



Product safety Directorate,

Ethiopian Food and Drug Authority

**National Guideline for Vaccine Safety Risk and Crisis
Communication**

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Foreword Message

Vaccines are generally considered as safe and effective. However, they are not completely risk-free and adverse events will occasionally result from vaccination. Vaccine safety related events can have a negative impact on immunization unless it is communicated timely and proactively to avoid loss of public trust in immunization. Thus, vaccine safety risk and crises communication guideline is required to address public concerns while promoting and advocating the benefits and importance of vaccines.

This guideline is developed to guide health care professionals and other stakeholders to effectively communicate vaccine safety and related issues. The guideline focuses on vaccine safety risk and crises communication activities such as responding to rumors, communicating with media, preparing key messages and press release/media briefing among others. Furthermore, the guideline will enable preparedness and response teams working on vaccine safety crises to optimize their communication plans in order to maintain, strengthen or regain trust in vaccines and immunization programs.

I would like to express my heartfelt gratitude to all those who participated in the realization of this guideline particularly the staff of EFDA, MOH, development partners, and all consultative and validation workshop participants.

Finally, I strongly recommend health care professionals and other stakeholders to use this guideline and forward comments and suggestions to EFDA.

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Director General
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Executive Summary

The success of an immunization program depends on high rates of vaccine acceptance and coverage. Although adverse event following immunization are very rare, the occurrences can easily become a crisis situation if not managed properly and proactively. Thus, National Guideline for Vaccine Safety Risk and Crisis Communication is needed to guide Ministry of Health, Ethiopian Food and Drug Authority and Health Care Professionals and other stakeholders in communicating vaccine safety risk and managing crisis.

This national guideline can be used to maintain and/or regain public trust in order to sustain an immunization program and achieve a high level of immunization coverage. Besides, the guideline supports proactive and timely response for vaccine safety related events to reduce vaccine hesitancy by addressing perceived and/or real public concerns on vaccine safety risk and crisis.

Clear communication about adverse event following immunization is used to control rumors and misconceptions about vaccine safety. In this regard, it is crucial to prepare the key messages for addressing potential concerns and challenges at individual and societal level by communicating only reliable information. In addition, the provided information should be extracted from credible sources and its content should be acceptable, meaningful, memorable, understandable and relevant to audiences.

Vaccine related concerns that arise from family/guardian/, community or health care professionals needs due attention. To address and influence the behavior of specific audience, four interrelated and interdependent communication approaches should be implemented. These approaches include empowerment and behavior change communication, communication for social change, social mobilization, and advocacy. During implementation of these four approaches, media engagement is highly required for effective communication.

The guiding principles of effective communication includes trust, credibility, transparency, empathy, equity, participation and feedback. An effective communication about adverse events following

immunizations requires media to promote and advocate immunization campaigns at any time by setting agenda. A strategic approach that combines different modes of communication (interpersonal, group, mass media and social media) is needed to deliver message effectively.

Communication with the media requires efficient coordination, communication plan, trained personnel, budget and practiced responses to potential issues around adverse event following immunization. Particularly, the vaccine safety risk and crisis communication plan should comprise plan for organizing press release/ media debriefing, maintaining database, developing a media kit, and monitoring media coverage and content of messages disseminated. Moreover, follow-up action with communications/media management is important to evaluate the impact of disseminated information qualitatively and/or quantitatively.

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Acronyms and Abbreviations

AEFI	Adverse Event Following Immunization
CIOMS	Council for International Organizations of Medical Sciences
Covid-19	Coronavirus Disease 2019
DTP	Diphtheria Tetanus Pertussis Vaccine
DTaP	Diphtheria, Tetanus, and Acellular Pertussis
DTaP- IPV-HepB-Hib	Diphtheria, Tetanus, Acellular Pertussis, Hepatitis B, Inactivated Poliovirus, and Haemophilus Influenzae type B
DTwP	Diphtheria, Tetanus, and Whole Cell Pertussis
DTwP-HepB-Hib	Diphtheria, Tetanus, Pertussis, Hepatitis B, and Haemophilus Influenzae Type B
EFDA	Ethiopia Food and Drug Authority
EPI	Expanded Program on Immunization
GVSI	Global Vaccine Safety Initiative
HCPs	Health-Care Professionals
IPC	Interpersonal Communication
IPV	Inactivated Polio Vaccine
LAV	Live Attenuated Vaccine
MMR	Measles, Mumps and Rubella
MOH	Ministry of Health
NRA	National Regulatory Authority
OPV	Oral Polio Vaccine
RI	Routine Immunization
TT	Tetanus Toxoid
SPC	Summary of Product Characteristics
UNICEF	United Nations Children’s Fund
VRE	Vaccine Safety-Related Event
VPDs	Vaccine-Preventable Diseases
VRE	Vaccine-Safety Related Event
WHO	World Health Organization

Definition of Terms

Adverse Events Following Immunization: any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine

Advocacy: any actions that speaks in favor of, recommends, argues for a cause, supports or defend, or pleads on behalf of others.

Antibody: a protein produced by the body's immune system when it detects antigens

Antigen: any substance that causes immune system to produce antibodies against it

Crisis Communication: the information that is exchanged by and between public authorities, organizations, the media, affected individuals and groups before, during and after a crisis.

Disinformation (Black Propaganda): a subset of propaganda and is false information that is spread deliberately to deceive.

Key Messages: main points of information that audiences should hear, understand and remember

Media: communication channels through which information is disseminated.

Misinformation: false, inaccurate, or misleading information that is communicated regardless of an intention to deceive.

Pandemic: an epidemic of an infectious disease that has spread across a large region

Press Statement/Release: an official statement delivered to member of the news media for providing the information.

Public Relation: a deliberate, planned and sustained effort to establish and maintain mutual understanding between an organization and its public.

Risk Communication: refers to the real-time exchange of information, advice and opinions between experts, officials and people who face a threat to their wellbeing, to enable informed decision-making

and to adopt protective behaviours by addressing the experiences, beliefs, values, and attitudes of message recipients, providers and public perspectives.

Rumor: currently circulating story or report of uncertain or doubtful truth.

Social Media: online communication channels where communities interact, collaborate and share contents.

Toxoid: a chemically modified toxin from a pathogenic microorganism, which is no longer toxic but is still antigenic and can be used as a vaccine

Vaccines: biological products that are used to stimulate an immune response that confers protection against infection and/or disease on subsequent exposure to a pathogen.

Vaccine crisis: an event, which will most likely or has already eroded public trust in vaccines and/or vaccination and the authorities delivering them and may create uncertainty. This requires immediate action and an effective response to curb the negative impact

Vaccine Hesitancy: a delay in acceptance or refusal of vaccination despite availability of vaccination services.

Vaccine Safety: a part of immunization safety that maintains the highest efficacy of, and lowest adverse reaction to, a vaccine by addressing its production, storage and handling.

1. Introduction

1.1. Background

Vaccines are biological products that are used to stimulate active or passive immunity that confers protection against infection and/or disease on subsequent exposure to a pathogen. In practice, however, no vaccine is completely risk-free and adverse events can occasionally occur following an immunization resulting in death; life-threatening conditions that requires hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/ incapacity, or is a congenital anomaly /birth defect. Vaccines play pivotal role in promoting health, saving lives, preventing 2 to 3 million deaths every year and reducing costs.

Based on the antigen used in their preparation, vaccines can be classified as live attenuated, inactivated, sub-units, toxoid and vector-based.

Live attenuated vaccines (LAV) are derived from disease causing pathogens that have been weakened under laboratory conditions. LAVs can have increased potential for immunization errors as some LAVs come in lyophilized (powder) form that must be reconstituted with a specific diluent before administration,

Inactivated or killed vaccines are made from microorganisms (viruses, bacteria, others) that have been killed through physical or chemical processes. Individuals may not develop the same protection after immunization as healthy individuals receiving the vaccine.

Subunit vaccines do not contain live components of the pathogen. They differ from inactivated whole-cell vaccines, by containing only the antigenic parts of the pathogen. The sub-units can be proteins, sugars, nucleic acids or conjugated form derived from the disease-causing organism. Protein based subunit vaccines present an antigen to the immune system without viral particles, using a specific, isolated protein of the pathogen. Polysaccharide vaccines are small, and often not very immunogenic. Consequently, they tend to be not effective in infants and young children (under 18–24 months) and induce only short-term immunity (slow immune response, slow rise of antibody levels, no immune memory). Conjugating each sugar molecule to a protein helps infants' and young children' immune system to generate a protective immune response and generates an excellent immune response in adults. The nucleic acid approach is a new way of developing vaccines. Researches in this area has

progressed very fast and some mRNA vaccines are getting emergency use authorization, which means they can now be given to people beyond using them only in clinical trials.

