VACCINE SAFETY COMMUNICATION

Guide for immunization programme
Managers and national regulatory authorities
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PREFACE

The aim of this document is to help immunization programme managers and national regulatory authorities to address the need for proactive and responsive communication on vaccine safety.

In 2013, the Expanded Programme on Immunization (EPI) unit of WHO Regional Office for the Western Pacific initiated the development of vaccine safety communication guidelines. Dr Teresa Stuart Guida (Lead author), Dr Md. Shafiqul Hossain (Technical & Secretariat guide), Dr Shin Jinho (Technical & Secretariat guide), Dr Ananda Amarasinghe (Editor) and Dr Sergey Diorditsa (Advisor) developed the guidelines.

The Regional Office for the Western Pacific acknowledges the support received from other team members in the EPI unit and from EPI focal points at country level in the Region. The Regional Office is also grateful for the valuable comments, input and support received from the Global Vaccine Safety team members from WHO Headquarters, from participants and facilitators who attended the training workshop on communication capacity-building for immunization held in Manila from 14 to 16 May 2014, and from many other individual vaccine safety and communication experts in the Region and worldwide.
### ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>AEFI</td>
<td>adverse event following immunization</td>
</tr>
<tr>
<td>BCG</td>
<td>Bacille Calmette-Guérin vaccine</td>
</tr>
<tr>
<td>CIOMS</td>
<td>Council for International Organizations of Medical Sciences</td>
</tr>
<tr>
<td>CSO</td>
<td>civil society organization</td>
</tr>
<tr>
<td>DTP</td>
<td>diphtheria tetanus pertussis vaccine</td>
</tr>
<tr>
<td>EPI</td>
<td>expanded programme on immunization</td>
</tr>
<tr>
<td>FAQ</td>
<td>frequently asked questions</td>
</tr>
<tr>
<td>GVAP</td>
<td>Global Vaccine Action Plan 2011–2020</td>
</tr>
<tr>
<td>GVSI</td>
<td>Global Vaccine Safety Initiative</td>
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<tr>
<td>HCP</td>
<td>health-care provider</td>
</tr>
<tr>
<td>ICT</td>
<td>information and communication technology</td>
</tr>
<tr>
<td>IPC</td>
<td>interpersonal communication</td>
</tr>
<tr>
<td>KAP</td>
<td>knowledge, attitude and practice</td>
</tr>
<tr>
<td>LNA</td>
<td>learning needs assessment</td>
</tr>
<tr>
<td>M&amp;E</td>
<td>monitoring and evaluation</td>
</tr>
<tr>
<td>MMR</td>
<td>measles mumps and rubella</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>NGO</td>
<td>nongovernmental organization</td>
</tr>
<tr>
<td>NRA</td>
<td>national regulatory authority</td>
</tr>
<tr>
<td>NIP</td>
<td>national immunization programme</td>
</tr>
<tr>
<td>NITAG</td>
<td>National Immunization Technical Advisory Group</td>
</tr>
<tr>
<td>PSA</td>
<td>public service announcement</td>
</tr>
<tr>
<td>Q&amp;A</td>
<td>question and answer</td>
</tr>
<tr>
<td>RI</td>
<td>routine immunization</td>
</tr>
<tr>
<td>SMART</td>
<td>specific, measurable, attainable, relevant and time-bound</td>
</tr>
<tr>
<td>SMS</td>
<td>short message service (through mobile phones)</td>
</tr>
<tr>
<td>SOP</td>
<td>standard operating procedure (in dealing with media)</td>
</tr>
<tr>
<td>SPC</td>
<td>summary of product characteristics</td>
</tr>
<tr>
<td>TT</td>
<td>tetanus toxoid vaccine</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
</tr>
<tr>
<td>VRE</td>
<td>vaccine safety-related event</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
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</table>
PURPOSE OF THIS GUIDE

This communication guide is intended to help expanded programme on immunization (EPI) programme managers, national regulatory authorities, health promotion personnel and health-care providers in the Western Pacific Region, who are increasingly called upon to plan and respond to communication around vaccine safety.

This guide enables effective planning and implementation of proactive communication actions to promote understanding of the importance of vaccines in preventing illness and preventable deaths, and raises awareness of vaccine risks and perceptions of risk. The guide also covers prompt and effective communication in response to an adverse event following immunization (AEFI) or any other vaccine safety concerns that threaten public trust in a vaccine and compliance with the immunization programme.

The guide offers systematic, scientific and practical approaches, tips and tools to help strengthen the capacity of the various stakeholders in planning, implementing, managing, monitoring and evaluating, and documenting communication interventions around vaccine safety issues and immunization.

It is paramount that all programme managers, regulatory personnel and health-care providers – who are frontline communicators in their communities – are knowledgeable about all aspects of management and response to vaccine safety issues and know how to use strategic communication effectively to maintain the public’s confidence in vaccines and in the national immunization programme.

This communication guide is designed to accompany the Immunization Safety Surveillance Guidelines produced by WHO Regional Office for the Western Pacific (revised 2014). The information in the guide may be adapted to different contexts and needs. A list of websites, references and links to other communication guides and tools is also provided, including documentation on communication initiatives on vaccine safety issues from other countries. It is important that users understand the logic, principles and concepts introduced in these guidelines so that they are able to guide, adapt and apply these concepts in national and local settings.
EXECUTIVE SUMMARY

Vaccine safety communication is an essential component of immunization services and programmes. Even before a vaccine safety issue occurs, programme managers and national regulatory authorities, working with a communication task force, must be ready to engage effectively with all concerned groups – parents and guardians, communities and the media – through strategic communication. Implementing a well-planned communication strategy will help to maintain the public’s confidence in vaccines and in the national immunization programme (NIP). An effective communication strategy can also contribute to sustaining high national immunization coverage and prevent a resurgence of vaccine-preventable diseases.

This guide offers practical approaches, tips and tools to enable programme managers to proactively engage stakeholders in planning, implementing, managing, monitoring and evaluating, and documenting communication interventions around vaccine safety issues and immunization. The eight chapters will help the communications team:

1. Explain the importance of vaccine safety communication and the six types of vaccine-related events (VRE) that negatively impact on national immunization programmes (NIP).

2. Plan strategies for vaccine safety communication that use an appropriate combination of communication for behaviour change, social change communication, social mobilization and advocacy. Engage the media across these four communication approaches.

3. Set up national and subnational systems for communication on vaccine safety, building partnerships with government agencies, professional organizations, academia, private sector, civil society organizations (CSO) and nongovernmental organizations (NGO).
4. Develop a communications plan for vaccine safety, which will include:

- commissioning a communication analysis and gathering information about the community’s knowledge, attitudes and practices (KAP), barriers/bottlenecks and opportunities to sustain confidence in immunization, particularly after a vaccine issue has occurred;
- being clear about roles and responsibilities – who will do what, how and when;
- strengthening the communication skills of partners, health-care providers, educators and the media on vaccine safety issues;
- designing and preparing appropriate materials to support interpersonal and media communication; and
- preparing a timeline for communication actions before, during and after a vaccine safety issue.

5. Prepare a media engagement plan.

6. Implement the communication plan by:

- responding swiftly using the coordinated communications plan and media plan;
- in the event of a rumour, assessing the origin and being prepared to respond with potential rapid assessment and communication approaches; and
- working through multiple channels.

7. Plan and conduct monitoring and evaluation to track progress and determine results, both achieved and not achieved.

8. Document and share lessons learnt, good practices and innovative approaches in communication actions on vaccine safety issues.
Immunization is vital to protect individuals, particularly children, from vaccine-preventable diseases. Since the expanded programme on immunization (EPI) was launched globally in 1974, it has provided enormous health and economic benefits to individuals, their families and society. Every year, vaccinations protect millions of children from diseases and disabilities and prevent approximately three million deaths from diphtheria, neonatal tetanus, pertussis (whooping cough), measles, and childhood tuberculosis (WHO and UNICEF, 2013).

Although the 37 countries and areas in the Western Pacific Region vary in demography, geography, sociocultural and economic status and immunization service capacity, the World Health Organization (WHO) recognizes a common need to strengthen communication capacity in the Region, make available documented experience, share lessons learnt and design proactive strategies. Improving communication capacity involves effectively engaging all stakeholders – national and regional policy- and decision-makers, health professionals and academics, United Nations agencies, programme managers, national regulatory authorities, clinicians and academics, health-care providers, media organizations, and families and communities – in communicating vaccine safety issues.

The modern communication environment allows any individual with a negative opinion about vaccine safety issues to voice their views online without professional input. In that context, the challenge for NIPs in the Region is to proactively apply innovative and participatory communication approaches with evidence-based messages.

WHO established the Global Vaccine Safety Initiative (GVSI) with a vision of establishing effective pharmacovigilance systems in all countries, specifically in order to be able to respond to vaccine safety issues promptly and efficiently and with scientific rigour (Box 1). GVSI aims to strengthen national capacities to address public concerns about vaccine safety in a clear, factual and timely manner. GVSI is based on the Global Vaccine Safety Blueprint, a global strategy to build and enhance capacity for vaccine safety of the Global Vaccine Safety Action Plan (GVAP).
Increased investment in strategic communication on vaccine safety supports the goal of NIPs, namely, to protect children from preventable diseases and death, in a sustained and equitable manner and to achieve the fourth Millennium Development Goal of reducing infant and child mortality and morbidity by 2015 and beyond.

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**BOX 1. GVSI: strengthens national capacities to address 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.”

Source: WHO, 2015

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**BOX 2. Recommendation to improve communication and social mobilization in EPI**

“While the donor organizations place much emphasis on delivering vaccines and technical support, communication elements of vaccination campaigns are overlooked. EPI heads in some countries suggest that UNICEF and WHO should commission technical reports to investigate social mobilization for EPI. Also, appoint a panel of experts to make recommendations to the country officials about how to improve communications.”

Source: UNICEF, 2001
1.1 UNDERSTANDING VACCINE SAFETY-RELATED EVENTS

Vaccines used in NIPs are extremely safe and effective. But while vaccines are safe, no vaccine is entirely without risk and no immunization programme is entirely free from vaccine safety issues. These issues need to be addressed through proactive communication.

There are six types of vaccine safety-related events (VRE) that can have negative impacts on NIPs and therefore require proactive communication strategies:

1. Adverse events following immunization (AEFI);
2. Temporary suspension of a vaccine;
3. Vaccine recall;
4. Replacement of a vaccine;
5. New research findings related to vaccines or immunization; and
6. A report in the media, or rumour about a vaccine.

Adverse events following immunization (AEFI)

Adverse events following immunization (AEFIs) can range from non-serious events, such as redness of the skin around the injection site or low-grade fever, to rare serious events. The Council for International Organizations of Medical Sciences (CIOMS) and WHO define an AEFI as “any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine” (CIOMS, 2012). A reported AEFI may be due to the vaccine, the immunization process or a coincidental event that is only temporally associated with immunization (Table 1). However, regardless of the cause, an AEFI can cause such concern that parents refuse further vaccination for their children, leaving their children susceptible to life-threatening and disabling vaccine-preventable diseases.

<table>
<thead>
<tr>
<th>CAUSE-SPECIFIC TYPE OF AEFI</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Vaccine product-related reaction</td>
<td>An AEFI that is due to one or more of the inherent properties of the vaccine product.</td>
</tr>
<tr>
<td>2. Vaccine quality defect-related reaction</td>
<td>An AEFI that is due to one or more quality defects in the vaccine product, including its administration device as provided by the manufacturer.</td>
</tr>
<tr>
<td>3. Immunization error-related reaction (formerly &quot;programme error&quot;)</td>
<td>An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and is thus inherently preventable.</td>
</tr>
<tr>
<td>4. Immunization anxiety-related reaction</td>
<td>An AEFI arising from anxiety about the immunization.</td>
</tr>
<tr>
<td>5. Coincidental event</td>
<td>An AEFI caused by something other than the vaccine product, immunization error or immunization anxiety.</td>
</tr>
</tbody>
</table>
Vaccine Safety

Temporary suspension of a vaccine

Temporary suspension of a vaccine from public use will heighten public attention and concern, particularly among individuals who were recently immunized (and their families), or who are planning to be immunized. This concern will arise regardless of the reason for the suspension. A vaccine suspension in another country may also necessitate a local communication response, especially if the programme uses the vaccine that is being suspended. Messages should describe the reason(s) for the suspension and the decision-making process that will resolve the uncertainty, as well as the safety criteria that must be met before the vaccine programme can be restarted. It is important to explain that suspensions are precautionary, reflecting a cautious, safety-first approach to vaccines, but not necessarily due to confirmed safety or quality issues.

Recall of vaccine

Very rarely, a national regulatory authority (NRA) may have to recall a vaccine for safety reasons, such as finding that the vaccine was contaminated with a chemical or deviated from regulatory requirements after its registration with the NRA. Because they are such an infrequent occurrence and due to the anxiety they cause among the public, vaccine recalls are broadly publicized and therefore always merit a special communication effort.

Vaccine replacement

Like the temporary suspension of a vaccine, vaccine replacement is a measure used to assure the safety, effectiveness and sustainability of the immunization programme. Vaccines are often replaced with updated and slightly reconfigured products. The public may become concerned about a vaccine replacement if they do not understand the reasons why the vaccine was replaced. Reassurance is needed about the purpose of the replacement.

BOX 3. MMR vaccine controversy

“"The measles, mumps and rubella (MMR) vaccine controversy centred on the 1998 publication of a fraudulent research paper in the medical journal, The Lancet, that lent support to the subsequently discredited claim that colitis and autism spectrum disorders could be caused by the combined MMR vaccine.

It was later revealed that the author of the original research paper had multiple undeclared conflicts of interest, had manipulated evidence and had broken other ethical codes. The Lancet partially retracted the paper in 2004 and fully retracted it in 2010. The author was found guilty by the General Medical Council of serious professional misconduct and was struck off the Medical Register in United Kingdom. The claims of this article were widely reported in the media. Vaccination rates in the United Kingdom and Ireland dropped sharply, which was followed by significantly increased incidence of measles and mumps, resulting in deaths and severe and permanent injuries. The scientific consensus is that no evidence links the vaccine to the development of autism, and that the vaccine’s benefits greatly outweigh its risks.”

