AEFI). The media release should have;

- 12.6.9.3.1 An outline of actions taken or planned (such as the AEFI investigation).
- 12.6.9.3.2 A description of the cause of the event (but only when this is known with certainty).
- 12.6.9.3.3 An assurance that corrective action has been taken or will be taken.
- 12.6.9.3.4 Reference to any relevant publication, video material or web site.
- 12.6.9.3.5 Sender’s name and spokesperson’s details.
- 12.6.9.3.6 Limited to one page of matter (400-500 words max).
- 12.6.9.3.7 Short sentences (not exceeding two lines).

12.6.9.4 Quotes from key officials may be used after seeking their permission. The quotes must be positive and carry the key messages.

12.6.10 Call a media conference:

12.6.10.1 Media conferences may need to be conducted if AEFI is being reported extensively and widely and there is a need to provide accurate

facts and de-sensationalize the story. A media conference enables all journalists to have the same information, thus there is then less likely of event being 'sensationalized'. Consider the following steps when preparing for the media conference:

12.6.10.1.1 HNIP takes the lead but identifies who facilitates the press conference.

12.6.10.1.2 If there are several members on the panel, agree beforehand on the key message(s) in response to the AEFI.

12.6.10.1.3 Agree on roles of each panel member beforehand, including the type of questions (media, political etc.) each panel member may best handle.

12.6.10.1.4 Panel members must avoid contradicting each other in the press conference unless it is critical to clarify something incorrect that has been said.

12.6.10.1.5 Have a media kit ready and share it with journalists. The media kit may consist of a media release with all the essential information, supplementary background information, benefits and a set of frequently asked questions about immunization.

12.7 Media Management post AEFI

12.7.1 All announcements for AEFI replated post shall be through a dedicated spoke person authorized by DoH, not to be announced by HCPs

12.7.2 Keeping promises to the media:

12.7.2.1 Ensure the media is updated on investigation findings by the promised date. If delays occur, promptly inform the media to manage expectations.

12.7.3 Providing answers to unanswered questions:

12.7.3.1 Address unanswered questions from media conferences as soon as possible by providing accurate information, especially if initial responses were unavailable due to data limitations.

12.7.4 Keeping the media informed about subsequent developments:

12.7.4.1 If any decision or action is taken at the highest levels following AEFI investigations or during the investigations and the public must know about it, keep the media informed though a press release or hard copy document.

12.8 Dealing with rumors and misinformation

12.8.1 In the context of immunization, rumor is defined as an unverifiable assertion that is circulating, or a statement without facts to confirm its truth. Rumors and misinformation about immunization are amongst the most serious threats to the success of any immunization program. Once rumors start, they can be very hard to stop.

12.8.2 Some examples of rumors:

12.8.2.1 "Vaccines are a contraceptive to control population or to limit the size of a certain ethnic group."

12.8.2.2 "Vaccines are contaminated by the AIDS virus or mad cow disease."

12.8.2.3 "Children are dying after receiving vaccines."

12.8.3 Unless the rumor can very easily be contained and addressed you must refer the matter to your supervisors as quickly as possible. You will need to work under their direction - action may even need to be taken at the Abu Dhabi level. The consequences of rumors can be serious and, if unchecked, they can travel quickly beyond your local area.

12.8.4 Common causes of Rumors

12.8.4.1.1 Inadequate information sharing by health care providers / professionals

12.8.4.1.2 Failure to communicate correct information about vaccine effects and schedules,

12.8.4.1.3 Failure to check whether caregivers know and understand information,

12.8.4.1.4 Failure to give clients opportunities to ask questions

12.8.4.1.5 Parents/caregivers' negative attitudes about immunization services

12.8.4.2 What you can do at the health facility

12.8.4.2.1 Under the direction of your supervisor:

12.8.4.2.1.1 Raise the Issue with DoH/ADPHC

12.8.4.2.1.2 Engage key opinion leaders, including policymakers, traditional and religious leaders, community representatives, and healthcare professionals.

12.8.4.2.1.3 Coordinate meetings at locations where participants feel comfortable and encouraged to ask questions and express concerns.

12.8.4.2.1.4 If there is an official mass media response from Abu Dhabi, actively encourage community members to view and discuss the message to enhance awareness and understanding.

12.8.4.2.2 Words of advice:

12.8.4.2.2.1 React swiftly and adapt your ongoing activities to give a quick response.

12.8.4.2.2.2 Develop strong relationships and trust with your community in advance (religious, social and media groups).

12.8.4.2.2.3 Give clear and consistent messages.

12.9 Emerging threat of infodemics

12.9.1 An infodemic is too much information including false or misleading information in digital and physical environments during a disease outbreak or immunization program. It causes confusion and risk-taking behaviors that can harm health. It also leads to mistrust in health authorities and undermines the public health response. An infodemic can intensify or lengthen outbreaks when people are unsure about what they need to do to protect their health and the health of people around them including vaccinations. With growing digitization – an expansion of social media and internet use – information can spread more rapidly. This can help to more quickly fill information voids but can also amplify harmful messages.

12.9.2 Infodemic management is the systematic use of risk- and evidence-based analysis and approaches to manage the infodemic and reduce its impact on health behaviors during health emergencies.

12.9.3 Infodemic management aims to enable good health practices through 4 types of activities:

12.9.3.1 Listening to community concerns and questions

12.9.3.2 Promoting understanding of risk and health expert advice

12.9.3.3 Building resilience to misinformation

12.9.3.4 Engaging and empowering communities to take positive action

4.Relevant References Documents			
No.	**Reference Date**	**Reference Name**	**Relation Explanation / Coding / Publication Links**
1	December 2019	Immunization stress-related response: a manual for program managers and health professionals to prevent, identify and respond to stress-related responses following immunization	https://www.who.int/publications/i/item/9789241515948
2	February 2022	DOH Standard on Administration of Vaccines in Outpatient Pharmacies	https://www.doh.gov.ae/-/media/FBA46167008C4CA4AD4C2C29D11B5E4B.aspx
3	September 2024	Standard On Reporting Suspected Adverse Drug Reactions and Adverse Events Following Immunization	https://www.doh.gov.ae/-/media/E7AC622D823C4907AEF7965022804259.aspx#:~:text=Expedited%20reporting%20of%20serious%20ADRs,case%20later%20than%2030%20days
4	August 2025	AEFI - ADVERSE EVENT FOLLOWING IMMUNIZATION Surveillance and Response OPERATIONAL GUIDELINES - 2024	https://mohfw.gov.in/sites/default/files/National%20AEFI%20Surveillance%20and%20Response%20Operational%20Guidelines%202024.pdf