Toxoid vaccines are based on the toxins produced by certain bacteria (tetanus or diphtheria). The toxin invades the bloodstream and is largely responsible for the symptoms of the disease. The protein-based toxin is rendered harmless (toxoid) and used as the antigen in the vaccine to elicit immunity.

Viral vector based vaccines do not actually contain antigens rather use the body's own cells to produce them. They do this by using a modified virus (the vector) to deliver genetic code for antigen, in the case of coronavirus disease-2019 spike proteins found on the surface of the virus, into human cells.

Vaccines can be administered intramuscularly, subcutaneously, intradermally or orally and as per the manufacturers' recommendations. Under recommended conditions, all vaccines used in EPI are safe and effective if used correctly. In practice, however, no vaccine is completely risk-free and adverse events can occasionally result after an immunization. There are six types of vaccine safety-related events (VRE) that can have negative impacts on EPIs, which require proactive communication strategies. These are adverse events following immunization (AEFI), temporary suspension of a vaccine, vaccine recall, replacement of a vaccine, new research findings related to vaccines or immunization, and a report in the media, or rumors about a vaccine.

A vaccine safety signal is information that indicates a potential link between a vaccine and an event previously unknown or incompletely documented, that could affect health. In addition, careful investigation of all serious AEFIs is critical to determine the likelihood of a causal link between a reported AEFI and the vaccine(s) administered or the vaccination process, or to find another cause.

The national guideline for vaccine safety risk and crisis communication is required to help proactive communication for ensuring the successful implementation of an immunization program in any given setting. Moreover, the guideline supports regulatory authorities and healthcare workers in provision of up to date and accurate information about the benefits and risks of vaccination to the public.

1.2. Rationale

EFDA developed this guideline with a vision of ensuring effective vaccine safety risk and crisis communication to all stakeholders promptly and efficiently. EFDA aims to facilitate and promote communication activities to address public concerns about vaccine safety in a clear, factual and timely

manner to maintain public trust and confidence in vaccination programs by addressing the experiences, beliefs, values, and attitudes of message recipients as well as providers.

1.3. Goal

This guideline will enable all stakeholders to optimize their communication plans in order to maintain, strengthen or regain trust in vaccines and immunization programs.

1.4. Objectives

This guideline will enable concerned bodies to achieve the following objectives

- To build confidence and public trust on vaccines and immunization program
- To communicate vaccine safety using appropriate communication channels
- To timely respond vaccine safety related events
- To enable release of updated information on vaccine safety risk and crisis
- To create common understanding on how, when , whom to communicate vaccine safety risk and crisis

1.5. Scope

This guideline emphasizes on vaccine safety communication, risk communication on AEFI, Communication with media and responding to vaccine safety crisis.

2. Vaccine Safety Communication

2.1. Introduction to Vaccine Safety Communication

During the pre-vaccine period, when no vaccine is available for a disease, there is a high number of people getting the disease. People are concerned about contracting the disease. When a vaccine for the disease becomes available, an immunization program commences. As more people get vaccinated, disease incidence decreases. At this point, people turn their attention from worry about the disease, to concern about possible side effects of the vaccine. People may start to question whether the vaccine is necessary or safe, some groups may spread rumors about the vaccine or program, and some people will stop getting immunized. If many people stop getting immunized, a resurgence of the disease may cause outbreaks.

In recent years, concerns are frequently raised about vaccines, immunization protocols and real or perceived AEFIs by members of the general public and in the media. Through various communication channels, people are aware that to avoid the disease they should turn back to immunization, which restores people's confidence on vaccines and the EPI. As a result, vaccination coverage increases once more and disease incidence declines as shown in Figure 1.

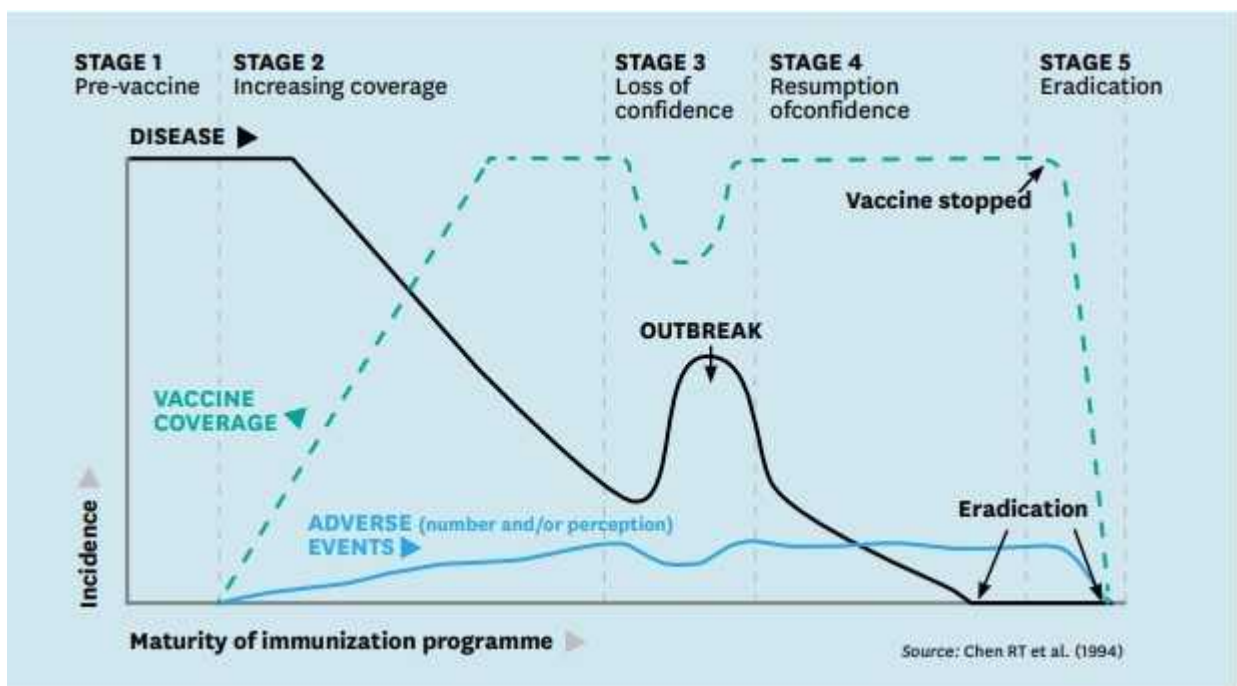


Figure 1. Impact of vaccine safety issues in the life cycle.

Vaccine safety communication is crucial for the successful implementation of an immunization program and to maintain public trust and confidence in vaccination programs. Regulatory authorities and healthcare professionals (HCPs) must be able to provide up-to-date and accurate information about the benefits and risks of vaccination to the public.

Trust is a key component in the exchange of information at every level and effective risk communications must address the experiences, beliefs, values, and attitudes of message recipients as well as providers. Parents, the public, HCPs and the media should be kept informed about the investigation, results and action already taken or going to be taken regarding the AEFIs. It is also crucial to highlight the benefits of immunization while communicating with the public/media/stake holders.

2.2. The Rationale for Vaccine Safety Communication

Rationale 1: To timely respond vaccine safety related events

Every vaccine safety issue must be quickly reported and investigated. A concerted strategic communication response should be prepared. Accurate information based on evidence must be disseminated in a timely manner to avoid loss of public trust in immunization. Vaccine safety related events can have a negative impacts on immunization and therefore require proactive communication strategies.

Rationale 2: To overcome vaccine safety related factors that may result vaccine hesitancy

Vaccination readiness is a fundamental individual disposition that need to be understood in promoting appropriate interventions. Measured on a population level, vaccination readiness can serve as an indicator that allows for identifying target groups and providing diagnostic support regarding interventions. Vaccine hesitancy is an emerging term in the discourse on determinants of vaccine acceptance or readiness. Vaccine hesitancy may explain why uptake of a vaccine or immunization program in a community is lower than would be expected in the context of the information given and services available. Understanding vaccine hesitancy or readiness will help communication planners design appropriate approaches to overcome behavioral barriers and reinforce positive determinants of vaccine uptake.

