MODULE 6
Communication
Overview

Every year, billions of doses of vaccine are given in immunization programmes around the world. Vaccines are designed to provoke an immune response in the body, and it is inevitable that this reaction carries a small attributable risk to the health of a tiny minority of recipients. This risk is hugely outweighed by the very significant benefits of immunization in terms of protection from vaccine-preventable diseases and their wide-ranging consequences.

Explaining risks and benefits of vaccines clearly to parents, guardians and vaccine recipients requires effective communication and interpersonal skills from trained health professionals in immunization programmes and educators such as school teachers.

This module will help you to understand public fear and concerns, and how you can improve your communication skills on the subject of vaccine safety.

Module outcomes

By the end of this module you should be able to:

1. Understand the need for improved communication on vaccine safety,
2. Critically evaluate and assess new information about vaccines before communicating to the target audience,
3. Gather information about the various target audiences, who they are, how they perceive vaccine risk and their knowledge about vaccines and safety,
4. Outline the fears and concerns of different groups associated with, or likely to be affected by, an immunization programme,
5. Design, simple, clear and tailor-made messages to communicate information about vaccine safety to your target audience (e.g. parent, vaccinee, clinic staff, media, health professional, drug regulatory authority, health minister, etc),
6. Identify the most suitable means and channels of communication to convey information to different target groups,
7. Understand the media as being an important ally in vaccine safety.
Risk communication

Need for improved communication

Concerns are frequently raised about vaccines and immunization protocols by members of the general public and in the media. These concerns can be serious and are often misplaced. See the graphic below for some factors that may trigger public concerns.

We need to improve the quantity, quality and targeting of communication about vaccine safety if we are to increase acceptance of vaccination through improved awareness of the risks and benefits.

Challenges to effective communication

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

Decline of childhood infections in high-income countries

The impressive decline in the rates and severity of childhood infections in high-income, industrialized countries during the twentieth century (see diagram) has effectively faded memories of the threats to health and life posed by once-common diseases such as measles, polio, pertussis, diphtheria and tetanus. The benefits of vaccination are no longer being reinforced by direct experience of the diseases that vaccines prevent.

Crude death rate* for infectious diseases – United States, 1900 – 1996**

![Graph showing the decline of childhood infections in high-income countries]


* Per 100,000 population per year.

Parents view that infectious disease is a thing of the past

Some parents in countries such as the USA and western Europe may feel that exposing a child to even a small potential risk from vaccination is unnecessary because they assume that infectious diseases are ‘a thing of the past’. Parents have to be made aware of the consequences of their decisions not to vaccinate their children – if herd immunity falls, the disease may re-emerge and spread through the population. This is what happened when concerns about the safety of the vaccine against measles, mumps and rubella (MMR) in the 1990s led to a sharp decline in vaccine uptake in the UK, followed by an increase in cases of measles, mumps and rubella.

Introduction of new vaccines

New vaccines are being introduced and a wider range of ages is being targeted for routine immunization. For example, teenagers in some countries are offered vaccines against human papillomavirus and bacterial meningitis. Likewise, elderly people are encouraged to seek vaccination against influenza. In the developing world, women of childbearing age are targeted for vaccination with at least two doses of tetanus toxoid to protect themselves and their newborns from the disease.

Communication with different age groups requires different skills and the use of age-appropriate language. Staff needs to be prepared and trained to deal with the different target groups and to expect different adverse events (e.g. immunization anxiety may occur at a different frequency in different age groups).

Transparency and accountability

Finally, good communication to all relevant stakeholders is essential to keep the trust of the public towards a transparent and accountable immunization service.

Communicate only reliable information

Before beginning a consultation or leading a training/education session, all health workers must carefully evaluate the reliability and validity of the information they give to clients, patients or professional colleagues.

The national AEFI coordinator is responsible for ensuring that a critical review of the vaccine literature is available to health workers.

Ensuring that the literature, library or database is accurate, and up to date, supports effective communication in several ways:

- It ensures that up-to-date vaccination policies and procedures are applied at national level,
- It facilitates effective management of rumours and community concerns arising from poor science or misleading reports in the media,
- It supports the detection, investigation and decision-making about actions needed in response to new safety concerns. These may originate from other places/countries or may occur during the introduction of new vaccines.

Before acting on new information about vaccine safety in the scientific literature, ensure that you critically review the published material yourself if this is within your expertise.

You can also seek advice from an expert who is qualified and trained to conduct an evaluation. Such experts can be persons from the National immunization programme (NIP) or the National regulatory authority (NRA). If appropriate expertise is limited or inaccessible, obtain guidance from international...
sources, such as the Global Advisory Committee on Vaccine Safety (GACVS) or WHO’s Vaccine Safety Net. The WHO evaluation of whether MMR vaccine increases the incidence of autism is a good example of an expert evaluation by the Global Advisory Committee on Vaccine Safety, responding to information needs of the public.

**WHO evaluation of whether MMR vaccine increases the incidence of autism**

In 1998, a researcher claimed that MMR vaccine increases the incidence of autism. Parents expressed their concerns and media reported widely on this statement. Global scientific advice on this issue was needed for professional staff to take informed decision on this issue.

WHO, based on the recommendation of its advisory body the Global Advisory Committee on Vaccine Safety (GACVS) (who.int/vaccine_safety/committee), commissioned a literature review by an independent researcher of the risk of autism associated with MMR vaccine. The existing studies did not show evidence of an association between the risk of autism or autistic disorders and MMR vaccine.

Based on the extensive review presented, GACVS concluded that no evidence existed of a causal association between MMR vaccine and autism or autistic disorders. The Committee expressed its belief that the matter would likely be clarified by an improved understanding of the causes of autism.

GACVS also concluded that there was no evidence to support the routine use of monovalent vaccines against measles, mumps and rubella vaccines over the combined vaccine, a strategy which would put children at increased risk of incomplete immunization.

GACVS recommended that there should be no change in current vaccination practices with MMR.

**Simplified and key messages**

In earlier modules and in the previous case study, we described and illustrated how you communicate complex detailed information about AEFIs accurately and systematically, using the approved procedures for reporting adverse events to higher levels (e.g. the NRA). The focus of this module is to support your ability to communicate appropriately targeted and simplified messages about vaccine safety to relevant audiences.

It is important to be clear about key messages and simple messages. To frame your communication simply and clearly, while covering all the essential points, you first need to know:

- Who is your intended audience?
- What is their background knowledge, attitudes and beliefs about vaccination?
KEY MESSAGES
- Key messages give the most important information that you want the public to know. One or two sentences get to the heart of the matter.
- Key messages help you to take charge of a situation that requires firm, unambiguous communication, e.g. to refute a misleading rumour or inaccurate report in the media.

SIMPLE MESSAGES
- Simple messages are "jargon free" and easy for the general public to understand.
- They "translate" complex concepts and information into readily accessible ideas and examples.
- They may be short (e.g. slogans used in a campaign poster), or much longer (e.g. an article in a magazine or on a website).