Source: The Editors of The Lancet, 2010
A media report or rumour about a vaccine

Media articles about vaccine safety range from factual accounts in scientific publications to anecdotal stories about vaccine reactions. There are many sources (internet, newspapers, radio, television) for local and international news about vaccines. Anti-vaccine lobbyists often use online campaigns against immunization. Vaccine safety issues, whether real or perceived, can spread rumours and misinformation, jeopardizing the success and sustainability of the NIP. In some countries, even in the middle of a measles outbreak, allegations about the safety of the measles vaccine sometimes dominated the discussion, over the importance of controlling measles (Pless et al. 2012).

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.

1.2 THE IMPACT OF VACCINE SAFETY-RELATED EVENTS ON NATIONAL IMMUNIZATION PROGRAMMES

Figure 1 illustrates the life cycle of a NIP, showing the impact of a vaccine safety issue such as an AEFI and its possible resolution. 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. People are concerned about controlling the disease. When a vaccine for the disease becomes available, an immunization programme 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 rumours about the vaccine or programme, and some people will stop getting immunized. If many people stop getting immunized, a resurgence of the disease may cause outbreaks.

Through various communication channels, people are reminded that to avoid the disease they should turn back to immunization, which restores people’s confidence in vaccines and the NIP. As a result, vaccination coverage increases once more and disease incidence declines. Ultimately, we hope that enough people get immunized for the disease to disappear altogether. So far this has happened only with smallpox, but it could happen with other diseases, such as polio and measles.
BOX 4. Pertussis and Diphtheria Tetanus Pertussis (DTP) vaccination in Japan

In Japan, vaccination against pertussis began in 1947. By 1974, there were few cases and no deaths. During a national debate about adverse events resulting from smallpox vaccine, news reports of neurological reactions after DTP vaccination gave rise to Japan’s movement against whole-cell pertussis vaccines. Activists alarmed the public with “unbalanced arguments concerning vaccine risks” and claimed that “vaccination would no longer be needed” because “there was practically no more pertussis in the community”. This national debate effectively created “a social problem”. Pertussis coverage for infants fell from nearly 80% in 1974 to 10% in 1976 (as shown in the Figure below). A pertussis epidemic occurred in 1979 with more than 13000 cases and 41 deaths. Japan began replacing whole-cell with acellular pertussis vaccines in 1981. The coverage has since increased, leading to a striking fall in pertussis incidence.
Vaccine safety-related events may be classified as having a low, medium or high impact (Table 2). The impact level can change, depending on how the issue is handled by programme managers and the public’s response. All high-impact events need urgent attention and communication response. Medium-impact events also need a timely response. Low-impact events should be carefully monitored, as these could become a medium- or high-impact event, at which point a prompt communication response would be essential. Maintaining a timely response is a key factor for successful communication in immunization safety (Annex 1).

**TABLE 2. Examples of vaccine safety-related events and their possible levels of impact on the national immunization programme**

<table>
<thead>
<tr>
<th>VRE</th>
<th>LOW IMPACT</th>
<th>MEDIUM IMPACT</th>
<th>HIGH IMPACT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vaccine reactions (AEFI)</strong></td>
<td>Non-serious AEFI reported in the country. e.g. injection site reactions following DTP vaccines.</td>
<td>Isolated serious AEFI; not fatal. e.g. intussusception following rotavirus vaccine.</td>
<td>Fatal or clustering serious AEFI cases within a geographical area or temporal clustering. e.g. clustering of anaphylaxis following a measles mass campaign.</td>
</tr>
<tr>
<td><strong>Temporary suspension of a vaccine</strong></td>
<td>Another country suspended a vaccine which is not used in the country. e.g. Country A temporarily suspends use of HPV vaccine. It has only low impact in Country B, which does not use HPV vaccine at all.</td>
<td>Another country suspended a vaccine (or vaccine brand) which is used in the country. e.g. Country A temporarily suspends use of HPV vaccine (one brand). It has medium impact in Country B, which uses another brand of HPV vaccine.</td>
<td>Vaccine use is suspended in the country (or even in another country). e.g. Country A temporarily suspends use of HPV vaccine (one brand), which has a high impact in the country. This will also have high impact in Country B, which uses the same brand of HPV vaccine.</td>
</tr>
<tr>
<td><strong>Vaccine recall</strong></td>
<td>Any recall by another country of a vaccine not used in the country.</td>
<td>Any recall by another country of a vaccine used in the country.</td>
<td>Any recall of a vaccine used in the country.</td>
</tr>
<tr>
<td><strong>Replacement of a vaccine</strong></td>
<td>N/A</td>
<td>Any replacement in the country, irrespective of the reason.</td>
<td>Any replacement in the country, as a result of an AEFI.</td>
</tr>
<tr>
<td><strong>New research findings related to vaccines or immunization</strong></td>
<td>Published in a low-credibility journal with less professional/public attention.</td>
<td>Published in a credible journal with some professional/public attention; the study is based on another country or vaccine is not used in the country.</td>
<td>Published in a credible journal with high public attention. The study is particularly about a vaccine used in the country.</td>
</tr>
<tr>
<td><strong>A report in the press, or rumour about the vaccine</strong></td>
<td>A report in the press with no/less public recognition, limited to local.</td>
<td>A report in a low credibility press with less or limited public attention.</td>
<td>A report/rumour in a media with high and wide readership/viewership/listenership with a high level of public sensitivity and attention.</td>
</tr>
</tbody>
</table>

*Source: WHO, 2012b*
1.3 UNDERSTANDING AND OVERCOMING VACCINE HESITANCY

Vaccine hesitancy is an emerging term in the discourse on determinants of vaccine acceptance. Vaccine hesitancy may explain why uptake of a vaccine or immunization programme in a community is lower than would be expected in the context of the information given and services available. Understanding vaccine hesitancy will help communication planners design appropriate approaches to overcome behavioural barriers and reinforce positive determinants of vaccine uptake.

The Strategic Advisory Group of Experts (SAGE) on Immunization Vaccine Hesitancy Working Group defines vaccine hesitancy as an individual’s behaviour, influenced by “3Cs”: issues of confidence (does not trust vaccine or provider), complacency (does not perceive a need for a vaccine, does not value the vaccine), and convenience (ease or difficulty of access). Vaccine-hesitant individuals hold varying degrees of indecision about specific vaccines or vaccination in general. Some may accept all vaccines but remain concerned about vaccines; some may refuse or delay some vaccines but accept others; and some may refuse all vaccines (The SAGE Vaccine Hesitancy Working Group, 2013).

**FIGURE 2.** Factors that promote or undermine vaccine confidence and collaboration with improved public confidence in vaccines.

- Evidence-based and transparent vaccination policies and recommendations
- Production of safe, effective and quality vaccines
- SPC safety information update
- National and supranational rules, regulations and guidelines: Marketing authorization and withdrawal
- Vaccines safety issues
- Fear of adverse events
- Disease no longer visible
- Misinformation
- Cultural issues and belief systems
- Lack of knowledge
- Collaboration and partnership between HCP and parents/vaccinee, regulators, academe, national and supranational health care organizations, civil society, public health actors, policy-makers and manufacturers
- Lack of trust in:
  - government
  - academia
  - vaccine industry
- Public disclosure
- Transparency
- Community engagement
- Social behaviour research

SPC: summary of product characteristics; HCP: health-care provider
(Source: www.mdpi.com/journal/vaccines)
Figure 2 shows the factors that promote vaccine confidence (in light blue boxes) and those that undermine vaccine confidence or lead to vaccine hesitancy (in dark blue boxes). Vaccine hesitancy may contribute to the delay or refusal of one or more vaccines. These factors, which influence vaccine acceptance, vary by setting. Responses need to be locally assessed. Because the issues (in the green boxes) influence vaccine acceptance, it is important to conduct a local communication analysis of knowledge, attitudes and practices (KAP). This analysis should include social norms, cultural beliefs and traditions associated with health and immunization among primary stakeholder groups (parents, guardians and health-care providers). The analysis should also look into channel availability and audience preferences, including existing community engagement mechanisms that can guide communication interventions.

During the planning stage for vaccine safety communication, programme managers need to consider issues around the “3Cs” of vaccine hesitancy that serve as barriers or facilitators to achieving desired actions by parents and caregivers (see Chapter 4, Table 3). It is particularly important to be prepared with appropriate communication messages using a mix of channels to counteract negative media publicity on AEFI and allegations by anti-vaccine lobbyists that could exacerbate vaccine hesitancy among the population.

**SUMMARY OF CHAPTER 1**

**RATIONALE FOR VACCINE SAFETY COMMUNICATION**

CHAPTER 1 presents the rationale for vaccine safety communication:

- Having knowledge and clear understanding of the five cause-specific categories of AEFI is important for effective vaccine safety communication.
- The level of impact that a vaccine safety-related event has on a national immunization programme may vary between low, medium or high. The vaccine safety communication response needs to be adjusted depending on the level of impact.
- Knowing the determinants for overcoming vaccine hesitancy is necessary for planning an effective communication strategy.

and provides the background for the six types of vaccine safety-related events (VRE) that require proactive communication strategies:

1. Adverse events following immunization (AEFI)
2. Temporary suspension of a vaccine
3. Vaccine recall
4. Replacement of a vaccine
5. New research findings related to vaccines or immunization
6. Rumour about a vaccine or report in the press.
CHAPTER 2.

Vaccine safety communication: the goal, objectives and strategies

2.1 THE GOAL AND OBJECTIVES OF VACCINE SAFETY COMMUNICATION

Communication goal

The goal of vaccine safety communication is to maintain public trust in vaccines and immunization safety so as to sustain the immunization programme and achieve a high level of immunization coverage, in order to prevent and control vaccine-preventable diseases in the country.

Specific communication objectives

The following communication objectives are framed in terms of desired behaviours and actions i.e. what specific groups should be able to do as a result of their participation and exposure to a mix of communication interventions.

Vaccine safety communication aims to achieve significant increases, over a specified timeline, among specific stakeholders.

Parents and guardians, communities and the public:

- understand and can explain the importance and benefits of vaccines and immunization;
- (after an AEFI episode) have restored confidence in vaccines and immunization and have trust in the national immunization programme; and
- complete the routine immunization schedules, maintaining high immunization coverage.

Health-care providers and other immunization programme implementing stakeholders:

- understand AEFI and risk-benefits of vaccines and immunization;
- can clearly explain vaccine safety issues and related events; and
- demonstrate their enhanced capacities in vaccine safety communication when dealing with vaccine safety issues and related events.
and community members, and motivation-
al messages from a mix of communication
channels – interpersonal, group, community,
mass media and social media – all contribute
to empowerment among vaccine recipients,
parents and guardians, characterized by
improved confidence and positive deci-
sion-making.

• 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 programme.

• Social mobilization aims to engage health-
care providers, teachers and students,
community leaders, community-based orga-
nizations, media, private sector and other NIP
stakeholders, partners and allies to initiate
actions that support and influence families
and communities to sustain immunization
practices. The ability of local government
authorities, health-care workers, teachers,
and other social mobilizers to effectively
communicate will depend on their own confi-
dence and trust in immunization and vaccine
safety. Therefore, their knowledge and per-
ceptions on vaccine safety and immunization
play a major role in creating a supportive
environment that leads to effective social
mobilization.

1 A supportive environment is one where parents and guardians feel
included and encouraged by their immediate social network when
sharing information and making decisions about vaccine safety
issues. In a supportive environment, the influence and trust of
other family members, neighbours, friends, community leaders and
health-care providers, makes parents and guardians feel confident
to engage in dialogue, seek more information, and reach a common
understanding and agreement about vaccine safety and completion
of immunization schedules.

2.2 COMMUNICATION
STRATEGIES AND
APPROACHES TO ADDRESS
VACCINE SAFETY ISSUES

A communication strategy aimed at sustain-
ing the national immunization programme,
particularly in the face of vaccine safety con-
cerns, involves understanding and influ-
cencing the behaviour of key individuals and
the social norms/practices of communities
and the health system. The Socioecological
Model (SEM) (McLeroy et al, 1988) shown
in Figure 3 shows the five levels to consider
when planning communication to influence
positive behaviour and social change, i.e. to im-
prove knowledge, attitudes, practices and social
norms around immunization and vaccine safety.
It is important to recognize the different levels of
a social system that influence decision-making
among individuals, families and communities
(see Figure 3).

There are four interrelated and interdependent
communication approaches that address and
influence the behaviour of specific audience
groups:

• Empowerment and behaviour 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 envi-
ronment brought about by encouragement
from family members, neighbours, friends

Media and other partners:

• address vaccine safety issues and related
  events accurately and objectively;
• are supportive of the national immunization
  programme; and
• promote the benefits of immunization.
Advocacy 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 NIP. Advocacy is designed to lead to political commitment, improved policies, programmes and structures and better allocation of resources to create an enabling environment for NIP.²

² An enabling environment refers to the national laws, regulations, policies, physical and social infrastructure, and financial resources that need to be in place for people to decide to avail themselves of immunization services to their advantage. An enabling environment is one where social institutions and the norms of a social system are inclusive and non-discriminatory of gender, race, ethnicity, class, religion, disability and socioeconomic status, thus facilitating individual, family and community decision-making in support of the goals of NIP.

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 behaviour 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.

2.3 COMMUNICATING RISK BEFORE AND DURING A VACCINATION SESSION/ CAMPAIGN

Vaccines are designed to stimulate an immune response in the body against infectious diseases, and it is inevitable that this reaction carries a small attributable risk to the health of a minority of vaccine recipients. This risk is outweighed by the significant benefits in terms of the protection from vaccine-preventable diseases that vaccination provides.

In risk communication, the communicator provides the intended participants with information about the expected type (positive or negative, good or bad) and magnitude (low or high, weak or strong) of a potential outcome from a behaviour or exposure (CDC, 2008). Such as vaccination. Risk communication happens before and during a vaccination session/campaign as a preparation for any VRE, to encourage positive behaviours and lessen any negative impact. Risk communication involves a two-way flow of communication between health-care providers and health authorities, parents, guardians and vaccine recipients, and the public at large.

To communicate risks effectively, health-care providers, health workers, teachers and other influencers, programme managers, and NRA need to have adequate knowledge about vaccine risk-benefits, effective communication skills, and the ability to use clear and simple language that the public understands. It is also important for them to be aware of the way the audience perceives risks from immunization and vaccines.