The seven C's (7C's) scale is used to search for further determinants of vaccination readiness, developing interventions that increase vaccination readiness, providing additional translations, and introducing additional components as shown in Table 1.

Table 1: The seven components of vaccination readiness.

Component	Definition	Short version item	Interpretation: High scores indicate
Confidence	Trust in the security and effectiveness of vaccinations, the health authorities, and the health officials who recommend and develop vaccines.	Vaccination side effects occur rarely and are not severe for me Political decisions about vaccinations are scientifically grounded. I am convinced the appropriate authorities do only allow effective and safe vaccines.	...high trust in vaccines and go along with increased vaccination readiness
Complacency	Complacency and laziness to get vaccinated due to low perceived risk of infectious diseases.	I do not need vaccinations because infectious diseases do not hit me hard. (R) Vaccination is unnecessary for me because I rarely get ill anyway. (R) I get vaccinated because it is too risky to get infected.	...low complacency and, thus, high vaccination readiness
Constraints	Structural or psychological hurdles in daily life that make vaccination difficult or costly	I make sure to receive the most important vaccinations in good time. Vaccinations are so important to me that I prioritize getting vaccinated over other things. I sometimes miss out on vaccinations because vaccination is bothersome. (R)	...everyday hurdles do not hinder in getting vaccinations
Calculation	Degree to which personal costs and benefits of vaccination are weighted	I get vaccinated when I do not see disadvantages for me. (R) I only get vaccinated when the benefits clearly outweigh the risks. (R) For each vaccine, I carefully consider whether I need it. (R)	...cost-benefits considerations about vaccinations are ignored and high vaccination readiness.

Collective Responsibility	Willingness to protect others and to eliminate infectious diseases.	I also get vaccinated because protecting vulnerable risk groups is important to me. I see vaccination as a collective task against the spread of diseases. I also get vaccinated because I am there by protecting other people	...vaccination readiness to protect others.
Compliance	Support for societal monitoring and sanctioning of people who are not vaccinated.	It should be possible to exclude people from public activities (e.g., concerts) when they are not vaccinated against a specific disease. The health authorities should use all possible means to achieve high vaccination rates. It should be possible to sanction people who do not follow the vaccination recommendations by health authorities.	...acceptance of punishment for refusing vaccinations and endorsement of benefits for vaccinated people.
Conspiracy	Conspiracy thinking and belief in fake news related to vaccination	Vaccinations cause diseases and allergies that are more serious than the diseases they ought to protect from. (R) Health authorities knuckle under to the power and influence of pharmaceutical companies. (R) Vaccinations contain chemicals in toxic doses. (R)	...dismissal of conspiracy beliefs around vaccinations.

Note: Confidence, collective responsibility, and compliance relate positively to vaccination readiness, complacency, constraints, calculation, and conspiracy relate negatively to vaccination readiness. To avoid confusion, all items should be scored so that high values indicate high vaccination readiness. Items that must be reverse coded are marked with an (R). Items of the short-scale are marked in bold.

When the spectrum of vaccine hesitancy is considered, it explores the spectrum of vaccination-related behavior, which ranges from total acceptance to rejection of all vaccines, and outlines the 3 major determinants of vaccine hesitancy: contextual factors, individual or group factors, and vaccine dependent factors as shown in Table 2.

Table 2: Determinants of vaccine hesitancy matrix.

Individual and group influences	Contextual influences	Vaccine/vaccination specific issues
<ul style="list-style-type: none"> • Personal or community experience with vaccination, including pain • Beliefs and attitudes about health and prevention <ul style="list-style-type: none"> • Knowledge and awareness, risk/ benefit • Immunization as a social norm <ul style="list-style-type: none"> • Trust in health system and providers 	<ul style="list-style-type: none"> • Media and public communication • Anti- or pro-vaccination lobbies • Local politics/policies • Perception of the pharmaceutical industry • Religion/culture/gender/ socio-economic • Accessibility of services • Trust in authorities 	<ul style="list-style-type: none"> • Risk/benefit (epidemiological/ scientific evidence) • Mode of administration • Reliability/Source of the vaccine • Vaccination schedule • New vaccines, formulations or recommendations • Any costs associated with vaccination <ul style="list-style-type: none"> • The strength of the recommendation/ attitude desk/ knowledge base of HCPs

Rationale 3: To increase vaccination coverage by addressing public concerns on vaccine safety

As vaccine-preventable infectious diseases continue to decline, people have become increasingly concerned about the risks associated with vaccines. Furthermore, technological advances and continuously increased knowledge about vaccines have led to investigations focused on the safety of existing vaccines, which have sometimes created a climate of concern.

Allegations regarding vaccine related adverse events, if not rapidly and effectively dealt with, can undermine confidence in a vaccine and can ultimately have dramatic consequences for immunization coverage and disease incidence. Alternatively, vaccine-associated adverse events may affect healthy individuals and should be promptly identified to allow additional research and appropriate action to take place. When vaccine safety concerns are addressed through effective communication, vaccination coverage can be increased.

2.3. Goal, Objectives and Desired Outcomes of Vaccine Safety Communication

The goal of vaccine safety communication is to maintain public trust in vaccines and immunization safety to sustain the immunization program and achieve a high level of immunization coverage (see Table 3).

Table 3: Target groups, objectives and desired outcomes of vaccine safety communication.

Target Group	Objectives	Desired Outcomes, Behaviors and Actions
A. Vaccinee/Care givers	<ul style="list-style-type: none"> ▪ Explain benefit and risk of vaccines and immunization; ▪ Build confidence and trust on vaccines and immunization program ▪ Complete the immunization schedules 	<p>Complete the immunization schedule</p> <p>Know the importance of immunization in protecting against diseases.</p> <p>Feel confident that vaccines are safe</p> <p>Bring children for routine immunization</p> <p>Always bring immunization card</p> <p>Talk about immunization benefits with other mothers/parents, neighbors, social network.</p> <p>Not be panic and manage minor risks of vaccines at home.</p>
B. Community leaders, community groups, civil society organizations, Non-governmental organization, community-based organizations, local government authorities, business sector, school officials, children’s/ adolescent clubs, youth groups, schoolchildren	<ul style="list-style-type: none"> ▪ To achieve high immunization coverage. ▪ To maximize community support ▪ To create supportive environment for AEFI management 	<p>The awareness of the community about the vaccines safety, risk and effectiveness in protection against diseases increases.</p> <p>Resistant parents, immunization dropouts, hard-to reach and those marginalized due to gender, class, caste, ethnicity, race, religion, disability, or socioeconomic status will be addressed.</p> <p>Father, grandparents, neighbors; relatives support mother/caregiver in routine immunization.</p> <p>A supportive environment for families during AEFI to help maintain confidence in vaccines and routine immunization will be created (RI).</p>
C. Frontline health-care providers:	<ul style="list-style-type: none"> ▪ Explain benefit and risk of vaccines and immunization; ▪ Explain vaccine safety issues and related events; and ▪ Demonstrate their enhanced 	<ul style="list-style-type: none"> ▪ Know and demonstrate good interpersonal communication (IPC) and social mobilization skills in the delivery of immunization tasks. ▪ Treat all persons/clients coming for immunization with respect and courtesy; answer their questions and address their concerns; show active interest in their opinions. ▪ Explain AEFI and risk-benefits of vaccine and immunization: possible minor side effects and its management (e.g., what to do if there is a minor side effect).

	<p>capacities in vaccine safety communication when dealing with vaccine safety issues and related events.</p>	<ul style="list-style-type: none"> ▪ Reach out and persuade resistant parents, immunization dropouts, hard-to-reach and those marginalized due to gender, class, caste, ethnicity, race, religion, disability, or socioeconomic status. ▪ Provide concerned families and communities with a consistent set of easy-to-understand messages regarding the vaccines, the diseases they protect against, when the next vaccination is due, any possible side effects and reasons why it is important for the child to be vaccinated. Explain any contraindication if relevant. ▪ Obtain information on child's health status including previous illnesses (not only at the moment of vaccination, but also at least two weeks before visit and also if there has been any chronic, long-term illness, e.g. congenital abnormalities). ▪ If AEFI is reported, show empathy and promptly visit affected family and community to understand their concerns. ▪ Report back to parents/community the results of AEFI investigation. ▪ Dispel rumors, fears and resistance to immunization. ▪ Assure families of vaccine safety to restore confidence in vaccines. ▪ Consider the views and needs of communities in planning vaccination schedules and venues, times and other aspects of the program.
<p>D. Religious leaders, religious groups</p>	<ul style="list-style-type: none"> ▪ To advocate vaccine ▪ To fill the gap related to religion regarding vaccine hesitancy 	<ul style="list-style-type: none"> ▪ Promote vaccination during sermons and informal discussions with congregation members. ▪ Counter community resistance to immunization and any loss of confidence due to AEFI.