Question 1*
Example key messages of a statement developed to respond to a public concern about a cluster of fatal AEFIs:

- Three children died after immunization with measles vaccine at a Central Clinic,
- Investigations found the cause of death is not due to the vaccine, but to problems arising from unsterile needles,
- Measles causes 750,000 deaths and debilitating disease in children worldwide every year,
- The measles vaccine is the only effective measure in the world for the control of measles,
- Staff training in injection safety and infection control will be prioritized to prevent similar adverse events from occurring.

Look at the example key messages. Which of the five categories of AEFI that you have learnt in Module 1 is the cause of the problem here?

Refrain from over-simplifying or withholding information

Vaccination clinic staff may fear that raising the topic of vaccine-associated risks with members of the public may cause alarm and generate concerns about vaccination where none existed previously. Some health workers may also be tempted to omit certain information about vaccine safety to parents, guardians or vaccinees, assuming a lack of understanding on their part. In particular, health workers may believe that members of the public cannot absorb complex scientific information, for example, about how the immune system responds to a vaccine and why vaccine reactions sometimes occur. For the same reason, health workers may be hesitant to explain the risks and benefits of a vaccine using the background rate of an adverse event, the rate of the same event in the vaccinated population, and how the population risk relates to the risk of an AEFI occurring in a vaccinated individual.

* The answer to all questions can be found at the end of this manual (page 202).
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Do

Inform vaccinees or their families. They deserve to know the details about the vaccine:
1. Name of the vaccine,
2. What the vaccine protects against,
3. Expected or potential adverse events,
4. What to do if they or their child experience an adverse event.

As a Healthcare provider, communicate this information in understandable terms, ideally in written form ahead of the time of vaccination.

Do not

Do not leave the vaccinees or their families uninformed. It is unethical to conduct an invasive procedure without informed consent.
Do not assume parents or the public will not understand information about vaccine safety.

Key point

It is important to emphasize that it is unethical to conduct an invasive procedure such as immunization without first obtaining informed consent from the vaccinee or from a responsible adult in the case of a child.
True consent cannot be given unless the essential information has been communicated to the target audience in simple, accessible language that enables the listener to reach an informed decision.

Risk perception

Health experts do not view the risks associated with a medical procedure (such as vaccination) in the same way as members of the public (parents, patients and vaccinees).
Experts understand risks in terms of numerical values and rates: for example, this table compares the risks of death due to three vaccine preventable diseases and the risks of adverse events following immunization with the approved vaccines.

Risks of illnesses and risks associated to the corresponding vaccines

<table>
<thead>
<tr>
<th>Illness</th>
<th>Death:</th>
</tr>
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<tbody>
<tr>
<td>Measles</td>
<td>• 1 in 3,000 cases in high income industrialized countries.</td>
</tr>
<tr>
<td></td>
<td>• As much as 1 in 5 cases during outbreaks in low- to middle-income countries.</td>
</tr>
<tr>
<td>Diphtheria</td>
<td>Death: 1 in 20 cases.</td>
</tr>
<tr>
<td>Tetanus</td>
<td>Death: 25–70 in 100 cases overall.</td>
</tr>
<tr>
<td></td>
<td>(10–20 in 100 cases with good intensive care management.)</td>
</tr>
<tr>
<td>Measles vaccine</td>
<td>Encephalitis or severe allergic reaction: 1 in 1,000,000 cases.</td>
</tr>
<tr>
<td>DTP vaccine</td>
<td>Continuous crying, then full recovery: 1 in 100 cases.</td>
</tr>
<tr>
<td>Tetanus toxoid vaccine</td>
<td>• Convulsions or shock (full recovery): 1 in 1,750 cases.</td>
</tr>
<tr>
<td></td>
<td>• Acute encephalopathy: 0–10.5 in 1,000,000 cases.</td>
</tr>
</tbody>
</table>
Public perception

In contrast to the perception of experts, parents, guardians and vaccinees rather want to know whether they or their child could be the “one in a million” who develops encephalitis following immunization with measles vaccine.

Other factors that may influence the way public tends to see risk, include:

Negligence of the danger of the disease

Most adults in high-income countries with high vaccination coverage have never seen a case of measles or any of the other vaccine-preventable childhood diseases. As a consequence, they may underestimate the probability of harm if the disease does develop.

Influence by individual context

The public is likely to perceive risk in broad religious, social or personal contexts. For example, some will distrust the medical system due to a personal prejudice against “experts” and a desire not to be influenced by them; others will uncritically accept all instructions from health workers because they feel intimidated or inferior.

Aversion to medicine

Adverse personal experiences from the past (e.g. the memory of a painful injection or a sore/swollen arm) may also negatively influence attitudes to vaccine-associated risk. The thought of being injected with a foreign substance derived from disease-causing organisms can induce fear and dread. Clients may feel reluctant to come to a clinic or other health facility, or to bring their children if the environment feels intimidating and the health workers are not reassuring or welcoming.

For all these reasons, it is important to understand the concerns of your target audience and the different approaches required to communicate effectively with persons planning to receive a vaccine, the public and your expert colleagues.
Personal perspectives influence perception

Concerns of the target audience

There are some common misconceptions about vaccination that are often cited by concerned parents as reasons not to get their children vaccinated. If staff can respond to these with accurate rebuttals perhaps they may not only ease parents’ minds but discourage them from taking other anti-vaccine “facts” at face value.

Sources of information

Lack of information, or inadequate or misleading information about vaccine safety increases the risk of the erosion of trust and confidence in health experts, immunization programmes and governments. Ultimately it can result in lost opportunities to protect health. WHO estimates that two million additional lives could be saved every year by the effective use of readily available vaccines.

Be aware of the different sources of information in your country. Even in remote rural locations in developing countries, the knowledge, attitudes and beliefs of the population towards vaccine safety are influenced by an increasingly wide range of information sources. Roll your mouse over the images to see what the main information sources might be.
Question 2

Select from the below sources of online information that may help you as immunization manager to powerfully share information with colleagues and the public on the safety of vaccines and immunization?

- Facebook
- Blogs
- Website
- Twitter
- Wikipedia
- Newsletters

The World Wide Web is a mine of useful information on various topics, but also contains websites of dubious quality. Many quality websites contain science-based information about vaccine safety. Others provide unbalanced and misleading information, which can lead to undue fears, particularly among parents and patients. At WHO’s Vaccine Safety Net website (www.who.int/vaccine_safety/initiative/communication/network/vaccine_safety_websites/) you can find Websites providing information on vaccine safety which adhere to good information practices.

Should you be seeking information on vaccine safety that you want to communicate in your country or region, consider the advice of the Global Advisory Committee on Vaccine Safety (GACVS) on how to identify good information practices for vaccine safety websites.89

Communicating in public

The most effective method of communicating an important message depends on many factors – including how the communicator gets the message across. Some people are gifted at presenting a message verbally to a large audience (e.g. in a lecture or meeting). Others may find large audiences intimidating, but may be excellent communicators in small groups or one-to-one interviews.