While immunization programme managers and health experts see risk in terms of morbidity and mortality rates, parents and guardians, along with the general public, tend to see risk in terms of the following (Reynolds et al, 2002):

- **Voluntary exposure to risk.** To parents and guardians, voluntary risk is more acceptable because they can freely decide to expose or not to expose themselves, their children or other family members to the risk, particularly when they believe that the benefits of vaccination outweigh the risk of AEFI or side effects. In vaccination programmes one of the objectives of risk communication is to promote the informed consent of vaccine recipients and their guardians. Informed consent to vaccination can only be given if the individual has received all the information he or she wants, and understands that information. Only then can an informed decision on vaccination be made. Risk communication demonstrates respect for the individual’s right to information.

- **Familiarity with the vaccine risk.** Parents’ and guardians’ familiarity with vaccine risk depends on them having balanced knowledge about adverse vaccine reactions, i.e. the benefits of the vaccination as well as the possible side effects. The health-care provider and vaccinator are responsible for discussing this information. The more informed and confident the parents and guardians are, the more predisposed they are to accept the vaccine. Lack of or inadequate communication about risks and benefits of the vaccine may negatively influence decision-making.

- **Familiarity with the disease risk.** This refers to the parents’ or guardians’ knowledge of any potential risk of morbidity and mortality, i.e. the risk of falling ill or dying, from an AEFI compared to the same risks from getting the disease. Parents and guardians in particular are keen to weigh the risks of illness and death associated with getting the disease against the probability of AEFI.
2.4 VACCINE SAFETY COMMUNICATION AS CRISIS COMMUNICATION

A crisis related to a vaccine is an unexpected series of events that may happen after a vaccine has been administered to a population group (particularly during or at the end of a campaign).

A crisis may arise when something goes wrong, for example as a result of genuine vaccine reactions or due to immunization-related errors that cause caregivers to withhold immunization of their children. A crisis may be caused by media publicity about an AEFI incident, even if it may have no basis or is triggered by unfounded rumours.

A vaccine safety-related event (VRE) such as AEFI could lead to a crisis for the Ministry of Health at the national level if it is not well managed and quickly acted upon. It is likely to become public through a combination of channels (e.g. mass media, Internet, social media platforms, mobile phone and word of mouth). The crisis may be made worse by a “cover-up” that is subsequently found out. This is why programme managers must act in a timely manner by mobilizing the communication task force, the technical group, spokespersons and media partners to dispel any misinformation quickly before it becomes a crisis.

Crises communication is a combined effort by health and immunization programme managers, the regulatory authority and local leaders to communicate with the public using all appropriate channels. Messages should assure the public that a vaccine safety issue is being investigated and will be resolved, and that the immunization programme will continue.

**BOX 5. Good communication before vaccination**

In late August 2011, polio broke out in China for the first time since 1999. It was evident that the virus had been imported from Pakistan. After the disease paralysed 18 people and killed one of person, China quickly responded by vaccinating 4.5 million children and young adults in immunization campaigns starting from early September 2011 in Xinjiang. The polio immunization campaign went house to house and to day care centres, kindergartens, schools, workplaces, markets, bus stations and airports to ensure that no child missed the vaccine. Within a short period, China returned to its polio-free status through this successful immunization campaign. One key to this success was a well-planned risk communication programme, before and during the campaign.

Source: WHO, 2012a
Example of how a country addressed crisis communication

In Country A, several serious incidents relating to AEFI have undermined public confidence in the national immunization programme (NIP). Between October 2012 and 30 March 2013 a total of 21 serious AEFI (12 deaths and 9 non-fatal) were reported associated with Quinvaxem, a 5-in-1 vaccine. Country A’s Ministry of Health invited an international team of experts to join local experts to review all serious AEFI cases documented since the vaccine was introduced in June 2010. The investigation found no causal link between Quinvaxem and the AEFI.

In mid-July 2013, four infants died immediately following the first birth dose of hepatitis B vaccine. A thorough investigation took place but the results have not been officially shared with the media and the public. These events have generated considerable public outrage and media reports that are critical of the quality of vaccines in Country A, and the ability of healthcare workers to follow vaccine protocols.

A communication strategy was developed to respond to the crisis. The strategy included the following actions:

- Ministry of Health, WHO and UNICEF jointly conducted three media workshops on immunization in cities X, Y and Z to brief the media on vaccine issues and share AEFI experiences from other countries with a view to rebuilding public trust, and improving media reporting in Country A.
- WHO held exclusive media interviews jointly with UNICEF.
- WHO and UNICEF issued a joint media statement and FAQ on Quinvaxem.
- Daily media monitoring of news items, articles or statements, which are shared with UNICEF and the One UN communications team.
- WHO with UNICEF supported the Ministry of Health in developing a national communication strategy on immunization.

The Ministry of Health, UNICEF and WHO learned the following lessons from this crisis:

- A lack of consistent and timely dissemination of information about the results of the AEFI investigation and about Ministry of Health efforts had contributed to sensational media reporting and temporarily diminished trust in Country A’s Expanded Programme on Immunization (EPI).
- A proactive approach with the media could have helped facilitate balanced coverage when the adverse events occurred. This could have included planning for and giving technical briefings to the media, prompt issuing of press releases, senior government officials serving as spokespersons on a regular basis, and having a designated communication team that can effectively liaise with health authorities, the media and communities in handling both risk and crisis communication.
- Regular risk communication training of high- and mid-level Ministry of Health staff is critical to improve media engagement and rebuild public trust in Country A’s immunization programme.

Source: WHO, 2013b
VACCINE SAFETY COMMUNICATION: THE GOAL, OBJECTIVES AND APPROACHES

The goal of vaccine safety communication is to maintain public trust in vaccines and immunization safety. Vaccine safety communication aims to sustain the immunization programme with high immunization coverage, in order to achieve the goal of the NIP, which is to prevent and control vaccine-preventable diseases in the country.

The specific communication objectives should be framed in terms of desired behaviours and actions by audience groups as a result of their participation in communication:

• Parents and guardians, communities and the public understand/can explain the importance of vaccines and immunization;
• Parents, guardians and the public, after an AEFI episode, have restored confidence in vaccines and express trust in the NIP;
• Parents and guardians complete their children’s immunization schedules;
• Programme managers, the national regulatory authority, health-care workers, the media and other stakeholders in vaccine safety communication have enhanced capacities for dealing with rumours and misinformation about AEFI and vaccine related events;
• The media – mass and social media – report and cover vaccine safety events accurately and objectively.

Based on the Socioecological Model of Communication, the four communication approaches for planning a vaccine safety communication plan are:

• Empowerment and behaviour change communication;
• Communication for social change and community mobilization;
• Social mobilization; and
• Advocacy.

The media cut across the four approaches as appropriate. The combined use of appropriate communication approaches and channels increases effectiveness.

The differences between vaccine safety as risk communication (communicating with families and communities about the benefits of vaccination as well as potential risks from VRE before and during a vaccination programme as a preparation for possible VRE) and as crisis communication (communicating with families, communities and the public about vaccine safety and benefits of immunization after a VRE has triggered a negative outcome) need to be understood and applied as mutually reinforcing strategies that aim to mitigate negative outcomes.
CHAPTER 3.

Establishing a system for vaccine safety communication

3.1 ESTABLISH COORDINATION MECHANISMS FOR COMMUNICATION

A national communication committee for immunization and vaccine safety

At the national level, one option would be to set up a communication committee that could have an interagency and interministerial structure within the National Immunization Programme. It might be called the National Communication Committee for Immunization and Vaccine Safety, and charged with overseeing the planning, implementation and monitoring of the communication programme for immunization and vaccine safety issues. It should include representatives from the Ministry of Health’s EPI Division, the National Regulatory Authority and the Department of Health Education/Promotion, as well as of other relevant government ministries such as the Ministry of Information and Social Communication, Ministry of Education, Ministry of Social Welfare, Ministry of Local Government, and professional associations, UNICEF, WHO, other development partners and media professionals.

Another option would be for a country to decide to delegate the same function to an existing committee such as the National Immunization Advisory Committee or National AEFI Committee, etc.

The roles and responsibilities or terms of reference of the national communication committee would include the following:

- Develop the national communication plan to address vaccine safety issues as part of NIP communication programme. The plan should be based on evidence from communication research or a communication analysis (see Section 3.2 and Annex 2).
- Agree on clear roles and specific assignments for participating institutions and individuals.
- Appoint a communication manager and a team to handle the day-to-day demands of implementing and managing communication activities.
- Select and appoint spokespersons.
- Facilitate the formation of lower level provincial or district communication plans, implement communication activities, and monitor desired outcomes around immunization and vaccine safety issues.
- Mobilize resources for implementing the
Box 7. National and subnational communication committees

The national and subnational communication committees should:
1. be functional and active;
2. have a clear understanding of their terms of reference and specific roles and assignments;
3. be able to coordinate and work quickly to assess and advise on communication needs of intended audiences;
4. be familiar with the communication plan and implement it;
5. identify and mobilize local resources;
6. be able to engage and mobilize the media, national and local influential figures, other partners and allies;
7. have identified key spokespersons who are provided with key messages; and
8. have a mechanism to ensure that all parties receive the same message, a ready-to-go press release and pre-positioned FAQs, Q&As and fact sheets for the media and partners, as well as interpersonal communication (IPC) tools and guides for health-care providers and local mobilizers.

Subnational communication committees for immunization and vaccine safety

Communication committees should be formed at subnational (provincial or district) level to plan at the local level and engage directly with health-care workers, local media, communities and the general public. Membership of the subnational communication committees for immunization and vaccine safety issues could include: provincial/district health team, line agencies corresponding to the interministerial membership of the national committee, provincial/district education authority, local NGOs, political leaders, religious leaders, local media executives and other partners. The provincial/district immunization officer could chair the respective subnational (provincial or district) level communication task force.

- Oversee and participate in implementing the communication plan.
- Develop and support orientation and training on different communication aspects for national and provincial/district NIP implementers and other stakeholders.
3.2 CONDUCT A COMMUNICATION ANALYSIS

A communication analysis provides the evidence and information needed to be able to plan a context-specific communication intervention for vaccine safety issues. A communication plan for any programme requires basic data and information gathered through baseline and formative research.

Consider the five components of a communication analysis:

1. Problem and programme analysis;
2. Communication environment analysis;
3. Audience/stakeholder/participant analysis;
4. Behaviour analysis; and
5. Communication channel analysis (UNICEF, 2010).

Annex 2 elaborates on the five components of a communication analysis and provides guide questions for conducting formative research.

3.3 STRENGTHEN THE CAPACITY OF STAFF AND IMPLEMENTING PARTNERS IN COMMUNICATION SKILLS, PROGRAMMING AND MANAGEMENT

Prior to implementation, training and orientation of key actors will be required across all aspects of the communication plan. Key implementers such as national and subnational (provincial/district) communication teams, and staff and members of the national and district coordinating committees, will need a series of training on all seven chapters of this Guide. Contract a communication for development training specialist to prepare and facilitate learning in needs-based training modules designed for different levels of participants. The modules and sessions should be practical, interactive, participatory and realistic by using country examples. Community leaders, healthcare workers, vaccinators and community health volunteers, teachers and community groups will be invited to participate in training to enhance their skills in interpersonal communication, counselling, group communication and community mobilization. Media orientations around vaccine safety communication issues will be a prerequisite for media engagement. Once these groups are trained, they in turn can train others and share their knowledge and skills toward reinforcing desired behaviours around immunization and vaccine safety.
These are the steps to follow when planning communication training and orientation for different participant groups:

- **Begin with a learning needs assessment (LNA).** Determine the participants to whom the training will be delivered. Prepare a learning needs assessment questionnaire to gauge entry-level knowledge, skills and expectations from the planned training.

- **Prepare a training plan.** Based on the LNA report, prepare the training plan that will outline

  - session topics, suggested training dates, participant profile, venue, travel and accommodations and related logistics, budget and training resources.

- **Identify and contract master trainers.** Explore potential trainers and facilitators with expertise in different areas of communication from among development partners, NGOs, academic institutions and past communication training consultants.

- **Develop training modules.** Develop training modules including session plans, tools and exercises, facilitator’s guide, and the participants’ training kit based on LNA. Prepare protocols for monitoring and evaluation of the training.

- **Conduct training of trainers.** Train sub-national level trainers on specific aspects of the communication programme that includes building participants’ skills in facilitation and presentation.

- **Assess the training programme and prepare a report with recommendations.** Use qualitative and quantitative parameters to assess the training by gathering feedback on the process, facilitator and sessions. Conduct pre- and post-training evaluation to measure learning retention.

- **Follow up the training.** Prepare a checklist for monitoring participants’ actual post-training performance and provide support as needed. Prepare a training follow-up report.

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Source: WHO Regional Office for the Western Pacific
3.4 FOSTER AND MOBILIZE PARTNERSHIPS

Strong partnerships are central to effective national and subnational coordination of communication. Identifying and engaging multiple partners at national, subnational and community levels fosters cooperation, collaboration, complementation, resource-sharing and capacity-building. Effective partnerships and collaborative arrangements also broaden ownership of the communication programme, make programmes work more efficiently and help avoid duplication of efforts. They help create a strong communication programme because each partner can contribute their own individual and organizational expertise, resources and affiliations, while tapping into the other’s tacit knowledge and relevant social networks. Partners can therefore broaden the reach and profile of the programme.

Build partnerships with the media

In the short and long term, building partnerships with the media is key to keeping the public regularly informed about and engaged with the benefits of immunization and to timely information sharing on vaccine safety issues. The media can reinforce messages shared through interpersonal communication to motivate families and communities to maintain trust in and sustain their demand for immunization services. In engaging the media it is important to understand their perspective to ensure a smooth and lasting partnership (UNICEF ROSA, 2005). See Annex 6 for tips on what the media are looking for and how they operate.

SUMMARY OF CHAPTER 3

ESTABLISHING SYSTEMS FOR VACCINE SAFETY COMMUNICATION

Before starting on a communication plan on vaccine safety and AEFI, it is important to set up the system that will enable the plan to be put into action. Follow these steps:

- Establish a national communication committee for NIP and communication committees at subnational (provincial or district) level.
- Conduct a communication analysis.
- Strengthen the capacity of staff and implementing partners in communication skills, programming and management.
- Set up a spokesperson system.
- Foster collaborative arrangements and mobilize partnerships for communication: build media partnerships and alliances.
CHAPTER 4.