E. Media	<ul style="list-style-type: none"> ▪ Address vaccine safety issues and related events accurately and objectively; ▪ Support the national immunization program; and ▪ Promote the benefits of immunization. 	<ul style="list-style-type: none"> ▪ Build professional relationships with journalists who have a good track record of maintaining high professional standards. ▪ If a rumour about vaccine safety begins to circulate, contact concerned body quickly before a crisis around misinformation develops, and give them the facts. ▪ Give adequate media coverage related to vaccine and immunization ▪ Keep messages simple and to the point – do not use academic jargon or complex arguments. Use statistics only when necessary. ▪ If unsure of the facts, do not be evasive or speculate. ▪ Give contact phone numbers and/or email addresses so the journalist can follow up on the story or check facts later. ▪ Remain polite and professional at all times – never lose your temper, even if provoked by “silly” questions or by a journalist with a confrontational style. ▪ Know your work and be prepared.
F. Program managers, National Regulatory Authority (NRA), academia	<ul style="list-style-type: none"> ▪ To prepare safety communication guideline ▪ To release updates on vaccine and vaccine risk events timely. ▪ To arrange platform for training, workshops, experience sharing forum 	<ul style="list-style-type: none"> ▪ Provide an enabling environment for health-care providers, media, community groups and families to maintain confidence in EPI. ▪ Organize orientation workshops for program managers down the administrative hierarchy. ▪ Set up an information-sharing forum to discuss effective approaches and lessons learnt from communicating vaccine safety issues and AEFI in other areas. ▪ Strengthen communication capacity and IPC skills of staff from agencies and institutions responsible for immunization. ▪ Develop a communication plan to respond to AEFI at subnational level. ▪ Support health-care providers with training in IPC skills and counselling and use of IPC tools to reinforce and ensure message recall.
G. Policy-makers,	<ul style="list-style-type: none"> ▪ To ensure 	<ul style="list-style-type: none"> ▪ Give political commitment and demonstrate

donors	<p>political commitment</p> <ul style="list-style-type: none"> ▪ To prepare policy on vaccine safety communication ▪ To ensure fund for immunization 	<p>political will through public pronouncements and participation in EPI.</p> <ul style="list-style-type: none"> ▪ Issue policy to integrate vaccine safety communication into communication strategy for immunization. ▪ Ensure that marginalized and vulnerable populations are included in EPI mapping. ▪ Include in public statements relevant messages about AEFI and the importance of sustaining routine immunization
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2.4. Challenges of Vaccine Safety Communication

Sustaining high vaccine coverage rates may become more of a challenge as people question the limitations of vaccines and new parents no longer see or hear about the diseases from which vaccines protect them. The following challenges are expected to affect vaccine safety communication

Provider

- Has little time for discussion
- Suffers a sense of rejection as wise advisor
- Limited access to information
- Poor health and other infrastructure
- Inadequate number of health workers
- Inadequate knowledge and skills
- Negligence and poor motivation of health workers
- Negative and inaccurate messaging
- Inadequate funding and political interference

Vaccinee/caregivers

- Illiteracy
- Wants control; wants to make decision
- Multiple ethnic groups with many languages
- Negative cultural and religious beliefs
- Inadequate social mobilization
- Vaccine hesitancy

- Social instability
- Need for target group specific communication

2.5. Communication Strategies and Approaches to address Vaccine Safety Issues

A communication strategy aimed at sustaining the national immunization program, particularly in the face of vaccine safety concerns, involves understanding and influencing the behavior of key individuals and the social norms/practices of communities and the health system.

The Socioecological Model as shown in Figure 2 illustrates the five levels to be considered when planning communication to influence positive behavior and social change, i.e., to improve knowledge, attitudes, practices and social norms around immunization and vaccine safety.

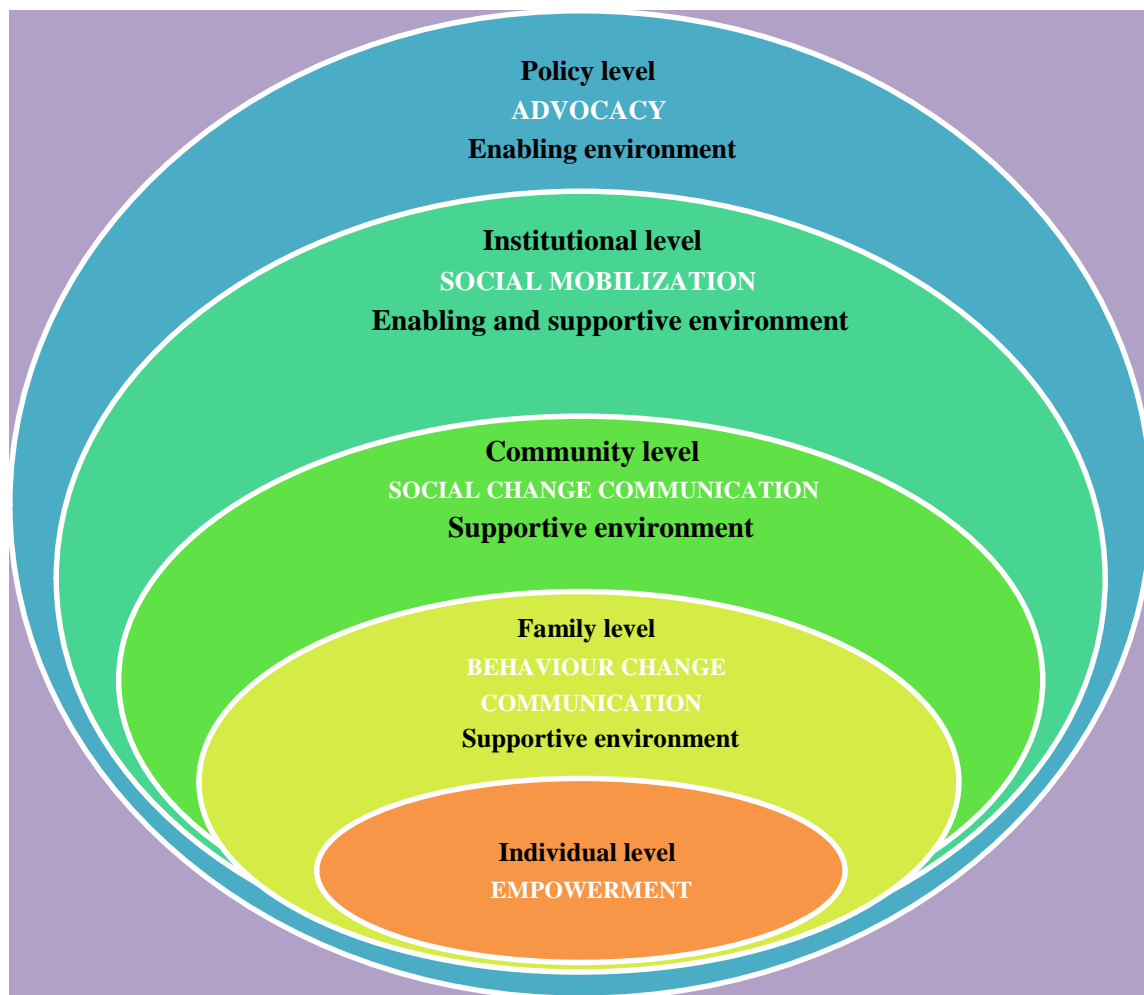


Figure 2. Communication approaches to address vaccine safety issues at five levels of the Socioecological Model of communication.

There are four interrelated and interdependent communication approaches that address and influence the behavior of specific audience groups as described in Table 4.

Table 4: Communication approaches that address and influence the behavior of specific audiences.