Whatever the setting or means of communication you choose, there are some general principles to keep in mind. These apply both when the communication is with one (interpersonal communication) or with many people:

**Target audience**

Gather as much information as possible about your target audience to ensure you design messages they will hear.

- Reflect on the capabilities and concerns of your target audience – what do they need to understand to make informed decisions?

  **FOR EXAMPLE**
  Providing reassurance to concerned parents, differs from communicating newly available evidence to experts at a conference.

- Consider the age range of your audience.

  **FOR EXAMPLE**
  Informing teenagers learning about papilloma virus and HPV vaccination at school versus talking to elderly people learning about influenza and flu vaccination at a community centre.

- Take into account differing educational levels.

* The answer to all questions can be found at the end of this manual (page 202).
Mind language problems.

FOR EXAMPLE
Talking to preschool children versus qualified nurses at an immunization clinic.

Respect gender differences.

FOR EXAMPLE
Speaking to someone with the same local language versus speaking to someone who has difficulties understanding your language.

Take differing religious contexts into account.

Communication objective

■ What is your single overarching communications objective?
■ What key messages are necessary to achieve that objective and consider the best ways to communicate them (for example, verbally, in writing or in pictures).

Structured communication

■ Communicate in a logical sequence.
■ Sum up the key points at the end.

Interactive communication

■ Encourage the audience to ask questions.
■ Thank the target audience for its attention.

Question 3*

Imagine that during an immunization campaign you have to communicate information in your country about vaccine safety and the benefits of immunization to either nervous parents and their child, or to teachers in a secondary school. Which of the following statements is correct? Several answers possible.

☐ A. Conduct an interview with a nervous young mother with her first baby choosing a quiet room to enable an atmosphere of trust.
☐ B. Be aware of your time schedule when interviewing concerned parents. You should not take more than a few minutes to look into their concerns.
☐ C. When communicating to teachers at a large secondary school, group them to get your message across to them at the same time and allow time for discussion to resolve potential information gaps in your audience.
☐ D. Provide information material (posters, videos, slides) to target audiences that supports your key messages and provides additional information.

* The answer to all questions can be found at the end of this manual (page 202).
Responding to vaccine safety crises

Rumours and crises

Allegations regarding vaccine-related adverse events that are not rapidly and effectively dealt with can undermine confidence in a vaccine and ultimately have dramatic consequences for immunization coverage and disease incidence.

Some situations that encourage rumour include:

- Serious social conflict,
- Economic and political uncertainty,
- Social transition and clashes of culture and beliefs,
- A history of discrimination and manipulation,
- Lack of transparency in a distant or authoritarian organization.

What is a vaccine safety crisis?

You may not be able to define it, but you certainly know when you are in one!

Crises in vaccine safety are characterized by an unexpected series of events that initially seem to be out of control. The outcome is usually uncertain when the crisis is first identified, and there is a threat to the success of a vaccine or immunization programme.

A crisis may have a “real” basis arising from genuine vaccine reactions or immunization errors, or it may have no foundation in reality and be triggered entirely by mistaken rumours. Often a crisis in vaccine safety originates in the identification of AEFIs, but is aggravated by negative rumours.

Whether a rumour triggers a series of events that build into a crisis depends on the nature of the rumour, how fast it spreads and whether prompt and effective action is taken to address it.

When approaching a crisis, keep in mind that this may not only be a challenge, but also an opportunity to improve the communication on immunization issues. You have the opportunity to dispel negative rumours, to take action to upgrade policies and procedures if required, and to correct any errors or lapses in best practice.

CRISIS CAN ENTAIL:
- Unexpected series of event.
- Events are out of control.
- The outcome is uncertain.
- Threat to existing situation.

EVERY CRISIS IS ALSO AN OPPORTUNITY TO:
- Improve communication.
- Dispel negative rumours.
- Take any required action to upgrade policies and procedures.
- Correct any errors or lapses in best practice.
**Question 4**

Consider the following scenarios. A new vaccine is introduced in a country and a cluster of serious AEFIs occurs including the death of a child.

Which of the following statements address(es) failures in communication that could increase the risk of these adverse events "exploding" into a national crisis and putting the immunization programme at risk?

Several answers possible.

- A. No one took responsibility for managing the event locally - the correct actions were not taken, or not taken quickly enough.
- B. Local communication about the event was poor, adding to the uncertainty and insecurity about what actually went wrong and whether it was being addressed. The parents of the dead child were not counselled, neither was empathy shown to them.
- C. The event was inaccurately reported in the media before you could deal with it.
- D. Rumours started circulating on social media sites.
- E. Someone involved in the original event was not truthful when interviewed about it and the lie was later exposed, adding to the perception that there was a conspiracy to hide the problem and that the health authorities could not be trusted.

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**Impact of rumours and crises**

The history of immunization is not only characterized by its unique success at achieving huge reductions in mortality (deaths) and morbidity (illness and disability) from vaccine-preventable infections and the global eradication of smallpox. It is also notable for the emergence of vaccine sceptics who firmly believe that vaccines are harmful and lobby against them. This – often very vocal – opposition has been a persistent challenge to immunization programmes since they first began over two centuries ago.²⁹

**Example 1: Whole-cell pertussis “scare”**

Many recent immunization programmes have suffered setbacks from immunization scares. Children have been needlessly put into danger by frightened parents that refused immunization for their children after “scare stories” about particular vaccines.

The graphs illustrate the impact of rumours about the pertussis whole-cell vaccine from about 1960 onwards in four different locations. Note how affected the vaccine coverage entails a rise in the incidence of pertussis.

These examples also show how negative beliefs about a particular vaccine can spread around the world and reduce public confidence in its safety.

* The answer to all questions can be found at the end of this manual (page 202).
Example 2: MMR and autism controversy in the UK

In 2008, 14 years after the local transmission of measles was halted in the UK, the Health Protection Agency for England and Wales declared it had once again become endemic, i.e. continuously circulating in the population. This was seen as a result of almost a decade of low MMR vaccination coverage across the UK.

Burgess, Burgess and Leask\(^5\) (2006) analysed how a report of a hypothesised link between measles-mumps-rubella vaccination and autism in 1998 became a major public health issue in the United Kingdom, leaving most experts surprised by its overwhelming influence on public opinion about MMR vaccination. Effectively communicating with parents of autistic children and members of the general public who believed that the truth about the vaccine was being concealed would have been critical to avoid the reduction of vaccination coverage.