Developing a vaccine safety communication plan

Vaccine-related crisis situations are to be anticipated in any immunization programme, during routine immunization or during the introduction of new vaccines. A proactive and reactive communication plan will ensure you are prepared. To facilitate implementation of the plan, it is important to involve all relevant stakeholders and allies at each step of the planning cycle. Planning for vaccine safety communication forms part of a broader planning process for EPI communication (UN Communication for Development, 2011).

When planning a communication strategy, ensure that the preparatory steps described in Chapter 3 are all in place – a communication coordination mechanism; partnerships for communication; findings from the communication analysis obtained from primary and secondary data; and a functioning communication team that can prepare the strategy, implementation plan and monitoring protocols, and mobilize partnerships.

The preparatory steps will lay the groundwork for the development of the vaccine safety communication plan. The Communication Planning Template in Annex 7 can serve as an outline for your communication plan.

4.1 THE STEPS FOR COMMUNICATION PLANNING ON VACCINE SAFETY ISSUES

When planning vaccine safety communication, follow these steps:

1. **Identify the audience groups.** There are three broader groups: family and community level; health service delivery and institutional level; and policy and system level (see section 4.2).

2. **Define SMART objectives.** Use evidence from the communication analysis to define specific, measureable, attainable, relevant and time-bound communication objectives in terms of key desired behaviour outcomes and actions by participant group (see Box 7).

3. **Prepare a strategic approach for implementation:**
   a) Design the strategy, specifying communication actions for each audience group, in relation to the following communication approaches: behaviour change communication, social change communication, social mobilization and advocacy.
b) Select the most appropriate mix of communication channels for each participant group—considering interpersonal communication methods, media, and community and social mobilization channels (see Chapter 5).

4. Develop tools for communication:
   a) Formulate key messages appropriate for each audience group, according to the desired behaviour outcomes.
   b) Develop a media engagement plan that includes how to be prepared and how to work with media (Chapter 6).
   c) Prepare for managing rumours, misconceptions and anti-vaccination arguments.
   d) Develop a work plan with budget.

5. Develop the monitoring and evaluation plan (Chapter 7).

### 4.2 IDENTIFY THE AUDIENCE GROUPS

The communication plan seeks to influence three audience groups to achieve the desired behaviour change and actions:

**PRIMARY AUDIENCES** – They are the people whose positive knowledge, attitudes, practices and beliefs about immunization, sustained trust in vaccines and continued acceptance of EPI we seek to influence through behaviour and social change communication. They are the:
- parents and guardians and vaccine recipients; and
- heads of households, grandparents, children and adolescents and relatives.

**SECONDARY AUDIENCES** – They are the people whose actions can influence the primary audiences to maintain their confidence in vaccines and NIP and sustain EPI coverage, through community and social mobilization, to provide a supportive environment for vaccine safety communication. They are the:
- EPI managers;
- Health-care providers (HCP), vaccinators, community health volunteers;
- Clinicians and academia;
- Community leaders and influencers including religious groups;
- Community groups including health management committees, parent-teacher associations, children and adolescent clubs;
- Private sector health-care institutions;
- Media and ICT organizations; and
- Civil society.
**FIGURE 4.** Audience groups and corresponding approaches to communication planning

**TERTIARY AUDIENCE** – Those to whom **ADVOCACY** will be addressed to create an enabling environment with the policies, structures and resources necessary for a successful NIP.

- National policy-makers
- Ministry of Health; NRA
- Development partners
- District, subdistrict leaders
- Media executives,
- NGOs, private sector

**SECONDARY AUDIENCE** – Those who undertake **SOCIAL AND COMMUNITY Mobilization** to provide a supportive environment to influence and inspire primary participants to adopt recommended behaviours and effect social change.

- EPI managers, clinicians
- HCP, vaccinators
- Community leaders
- Religious leaders
- NGOs, CSOs, CBOs
- Media journalists, broadcasters

**PRIMARY AUDIENCE** – Those whose improved knowledge, attitudes and confidence in vaccine safety resulting from **BEHAVIOUR AND SOCIAL CHANGE COMMUNICATION** would predispose them to collectively act upon the recommended behaviours and social practices leading to widest coverage of EPI and low incidence of preventable diseases.

- Primary caregivers – mothers, fathers
- Grandparents, older children
- Extended family
- Neighbours, friends, social network

**TERTIARY AUDIENCES** – They are the participants at whom advocacy is aimed, whose decisions we seek in order to develop policies and legislation, allocate resources and institute structures and mechanisms for NIP and vaccine safety. They provide an enabling environment for vaccine safety communication. They are:

- national and subnational leaders and decision-makers, policy-makers;
- donors;
- programme managers and the national regulatory authority; and
- the media.

Table 3 shows different audience or participant groups with examples of desired behaviours (knowledge, attitudes, practices and skills) and actions intended to maintain confidence in vaccines and the NIP.
### TABLE 3. Desired outcome behaviours and actions resulting from vaccine safety communication and immunization by audience/participant group

<table>
<thead>
<tr>
<th>AUDIENCE/PARTICIPANT GROUP</th>
<th>DESIRED OUTCOME BEHAVIOURS AND ACTIONS</th>
</tr>
</thead>
</table>
| **A. Mothers and fathers, guardians, grandparents, siblings, extended family members** | • Complete the immunization schedule of their children.  
• Know the importance of immunization in protecting against diseases.  
• Feel confident that vaccines are safe and give protection against diseases.  
• Bring children for routine immunization.  
• Always bring immunization card.  
• Father, grandparents support mother/caregiver in routine immunization.  
• Talk about immunization benefits with other mothers/parents, neighbours, social network. |
| **B. Community leaders, community groups, CSOs, NGOs, CBOs, local government authorities, business sector, school officials, children’s/adolescent clubs, youth groups, schoolchildren** | • Explain the importance of immunization and vaccines - that these are safe and provide effective protection against diseases.  
• Reach out to resistant parents, immunization dropouts, hard-to-reach and those marginalized due to gender, class, caste, ethnicity, race, religion, disability, or socioeconomic status.  
• Understand and explain the risks and benefits of immunization.  
• Provide a supportive environment for families during AEFI to help maintain confidence in vaccines and RI. |
| **C. Frontline health-care providers: vaccinators, clinicians: doctors, nurses** | • Know and demonstrate good 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).  
• Reach out and persuade resistant parents, immunization drop outs, 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 rumours, 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 programme. |
| **D. Religious leaders, religious groups** | • 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** | See Chapter 6: Build alliances with media. |
F. Programme managers, NRA, academia

- Provide an enabling environment for health-care providers, media, community groups and families to maintain confidence in NIP.
- Organize orientation workshops for programme 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, donors

- Give political commitment and demonstrate political will through public pronouncements and participation in EPI.
- 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.

4.3 DEFINE SMART COMMUNICATION OBJECTIVES IN TERMS OF DESIRED BEHAVIOUR OUTCOMES

What is a SMART (specific, measurable, attainable, relevant, time-bound) behaviour objective/result? Communication objectives are best stated in terms of a desired behaviour change/result or the maintenance of an existing desired behaviour. A SMART behavioural outcome has at least three features that facilitate measurement during monitoring and evaluation:

- Clear identification of the participant group (Specific).
- Description of the desired behaviour, showing the baseline data against a targeted percentage increase (Measurable) and/or how many times the behaviour should take place, i.e., to complete scheduled immunizations (Attainable).

The expected results being aimed at, in terms of a percentage increase, considering sociocultural, economic physical and other factors (Relevant), which could be observed and measured over a specific period of time (Time-bound).

**BOX 8. Example of a SMART communication objective**

SMART communication objectives are specific, measurable, attainable, relevant and time-bound. For example:

“Within 12 months after a reported serious AEFI incident from pentavalent vaccine in District B, (from a baseline of 45%) 75% of parents and guardians who participated in communication activities will demonstrate their restored confidence in pentavalent vaccine by completing their child’s immunization schedule.”
4.4 PREPARE STRATEGIC APPROACHES FOR DIFFERENT AUDIENCE GROUPS

Select the most appropriate mix of communication approaches for each audience group when implementing the communication plan (see Chapter 5).

4.5 PREPARE A WORK PLAN WITH A BUDGET

The work plan needs to include a list of activities, responsible persons/institutions and the funding requirements. It is fundamental to have assured and available funds for implementing communication activities both at national and subnational levels. Therefore, preparing a budget for identified communication activities will be necessary to ensure that funds are allocated in advance. This is a vital step for timely implementation of the activities in the vaccine safety communication plan.

4.6 PREPARE THE MEDIA ENGAGEMENT PLAN

See Chapter 6.

4.7 PREPARE TO MANAGE RUMOURS, MISCONCEPTIONS AND ANTI-VACCINATION ARGUMENTS

Despite the near eradication/elimination of EPI target diseases such as polio and measles, parents’ misconceptions and fears of AEFI as well as rumours about short- and long-term repercussions of vaccination have resurfaced and continue to spread through the Internet, social media, the mass media, and by word of mouth. Anti-vaccination attitudes and arguments about vaccine safety can be detrimental to the general public, as parents in particular may choose not to have their children vaccinated.

- Prepare “frequently asked questions” packs for use by all health workers, especially before a vaccination campaign or the introduction of a new vaccine. See Annex 5 for an example.
- Identify and involve women’s groups, ethnic, religious and political minorities, other marginalized groups, as well as children, adolescent and youth clubs, in communication activities.
- Schedule immunization campaigns separately from the timeframe for other leading public health campaigns (e.g. family planning, AIDS awareness campaigns, etc.).
- Partner with and engage the media through their executives, editors and journalists – from mainstream radio and TV, community radio, cable TV operators, print, mobile phone companies, Internet service providers – for accurate messaging through two-way communication.
- Tap into the Internet through social networking platforms and Internet radio for dissemination and feedback.
DEVELOPING A VACCINE SAFETY COMMUNICATION PLAN

Before planning the communication strategy, be sure that the preparatory steps (see Chapter 3) are all in place: a communication coordination mechanism and a communication task force; partnerships for communication; findings from the communication analysis obtained from primary and secondary data; a spokesperson system; media alliances and a media plan.

When developing the plan, follow these steps:
1) Identify the audience groups – primary, secondary and tertiary audience groups.
2) Define SMART communication objectives in terms of key desired behaviour results and actions by each participant group.
3) Prepare the strategic approach (see Chapter 5):
   • Design the strategy, specifying communication actions for each audience group, in terms of the following communication approaches: interpersonal and group communication, community mobilization, social mobilization, and advocacy.
   • Select the most appropriate IPC tools, and mix of communication channels.
   • Develop a media engagement plan.
   • Develop a work plan and budget.
4) Preparing for managing rumours, misconceptions and anti-vaccination arguments.
5) Develop monitoring and evaluation.
CHAPTER 5.

Implementing the communication plan

5.1 GUIDING PRINCIPLES IN VACCINE SAFETY COMMUNICATION

The following guiding principles are at the heart of vaccine safety communication:

- **Trust**: Build a reputation as a trustworthy source of evidence-based information on vaccine safety. Trust will influence whether the public/audience will act positively on the messages.

- **Credibility**: Communication effectiveness depends to a large degree on whether the audience perceives communicators, such as a spokesperson, to be credible. Four factors determine whether the audience sees the spokesperson as credible: (i) caring attitude, (ii) right expertise, (iii) honest, and (iv) dedicated to the work.

- **Transparency**: Credibility and trustworthiness are built on transparency. Transparency means a sincere and consistent effort to disclose information to the audience about different sides of the situation, and provide them with accurate, unbiased and evidence-based messages. Transparency will make the audience more receptive to messages on AEFI, immunization and vaccine safety.

- **Empathy**: Showing empathy means sensitivity to the affected family’s reactions to AEFI, including having the ability to adjust to their culture and local situation, and being sensitive to issues around gender, caste, class or ethnicity, disability and socioeconomic status.

- **Equity**: This entails giving particular attention to and ensuring the inclusion of people who are vulnerable, marginalized and tend to be discriminated against or treated unfairly in the context of gender, caste, ethnicity or race, religion, geographic area, disability or socioeconomic status.

- **Participation**: Ensuring the participation of stakeholders in the strategic communication process allows their social and cultural specificities and perspectives to be factored into the design, testing and implementation of the communication intervention.

- **Feedback**: A proactive response and feedback mechanism for vaccine safety-related events helps to maintain the public’s perception of the NIP’s trustworthiness, credibility and transparency. Ensure that the necessary resources are in place: staff assigned to gather feedback from affected families and communities and give objective responses, through the same channels that messages originated from – whether directly from personal sources, or indirectly through radio, or newspaper, mobile phone, Internet or other social media.
5.2 COMMUNICATING WITH FAMILIES AND COMMUNITIES

A communication plan should combine the following communication approaches, based on what is known about the participant or audience groups (Figure 5). Communicating through a combination of channels will promote and reinforce deeper understanding of vaccine safety issues and foster positive attitudes that, over time, will lead communities to practise and complete immunization schedules being a social norm.

**Interpersonal communication**

Different means of communication can be used to reach and engage families and communities directly using face-to-face or interpersonal methods, such as one-on-one home visits or community dialogues between health-care providers and mothers/mothers-to-be and other family members. Parents and guardians will remember and accept messages exchanged through interpersonal communication (IPC) when these are exchanged in the local language and cultural context. Messages communicated through face-to-face interaction could be reinforced with supporting information using IPC tools (also referred to as information, educa-

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### FIGURE 5. Combining communication approaches on vaccine safety issues

**INTERPERSONAL COMMUNICATION CHANNELS**

Communicate through and with:
- Heads of households, neighbours, friends, women’s groups, children and youth groups
- Community, hospital health-care providers, vaccinators and volunteers
- Other educators; teachers, volunteers, CSOs, NGOs

**COMMUNICATING WITH FAMILIES AND COMMUNITIES**

**MEDIA**
- Print (newspapers),
- Broadcast (radio/TV),
- Electronic media (Internet, social media),
- Mobile phone providers

**COMMUNITY AND SOCIAL MOBILIZATION CHANNELS**
- Educational teams: academia, teachers, school clubs
- Religious and community leaders: special programmes to promote immunization and address VRE
- Engage local celebrities (sports heroes, artists, musicians, singers, film, TV and radio personalities) as champions for immunization
Vaccine Safety communication

Push text messages or SMS/voice SMS with key vaccine safety messages and for monitoring behaviour results of the communication activities.