Communication Approaches	Description
Empowerment and behavior change communication	Aims to create common understanding and positive attitudes about vaccines and to maintain confidence in immunization among vaccine recipients, parents and guardians. A supportive environment brought about by encouragement from family members, neighbors, friends and community members, and motivational messages from a mix of communication channels – interpersonal, group, community, mass media and social media
Communication for social change	Involves community mobilization, which highlights the important role of community leaders/stakeholders in organizing community dialogues with parents and other target groups for immunization, and in strengthening the capacity of their health-care workers in providing inclusive services. In so doing, they create a supportive environment that motivates all segments of the population to become informed and get involved, to access timely and relevant information about vaccine safety, and to feel confident about the benefits of the immunization program.
Social mobilization	Aims to engage healthcare providers, teachers and students, community leaders, community-based organizations, media, private sector and other EPI stakeholders, partners and allies to initiate actions that support and influence families and communities to sustain immunization practices. The ability of local government authorities, HCPs, teachers, and other social mobilizers to effectively communicate will depend on their own confidence and trust in immunization and vaccine safety. Therefore, their knowledge and perceptions on vaccine safety and immunization play a major role in creating a supportive environment that leads to effective social mobilization.
Advocacy	It is the deliberate process, based on demonstrated evidence, of informing, motivating and influencing decision-makers, stakeholders and relevant audiences to support and implement actions that contribute to the fulfilment of the goals of the EPI. Advocacy is designed to lead to political commitment, improved policies, program, structures, and better allocation of resources to create an enabling environment for EPI.

Media engagement cuts across these four approaches: any communication strategy involves developing, pre-testing and using creative communication materials, and engaging the media across the different communication approaches described above. Owing to their wide reach and fast transmission potential, the media can multiply immunization and vaccine messages swiftly, efficiently, consistently and pervasively, reinforcing messages exchanged through interpersonal, group and community channels. “Media” includes mass media (radio, television, print) and digital social media – the use of mobile phones and the internet for social networking, email, and knowledge access and sharing. To achieve the intended behavior outcomes, communication planners need to apply formative research with specific audience groups to determine the most appropriate combination of interpersonal, group and community channels, mass and social media for a specific message.

3. Risk Communication on Adverse Event Following Immunization

3.1. Significance of Risk Communication on AEFI

Immunization program success depends on high rates of vaccine acceptance and coverage. Occurrence of AEFI may influence the success of immunization program. Although AEFIs are very rare, they are deemed newsworthy and are exaggerated by the media fueling public anxiety. Often, in the absence of any official communication about these serious AEFIs, rumors and self-styled health experts fill the void and take the opportunity to attack the immunization program. This negative news about vaccines can go "viral" on the internet, eroding the public trust. The process of misinformation and disinformation would also be another threat to the whole effort to maintain and sustain the safety of vaccines and vaccination. In many cases, immunization program managers who are otherwise well versed in the technical aspects of vaccination may not be adequately equipped to respond to the communications issues on AEFIs.

An appropriately balanced, professionally evaluated information should be effectively communicated to build trust and confidence at every level. In this regard, effective risk communication must address the experiences, beliefs, values, and attitudes of message recipients and providers. Furthermore, parents, the public, HCPs and the media should be kept informed about the investigation, results and action already taken or going to be taken regarding the AEFIs.

3.2. Goals of Risk Communication on AEFIs

The goal of vaccine risk communication is to achieve a successful and sustainable trust and confidence on immunization programs among stakeholders.

3.3. Sources of Information

Source of information regarding vaccine safety range from factual accounts in scientific publications to anecdotal stories about vaccine reactions. Anti-vaccine lobbyists often use online campaigns by disseminating information against immunization that induce rumors and misinformation jeopardizing the success and sustainability of the immunization program. Besides, lack of adequate information about vaccine safety increases mistrust and confidence loss in health experts, immunization programs and governments. On the other hand, an accurate and credible information positively influences the knowledge, attitudes and beliefs of the population towards vaccine safety.

Information about vaccine safety can be obtained from different sources such as radio and television, printed materials, mobile phone messages, video, local health workers, health education campaigns, visiting experts, online resources and communication networks like social media, religious and community leaders, and parents and guardians.

To obtain evidence-based information about vaccine safety there are many websites that contain credible sources of information. Some of these websites include:

- WHO's Vaccine Safety Net Website
- Global Advisory Committee on Vaccine Safety
- CDC's Immunization Safety Office
 - The Vaccine Adverse Event Reporting System
 - The Vaccine Safety Data Link
 - The Clinical Immunization Safety Assessment Project
- Vaccine Manufacturing Industries Website
- UNICEF Website
- GAVI Website
- EFDA Website
- MOH Website

In addition to using data from the above sources, findings from clinical trials, recommendations (reports) from EFDA and MOH, guidelines, medical reports, published studies, and visiting experts from national, regional, and charity organizations can also be used as a source for vaccine safety.

3.4. Communication of Only Reliable Information

These days anyone can broadcast his/her opinions and views on nearly any subject, including vaccine safety. The information provided need to be acceptable, meaningful, memorable, understandable and relevant for the audience. However, no matter how sound the contents of information may appear to be, all provided information might not be reliable, as bias and opinion compromise even recent information's objectivity and trustworthy. In general, information from a recognized author and/or presented by a reliable publisher is more credible than anonymous information published by a commercial source. Therefore, all HCPs must carefully evaluate the reliability and validity of the information before communicating to clients, patients or professional colleagues.

When evaluating the reliability and accuracy of the information, the following questions should be taken into account.

- Is the author a properly trained expert in the field he or she is commenting on?
- Is the source peer-reviewed, meaning, is it agreed upon by multiple credentialed members of the same field?
- Are the findings conclusive?
- Is the association noted as "causal" or "correlated"?
- Was the sample large enough to provide stable and projectable data?
- Who funded the research and why?

It might be important to seek advice from an expert who is qualified and trained in literature evaluation and/or experts from the MOH or EFDA. If appropriate expertise is limited or inaccessible, obtain guidance from international sources, such as the Global Advisory Committee on Vaccine Safety or WHO's Vaccine Safety Net.

Communicating only reliable information that is accurate, and up to date, supports immunization program in several ways:

It ensures that up-to-date vaccination policies and procedures are applied at every level

It facilitates effective management of rumours and community concerns arising from poor science or misleading reports in the media

It supports the detection, investigation and decision-making about actions needed in response to new safety concerns, which may originate from other places/countries or may occur during the introduction of new vaccines.

3.5. Challenges to Effective Communication

Challenges for effective communication include:

- Faded memories of the threats to health and life posed by vaccine preventable diseases (VPDs) due to decline of childhood infections and deaths from VPDs
- Views of parents on VPDs
- Some parents may feel that exposing a child to even a small potential risk from vaccination is unnecessary
- Negligence of HCPs to provide necessary information before, during and after immunization
- Absence of clear and standardized guideline on communication of AEFI

- Requirement of different skills, awareness appraisal and age-appropriate language and dialect to overcome information gap to deal with the different target groups
- Mass campaigns or supplemental immunization activities as shown in Figure 3.
 - Due to immunization via mass campaign, adverse events may be more noticeable to staff and to the public and contribute for the crisis.
- Presence of different views and personal experiences such as religious belief, social context, distrust of medical system, fear of being injected with a substance derived from disease-causing organism, past adverse event experience, and feeling of intimidation
- Overcoming established attitudes, values, beliefs, behaviors & preconceived perceptions about immunization
- Lack of reliable source of information about immunization risks
- Context of communication: communicating the risk considering the actual vaccine and societal acceptance
- Lack of adequate resources such as experts and logistics in relation to mass communication
- Variety of interests from individuals, groups or members of society concerning the benefits and risks of vaccination
- Lack of integration of stakeholders in the communication process and campaign for consistent and standardized immunization information dissemination for the community
- Infodemics: Information overload, unfiltered information, misinformation and disinformation about the risks and crisis of AEFI
- Information gap or lack of information from a variety of media suitable according to user's media preference (such as mainstream, electronic, social or digital media) taking into account of their media access