1995: Uptake of MMR vaccine peaks at 92% of eligible infants.
1998: Research studies claiming an association between MMR and autism are published in 1998 by a group led by Andrew Wakefield
1999: Wakefield’s claims prompt huge coverage in the media and a crisis of confidence in the vaccine, which leads to a rapid decline in its uptake.
2000: Confidence in the vaccine continues to decline. Outbreaks of measles occur in the UK and in some other countries as the MMR coverage rate declines.
2001: Tony Blair, the Prime Minister at the time, is placed under extreme pressure to say whether his young son Leo has been given the MMR vaccine. Blair’s refusal to answer the question adds to public concerns.
2002: Vaccine uptake continues to decline. Further outbreaks of measles occur.
2003: Vaccine uptake continues to decline.
2004: Evidence from large-scale studies begins to prove that there is no casual association between autism and MMR, and Wakefield’s research is eventually exposed as without foundation. Vaccine confidence starts to grow again.
Health-damaging outcomes of negative rumours are not confined to high-income countries. There are many other cases from all over the world. For example, in 2009, the death of a 7-year-old child in Taiwan, following his vaccination against the H1N1 strain of influenza virus, led to rumours that the vaccine was responsible. These rumours were followed by a 30% drop in the number of children receiving it.

Question 5

Which of the following statements would you think to be the main reason for less tolerance towards vaccines, making them more likely to be the subject of negative rumours and “scare stories” than is the case for medical drugs?

- A. Vaccines are more expensive than many drugs which creates less tolerance in the public’s perception.
- B. Public tolerance towards adverse reactions is lower compared to side-effects of drugs as vaccines are given to healthy people.
- C. Parents consenting to vaccinating their child, perceive a harm possibly linked to a vaccine as more grave because it could have been avoided.
- D. The public awareness towards vaccine preventable diseases in industrialized countries is high, leading to a resentment towards vaccines.

Responding to rumours and crises

Preparatory work

Key point

Expect crises! They will happen. Be prepared.

When planning your communication to effectively deal with rumours and crises, consider the following three questions:

- Who are your “allies” in dealing with a crisis in public confidence in vaccine safety?
- What are the main elements of your communication plan to deal with rumours and crises effectively?
- Why could your crisis communication plan fail?

Particularly knowing the persons available to support you during a crisis is important. Think of who is best positioned to support you in developing and implementing your crisis communication plan. Professionals working in your post-marketing surveillance system may be well positioned to resolve a crisis swiftly by providing facts and information and supporting the communication. Also think about possible alliances outside your usual contacts, who could add their expertise or support; for example, an organization that might fund aspects of your communication strategy such as printing leaflets, or a scientific journalist who might write an evidence-based article counteracting unfounded information arising from a rumour.

* The answer to all questions can be found at the end of this manual (page 202).
Before you begin work on your crisis communication plan, also make sure that you have clear information and understanding of the crisis or rumour.

Developing a crisis communication plan

Communication in the context of a vaccine-related crisis follows the same steps as any other planning process, but because of the urgency of the situation, compressed time scales apply and you must be able to implement the plan quickly. Inclusive planning and action are critical – all stakeholders should be involved as soon as possible. Remember that communication is not an isolated exercise, but part of a broader action plan for handling the crisis.

Key point
Do not hesitate in taking essential actions if some stakeholders cannot be contacted immediately or do not respond quickly.

There are four basic elements of a communication plan.

Decide on your overarching objectives

What are the overarching objectives of your communication strategy? It may be, for example:

- Within 1 year, to reverse the 10% drop in immunization coverage caused by adverse rumours about the vaccine,
- To demonstrate increased public confidence in the vaccine and the immunization programme within 6 months, through surveys of knowledge, attitudes and beliefs.
Define your target audiences

- The people most affected by the rumour or crisis,
- The most influential people to communicate your vaccine safety messages to,
- Internal to the immunization programme or the organizations that govern its operation: e.g. health workers, government ministers, national or international vaccine safety committees,
- External to the immunization programme: e.g. patients/clients, the public, community organizations, pressure groups or the media.

Choose your key messages

- What do you want the audience to hear and retain?

Select the channels of communication

- Choose methods that will reach the largest possible number in your target audience and have highest impact – based on the funding and other resources you have available,
- Be creative about the “how” – effective communication channels may be neglected by opting for the obvious routes,
- Do not underestimate “people power”, for example, by using social media to counteract misleading rumours.

Question 6

“Patients die after being given measles vaccine in Bukkala.” Imagine that a crisis was triggered by a report in a mainstream newspaper. A paper has alleged that several children died due to a measles vaccine in a local immunization clinic. You have been asked to formulate a statement on the situation.

Which of the following suggested actions is/are correct (several statements possible)?

- A. Provide a simple explanation of the situation.
- B. State if there is no evidence that the death was caused by the vaccine itself.
- C. Inform if there is an investigation ongoing.
- D. Provide information on the safety profile of the vaccine.
- E. Provide information on the risk posed by the disease that the vaccine prevents.
- F. If you do not have sufficient information to respond to a journalist’s request available, answer with “No comment”.

* The answer to all questions can be found at the end of this manual (page 202).
Communicating with the media

“The media” have already been mentioned, referring to a wide range of communication organizations, methods and technologies. In the final part of this module, the focus is on how someone like you can:

- Communicate your key messages about vaccine safety to the mass media – including the countering of negative rumours,
- Deal effectively with questions from journalists working for newspapers, television, radio and (increasingly) the authors of online blogs and internet news services,
- Design a press release or prepare for an interview by following some simple principles.

There are positive and negative aspects of media coverage.

Positive aspects of media coverage

Well-researched, responsible journalism is important. It can help:

- Communicate public health messages,
- Expose malpractice and negligence, and
- Highlight controversy and inconsistencies in policies and strategies affecting the public.

Negative aspects of media coverage

The news media have to make a profit, e.g. by selling newspapers or advertising space on television. If some journalists are only interested in features of your story that boost sales figures, the task of communicating is becoming more difficult.

Journalists decide on what the news agenda is and cover news that interest their target audience:

- Newsworthy stories are more likely to be dramatic, are targeted at affecting many people, and may focus on famous people or young children,
- Stories could be controversial (e.g. the MMR vaccine and autism), or involve conflict between individuals or organizations and often focus on scandal, corruption and fraud.

Adverse events following immunization are likely to be reported as they involve children and possibly prevalent negative rumours. They can result in sensationalist reporting, especially if the journalist did not fully understand the issue.

AEFI coverage can be extremely negative if you are not prepared to answer media questions and to get on top of the news before journalists do. Understanding the media, how they work and what they want and establishing good relations with specific media and journalists will help to ensure fair coverage.

<table>
<thead>
<tr>
<th>CAN HELP YOUR WORK</th>
<th>CAN HARM YOUR WORK</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Communicating public health messages keeping the public informed.</td>
<td>- Inaccurate or unbalanced news coverage.</td>
</tr>
<tr>
<td>- Exposing malpractice and negligence.</td>
<td>- Gearing conflicts by publishing dramatic stories.</td>
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<tr>
<td>- Helping improve inconsistencies in policies and strategies affecting the public.</td>
<td>- Publishing sensational stories (implying conspiracies, scandal, corruption and fraud).</td>
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Preparing a press release

Frequent press releases from the authorities concerned in investigating the death ensure that journalists are kept informed of the facts as they become known. This prevented adverse and ill-informed speculation from growing about the cause of the tragedy. In preparing an appropriate press release, you should consider two aspects: the title and the content. The title should be short and to the point – but it should also arouse interest, as in this example. The content of the press release should be clear and simple – short sentences are best.