5.3 COMMUNICATING WITH HEALTH-CARE PROVIDERS, HEALTH WORKERS AND EDUCATORS

The quality of interaction between health-care providers and parents/guardians is a determinant of the completion of a child’s immunization schedule. High immunization drop-out rates and guardians’ negative attitudes about immunization services are often due to poor or inadequate information sharing and counselling by health workers (Waisbord and Larson, 2005). Aside from being the only source of health information for many communities, health-care providers reflect the cultural values and social norms of the communities where they work.

Immunization service providers and health professionals at all levels need to be equipped with accurate immunization facts and information about vaccine safety issues/AEFI. They need to have good interpersonal communication (IPC) and counselling skills so that they can explain risks and benefits clearly to parents, guardians and vaccine recipients (See Annex 9). IPC and counselling involve cultivating good listening skills and the ability to empathize, clarify doubts, motivate and be supportive of parents and guardians.
**Feedback system on AEFI investigation and findings**

When an AEFI occurs, it is crucial for programme managers and the NRA to encourage and support health-care providers to report adverse events and give them timely feedback on the findings of investigations and causality assessments. This will give health-care providers updated information to communicate to the public, which will help in maintaining public confidence both in the health staff and in the immunization programme. It is important to be supportive when communicating with frontline health-care providers, and avoid blaming them, particularly in the case of immunization-error related events. This is because fear of blame or sanction is why many health workers do not report AEFI.

**Training**

Training provides an opportunity to empower health staff with up-to-date information and to discuss the current vaccine safety-related event (VRE) issues. A VRE can be an opportunity to train staff on vaccine safety. Such training should be carried out through lively discussions and group exercises rather than one-way lectures, as a participatory training methodology will enable health staff to clarify and put right any uncertainties they may have about vaccine and immunization safety. It is essential that training adequately addresses the ongoing VRE. In addition, training modules could cover the following areas: types of AEFI, vaccine reaction rates (Annex 3), risk-benefits of vaccines, follow-up actions and communication approaches at different participant levels. The training should include scenario-based practical sessions to improve skills (Annex 9). In the course of the training, frequently asked questions on immunization and vaccine safety (Annex 5) can be used in role playing exercises to develop participants’ Q & A skills on these topics.

**Sharing information**

Information to be shared with and among health staff needs to have been prepared in advance. The content, breadth and depth of information can be adjusted depending on the role and job responsibilities, i.e. in delivering immunization services. Furthermore, health staff must be well informed about the guiding principles of communication described in section 5.1, as they are the key to convincing the primary audience (parents and community) on vaccine and immunization safety.

Leading clinicians or academics (e.g. paediatricians and physicians) who command public respect, the media and politicians are an important resource to tap into when communicating with the public and the media. Their active participation will help to win people’s trust in vaccines and in the immunization programme, because the public and the
media look up to them as credible sources of information. It is therefore essential to stay in close communication with them by sharing up-to-date information about any ongoing VRE.

5.4 COMMUNICATING WITH COMMUNITY LEADERS AND RELIGIOUS COMMUNITIES

Community leaders and religious organizations are regarded by their constituents as credible sources of information. Garner the trust and support of community leaders and religious groups by approaching them with an informed respect for their views: they have the power to shape public opinion and can improve the links between families, communities and health services. Religious leaders also serve as effective communication channels and social mobilizers when it comes to combatting rumours and unfounded negative opinions about vaccine safety and AEFI.³


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**SUMMARY OF CHAPTER 5**

**IMPLEMENTING THE COMMUNICATION PLAN**

Trust, credibility, transparency, empathy, equity, participation and feedback are the guiding principles of communication and are at the heart of the work of communicators for vaccine safety. The communication plan for vaccine safety communication should address key actions aimed at three important audience groups:

- Families and communities;
- Health-care providers, health professionals and educators;
- Opinion/religious leaders.

A strategic approach should be used that combines effectively different modes of communication – interpersonal, group, mass media and digital social media.
CHAPTER 6.

Media engagement plan

The media – print and broadcast media (radio and television) and digital media via the Internet and mobile phones – are an important gateway and make it possible to engage in two-way communication with the public in real time. The media shape the public’s views and attitudes towards vaccines and immunization. Effective media relations require the NIP to have a media engagement plan, trained staff, a budget and practised responses to potential “issues” around AEFI.

The media like to report on news that covers breakthroughs, the dramatic, diseases, disasters, the unexpected (AEFI, disease outbreak, etc.), scandal, personalities, celebrity link, and power. The media decide on what news to cover and publish. Vaccine safety issues can be controversial and this is why it is important to expect the media to respond when a crisis around vaccination occurs. It is advisable to be prepared with a media relations plan.

Tips for preparing a media plan:

1. Maintain a database of media contacts

Set up and maintain a database of media organizations (print, radio, television and telecommunications) and their focal persons, media editors and print and electronic media journalists and relevant online contacts via social media platforms (Email, Facebook, Twitter, Skype, Viber, Facetime, Facebook, Twitter, LinkedIn, Google Hangout, etc.). Establish rapport and maintain two-way communication so that they can refer to the relevant authority in case of any queries. Include three levels of media contacts in the database – (i) executives, (ii) editors/journalists, and (iii) reporters – with regularly updated contact numbers, email addresses and social media accounts. Include:

- National, state and district-level media executives and their support staff;
- Journalists as editors and reporters of national and community newspapers;
- Station managers and anchor persons of mainstream television stations;
- Local cable TV operators at province/district level;
- Station managers and broadcasters of national and community/FM radio stations; and
- National telecommunications executives and Internet service providers.
2. Develop a media kit
This should contain key messages given in the form of Q&As or frequently asked questions (FAQs), fact sheets, progress reports, case studies with photos, graphs and relevant illustrations and other audience-appropriate materials. Ensure these are distributed to all concerned including health professionals, vaccinators, community influencers and media representatives.

3. Conduct training and field visits for journalists
Attending training workshops and making field visits will give journalists a better understanding of the advantages of immunization as well as the complexities of an immunization programme. This involves building alliances and forming a media consultative group. Prepare monthly or quarterly updates on routine immunization or new developments relating to immunization and vaccine safety issues that can be shared easily with the media.

4. Set up a spokesperson system
Select and train an appropriate spokesperson at the national level and several spokespersons at lower administrative levels to act in the event of an AEFI or a rumour.

- Appoint spokespersons at national, provincial/district levels.
- Prepare a list of potential spokespersons – these could be relevant health and immunization experts at provincial/district level. Share this list with all the concerned focal points and Ministry of Health communication staff at the subnational (district, province) and national levels before an immunization campaign starts.
- Select spokespersons who can speak with authority, are trusted and well regarded by the intended audience. She/He may not necessarily be a medical expert, but must have competent knowledge of the immunization programme and be well versed on AEFI issues.
  - She/He should also possess the requisite media skills to present herself/himself well on radio, TV, other electronic social media, as well as social and religious gatherings.
  - Once spokespersons have been identified, organize a media skills orientation for them. Ensure continuous training and updating of their communication skills.
  - Equip them with prepared key message sheets and other important information on vaccine and immunization safety. See Annexes 3, 4 and 5 for relevant information on vaccine preventable diseases and vaccines, key messages on vaccines and vaccine safety issues, and frequently asked questions with answers for spokespersons.

5. Plan to organize media briefings
To keep media informed periodically about progress on AEFI incidence or investigations and other vaccine-related events, safety surveillance, clinical studies and key policy decisions. Organize media collaboration meetings with state/provincial level and district level journalists. Seek the help of development partners, media and communication agencies to hold media briefings on updates, latest data, challenges and successes in EPI. Maximize online platforms such as email and social media to keep media contacts regularly informed of all AEFI-related developments.

6. Prepare a press statement for the media
 Particularly if a severe AEFI is reported, a press statement will be essential (See Annex 8 for an example of a press statement). The press statement should include:

  - A complete account of the event, specific to its context (e.g. an isolated event or a cluster of AEFI, or coincidental event);
  - An outline of actions taken or planned (such as the AEFI investigation);

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*See Annex 5 for examples of related FAQs.*
8. How to prepare for a media interview

Before the interview:
- Review the information you communicate – is the data correct? Are the sources reliable?
- Prepare key messages. Key messages used in press releases can be repeated in interviews.
- Find out who is conducting the interview and which media entity they work for.

During the interview:
- Maintain eye contact with the interviewer.
- Dress in a professional manner.
- Think before you speak and take time to frame your answers.
- Speak clearly and audibly in simple conversational language.
- Stick to the facts and avoid speculation or personal opinions.
- Make sure you get your key message into the dialogue – more than once if possible.
- Be warm, friendly but determined to get the right message across.
- Be enthusiastic and engaged in the conversation – try not to look nervous, even if you feel uncomfortable about being interviewed.
- Never say, “no comment”.
- Remember that there is no such thing as an “off the record” statement that you can be certain the interviewer will keep confidential.
- Try to imagine how the interview will appear to members of the target audience. Will they be persuaded by your message?

Dealing with difficult questions:
- Bridge: If you get stuck with a question, move on to your key messages.
- Be assertive, not aggressive.
- Keep calm.
- Take your time and don’t let the interviewer interrupt you when giving your key message.
- Make sure you know all the facts.

7. Guidelines for engaging with the media

The following guidelines for media engagement are essential to building and maintaining good relationships (WHO, 2013b):

- 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 these journalists quickly before a crisis around misinformation develops, and give them the facts.
- Keep messages simple and to the point – do not use academic jargon or complex arguments. Use statistics only when necessary.
- Be willing to answer questions and be honest. 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.
- Never say, “no comment”.
- 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.

- A description of the cause of the event (but only when this is known with reasonable certainty and evidence);
- An assurance that corrective action has been taken or will be taken;
- Provide information on the five Ws and H of journalism (when, where, who, what, why and how).
- Provide reference to any relevant publication, video material or web site;
- Provide names and contact details of persons to be reached for additional information or materials;
- Use the Ministry’s standard press release format and immunization logo or brand (if any).
9. How to prepare a press release

Write a press release that will provide a reporter with pertinent information about the issue.

**Headline**

- The headline should arouse the interest of the editor who will decide whether to publish it.
- Make it short but interesting.

**Content**

- Use a strong lead sentence that will arouse interest in the story. Include as many as possible of the five Ws (who, what, when, where, why).
- With the main points in the lead sentence, present all other relevant facts in a logical sequence, with the least important fact at the end of the story. In news writing, this is referred to as the “inverted pyramid” style.
- Include a quote from a person of authority – e.g. Minister of Health, head of NRA or EPI manager; it adds interest and lends credibility to your story.
- Use short, simple and non-technical sentences.
- The press release should not be more than two pages in length; a one-pager is ideal for an editor and will have a better chance of being published as it is. Expect the editor to cut out what he or she deems not essential given the limits of broadcast time and/or print space.
- On the top left of the page, write the release date and name of the city of origin.
- At the bottom left of the press release, write the name, title, organization and telephone number of the contact person, or of the person responsible for the press release who can be reached for any questions.

10. Plan to monitor media coverage

- Plan to monitor media coverage and reporting trends, especially the local media, to track message delivery, reach, and inaccurate reporting and audience feedback. Meeting with supporters as well as critics from the media, and gathering feedback to improve performance, is part of good communication practice. If called for, it is good practice to issue corrections (rejoinders) through media and online outlets in case incorrect reporting continues.

- *Effective Media Communication during Public Health Emergencies: A WHO Handbook* (Hyer and Covello, 2005) can be adapted for planning media communication aimed at responding to AEFI. The handbook is a useful reference of practical tips for operationalizing the steps mentioned above.
MEDIA ENGAGEMENT PLAN

The guiding principles of communication are trust, credibility, transparency, empathy, equity, participation and feedback. These principles are at the heart of vaccine safety communication. The communication plan should address the following key implementation areas:

Media engagement preparedness:
- Maintain database;
- Develop a media kit;
- Conduct training for media;
- Set up a spokesperson system;
- Plan for organizing a media debriefing;
- Prepare a press release;
- Plan to monitor media coverage.

Guide for engaging with the media:
- How to prepare for a media interview: before, during and after interview;
- How to prepare a press release.
CHAPTER 7.

Monitoring and evaluating vaccine safety communication

Monitoring and evaluation (M&E) enables the programme to track progress as well as demonstrate any outcomes – both intended and unintended – that result from implementation of communication strategies and interventions.

Monitor and evaluate EPI communication activities around vaccine safety and AEFI on a regular basis or in specific timeframes. A communication plan supporting NIP and addressing vaccine safety issues, particularly AEFI, must include a system to monitor the inputs, process, outputs and outcomes, and evaluate the results and impact. Monitoring and evaluation are complementary activities in the communication strategy.

7.1 WHAT IS MONITORING?

Monitoring is performed during implementation to determine whether planned activities are on track and are effectively engaging audiences toward desired responses. It aims to:

- Track the proper and timely use of resources;
- Measure and document what has been accomplished at different stages of the programme;
- Determine whether the activities are effective so far, i.e. meeting the communication objectives of improving knowledge, attitudes toward vaccines and increasing actions by intended participant groups in favour of EPI; and
- Find out if adjustments need to be made during implementation.

Qualitative information and quantitative data gathered from monitoring permit programme managers to assess whether communication efforts are so far achieving short-term effects on knowledge, attitudes and practices, and have any potential long-term impact on sustaining confidence and acceptance of vaccines and other immunization-related behaviours (UNICEF ROSA, 2005).
Box 9. The main questions in monitoring vaccine safety communication interventions

- Have families and communities improved their understanding about vaccines and immunization?
- What is their current perception of vaccines and diseases? Has it improved?
- What was the families’ and community’s response to any AEFI that occurred?
- Are there any general issues around public confidence in vaccine and immunization safety? What are they? Why?
- What common social practices and beliefs on vaccine and immunization safety are there in communities that serve as barriers to immunization?
- What are some sociocultural opportunities, values and social norms that can help sustain immunization?
- Are the intended audiences being reached, including the vulnerable and marginalized groups?
- How are the different stakeholders involved? (e.g. parents, community leaders and local groups, health workers, religious leaders, journalists, decision-makers).
- Were messages discussed through IPC, broadcasted over radio and TV, printed, or transmitted by text messages, voice messages, email or social media? By whom? Where? How often?
- What other channels have been used effectively, i.e. having wide audience appeal (e.g. entertainment education through community theatre, video showing using mobile AV vans, or use of Internet and mobile phones?)
- Are messages correctly understood?
- Are there changes in the knowledge, attitudes and practices related to immunization among the groups of people who need to be reached?
- Is the immunization coverage improving or not and to what extent? Why?