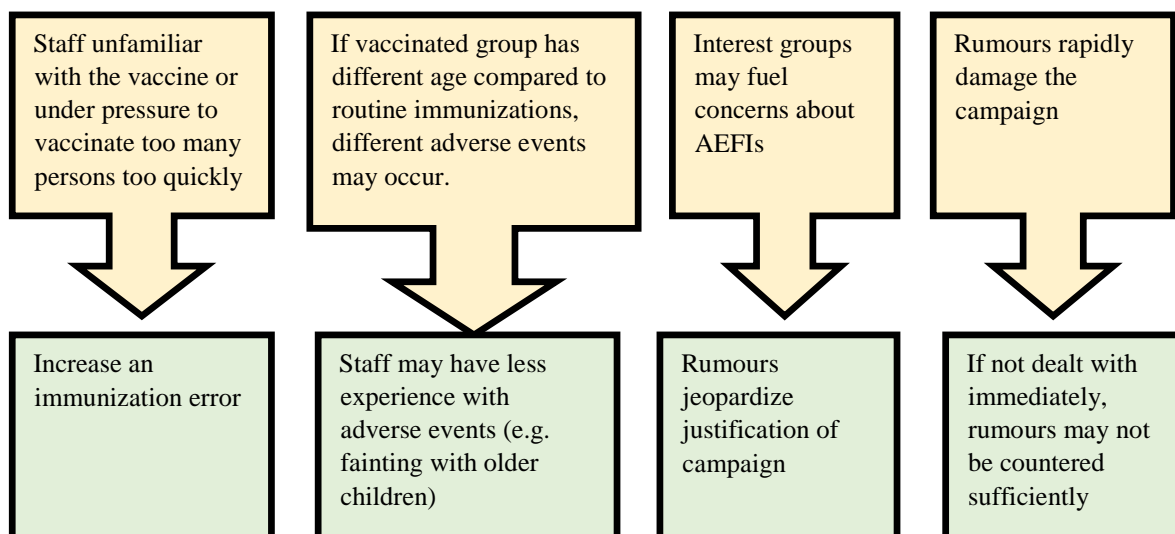


Figure 3. Common safety issues or concerns related to mass vaccination campaigns.

3.6. Communication around AEFI

An AEFI, whether real or perceived, can easily become a crisis situation if not managed properly and proactively. Thus, an exhaustive preparation for communication around AEFI is important to address any event capable of weakening trust in vaccines and immunization program.

When communicating an AEFI technical/academic terms and long words or sentences must be avoided. During communication, the points of communication should be simple, specific and with appropriate local languages. Communicating around AEFI is essential in at least three situations, namely:

- Explaining properly the benefits and expected AEFIs of a recommended vaccine
 - Voluntary exposure to risk
 - Familiarity with the vaccine risk
 - Familiarity with the disease risk
- Addressing public concerns and upcoming or persistent rumors about vaccine safety
- Preparing to address vaccine safety crises if and when they occur by using standard guidelines for managing vaccine crises and AEFI

3.6.1. Communication before the Occurrence of AEFI/Vaccine Safety Crisis

Careful communication before the occurrence of a vaccine safety crisis or AEFI ensures that people are less likely to respond entirely negatively when an issue does arise. Furthermore, accurate and timely communication encourages informed decision-making, positive behaviors and public trust.

Thus, communication should start before the vaccine is even rolled out and continue throughout the vaccination campaign. Some principles to keep in mind as you carry out this ongoing communication are as follows:

- **Communicate with openness and transparency**- Ensure that the following points are addressed:
 - What AEFIs are and why they are being monitored.
 - The role of trials in the evaluation of vaccine safety and efficacy.
 - What is known about safety, known AEFIs and their rates during vaccine trials and rollout so far.
 - What we know now, where uncertainty remains and what is being done to fill information gaps.
 - Plans for ongoing monitoring, detecting and managing of AEFIs and safety signals.
 - The benefits of the vaccine.
- **Do not overpromise**

No vaccine is 100% safe. Any overconfidence about risk estimates that are later shown to be incorrect contributes to a breakdown of trust among people involved.
- **Acknowledge uncertainty**
 - Admit uncertainty of AEFI bearing in mind that with new vaccines like the ones for COVID-19, there is a lot that is still unknown.
 - Communicate what you do not know as well as what you know.
 - Investigate AEFI fully and keep the community informed. Avoid making a premature statement about the cause of the event before the investigation is complete.
 - If the cause is identified as immunization error related event, it is vital not to lay personal blame on anyone, but to focus on system related problems that resulted in the immunization error(s) and steps being taken to correct the problem.
- **Prime people to expect that they may see or hear misinformation**

Encourage peoples to seek information from reputable sources and not to spread the misinformation further

3.6.2. Communication during AEFI/Vaccine Safety Crises

Communicating about an AEFI during a potential crisis can make people feel uncomfortable; our first instinct may be to try to ease community concerns and reassure people. However, it is essential that we are open and transparent about what is happening and that we are proactive in communicating ahead of others in order to build and maintain trust. Lack of honesty and withholding information, on the other hand, can erode trust. In this digital age, news travels fast. If you do not announce the issue yourself, someone else will, and they will get to frame the story to suit their own objectives. The following principles can have tremendous influence on how the issue is perceived and contribute to build trust.

- **Communicate first:** The response provided during the first hours and days of a crisis is fundamental and defines the development and final impact that a crisis can have on the community's trust in vaccines. People are more likely to believe the first source and message that they receive. Even if little information is known at this point about the AEFI or crisis, communicating early will increase credibility and trust. Even though first communication to the society regarding the safety issue in hand is important, special emphasis should be given for the consequences of the communication on the society and the impact of the information on the health system of the country.
- **Be frequent in updating the public:** Regularly update the public about progress related to the situation and communicate new evidence and useful information through the appropriate media such as mainstream media (TV, Print media, Radio), digital media (websites and streaming channels), social media, mobile messaging, direct lines of communication with the responsible authorities, etc.). It is recommended to update the target message for the public daily and to update contemporary messages weekly to be incorporated with latest researched data from its credible and reliable source. Let the community know when you will share updated information and always fulfil that commitment, even if no new information is available. Continue to update the public with short and to the target messages frequently can be effective.
- **Be transparent and honest about what has happened:** In the initial phase, it is fundamental to maintain a high level of transparency in internal communications (working group) and external communications (with the public). Although not all information is available at this time, it is important to communicate what is known and what actions have been undertaken to

obtain more information on the event. Be open about what is not yet known and what you are doing to find out more information.

- **Avoid over-reassuring people.** For example, even if you mention that most AEFIs turn out not to be caused directly by the vaccine, also acknowledge that serious AEFIs may occur, which is why there are safety monitoring systems in place.
- **Be empathetic:** It is very important to express our sincere support for the people affected by the event. Recognize the public’s concerns and fears regarding the situation. Different behaviors related to social, cultural, ideological, and religious determinants and risk perception should be respected. In this context, it is important to prepare messages to close the gap between experts (authorities and health workers) and the public. Show that you care and that you understand that people may be concerned.
- **Respond to commonly raised questions and concerns:** If the situation so requires, it is important to maintain a frequent public presence and favor proactive responses based on the concept of bidirectional communication (participatory dialogue in which health authorities and the public participate). Enhance capacity to answer questions coming in through trusted influencers (e.g., health care workers) and two-way platforms such as hotlines or social media (e.g., through surge staffing and provision of frequently asked questions). Even if the answer is just to say, ‘we don’t know that yet’ Address misunderstandings and rumors.
- **Let people know how they can get in touch for further information or to raise concerns** (such as through a hotline, credible websites (WHO, CDC, UNICEF, EFDA, EPHI and FMOH) and other recognized organization communication platforms.

3.6.3. Communication with Stakeholders

Vaccine safety information needs to be shared by MOH and/or EFDA in collaboration with other stakeholders to ensure the dissemination of correct information and thereby ensuring the smooth functioning of the national immunization program. This may be done at two stages: sharing preliminary information at the initial stage and sharing the final data/report after completion of investigation/causality assessment. There are many parties to whom communications should be tailored to meet their particular needs. These include:

-) Ministry of Health
-) Ethiopian Food and Drug Authority

-) Ethiopia Public Health Institute
-) National and sub national coordination platforms (safety advisory committee and AEFI task forces)
-) Indigenous social institutions (*Idir, Equib*), religious and cultural platforms.
-) Parents and the community
-) Health care workers
-) The media
-) National and local government authorities, politicians
-) Professional associations, higher education institutions, hospitals and health facilities
-) International and local partners like WHO, UNICEF, CDC and others
-) Vaccines and vaccine supplies manufacturers and others

The principles of communication that are commonly applied during communication with stakeholders include the need to:

-) Listen empathetically to concerns
-) Reassure and support but do not make false promises
-) Communicate frequently
-) Build up and maintain the relationship among the stakeholders
-) Inform about possible common adverse events and how to handle them
-) Prepare factsheets on adverse events and other key information for all audiences
-) Continuously communicate during the investigation period to assure understanding of both the situation and the risk-benefit of vaccination.
-) Do not lay blame, especially not on the HCPs, but focus on the correction and quality of the immunization system.