Present all the relevant facts in a logical sequence, getting your main points in at the beginning – get help from your colleagues to design your press release.

Include a quote if you can get one from a well-known person or someone with a prestigious job title.

If the press release is in response to “bad news” (e.g. a cluster of AEFIs) – do not avoid the negative or controversial issues; if you do not deal with them, you will leave room for misinterpretation.

Two pages of text are the most you should write (less is better) – anything longer risks getting cut back by an editor who may change the intended message when your press release is shortened.

At the end, give your name, title, organization, telephone number(s) and email address if you have one for journalists to contact you for interview requests or more information.

Interactive exercise

Below are various parts of a press release which have been mixed up by your assistant. Bring the information units into the right sequential order by entering numbers 1–4 in the corresponding boxes beside the press release.

Try to describe the situation, outline which follow up action has been taken, provide additional background information and close with an action statement by the Ministry of Health.
Question 7.

**AEFI death in Lukurna, Lisusistan: Initial findings**

A. Following standard procedures, the Ministry of Health of Lisusistan appointed a high level team of experts to investigate promptly the child’s cause of death.

The investigation revealed no link between the death of the child and the vaccination. According to the experts, the probable cause of death was asphyxia.

B. So far, no other serious adverse event was reported. Our officials will continue to monitor ongoing immunization activities to ensure the safety of children in Lisusistan.

C. Every day, an estimated 20 children die from non-vaccine related causes in Lisusistan. Consequently it can be expected that a some death cases can coincidently occur in short temporal relationship following vaccination.

D. Pentavalent vaccination was introduced 2 months ago and about 50,000 doses have been administered by today.

Two days ago, the death of a three month old boy from Lukurna Health Centre has been reported.

This child had received a dose of pentavalent vaccine 4 days ago together with 23 other children. Of these other children, none had an untoward reaction to the vaccine.

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**Preparing for an interview**

Preparing for an interview is comparable to preparing a press release, but it is even more important that you find out who is conducting the interview and which organization they work for. The individual or their organization may have a particular point of view (e.g. a bias in favour of or against vaccination), or they may have a reputation for fairness in news reporting. Another consideration might be whether the interviewer has medical or scientific training that will influence the kind of questions you could be asked. Above all consider the emphasis you need to place on the key messages you want to get across.

During the interview, follow these simple rules.

- 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,

* The answer to all questions can be found at the end of this manual (page 202).
■ 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.

Most of all – try to imagine how the interview will appear to members of your target audience. Will they be persuaded by your message?

- Build professional relationships with journalists you trust to maintain high standards.
- Contact trusted journalists quickly if a rumour starts to circulate – before a crisis develops – so you can give them the facts.
- Keep your messages simple and to the point.
- Be willing to answer questions and be completely honest. Refer to someone who knows the answer if you don’t.
- Give contact information so the journalist can follow up on the story or check facts with you later.
- Remain polite and professional at all times – never lose your temper, even if provoked.
- Know your work and be prepared.

Remember that journalists are not interested in destroying your reputation or tricking you!
Summary

You have now completed the learning for this module. These are the main points that you have learned.

✔ Clear communication is needed to dispel rumours and misconceptions about vaccine safety.

✔ Prepare your key messages so that they address the issues in a clear, simple way and that reach your specific audience.

✔ Know who your audience is, and understand their concerns and their perception of risk.

✔ Choose the most appropriate means of communicating as this will affect your success.

✔ Develop a plan for communicating, especially in the event of a crisis.

✔ When communicating with the media, understand their perspective and how it can affect you.

You have completed Module 6.
We suggest that you test your knowledge!
ASSESSMENT 6
Question 1

Read each of the points listed below and choose the correct option from the list below to indicate whether the information is:

- more likely to influence how health experts evaluate vaccine risks
- more likely to influence how members of the public evaluate vaccine risks.

1. Simplified key messages about vaccine safety and the risk of adverse events.
   
2. Morbidity and mortality rates following immunization with specific vaccines.
   
3. Adverse personal experiences of vaccination in the past.
   
4. Rumours of adverse events following immunization.
   
5. Population data on the incidence of AEFIs relative to the incidence of disease-related harm.
   
6. Research studies on vaccine safety in specialist journals.
   
7. Information that supports informed consent to vaccination.
   
8. Information in accessible language about the symptoms and complications of vaccine-preventable diseases.

Select one:

- a General public
- b Health experts

Question 2

Is this statement true or false?

More parents in developing countries compared to industrialized countries may feel that exposing a child to even a small potential risk from vaccination is unnecessary because they assume that infectious diseases are 'a thing of the past'.

Select one:

- True
- False
Question 3
Which of the following general principles of communication should be kept in mind when informing a community group about the local vaccination programme?
Select one or more:

- A. The messages about vaccination should be kept positive at all times and any unhelpful questions should be discouraged.
- B. The age range in the audience should be considered, so that age-appropriate language, information and diagrams can be used.
- C. Decide what your key messages are, the most important information you want your audience to hear, and state the points simply.
- D. Avoid mentioning anything that might concern parents and stop them from giving consent for their children to be vaccinated.
- E. Reflect on the fears and concerns your audience may have about vaccination and ensure that you give them all the information they need in order to make informed choices.

Question 4
Which of the following are helpful suggestions to get your message across with journalists?
Select one or more:

- A. Build professional relationships with journalists who you think you can trust to maintain high standards.
- B. Be proactive and contact journalists if a rumour about vaccine safety starts to circulate.
- C. Keep your messages simple and to the point.
- D. Journalists want to hear complex scientific information. Make sure to use academic jargon or complex arguments.
- E. Remain polite but authoritative – if you feel not confident to respond to a difficult question, respond with ‘No comment’.
- F. Give contact phone numbers and/or email addresses so the journalist can follow up on the story or check facts with you later.
Question 5

Below find the press statement of the interactive exercise in Module 6. Link the paragraph of the press statement to its corresponding main message from the list below.

AEFI death in Lukurna, Lisusistan: Initial findings.

1. Pentavalent vaccination was introduced 2 months ago and about 50,000 doses have been administered by today.

2. Two days ago, the death of a three month old boy from Lukurna Health Centre has been reported. This child had received a dose of pentavalent vaccine 4 days ago together with 23 other children. Of these other children, none had an untoward reaction to the vaccine.

3. Following standard procedures, the Ministry of Health of Lisusistan appointed a high level team of experts to investigate promptly the child’s cause of death. The investigation revealed no link between the death of the child and the vaccination. According to the experts, the probable cause of death was asphyxia.