7.2 WHAT IS EVALUATION?

Evaluation tries to answer the questions “what happened?”, “were the objectives achieved?”, and “why/why not?” It helps determine whether implementation of the communication plan produced the intended results in terms of improving and maintaining parent/guardian confidence in vaccines and immunization. Evaluation helps:

- to make decisions on which aspects of the communication strategy to improve, scale up or scale down and which aspects to allocate more resources;
- to identify emerging issues to be addressed in future communication interventions;
- to find out whether or to what extent the benefits of the communication outweigh the costs; and
- to convince others of the value of the communication efforts.
7.3 WHAT ARE INDICATORS?

Indicators are ways to measure progress and demonstrate whether or not communication initiatives are meeting the intended results. Most communication indicators are process-oriented and focus on measuring the behaviour outcomes based on participation of intended audiences in communication activities. Indicators are most effectively measured and monitored at community level through a combination of qualitative and quantitative methods, e.g. focus group discussions, interviews with parents and guardians, observation of vaccination sessions, community mapping and using other participatory tools and techniques.

The impact and outcome of communication efforts are tied to other NIP indicators and must therefore be measured within that context. Listed below are the types of indicators and sample indicators to be measured.

### TABLE 4. Monitoring and evaluation indicators

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<th>TYPE OF INDICATOR</th>
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| **Input indicators** | • Presence of a communication plan as a component of EPI, vaccine safety and AEFI within the national immunization programme.  
  • Presence of a roster of potential members of a communication committee and communication specialists that can support implementation of different aspects of the communication plan (See output indicators, bullet point 1).  
  • Amount of funds allocated for the communication component to support the NIP programme in general and vaccine safety issues and AEFI in particular.  
  • Number of planned communication activities for vaccine safety.  
  • Number and kinds of generic IPC tools, entertainment-education packages, media and visibility materials designed, pretested, produced and disseminated (or prepositioned).  
  • Communication analysis conducted and plans prepared to respond to AEFI, and those that map EPI-resistant groups and proposed strategies for reaching them. |
| **Output indicators** | • Percentage of NIP programme budget used for communication activities: a) communication analysis/formative research; b) media engagement; c) production of training modules, creative and media products, IPC and visibility materials; d) staff training and strengthening interpersonal communication and counselling skills of HCP; e) community/social mobilization; f) monitoring and evaluation; g) documentation.  
  • Percentage of planned activities actually conducted that reached the vulnerable, often hard to reach population groups.  
  • Number and contents of IPC tools and visibility materials used to reinforce vaccine safety messages during community mobilization, meetings, trainings, home visits and facility visits, and made visible and used in health facilities.  
  • Number of HCP and vaccinators trained in inclusive vaccine safety communication; number of training sessions conducted.  
  • Number of meetings held with community and religious leaders, school administrators, other community groups.  
  • Percentage of budget spent on communication activities according to the plan. |
7.4 HOW IS MONITORING AND EVALUATION DONE?

- Undertake joint monitoring and evaluation (M&E) with designated members of the coordinating committee and partners who are competent in monitoring and evaluation. Identify and agree upon indicators to be monitored and to be evaluated (input, output, outcome and impact indicators) and means of verification.

- Evaluation research will make it possible to analyse whether the changes that happened could have resulted from what the programme did, and help answer questions on the extent to which communication activities contributed to any observed results.

- Set up a system for ongoing dialogue with communities and affected families. This will allow all parties to actively listen to their concerns on vaccine safety issues and AEFI and to identify problems with the response. Be sure to track if there are groups that are not reached, or if misconceptions and misunderstandings occur, or if there is poor quality service by health-care providers.

- Supplement these discussions through electronic communication channels (e.g. mobile phones) to give concerned community constituents more space to voice concerns and feedback.

- Dialogue with health officers and health workers in charge of immunization.

- Review media coverage: look into the style and accuracy of reporting. Are the rights of the child/vaccine respected? Are certain media executives, editors/managers and journalists more supportive or unsupportive than others? Include local, national and regional media in the review.

- Monitor immunization coverage data.

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<tr>
<th>TYPE OF INDICATOR</th>
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| Outcome indicators (linked to EPI indicators) | - Percentage of HCP/vaccinators providing key messages on vaccine safety issues during immunization sessions.  
- Percentage of parents/guardians, including those from marginalized communities, who know where to take a child with AEFI for treatment.  
- Percentage of households in affected communities, including those from marginalized communities who were visited by HCP/community health volunteers/mobilisers; and those who availed of services in health facilities; and outreach events.  
- Percentage of parents/guardians who claim that they have trust in NIP. |
| Impact indicators | - Percentage of dropout rate of immunization coverage due to AEFI.  
- Percentage of children completing vaccination schedules.  
- Number of AEFI-related crises that occurred in pre and post periods of implementing vaccine safety communication activities. |
SUMMARY OF CHAPTER 7

MONITORING AND EVALUATION

- A communication plan supporting NIP and addressing vaccine safety issues particularly AEFI must include a system to monitor the inputs, outputs and behaviour outcomes, and evaluate the results and impact.
- Questions and answers as well as tips are offered on: “why and what do we monitor and evaluate?” And “how do we monitor and evaluate?”
- Indicators are used to measure and demonstrate whether or not the communication initiative is meeting the intended behavioural results.
- There are four types of indicators – input, output, outcome and impact.
CHAPTER 8.

Documenting lessons learnt, good practices and innovations in vaccine safety communication

Documentation may, depending on its focus and use, benefit: other programme managers; regulatory authority and health promotion staff within the country, in the region and other regions; media and other partners; spokespersons; donors; members of the communication coordinating committee and subnational working groups; and families and communities concerned with issues on immunization and vaccine safety.

Engage the services of a team of documentation specialists. They could be journalists or feature writers, photographers and videographers working in the health sector who could prepare high-quality case studies, features, vignettes and human interest stories that could be turned into drama scripts for radio, TV and film, monitoring and progress reports, powerpoint presentations on communication actions around vaccine safety, AEFI, combatting rumours and other immunization issues. Disseminate these as appropriate using different formats and communication platforms that appeal to different audience groups, including online through the ministry of health website. These products will contribute to:

- critical analysis of reports from the monitoring process and/or evaluation of results of communication actions;
- adjusting and fine tuning the strategic communication action plan;
- providing material for learning from experience, by allowing sharing and networking, active discussion and feedback from and to communities and health-care providers, on progress, challenges and opportunities;
- providing valuable information on where added resources are needed, and improvements or adjustments that need to be made to the communication work plan;
- mobilizing resources from donors, stronger collaboration during coordination meetings with partners and media, and improved cooperation with primary stakeholders during community gatherings.
Case studies can also be commissioned accompanied by action photos, audio and video formats, including stories from stakeholders sharing a day in their lives. For example, individual accounts of vaccine safety responses, information seeking and sharing, use of social media, community radio, traditional community media, IEC materials. Case studies can focus on issues (e.g. overcoming vaccine hesitancy) or practice (e.g. counteracting a rumour using the community public address system). The three categories defined below are recommended.

### 8.1 DOCUMENTING LESSONS LEARNT

Lessons learnt are more detailed reflections of positive (successes) or negative (failures) lessons from implementing community level strategies and media engagement when communicating about vaccine safety, combating rumours and anti-vaccination campaigns over a given timeframe. It is useful to write down and record in audio or video formats any positive and/or negative lessons from undertaking different communication actions around behaviour and social change communication, community mobilization, social mobilization, media engagement and advocacy. These lessons can form the basis of future planning and be shared with other groups who intend to embark on similar undertakings.

### 8.2 DOCUMENTING GOOD PRACTICES

Good practices are documented and assessed programming practices that provide evidence of success/impact in using a combination of participatory communication elements to address vaccine safety issues – that engage audience groups, strengthen capacities to combat rumours and negative messages, foster interpersonal exchange, effectively engage mass media, and foster confidence in vaccines – and so are valuable for replication, scaling up and further study. They are generally based on similar experiences or models learned from different countries and contexts.

### 8.3 DOCUMENTING INNOVATIVE ACTIVITIES

Innovations are summaries of new communication approaches that are being piloted over the short term that can demonstrate effectiveness and efficiency in achieving intended results. For example, involvement of children’s school clubs or community organizations in monitoring AEFI, immunization drop-outs and coverage through the coordinated use of their mobile phones could be piloted and evaluated as an innovative technique.
DOCUMENTING LESSONS LEARNT, GOOD PRACTICES AND INNOVATIONS IN VACCINE SAFETY COMMUNICATION

• It is important to document and report communication experience around vaccine safety issues.
• Engage the services of documentation specialists and journalists working in the field of health to prepare high-quality case studies, features, vignettes and human interest stories, based on monitoring and evaluation reports, interviews, and field visits. Engage them in preparing progress reports in plain language, power point presentations and people’s stories about communication actions around vaccine safety, AEFI, counteracting rumours and other immunization issues.
• Three categories of documentation are described: innovations, good practices and lessons learnt.
• These documents, if well planned and well written, will prove useful in mobilizing more resources from donors, inspire stronger collaboration of partners, allies and the media, and wider cooperation and concerted action among parents, guardians and their communities
WEBSITES ON VACCINES SAFETY COMMUNICATION

WHO Global Vaccine Safety

WHO Regional Office for the Western Pacific Immunization safety
http://www.wpro.who.int/topics/immunization_safety/en/

WHO Vaccine Safety Training
http://www.vaccine-safety-training.org/

WHO Immunization, Vaccines and Biologicals
http://www.who.int/immunization_monitoring/data/en/

UNICEF Immunization
www.unicef.org/immunization

Gavi, the Vaccine Alliance
www.gavi.org

Centers for Disease Control and Prevention Vaccine Safety
www.cdc.gov/vaccinesafety/index.html

Allied Vaccine Group
www.vaccine.org

Immunization Action Coalition
www.immunize.org

Institute for Vaccine Safety – Johns Hopkins School of Public Health
www.vaccinesafety.edu

Gates Children’s Vaccine Program at PATH
http://www.path.org/vaccineresources/

The Communication Initiative
www.comminit.com

New Vaccine Initiative
https://sites.google.com/site/commframe/annexes/annex-2

UNICEF Immunization Summary

WHO, UNICEF, World Bank: The state of the world’s vaccines and immunization, 2009

Brighton Collaboration
www.brightoncollaboration.org


Revised classification from the Council for International Organization of Medical Sciences (CIOMS) and Definition and Application of Terms for Vaccine Pharmacovigilance. Report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance; CIOMS; 2012.


## ANNEX 1. TIMELINE FOR COMMUNICATION RESPONSE TO AEFI AT NATIONAL LEVEL

<table>
<thead>
<tr>
<th>TIMING OF AEFI</th>
<th>COMMUNICATION ACTION</th>
</tr>
</thead>
</table>
| **Before AEFI** | • Establish a communication task force.  
• Build relationships with media, partners and health staff.  
• Install AEFI monitoring system.  
• Assemble a bank of information about AEFI.  
• Conduct communication analysis.  
• Prepare communication plan and media plan.  
• Develop, pre-test, pre-produce and pre-position IPC tools.  
• Develop and preposition “back pocket” materials for media (FAQs, Q&As, facts sheets, etc.).  
• Select and train the spokesperson/s.  
• Give media orientations.  
• Provide ongoing information to media about the programme.  
• Train relevant staff on IPC, counselling, media relations, communication plan, management and coordination. |
| **During AEFI** | **Immediately:**  
• Explain the importance of immunization and vaccines - that these are safe and provide effective protection against diseases.  
• Activate communication task force.  
• Identify what has happened - verify the report.  
• Gather information and analyse data.  
• Decide what to communicate.  

**Within 24 hours:**  
• Implement the communication plan.  
• Alert the spokesperson.  
• Select the media (radio, TV, print etc.).  
• Prepare/update media and IPC materials for your “back pocket”.  

**Within 72 hours:**  
• Consider to prepare a media release.  
• Consider to organize a media conference.  

**Ongoing:**  
• Monitor activities, ongoing responses of audience groups and outcomes of communication actions.  
• Counteract any spread of rumours.  
• Provide IPC tools to health-care workers; FAQs, Q&As, fact sheets to partners, media and public.  
• Provide ongoing information to media about the programme. |
| **After AEFI** | • Evaluate communication actions, behaviour outcomes and feedback to help plan future AEFI responses.  
• Document lessons learnt, good practices and innovative actions. |

Adapted from: WHO Vaccine Safety Events: Managing the communication response: A Guide for Ministry of Health EPI Managers and Health Promotion Units. Regional Office for Europe, Copenhagen, Denmark, 2012.
ANNEX 2. FORMATIVE RESEARCH: THE FIVE COMPONENTS OF A COMMUNICATION ANALYSIS

A communication analysis will provide quantitative and qualitative data and evidence that is essential to guide the development of the communication strategy and action plan for vaccine safety. Although realistically it may not be possible to ask and answer every one of these questions, they are included here as a reminder of the level of depth that is required in order to understand the multiple influences and determinants of people’s behaviours and predispositions to respond to and participate in EPI and vaccine safety communication.

1. Problem and programme analysis

A problem analysis should answer the following questions:

- What is the problem, e.g. AEFI? Rumours? Misconceptions? Political influence?
- Who is affected by the problem? Where are they?
- What immediate-, short- and long-term measures are being taken to address the problem?

A programme analysis should answer the following questions:

- What has been the programme’s response to the problem, e.g. AEFI? What are authorities doing to investigate the problem? Is there a proactive communication plan for dealing with the response?
- Is communication integrated into the NIP’s government structure, plans and programmes? Do they have dedicated communication staff? Is the communication component included in the budget?
- If so, what structure and coordination mechanism has the programme established for communication? What other structures and partnerships are needed to make communication interventions effective?