3.6.4. Communication with Parents and Community

In communicating with the community, it is useful to develop links with community leaders and the peripheral HCPs so that information can be rapidly disseminated. Maintaining lines of communication with the community is important throughout the investigation. Upon completion of the investigation, the cause of the event(s) needs to be communicated to the community. This communication must include information about the steps being taken to remedy the situation and to prevent a recurrence.

Key points to consider when communicating with the parents/guardians/relatives of the recipient and the community:

-)] Listen empathetically to parents and their concerns in order to identify:
 - Capabilities and concerns of target audience - what do they need to understand to make informed decisions?
 - Consider the age range of your audience
 - Take into account differing educational levels
 - Mind language problems
 - Respect gender differences
 - Take differing religious contexts into account
-)] Reassure and support the parent or recipient but do not make false promises
-)] Assist the parents/guardians for hospitalization, if necessary
-)] Communicate frequently with the parents/guardians regarding the progress of the patient
-)] Prepare a factsheet on adverse events for parents, community, health staff and media
-)] Build up and maintain relationship among health staff, community, and the media
-)] Inform individual parent about possible common adverse events and how to handle them
-)] Continuously communicate with parents and community during the investigation period to assure understanding the risk-benefit of vaccination
-)] Do not blame the HCPs but focus on the correction and quality of the EPI system

3.6.5. Communication with Healthcare Professionals

Despite the fact health staff should have some training or at least experience in communication skills by the nature of their work, it is important to specifically address communication with health workers in order to resolve issues with vaccine hesitancy that may arise in this group when communicating with public health authorities, regulatory bodies and investigators. Recommendations in this regard are summarized as follows:

-)] Provide transparency and ensure that HCPs are aware on policies, guidelines and other working documents regarding vaccination and the approval and quality control of vaccines
-)] Maintain a fluid dialogue between HCPs, health authorities, and regulatory bodies
-)] Communication should be among all levels of health authorities involved
-)] Reassure the staff of their knowledge, ability, skills and performances

-) Do not blame the HCPs but focus on the improvement for coverage correction and quality of immunization program
-) Keep them updated on investigation process, progress and findings
-) Support HCPs with tools and training specifically designed to address vaccine hesitancy
-) Empower individuals in decision-making
-) Focus communication interventions on empowerment: avoid criticizing hesitancy and focus efforts on empowering HCPs with knowledge, providing them with tools for them to answer their patients' questions
-) Create awareness about collective benefits of vaccines to reduce morbidity and mortality of the VPDs, and economical cost effectiveness
-) Provide information on the right to be protected against VPDs and on the collective duty to prevent suffering and disease in others, especially in patients who are cared for by health staff (collective immunity)
-) Highlight the risks associated with vaccine rejection
-) Communicate the importance of differentiating relative risks, i.e., the major risks of disease versus the minor risks of vaccines or vaccination.
-) Talk about the minimal risks associated with vaccination
-) It is important to be transparent and appropriate in acknowledging adverse events, and to report on the evidence with proper perspective
 - In order to maintain and build trust, mistakes that may have been made in the past (even if they are mistakes made many years ago in other countries) must be acknowledged, as well as the slight but real possibility of adverse events in the present. Current successes should also be mentioned, such as the eradication of smallpox or the elimination and control of other diseases such as polio.
-) Explore, review and presents about scientific facts and evidences related to vaccine AEFI to create awareness, tackle rumors, misconceptions and increase vaccine uptake
-) Show commitment to vaccination: Evidence confirms that those who administer vaccines communicate more successfully when they use the presumptive approach (i.e., presuming that HCPs will receive the vaccine) rather than the participatory model (asking HCPs their opinion about being vaccinated)

-) Develop and utilize vaccine hesitancy assessment tools to identify and take appropriate interventions at each level
-) Using screening tools to detect vaccine hesitancy helps tailor messages and communication strategies to address concerns that are specific to HCPs and provide information on areas where concerns or misconceptions exist
-) Provide adequate information about vaccines benefits regarding to reducing morbidity and mortality from the VPDs and AEFI
-) There are positive messages specifically targeting HCPs, which can improve their attitude towards vaccines. For example: “Vaccines protect not only the HCPs who receive them, but also other vulnerable groups, such as patients with cancer or immunodeficiency”
-) Ensure safety of local HCPs and vaccinator as they might become targets of hostility or be attacked by affected community members

4. Communicating with Media

The media is an important gateway to inform the public and shapes their view and attitudes towards vaccines and immunization. Conventional media coverage and the rapid growth of the internet and social media have made it easier to find and disseminate immunization-related concerns including misperceptions. In the long-term, building partnerships with media is key to keep the public regularly informed about immunization and its benefits, to motivate families and communities to make use of immunization services, and to advocate for continued and increased investments in immunization.

Different media channels exist for communicating with the public. The media channels (mainstream media, social media and community media) play an important role in public perception through dissemination of timely and genuine information regarding vaccine safety rumors and public anxiety on the issue. Selection of a channel or mix of channels appropriate to the specific audience that you aim to reach is important.

Understanding what the media want from a story will assist communication with them. In certain situations, media coverage can lead to public concern about immunization. In these situations, it is important to coordinate with professional organizations, HCPs and workers before responding to or addressing the media. The coordination should include preparation on dealing with public concern on this issue, to minimize any potential harm to the immunization program. It is also useful to have other groups and individuals that merit public respect and authority to publicly endorse and strengthen key messages.

Communicating with media requires particular skills as reporters are trained professionals and their perspective must be properly understood. The media are interested in stories that will attract attention. Dramatizing and personalizing events can both highlight success as well as create a sense of panic about an AEFI with a particular vaccine product regardless of whether they are either unrelated to immunization (coincidental) or a localized immunization error. Another important fact is that media want early responses to their questions. Therefore, waiting for the conclusion of an investigation is rarely possible. Information may need to be disseminated early and often, and it is vital to be honest about what is known and what is not known, and to avoid being evasive and unresponsive.

As health topics are popular among the public, the media can be leveraged positively for the success of immunization program. The media can be helpful allies in communicating public health messages and in reminding the public about the benefits of immunization. Thus, building a personal relationship with key health reporters will help them to understand the public health perspective.

4.1. Media Planning for Communication

Effective communication with the media requires efficient coordination, communication plan, trained personnel, budget and practiced responses to potential issues around AEFI. The communication plan should be in place before a new vaccine is introduced, before and during an immunization campaign and as part of an ongoing communication support to routine immunization program. Table 5 lists the elements of a good media plan for communication.

Table 5: Media plan for communication.

Elements	Details of Activities
A database of journalists	<ul style="list-style-type: none"> • A list of print and electronic media journalists covering health (local, national, international) with contact information • Use of a database where updating can be done immediately • Updating regularly any changes in the media list
Information packages	<ul style="list-style-type: none"> • 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 nationally • The information package needs regular updating • Provide an updated information package with documents including frequently asked questions on immunization in general, for specific disease and AEFI (Factsheet or a technical brief on a specific VPDs etc.) • Recent updates: statistics, progress made in country, the Sub-Saharan Africa, globally • Contact addresses of spokespersons (experts) in the MOH, regulatory authorities and other stakeholders

The draft media release	<ul style="list-style-type: none"> • Must specifically answer the six W's for journalists: <ul style="list-style-type: none"> • Who is affected/or responsible? • What happened? What is being done? • Where did it happen? • When did it happen? • Why did it happen? • Will it happen again?
Information specific to media characteristic	<ul style="list-style-type: none"> • Local media: read and believed by more people in the community than national media • National media: has a wider reach and influences national agendas • International media: can influence national agendas
A spokesperson system	<ul style="list-style-type: none"> • The MOH and/or EFDA <ul style="list-style-type: none"> ○ identify an appropriate spokesperson(s) ○ may delegate this responsibility if deemed necessary ○ share contact details of spokesperson ○ ensure spokesperson(s) has experience or training in dealing with the media

Note: The MOH and/or EFDA shall be responsible for communicating the AEFI to media, public and stakeholders to limit the possibility of conflicting messages coming from different sources and unauthorized channels.