4. Every day, an estimated 20 children die from non-vaccine related causes in Lisusistan.

5. Consequently it can be expected that some death cases can coincidentally occur in short temporal relationship following vaccination.

6. So far, no other serious adverse event was reported. Our officials will continue to monitor ongoing immunization activities to ensure the safety of children in Lisusistan.

You have completed Assessment 6.
Assessment solutions

Question 1
Correct answers are: 1–a, 2–b, 3–a, 4–a, 5–b, 6–b, 7–a, 8–a.

Perception of risk varies strongly depending on the audience.

Health experts do not view the risks associated with a medical procedure (such as vaccination) in the same way as members of the public. They understand risks in terms of numerical values and rates: for example, this table compares the risks of death due to three vaccine-preventable diseases and the risks of adverse events following immunization with the approved vaccines.

Parents, guardians and vaccinees, however, rather want to know whether they or their child could be the “one in a million” who develops encephalitis following immunization with measles vaccine.

Question 2
The correct answer is 'False'.

The impressive decline in the rates and severity of childhood infections in industrialized countries has effectively faded memories of the threats to health and life posed by once-common diseases such as measles, polio, pertussis, diphtheria and tetanus. The benefits of vaccination are no longer being reinforced by direct experience of the diseases that vaccines prevent.

Question 3
Answers B, C and E are correct.

Answer A
Discouraging questions will prevent you from responding to concerns of the audience. Questions should be encouraged and negative attitudes and concerns should be openly discussed.

Answer D
Trust in vaccine safety can easily be eroded if you attempt to disguise or conceal the possible adverse effects that may follow immunization. Everyone, either the person receiving a vaccine or his/her parents, deserves to know the name of the vaccine, what the vaccine is protecting against, any what adverse event can be expected from it. They should also be informed on what to do if they or their child experience an adverse event. It is up to the health care provider to communicate information in understandable terms for each individual. Ideally, this would happen in written form ahead of the time of vaccination.
Question 4

Answer A, B, C and F are correct.

Answer D
Do not use academic jargon or complex arguments – this may lead to misunderstanding and frustration among your audience.

Answer E
Responding to journalists with ‘No comment’ may lead to acrimonies. Be willing to answer questions and be completely honest. If you are not sure of the facts, do not be evasive or speculate, but offer get back to journalists with this information shortly after the interview.

Question 5

Correct answers:
1. Introduction,
2. Information on the event,
3. Response undertaken to respond to this event,
4. Supporting scientific facts,
5. Information on possible cause,
6. Future Follow-up actions.
You have completed Assessment 6.

A General Assessment is available online to test the knowledge you acquired in this course and to provide you with a certificate upon successful completion.

Visit the General Assessment at:
http://assessments.vaccine-safety-training.org
Glossary

Acellular pertussis (aP) vaccine
A preparation of subunit proteins from pertussis bacteria, used to immunize against pertussis.

Adjuvant
A pharmacological agent (e.g., aluminum salt, oil-in-water emulsions) that modifies the effect of other agents, such as a drug or vaccine, while having few if any direct effects when given by itself. Adjuvants are often included in vaccines to enhance the recipient’s immune response to a supplied antigen, while keeping the injected foreign material to a minimum.

ADR surveillance
A surveillance system designed to collect adverse drug reactions following administration of a drug used for prophylaxis, diagnosis, or therapy of diseases, or for the alteration of a physiological process. This type of surveillance typically relies on health professionals associating an adverse reaction in an individual as a possible consequence of the drug and reporting it to the national pharmacovigilance centre, NRA or appropriate authority.

Adrenaline
A drug used to treat severe allergic reaction (anaphylaxis). Also a hormone produced by the adrenal gland.

Adverse drug reaction (ADR)
A response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function.

Adverse event (or adverse experience)
Any untoward medical occurrence that may appear during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with the treatment.

Adverse event following immunization (AEFI)
Any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

Adverse event of special interest (AESI)
A relatively new AEFI classification that started with pandemic vaccine development. AESI refers to adverse events of significant scientific, medical, and public interest among pandemic vaccines.

AEFI surveillance (also known as vaccine safety surveillance)
A surveillance system designed to collect adverse events temporally associated with receipt of vaccines. This type of surveillance typically relies on health professionals associating an adverse event in an individual as a possible consequence of vaccination and reporting it to the NRA or appropriate authority.

Anaphylaxis
An acute, multi-system, allergic reaction (IgE mediated) to a substance, such as vaccination, drugs, and food. Symptoms of anaphylaxis may include breathing difficulties, loss of consciousness, and a drop in blood pressure. This condition can be fatal and requires immediate medical attention.

Antibiotic
A substance that kills or inhibits the growth of bacteria. Antibiotics (in trace amounts) are used during the manufacturing phase of some vaccines to prevent bacterial contamination of the tissue culture cells.
**Antibody**
A special protein produced by plasmocytes in response to antigens (foreign substances, e.g., bacteria or viruses). Antibodies bind with antigens on microorganisms as one of the initial steps of the body's protection against infection.

**Antigen**
A foreign substance in the body that triggers the production of antibodies.

**Asthma**
Chronic respiratory disease characterized by constriction of the bronchial tubes to the lungs, which causes sudden and recurring breathing problems, coughing, chest tightness and wheezing.

**Asymptomatic carriage**
An infection or colonization by a pathogen that does not cause symptomatic disease.

**Atopy**
A genetic predisposition toward the development of immediate hypersensitivity reactions against common environmental antigens (atopic allergy), most commonly manifested as allergic rhinitis but also as bronchial asthma, atopic dermatitis, or food allergy.

**Attenuated vaccine** – See Live attenuated vaccine.

**Autism**
A chronic neural development disorder usually diagnosed between 18 and 30 months of age. Symptoms include problems with social interaction and communication as well as repetitive interests and activities. At this time, the cause of autism is not known.

**Auto-disable (AD) syringes**
AD syringes are self-locking syringes that can be used only once. AD syringes are the preferred equipment for immunizations requiring injections.

**Autoimmune disorders**
A condition that occurs when the immune system mistakenly attacks and destroys healthy body tissue. There are more than 80 different types of autoimmune disorders.

**B**

**Bacillus Calmette-Guérin (or Bacille Calmette-Guérin, BCG)** – See Tuberculosis vaccine.

**Bacteria**
Single-celled life-forms that can reproduce quickly on their own. Some bacteria cause disease.

**Bacterial carriage**
A bacterial infection or colonization that does not cause symptomatic disease.

**Bacterial meningitis**
Inflammation of the membranes that surround the brain and spinal cord; caused by a bacterial infection.