2. Communication environment analysis

A communication environment analysis describes the broader communication landscape - the institutions within which communication takes place at the national, subnational and local levels, and the social, cultural, economic, political, and geo-physical factors. This includes the following questions:

- In a centralized or a decentralized structure, how do the current political system and the health system in the country influence the channels of communication, the flow of information through the interpersonal channels in communities, the mass media and ICT?
- Describe the sociocultural profile as it relates to equity in immunization services and in addressing vaccine safety issues – what is the impact, both positive and harmful, of different groups on immunization practices and response to vaccine safety issues.
- What political, economic, sociocultural and geophysical constraints and opportunities hinder or facilitate the flow of communication from the bottom-up, top-down and across the various ethnic, religious and marginalized groups?
- Is there documentation available about past experiences of communication activities on immunization and AEFI and their impact? If so, this should be analysed for its current relevance in terms of past lessons learnt and good practices in addressing vaccine safety concerns.
3. Audience/participant analysis

Every individual is part of other larger units: a family, a neighbourhood, a social network, a community, an occupational group, a society, a religion and others. Each of these units directly or indirectly influences how an individual makes decisions and behaves. The first step in analysing behaviour is for people to share information about who influences them about an issue. The purpose of audience analysis is to identify relevant audience groups, their characteristics, and what influence they have on each other to bring about and maintain the practice of desired behaviours. Different communication approaches, messages and content will be designed to address communication objectives for each group.

Who are the audiences/participants in vaccine safety communication?

Audiences/participants in vaccine safety communication can be classified as primary, secondary and tertiary. (See section 4.2)

4. Behavioural analysis - determining desired behaviours/actions; barriers and motivators to vaccine safety communication of participant groups

Our communication goal is for parents and guardians to have confidence in vaccines and in immunization so that their children will be protected from vaccine-preventable diseases. But when parents are confronted with contradictory beliefs, attitudes and rumours about risks of adverse reactions to vaccines, making them reluctant to have their children vaccinated, simply communicating knowledge about vaccine safety is not enough. We need to look into potential barriers to people’s decisions to adopt or continue desired behaviours.

Behavioural analysis entails asking the questions: (See Table 3. Key behavioural results for vaccine safety communication and immunization by audience group)

- What do we want parents, guardians and their families to know, feel and do as a result of vaccine safety communication?
- What do we want communities to know, feel and do in order to provide a supportive environment for families and communities on immunization?
- What do we want health-care providers, programme managers, clinicians, academics, policy- and decision-makers to know, feel and do to provide an enabling environment for the immunization programme?
- What are the barriers that prevent these groups from performing the desired actions?
- What are the predisposing (KAP, social norms, values, beliefs), supportive (family, friends, community) and enabling (policies, health service delivery system, financial, communication environment, etc.) factors that can motivate them to practice the desired behaviours?

5. Communication channel analysis

Communication channel analysis involves a comprehensive review of the mix of communication channels available and how these can be accessed and used by intended participant groups. The analysis looks into what combination of channels, materials, networks and creative treatments have been used effectively or ineffectively in the past or are lacking in the programme. How can the effective channels, materials and creative approaches be used or adapted for the current programme? Which channels, materials and treatments are ineffective and not audience appropriate and need to be dropped or improved? Communication channel analysis describes:
• The culture of interpersonal communication and social networking in the community and larger society – especially as relevant to the selected participant groups.

• The role, capacities and constraints of health-care providers as interpersonal channels of communication. These are the groups listed as secondary participants who come into contact with the primary participants such as parents, guardians and vaccine recipients.

• The availability and local use of community and traditional media and their potential and/or current application to support communication objectives.

• The use, coverage and control of national and community radio and television/cable TV and their potential and/or current use.

• The use and coverage of print media related to languages used and literacy rates – national and local – and their potential and/or current use in communication for development (C4D).

• The use of ICT, mobile phones and social media platforms, their potential and/or current use for messaging and monitoring immunization coverage.

Source: Adapted from UNICEF Guidelines for undertaking a communication for development situation analysis. Prepared by Teresa Stuart and Judith Graeff, C4D Unit, Division of Policy and Planning, UNICEF New York, USA, 2010.
## ANNEX 3. DISEASE, VACCINE STATUS IN THE REGION AND ADVERSE REACTION RATES

### TUBERCULOSIS

<table>
<thead>
<tr>
<th>Disease</th>
<th>Vaccine Status in the Region</th>
<th>Adverse Reactions &amp; Rates*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuberculosis</td>
<td>All countries and areas in the WP Region have introduced BCG vaccine into their national immunization programme.</td>
<td>Suppurative adenitis 100-1000 per 106</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BCG osteitis 100-1000 per 106</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Disseminated BCG-itis 100-1000 per 106</td>
</tr>
</tbody>
</table>

### DIPHThERIA, PERTUSSIS, TETANUS (DPT)

<table>
<thead>
<tr>
<th>Disease</th>
<th>Vaccine Status in the Region</th>
<th>Adverse Reactions &amp; Rates*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria</td>
<td>All countries and areas in the WP Region have introduced diphtheria, pertussis &amp; tetanus containing vaccine into their national immunization programme and these diseases have been largely eliminated from the Region.</td>
<td>Whole cell WP vaccine Fever 37.2°C - 39°C 12.4% - 44% Injection site Redness 12.4% - 44% Swelling 22.4% - 38.5% Persistent screaming 3.5% HHE 57-250 per100,000 Seizures 6 per 100 000 Encephalopathy 0.5-3 per 106 Anaphylaxis 1.3 per 106</td>
</tr>
<tr>
<td>Pertussis</td>
<td></td>
<td>Acellular aP vaccine Fever 37.2°C - 39°C 2.8% - 20.8% Injection site redness 2.8% - 20.8% Swelling 4.2% - 20.1% Persistent screaming 0-0.2% HHE 14-62 per100,000 Seizures 0.5 per 100 000</td>
</tr>
<tr>
<td>Tetanus</td>
<td>Brachial neuritis 5-10 per 106 Anaphylaxis 1-6 per 106</td>
<td></td>
</tr>
</tbody>
</table>

- Tuberculosis is a chronic disease caused by *Mycobacterium tuberculosis*. Primary infection often goes unnoticed clinically; it may progress to pulmonary tuberculosis, military tuberculosis or meningitis. Annually 8.8 million cases/year (2010) with 1.45 deaths/year (2010). The only vaccine available for the prevention of tuberculosis is BCG (bacillus Calmette-Guérin), which was first developed in 1920s.

- Diphtheria is a potentially acute disease caused by *Corynebacterium diphtheriae*. Devastating diphtheria epidemics affecting mainly children have been described from many countries throughout history. Mortality rate is 2%-10%.

- Pertussis (whooping cough) caused by *Bordetella pertussis*. The clinical outcome of pertussis depends on factors such as age and vaccination status. Older age groups represent an important source of infection for susceptible infants.

- Tetanus is caused by *Clostridium tetani*. The disease may affect any age group. The immunized mother passes antitoxin via the placenta to her fetus, thereby preventing neonatal tetanus. If not treated, the mortality of neonatal tetanus is 95% and with treatment, 20-90%.
<table>
<thead>
<tr>
<th>DISEASE</th>
<th>VACCINE STATUS IN THE REGION</th>
<th>ADVERSE REACTIONS &amp; RATES*</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLIOMYELITIS</td>
<td>Although the global eradication programme is rapidly clearing poliomyelitis from many parts of the world, the threat of reintroduction remains. The Region has been maintaining polio-free status since 2000.</td>
<td>Oral Polio Vaccine (OPV)</td>
</tr>
<tr>
<td></td>
<td>All countries and areas in the WP Region have introduced OPV or IPV vaccine into their national immunization programme.</td>
<td>Vaccine Associated paralytic Polio (VAPP) - 1 per 6.4 million doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Injectable Polio Vaccine (IPV)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Injection site erythema 0.5%-1.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Induration 3% - 11%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tenderness 14%- 29%</td>
</tr>
<tr>
<td>HEPATITIS B (HEP B)</td>
<td>Caused by hepatitis B virus (HBV), it is a major cause of acute and chronic hepatitis in the world. 80-90% of those infected during the first year of life will develop chronic infection leading to liver cirrhosis and liver cancer.</td>
<td>All countries and areas in the WP Region have introduced Hep B vaccine into their national immunization programme.</td>
</tr>
<tr>
<td></td>
<td>All countries and areas in the WP Region have introduced Hep B vaccine into their national immunization programme.</td>
<td>Fever &gt; 37.20°C 1%-6%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Headache 3%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Injection site pain 3%-20%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Redness 3%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Swelling 3%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Anaphylaxis 1-2 per 106</td>
</tr>
<tr>
<td>HAEMOPHILUS INFLUENZAE TYPE B (HIB)</td>
<td><em>Haemophilus influenzae b</em> (Hib) is a common cause of bacterial meningitis, pneumonia and septicaemia in children. Risk peaks in the second six months of life, then decreasing to become very rare after the fifth birthday. Neurological Impairment is 15%-30% and mortality is 5%. As of 2014, 35 countries and areas in the WP Region have introduced Hib vaccine into their national immunization programme. None known.</td>
<td>As of 2014, 35 countries and areas in the WP Region have introduced Hib vaccine into their national immunization programme.</td>
</tr>
<tr>
<td>MEASLES</td>
<td>Measles is a highly infectious, acute viral illness. Complications are more common in children under the age of 5 years.</td>
<td>None known.</td>
</tr>
<tr>
<td></td>
<td>Otitis media 7%-9%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pneumonia 1%-6%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Encephalitis up to 1%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>As of 2014, of the 37 countries and areas in the WP Region, 34 have likely interrupted transmission of indigenous measles virus.</td>
<td>Fever 2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Injection site reaction 17%-30%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute arthralgia 25%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute arthritis 10%</td>
</tr>
</tbody>
</table>
## Rubella

- **Disease:** Generally mild illness but can rarely cause more serious illness, similar to measles with encephalitis. If infected in first eight weeks of pregnancy up to 85% of infants could be affected with congenital rubella syndrome (deafness, blindness, brain damage and heart problems).

  - **Vaccine Status in the Region:** As of 2014, of the 37 countries and areas in the WP Region, 34 have introduced rubella vaccine into their immunization programme.

  - **Adverse Reactions & Rates:**
    - Fever: 5% - 10%
    - Rash: 5%
    - Injection site reaction: 17% - 30%
    - Febrile seizures: 1 in 2000 - 3000
    - Encephalomyelitis: 1 per 106
    - Thrombocytopenia: 1 per 30,000
    - Anaphylaxis: 1 - 3.5 per 106

## Pneumococcal Infections

- **Disease:** Pneumococcal disease is a leading vaccine preventable child killer. Complications: hearing impairment, septicaemia, septic arthritis, osteomyelitis, pneumonia, meningitis. Mortality is 1.4 million/year (<5 years) globally.

  - **Vaccine Status in the Region:** As of 2014, 20 countries and areas in the WP Region have introduced PCV vaccine into their national immunization programme.

  - **Adverse Reactions & Rates:**
    - Fever > 39°C: <1%
    - Injection site reaction:
      - Unconjugated vaccine: 50%
      - Conjugated vaccine: 10%

## Human Papilloma Virus Infections (HPV)

- **Disease:** Human papilloma virus (HPV) infections leading to cervical cancer, which is the second highest cause of cancer deaths in women. 70% of cervical cancers are caused by HPV.

  - **Vaccine Status in the Region:** As of 2014, 19 countries and areas in the WP Region have introduced HPV vaccine into their national immunization programme.

  - **Adverse Reactions & Rates:**
    - Fever: 3% - 13%
    - Headache: 3% - 30%
    - Injection site pain:
      - Up to 78%
    - Redness:
      - 25% - 30%
    - Swelling:
      - 5% - 26%
    - Rash:
      - 1%
    - Arthralgia:
      - 10%
    - Anaphylaxis:
      - 1.7 - 2.6 per 106

## Rotaviruses Infection

- **Disease:** Rotaviruses are the most common cause of severe diarrhoeal disease in young children throughout the world and responsible for around a half million deaths among children aged <5 years each year.

  - **Vaccine Status in the Region:** As of 2014, 9 countries and areas in the WP Region have introduced rotavirus vaccine into their immunization programme.

  - **Adverse Reactions & Rates:**
    - Intussusception: 1 - 2 per 100,000
    [For first dose in some populations. No apparent increase identified with subsequent doses]

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*Source: WHO vaccine reaction rates information sheets. [www.who.int/vaccine_safety/initiative/tools/vaccinfosheets](www.who.int/vaccine_safety/initiative/tools/vaccinfosheets)*
ANNEX 4. KEY MESSAGES FOR SPOKESPERSONS ON IMMUNIZATION AND VACCINES

Spokespersons should repeat these messages consistently during interviews:

KEY MESSAGES ON IMPORTANCE OF A SUSTAINED IMMUNIZATION PROGRAMME

- Immunization is key to achieving the goal of reducing vaccine preventable deaths among children under five years old.
- In the past, millions of people died or were disabled from diseases that we can now prevent with vaccines. If we do not continue to vaccinate, these diseases will return and claim more lives.
- Immunization currently prevents an estimated 2-3 million deaths every year. But, an estimated 22 million infants worldwide are still missing out on basic vaccines.
- Vaccines save lives.
- It is more hazardous not to vaccinate, because of the potential serious complications of the disease.
- It is much safer to be vaccinated than to contract the disease.
- Vaccines can cause reactions, but mostly they are mild, do not last long and self-limited; very rarely do they lead to serious or long-term problems.
- The safety of vaccines is of fundamental concern to health-care providers, and if there are any perceived or real problems with safety, these are investigated and corrected.
- The safety of vaccines is closely monitored by surveillance, and thereby safety of vaccine and immunization is ensured.
- All vaccines have a safety profile, meaning they have expected minor reactions, but these are usually mild and temporary.

INVESTING IN IMMUNIZATION

- Immunization remains one of the most cost-effective health interventions, even with newer, more expensive vaccines.
- By keeping children healthy, immunization helps to extend life expectancy and time spent on productive activities. Immunization therefore helps to reduce poverty.
- A fully immunized child is more likely to attend school, have greater cognitive abilities, and be a more productive member of society and less likely to be disabled as result of serious disease.

RECALL/SUSPENSION

- Many types of products including cars and food products are sometimes recalled temporarily or even withdrawn permanently from the market because of a safety concern after the product was used widely. Medicinal products are also sometimes recalled or withdrawn from use. Similarly a vaccine or vaccines lots can be withdrawn or recalled for safety purposes, but it happens rarely. All these are safety precautions.

VACCINE DEVELOPMENT

- New life-saving vaccines have been developed and others will soon be available.
- Systems have been put in place to ensure the safety, effectiveness and quality of vaccines.
Annex 5. Frequently Asked Questions (FAQs) About Combined Vaccines

Are Vaccines Safe?
Vaccines are very safe. They prevent dangerous, deadly diseases that can lead to blindness, deafness, brain damage, heart problems, pneumonia, and paralysis and carry a risk of life-long disability or death. Vaccines have saved millions of lives.