Other Tips for Media Communication

Media interest is usually greatest initially when relatively little is known. In this environment, rumors can flourish and the potential for harm is huge. A media conference, convened early even if there is only very limited information to give, can provide a uniform message to all at the same time, thus avoiding any conflicting messages. This will also prevent the circulation of rumors and build a relationship with the reporters. At the end of the press conference, advise that a further conference will be held within a day or so, at which time full details of the event and the investigation will be provided. A media or press conference requires expert planning and expert communications input to ensure that messages are clear, unambiguous and that all expert spokespersons are well prepared.

Professional associations and other stakeholders may have better acceptance in a crisis situation. Providing them an opportunity for their unified support for immunization and the approach being taken to handle/investigate the problem can help considerably. Moreover, using all potential media that can reach all community members and targeting audience is also crucial to achieve communication objectives.

4.2. Preparing Key Messages

Key messages are phrases or short statements designed to remain in the minds of the viewers/readers for extended periods. They capture the essential information you want to convey and can function as “sound bites” during on-camera interviews or as headlines in a newspaper story and create a ‘word picture’ (a graphic or vivid description) to get the message across. Having key messages prepared in advance will allow you to communicate quickly and effectively with your audience. Ideally, the media and the public will remember and also repeat your key messages.

The key messages should be kept to a minimum and should include some of these facts:

- The benefits of immunization in preventing certain diseases are well proven. VPDs caused millions of deaths and/or disabilities before the introduction of vaccines, and that situation would return without continued use of vaccines
- It is risky not to immunize children and communities (risk of disease and complications)
- Vaccines may or do cause reactions but these are usually mild, self-limiting and very rarely cause serious or long-term problems
- Immunization safety is of paramount importance and maintaining confidence in immunization programs depends on it
- Any suspicion of a problem is investigated (an advantage of well-established immunization safety surveillance), and is remedied

There are many sources of key messages such as the aforementioned ones. They should be consulted and tailored to the local culture and understanding.

It is rarely necessary to suspend an immunization program during an investigation unless it is obvious that there is a problem with the vaccine that warrants such drastic steps. The vast majority of situations prove to be coincidental or due to a very localized problem (depending on type of event), and the immunization program must continue to keep the population safe from disease.

In an interview situation, make sure that you state your key messages early on (long interviews may be cut). Even if you are not asked a question that requires your key messages in the answer, make sure you weave them in somehow.

4.3. Preparing a Press Statement/Briefing

It requires good judgment to decide whether to transmit a message by issuing a printed version of the information (a press release) or provide it through a live presentation (a press/media briefing). The press release benefits from the time you spend on getting the details right. It should be a team effort. It can be distributed widely and cannot easily be misquoted. You have much more control over the information in this way, but it is not as dynamic as a live conference. A press release can be “embargoed” until a given date so that you can time its release for some strategic impact.

The press release needs to include a complete account of events (in terms that will be understood by people not familiar with health services or immunization), framed in their appropriate context (i.e., an isolated event, a coincidental event) so that it limits the concern from spreading about the event to the immunization program in general.

4.3.1. Points to be Considered during Preparation of Press Release

An effective press statement/release must specifically answer the six W’s (Table 5) and should include a one-page (400-500 words) account written in short sentences outlining:

- A complete account of the event, framed in its context (e.g., an isolated event or a cluster of AEFI, or a coincidental event)
- No technical jargon
- An outline of actions taken or planned (such as the AEFI investigation)
- A description of the possible cause of the event (when identified with reasonable certainty, not just a working hypothesis)
- An assurance that corrective action will be taken, and what steps have already been taken
- Reference to any relevant publication or web site for further information
- Sender’s name and spokesperson’s details
- Repetition of key message

By following a standard press release structure as shown in Figure 4, you are ensuring that a reporter knows how to find what they are looking for in your release, and allowing them to quickly determine if they want to cover your announcement.



Figure 4. Press release structure (source: <https://prowly.com/magazine/how-to-write-press-release-guide/>)

4.3.2. Steps in Preparing for a Press/Media Briefing

Press/Media Briefing may need to be given if AEFI is being reported extensively and widely and there is a need to provide accurate facts and de-sensationalize the story. The following steps should be considered when preparing a press/media briefing

- Identify the spokesperson(s)
- Identify the key messages you want to communicate
- Develop “sound bites” that you can say naturally as part of an interview
- Prepare a media kit for reporters and other community leaders, which consists of a press release with all the essential information; supplementary background information, such as benefits of immunization, and questions & answers that respond to the likely concerns of the public
- Check out the physical set-up of the room before speaking
- The room size, acoustics, microphone and audio-visual set-up
- Choose a relevant location e.g., a laboratory

- Focus your presentation on one or two main messages and repeat these in different ways again and again
- Do not turn your presentation into facts and data where your main message could get lost
- Practice giving your presentation before a colleague who can offer comments on how to improve your delivery
- Make a good first impression
- Be confident, make eye contact with your audience and change your pace, tone and hand gestures at key points
- Use powerful visual aids to emphasize main points
- Make sure overheads or slides can be quickly understood
- Avoid complex graphs, small type, or too many words

N.B: Your enthusiasm and concern about the issue will often be remembered more than the words you say

Following a press/media briefing by MOH and/or EFDA, health reporters should disseminate accurate and balanced information to the public. Thus, reporters should consider the following tips during their report on vaccine related information.

- Don't just report the topline
- Don't trust data automatically
- Use trusted and reliable sources
- State the source
- Define the terms
- Use clear language
- Explain the stage
- Disclose the side effects
- Use appropriate imagery
- Remind everyone the benefits of the vaccine

4.4. Communication on Social Media

Today, much of human health-related communication occurs on digital media, mainly social media. Moreover, many HCPs are on social media, where they can interact with others to help them resolve vaccine concerns to strengthen confidence and contribute to mitigating rumors or false information on this topic. The following points should be considered while interacting on social media:

- Address fears and doubts through dialogue and by disseminating scientific evidence
- Share professional accounts (e.g. scientific associations, official university accounts, your official accounts)
- Combine information and scientific evidence with entertaining messages to facilitate interaction and understanding (e.g. sharing videos or infographics)
- Keep patient information confidential, and never share on social media
- Share personal stories (e.g. talk about when you, your own children or family members were vaccinated) if possible

4.5. Follow-Up Actions with Communications/ Media Management Post AEFI

In any communication intervention, it is essential to develop a system to monitor the process and evaluate the results. Even if a crisis situation is short-lived, for instance if there was no apparent effect of an AEFI on local immunization coverage, we should be able to assess our communication plan and if needed modify the strategies in light of the experience. The key points to be included during follow-up activity with communications of AEFI to media

- include communication indicators in the immunization monitoring plan
- ensure that data collection and analysis include qualitative indicators which provide information about attitudinal and behavioral related information
- share immunization data with health educators and engage them in data analysis, micro-planning and work plan development

Moreover, during follow up activity development, keep the following points into consideration.

- **Keeping promises:** If it has been promised that updates about the investigation will be disseminated, make sure that this is kept by the promised date. If the findings have been delayed, ensure that the delay is communicated.

- **Providing answers to unanswered questions:** If a question cannot be answered for any reason, get back to the requestors with the answers as soon as possible.
- **Keeping the public informed about subsequent developments:** 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 them informed through a press release to the media or other locally appropriate means.

Ministry of Health and/or EFDA shall have the responsibility to monitor all claims and authenticity of publications on AEFI and shall take appropriate measures including but not limited to:

- Analyze rumor, its level and potential to cause damage
- Anticipate how situations might evolve following response: prepare before responding
- Deal with simple mistakes in reporting with a simple solution
- If the rumor is confined to a small audience, correct it within the 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
- Plan how to prevent future rumors

The methodology employed for media monitoring (broadcast, print and electronic media) is both qualitative and quantitative. Radio and television are monitored during prime time viewing hours while newspapers and magazines are monitored daily to assess the coverage of vaccine safety and crisis communication.

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