**BCG osteitis**
A rare reaction from BCG vaccination, causing inflammation of the bone.

**Bell's palsy**
Paralysis of one of the facial nerves (the nerves that supply muscles on the face), due to unknown cause. It is characterized by an asymmetric facial expression, due to the paralysis of one side. Several conditions can cause a facial paralysis, e.g., viral infections, brain tumor, stroke, and Lyme disease. However, if no specific cause can be identified, the condition is known as Bell's palsy.
**Biologicals**
A medical product prepared from biologic material of human, animal, or microbiologic origin (e.g., blood products, vaccines, insulin).

**Biosynthetic technology**
A method for producing a chemical compound using a living organism.

**Booster injection**
An additional vaccine dose needed to “boost” (increase) antibody levels after completion of the primary immunization, which may be a series of up to three doses.

**Brachial neuritis (also known as brachial plexus neuropathy or neuralgic amyotrophy)**
A neuropathy that presents as a deep, steady, often severe aching pain in the shoulder and upper arm and may include muscular weakness.

**Bradycardia**
Abnormally slow heartbeat.

**Brighton Collaboration**
An international voluntary collaboration to facilitate the development, evaluation, and dissemination of high quality information about the safety of human vaccines. For more information, see http://www.brightoncollaboration.org.

**Buffers**
Substances that minimize changes in the acidity of a solution when an acid or base is added to the solution. Buffers are used in the manufacturing process of some vaccines.

**Burden of disease**
The impact of a disease in a defined population, usually expressed in terms of mortality or morbidity rates, or some other measure such as years of healthy life lost or disability adjusted life years (DALYs).

**Carrier protein**
A protein linked to a weak antigen to increase its immunogenicity when used as a vaccine.

**Case control study**
Study that compares a group of persons with an outcome of interest (e.g., a disease, health condition, unintended drug response) to a control group of people without it. The two groups are compared for differences in past exposures (e.g., drugs, vaccines) or other pre-existing conditions that might explain the difference in outcome.

**Causality assessment (or causality association)**
The systematic review of data about an AEFI case to determine the likelihood of a causal association between the event and the vaccine(s) received.

**Cell-mediated immunity**
An immune response not involving antibodies, in which specific blood cells, leukocytes, and lymphocytes attack and remove antigens.

**Challenge, dechallenge and rechallenge**
A testing protocol in which a medicine or drug is administered, withdrawn, then re-administered, while being monitored for adverse effects at each stage. It is one of the standard means of assessing adverse drug reactions but is usually not possible in vaccine trials or AEFI investigations.
**Cholera**
An acute infectious disease of the small intestine, caused by the bacterium Vibrio cholerae and characterized by profuse watery diarrhea, vomiting, muscle cramps, severe dehydration, and depletion of electrolytes.

**Chronic fatigue syndrome (CFS)**
A debilitating and complex disorder characterized by profound fatigue of six months or longer duration that is not improved by bed rest and that may be worsened by physical or mental activity. Persons with CFS most often function at a substantially lower level of activity than they were capable of before the onset of illness. In addition to these key-defining characteristics, patients report various nonspecific symptoms, including weakness, muscle pain, impaired memory and/or mental concentration, insomnia, and post-exertional fatigue lasting more than 24 hours. In some cases, CFS can persist for years.

**Clinical efficacy**
The ability of a medical intervention (e.g., vaccine, drug, procedure) to produce the desired clinical effect (e.g., protection, cure, symptomatic relief).

**Clinical trial**
A systematic study of a medical intervention in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reaction to the intervention. Clinical trials also study the absorption, distribution, metabolism, and excretion of the products with the objective of ascertaining their efficacy and safety. Clinical trials are generally classified into Phases I to IV. Phase IV trials are studies performed after the licensure and introduction of pharmaceutical products. They are carried out to expand the evidence base of the product characteristics for which the marketing authorization was granted.

**Cluster**
Two or more instances of an event related in time, place, population subgroup, or common exposure (e.g., vaccine). AEFI clusters are usually associated with a particular provider, health facility, and/or a vial of vaccine that has been inappropriately prepared or contaminated.

**Coincidental event**
An AEFI classification referring to an adverse event that occur after a vaccination has been given but are not caused by the vaccine or its administration.

**Cold chain**
A system used to transport vaccines at a constant temperature involving a chain of refrigerators and portable cool boxes. Most vaccines and diluents need to be transported and stored in a cold chain between 2°C to 8°C.

**Combination or combined vaccine**
A vaccine that consists of two or more antigens in the same preparation (e.g., MMR, DTP).

**Confounding factor**
A confounding factor is anything that is coincidentally associated with an event (for example, an AEFI), which may mislead the investigator into wrongly concluding that it is influencing the rate of an adverse vaccine reaction.

**Congenital**
A condition that is present at birth, though not necessarily hereditary.

**Conjugated vaccine**
A vaccine in which two compounds (usually a protein and polysaccharide) have been joined together to increase the vaccine’s effectiveness.
**Conjugation technology**
A vaccine technology in which two compounds (usually a protein and polysaccharide) are joined together to increase the vaccine's effectiveness.

**Contraindication**
A condition that makes a particular treatment or procedure, such as vaccination with a particular vaccine, inadvisable. Contraindications can be permanent, such as known allergies to a vaccine component, or temporary, such as an acute febrile illness.

**Controlled study**
A study that compares a group with an exposure or outcome of interest with a group that does not have the exposure or outcome. When study subjects are randomly assigned to exposed or unexposed groups by the study researcher (e.g., are assigned to receive or not receive a vaccine or drug) and subsequent differences in outcomes measured, the study is called a randomized clinical trial. Studies in which exposure status is not controlled by researchers are called ‘observational’ and include cohort and case-control studies.

**Convulsion** – See Seizure.

**Cost-effective**
This refers to a type of economic analysis that allows comparison of different intervention options by estimating the cost per health outcome for each alternative intervention. It indicates which interventions provide the greatest impact for a given cost.

**Cost-saving**
The case in which the cost of an intervention (e.g., the cost of delivering a vaccine) is less than the cost of not intervening (e.g., the cost of disease in the absence of vaccination). In this example, the intervention saves money.

**Crohn’s disease**
A chronic medical condition characterized by inflammation of the bowel. Symptoms include abdominal pain, diarrhea, fever, loss of appetite, and weight loss. The cause of Crohn’s disease is not yet known, but genetic, dietary, and infectious factors may play a part.

**Depot effect**
Some adjuvants used in injectable vaccine formulations act as a storage depot for the antigen, allowing its slow release and gradual absorption into the body; this depot effect maximizes the immune response to the vaccine.

**Diabetes**
A chronic health condition in which the body is unable to produce insulin and properly break down sugar (glucose) in the blood. Symptoms include hunger, thirst, excessive urination, dehydration, and weight loss. Treatment of diabetes requires daily insulin injections or other diabetes medication, proper nutrition, and regular exercise. Complications can include heart disease, stroke, neuropathy, poor circulation leading to loss of limb, vision problems, and death.