How Can We Be Sure That Vaccines Are Safe?
Remember that there is nothing in life that is 100% safe – not even water, since you can drown in it. No medicinal product is 100% safe, although some are lifesaving. Similarly, although vaccines are very safe, there is the possibility of adverse events.

Vaccine development is a costly process. A vaccine has to pass a lengthy testing process before it comes on to the market for public use. Vaccines also have to be licensed for use by the National Regulatory Authority (NRA). This means that vaccines have to undergo extensive additional safety and quality checks before they can be brought into the country. In addition, they are also monitored for safety after licensure. WHO prequalification of vaccines is another option for assuring vaccine safety.

UNICEF assists countries in the purchase of vaccines that are WHO prequalified for the national expanded programme on immunization (NEPI). This means the vaccines we use are safe, as they have passed and meet global safety and quality standards.

If any adverse reaction does occur, this is usually minor and self-limited, lasting only for a few days. Such side effects do not disrupt daily activities. Serious adverse reactions from vaccines are extremely rare. Vaccine safety is closely monitored by the national expanded programme on immunization so that any problems can be dealt with quickly and timely.

At What Rate Do AEFI Occur in a Vaccination Campaign?
During a mass vaccination campaign or supplementary immunization activity, millions of doses of vaccine may be given.

That means that even if AEFI occur at the same rate as for the rest of the year, we can expect that this would result in a more concentrated occurrence of AEFI than usual. For instance, if the expected rate of high fever following administration of measles vaccine is 2% of vaccines and a country gives on average 100,000 doses of measles vaccine in one year, then it would be expected that over the year 2000 children would be reported with high fever following administration of measles vaccine.

This works out as approximately 40 children per week (2000 over 52 weeks = around 40). If a campaign were to be carried out in which 100,000 doses of measles vaccine were given in one week, we would expect 2000 children with high fever to be reported in that week. The rate remains the same, and it is only the number of high fever cases reported during that one week of vaccination campaign that is causing concern. Parents and guardians need to be reassured that vaccines are safe and that the reported AEFI numbers are still within the expected, low rate of 2%.
WHAT IS A COINCIDENTAL DEATH?
Every year a certain number of children under 1 year and under 5 years will die, due to various causes. This is expressed as a rate per 1000 live births for every country. Because we give many vaccines to children this age, it is possible that death might occur after any of these vaccinations, although caused by another condition, such as pneumonia, meningitis etc. These are called ‘coincidental child deaths’ and should not be attributed to immunization. In these cases a proper causality assessment, particularly supported with postmortem findings, can prove that the vaccine has no link to the death.

IS IT TRUE THAT VACCINES CAN CAUSE AUTISM?
All parents have questions about the risks associated with immunization; some worry that vaccines may cause health problems such as autism. Over the past decades, several expert research committees around the world have investigated reports that claim a link between autism and MMR vaccines. Their research has found no evidence of a link between MMR vaccine and autism.

WHAT IS BEING DONE BY NATIONAL EPI TO MONITOR THE SAFETY OF VACCINES?
Here are the steps that are in place to ensure vaccine safety:

1. Before licensure, regulatory processes called ‘Good Laboratory Practices’, and ‘Good Clinical Practices’ ensure that laboratory and clinical studies done to provide evidence of product safety meet the highest standards of quality.
2. Vaccines are only approved and recommended if there is sufficient evidence that they are both effective and safe, with a high margin of safety.
3. Before and after licensure, regulatory processes called ‘Good Manufacturing Practice’ are in place to ensure the highest quality of manufacturing is used to produce vaccines.
4. Vaccine manufacturing facilities are regularly inspected and given a license by regulators.
5. Even though WHO prequalifies vaccines, every new lot of vaccines produced has to be cleared by regulators before it is approved for use in a country. The “lot release” programme ensures, to the extent possible, that each new lot of vaccine matches the lots used to establish safety and effectiveness that were the basis for licensure.
6. Regulators and public health authorities continuously monitor vaccines through post marketing/licensure surveillance (AEFI surveillance) after they have been approved to detect any previously unrecognized safety concerns – for the product as a whole, for a new lot or for population subgroups that may have a higher risk of selected adverse reactions.
7. Vaccine safety is an international concern. Information on possible safety concerns is communicated very rapidly among different countries.

This careful monitoring ensures that public health authorities can act quickly to address concerns. In addition, research continues to improve the safety profile of vaccines.

Source: WHO Regional Office for the Western Pacific, 2013.
WHAT ARE COMBINED VACCINES?

- Combined vaccines have been developed to put together more than one antigen (disease agents against two or more diseases) into a vaccine to give in one single injection. Instead of your baby having many injections to provide protection against several vaccine preventable diseases, your baby receives only one injection that combines the same amount of vaccine against specific diseases.

- Examples of combination vaccines are:
  - DTP (a combination of diphtheria, tetanus and pertussis vaccines).
  - MR (measles and rubella vaccine).
  - Pentavalent vaccine is a combination of DTP and Hepatitis B and Hib (Haemophilus Influenzae) vaccine.

WHAT ARE THE ADVANTAGES OF COMBINED VACCINES?

- Combined vaccines mean that the child will get fewer injections.
- Combined vaccines give the same amount/level of protection as the vaccines given separately.
- Combined vaccines are as safe as vaccines given separately.
- Combined vaccines may help to reduce anxiety and limit the pain or discomfort that the baby may feel at an immunization visit.
- Combined vaccines make it easier to complete the child’s scheduled immunizations on time and help avoid delays.
- New combined vaccines are currently being developed.

WHAT ARE THE DIFFERENT TYPES OF PERTUSSIS VACCINE?

- The vaccine for Pertussis (whooping cough) can contain either the whole cell, killed of the bacteria (germ) responsible for this disease, i.e. whole cell Pertussis vaccine (DTwP), or only parts of a cell, that is acellular Pertussis vaccine (DTaP).

WHY DOES THE FEE-BASED SYSTEM OFFER ACELLULAR PERTUSSIS, WHICH WE HAVE HEARD IS BETTER, WHILE THE FREE VACCINE SYSTEM OFFERS WHOLE-CELL KILLED VACCINE? WHY GIVE OUR CHILDREN CHEAPER VACCINES?

- The acellular pertussis vaccine is more expensive because its production costs are high. However, paying more for a vaccine does not necessarily mean that it will be better. The difference between the two vaccines is that acellular pertussis vaccines have fewer side effects (mainly minor ones) but the vaccines are both of good quality and offer good and higher protection. New evidence even suggests that in terms of longer term protection, the whole-cell killed vaccine is better.

ANNEX 6. UNDERSTANDING THE MEDIA
The media also play an important role in advocating for continued and increased investments in immunization. When engaging the media, it is important to understand their perspective – what they are looking for and how they operate.

The media are bound by:
- autonomy;
- the need to attribute and check facts and quotes;
- media deadlines; and
- competition with other media – to "scoop" or get an exclusive.

The media like:
- a fast response;
- accuracy and simplicity;
- statistics with explanation;
- context (part of a wider picture);
- comments or explanation from the highest authority possible; and
- both or multiple sides of the story.

The media will ask:
- WHO – is affected/is responsible?
- WHAT – has happened?
- WHAT – is being done?
- WHERE – has it happened?
- WHEN – did it happen?
- WHY – did it happen?
- WILL – it happen again?

ANNEX 7. COMMUNICATION PLANNING TEMPLATE

The communication planning template suggested below may be used as a guide when preparing the outline of a vaccine safety communication strategy. It is good practice to research and prepare your communication plan in advance as part of your preparedness measures for VRE/AEFI and to counter-act any anti-vaccination rumours.

1. Background. Describe the principal findings from the communication analysis – the programme and problem analysis, the communication landscape, audience/participant analysis, analysis of barriers and motivators to the desired behaviours, and channel analysis. The background is a situation analysis that explains the context for the communication initiative being undertaken.

2. Communication goal. The communication goal is expressed in terms of what should happen over a given time that will help achieve your programme goal and that could be achieved by and/or contributed to by communication interventions. For example, “To achieve a high level of trust in vaccines among parents and guardians with a view to sustaining high immunization coverage in the country”.

3. Communication objectives. Objectives should be formulated in terms of key behaviour results or desired actions by your primary or priority audience group as well as by secondary (health-care providers, community) and tertiary (leaders, influencers) audiences. Ensure your communication objectives are SMART – specific, measurable, attainable, relevant and time-bound.

4. Communication strategy. The strategy provides guidelines on the communication actions and describes how the intended behaviour outcome(s) for each participant group is/are to be achieved, as guided by evidence from the communication analysis. The strategy details the communication approaches and entry points – IPC, group communication, community mobilization, social mobilization, media engagement, advocacy – with the primary participant group (for behaviour and social change); with the secondary participant group (for community engagement and social mobilization); and/or with the tertiary participant group (for advocacy).

5. Implementation plan. The implementation plan describes the communication actions outlined in the strategy. Present the implementation plan in several related matrices or tabular format. Then prepare a work plan in the form of a table with columns that detail the following:
   - milestones by communication approach;
   - activities to achieve behaviour results;
   - coordination and management: responsible person/internal or partner agency;
   - timeframe; and
   - estimated budget.

6. Monitoring and evaluation plan for vaccine safety communication provides details of the indicators to be measured, methods for data gathering, responsible group or agency, required training on methods and tools, system for reporting and sharing information from M&E with communities, the media and with the government.

Source: Dr Teresa Stuart Guida, WHO Regional Office for the Western Pacific, Communication Consultant, November 2013.
ANNEX 8. PRESS STATEMENT

Suspension of pentavalent vaccine use by the government of Country A

Holding statement from WHO in Country A

On 4 May 2013, the Ministry of Health of Country A announced the temporary suspension of pentavalent vaccine, a combination vaccine that protects against diphtheria, tetanus, pertussis, hepatitis B and Haemophilus influenzae type b infections. This suspension follows a recent increase in the number of reports of adverse events following immunization (AEFI) with pentavalent vaccine and, in most instances, oral poliovirus vaccine, including the death of young infants within a few days of receiving the vaccine.

WHO was invited by Country A authorities to review the 43 serious AEFI cases that have been documented in the country since pentavalent vaccine was introduced in mid-2010, including the 21 most recent cases (12 deaths and nine who recovered) reported between 1 October 2012 and 31 March 2013. This review involved one independent clinical expert together with WHO staff from Headquarters, regional and country Offices who collaborated with national experts and UNICEF colleagues in assessing clinical and other information available.

Based on this review, it appears that nine non-fatal cases could correspond to known vaccine reactions. Transient reactions of this type, including allergies, seizures and decreased muscle tone, are to be expected in a very small number of recipients of the vaccine. These effects of the vaccines pass, while the benefits of the vaccine remain, and save lives.

After careful investigation, it was found that other serious AEFI reported in Country A were either coincidental health problems related in time but not causally related to the use of pentavalent vaccine, or cases for which the information available does not allow for a definite conclusion (which is a common situation when individual cases are assessed). However, there are no elements of those cases that could be consistent with an effect of the vaccine.

Pentavalent vaccine was prequalified by WHO in 2006 and, to date has been used in more than 90 countries with more than 400 million doses of vaccine administered. This and other similar pentavalent vaccines are extremely safe: no fatal AEFI has ever been found to be associated with this vaccine. Pentavalent vaccine can cause limited reactions such as fever or local reaction (transient inflammation at the injection site) in a small proportion of vaccinated infants.

WHO is collaborating with Country A authorities in further assessing those events. AEFI associated with pentavalent vaccine from other countries are also consistent with the known reactions that could be expected from each of the individual vaccine components. An update will be provided in due course to relate progress with the assessment of AEFI from Country A.

Source: NRA and vaccine safety focal point, WHO Regional Office for the Western Pacific, 2013.
ANNEX 9. EFFECTIVE INTERPERSONAL COMMUNICATION FOR HEALTH-CARE PROVIDERS AND VACCINATORS: TRAINING SCENARIO

Scenario: AEFI of pentavalent vaccine has occurred in Country A

As health-care workers, it is essential for you to demonstrate effective interpersonal communication (IPC) skills in your delivery of health-care services to the community.

Start by warmly greeting parents who have come to the health centre for their child’s immunization.

They may have heard stories about pentavalent vaccine and may be unsure about whether to trust you and other health-care workers. They may also have lost confidence in the immunization programme. So, it is very important at this time that you build trust. You can do this by showing a caring attitude and by doing your job well. If you personally are concerned about the vaccine speak to your supervisor.

When a parent or guardian comes to you with their baby:

- Ask how they are and how their day was so far.
- Ask how their baby is. If the baby has not been well, tell the parent/guardian to bring the baby back for immunization on another day when the baby is better.
- Ask the parent/guardian if they have any questions about pentavalent vaccine. They may be worried about the risk they feel they are taking for their baby, even though it is small, by saying yes to the vaccine.
- Tell them that the tests of pentavalent vaccine have proved that the vaccine is safe and of good quality.
- Tell them there is no link between the previous deaths and pentavalent vaccine.
- Tell them the diseases that pentavalent vaccine prevents cause lots of pain and suffering for children and can even cause death.
- Tell them the government will never allow unsafe vaccines and vaccines that are not of good quality to be given to children in Country A.
- Tell them that pentavalent vaccine was also suspended in Country B and after independent tests the vaccine was re-introduced.
- Tell them that pentavalent vaccine is currently being used in more than 90 countries around the world.
- If the parent/guardian is still worried about safety, tell them that nothing in life is 100% safe – not even water is safe as you can drown in water. No medicines or vaccines are 100% safe, but vaccines are among the safest tools of modern medicine.
- Tell the parent/guardian that it is usual/normal to expect a possible minor adverse reaction, like local reactions (pain, redness, and swelling) or mild fever, but that this does not last long. Serious adverse reactions from vaccines are very rare.
- Tell the parent/guardian that a severe allergic reaction can occur but is extremely rare. If it does occur, it is usually within 30 minutes, which is why you ask them to sit at the clinic for 30 minutes after immunization. It’s also why you ask them to watch/monitor their baby for the next 48 hours, because most minor adverse reactions occur during that period. If the baby is not well, you ask them to come back to the health centre.
- Tell them that if they hear false rumours about the vaccine’s safety they should discuss this with you as you are a health worker and you have learned about vaccines and have the correct information.