**Diluent**
A fluid provided in a vial or ampoule that is mixed with lyophilized vaccine powder before the vaccine can be injected. Diluents are not interchangeable. Vaccines have different diluents; mixing and administering the wrong diluent with a vaccine has led to serious adverse events including death.
Diphtheria
A disease caused by toxigenic strains of Corynebacterium diphtheriae. Often marked by the formation of a false membrane in the throat, diphtheria is a serious vaccine-preventable disease that can cause death in unvaccinated children.

Diphtheria toxoid vaccine
A vaccine containing diphtheria toxoid, used to immunize against diphtheria.

Disseminated BCG infection
Tuberculosis (BCG) vaccine-induced infection that is spread over a large area of the body, a tissue, or an organ. This can result in death (referred to as Fatal disseminated BCG infection).

Dose-response
The relationship between the dose of an active substance (e.g. a vaccine or drug) or radiation exposure, and the response in the body of exposed individuals.

Drug (or medicine)
Any substance in a pharmaceutical product that is used to modify or exploit physiological systems or pathological states for the benefit of the recipient. The term drug/medicinal product is used in a wider sense to include the whole formulated and registered product, including the presentation and packaging, and the accompanying information. Vaccines are drugs/medicines.

DT vaccine
A preparation of diphtheria and tetanus toxoids together in one vaccine, used to immunize children and adolescents against diphtheria and tetanus. The DT vaccine given to adults contains a reduced amount of diphtheria toxoid.

DTaP vaccine
A combination of diphtheria and tetanus toxoids with acellular pertussis vaccine together in one vaccine, used to immunize against diphtheria, tetanus, and pertussis.

DTP vaccine
A combined preparation of diphtheria and tetanus toxoids with pertussis vaccine together in one vaccine, used to immunize against diphtheria, tetanus, and pertussis (also sometimes referred to as DPT vaccine). When an acellular pertussis vaccine is used, the combination is usually abbreviated DTaP. When the whole cell pertussis vaccine is used, the combination is usually abbreviated DTwP.

DTwP vaccine
A combination of diphtheria and tetanus toxoids with whole cell pertussis vaccine together in one vaccine, used to immunize against diphtheria, tetanus, and pertussis.

Effectiveness – See Vaccine effectiveness.

Efficacy – See Vaccine efficacy.

Elimination
Reduction to zero (or a very low defined target rate) of new cases of an infectious disease in a defined geographical area as a result of deliberate efforts; continued measures to prevent re-establishment of transmission are required.

Emulsion
A mixture of two liquids that do not mix resulting in one of the liquids dispersed throughout the other in small droplets.
Glossary

**Encephalitis**
Refers to an encephalopathy caused by an inflammatory response in the brain. This is usually manifested with systemic constitutional symptoms, particularly fever and pleocytosis of the cerebrospinal fluid. However, the terms encephalopathy and encephalitis have been used imprecisely and even interchangeably in the literature.

**Encephalopathy**
Refers to a variety of conditions affecting the brain resulting in alterations in the level of consciousness, ranging from stupor to coma. At times, febrile seizures, afebrile seizures, and epilepsy have been considered components of encephalopathy. However, the terms encephalopathy and encephalitis have been used imprecisely and even interchangeably in the literature.

**Endotoxin**
A toxin contained in the cell walls of some microorganisms, especially gram-negative bacteria, that is released when the bacterium dies and is broken down in the body. Fever, chills, shock, and a variety of other symptoms may result, depending on the particular organism and the condition of the infected person.

**Epidemic**
The occurrence of disease within a geographical area and/or population that is in excess of what is normally expected for a given period of time.

**Epidemiology**
The study of the distribution and determinants of health and disease in human populations.

**Equine-derived**
A substance extracted from horses, e.g. some antibodies used in passive immunization are extracted from the serum of horses exposed to the target antigen.

**Eradication**
The complete and permanent worldwide reduction to zero new cases of an infectious disease through deliberate efforts; no further control measures are required.

**Evidence-based**
Research based on systematic investigation of the outcomes of controlled interventions; the results have been verified by other researchers using the same methods.

**Expanded Programme on Immunization (EPI)**
An international programme launched by WHO in 1974 to increase immunization of the world’s children. EPI originally targeted vaccines for six diseases: measles, diphtheria, pertussis, tetanus, tuberculosis and poliomyelitis. EPI and national immunization programme (NIP) are used interchangeably.

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**F**

**Fatal dissemination of BCG infection**
Tuberculosis (BCG) vaccine-induced infection that is spread over a large area of the body, a tissue, or an organ, and results in death.

**Febrile**
Relating to fever; feverish. A febrile seizure is a seizure or convulsion that occurs during a high fever. Common in children under five years of age, rarely resulting in long term injury.

**Freund’s adjuvant**
A water-in-oil emulsion added to some vaccines to increase the immune response to the vaccine antigen.
Global Advisory Committee on Vaccine Safety (GACVS)
Established in 1999, the GACVS advises the WHO on vaccine-related safety issues and enables WHO to respond promptly, efficiently, and with scientific rigor to issues of vaccine safety with potential global importance. The committee also assesses the implications of vaccine safety for practice worldwide and for WHO policies. For more information, see http://http://www.who.int/vaccine_safety/en/.

Good manufacturing practice (GMP)
Guidelines that outline the aspects of production that would affect the quality of a product. Many countries have legislated that pharmaceuticals, biologicals, and medical device companies must follow GMP procedures, and have created their own GMP guidelines that correspond with their legislation to assure the quality of those products. WHO also proposes GMP guidelines that are used by many countries.

Guillain-Barré Syndrome (GBS)
A rare neurological disease characterized by loss of reflexes and temporary paralysis. Symptoms include weakness, numbness, tingling, and sensitive disorders that spreads over the body. Muscle paralysis starts in the feet and legs and moves upwards to the arms and hands. Sometimes paralysis can result in the respiratory muscles causing breathing difficulties. Symptoms usually appear over the course of one day and may continue to progress for three or four days up to three or four weeks. Recovery begins within two to four weeks after the progression stops. While most patients recover, approximately 15 to 20% experience persistent symptoms. GBS is fatal in 5% of cases.

Haemophilus influenzae type b (Hib)
Bacteria that can cause serious invasive illnesses, such as pneumonia and meningitis; most common in children and persons who are immune compromised (less able to fight off infections). Hib is one of six types of bacteria that are major causes of bacterial meningitis in unimmunized infants.

Haemophilus influenzae type b (Hib) vaccine
A subunit polysaccharide-conjugate vaccine used to immunize against invasive Hib disease.

Hepatitis B
A viral infection of the liver that is transmitted through contact with blood or other body fluids that are infected with the hepatitis B virus. Some infections, especially those acquired in infancy, can become chronic and result in cirrhosis and primary liver cancer in adulthood.

Hepatitis B vaccine (HepB)
A subunit protein-based recombinant vaccine used against hepatitis B infection.

Herd effect
The resistance of a group to invasion and spread of an infectious agent, based on the resistance to infection of a high proportion of individual members of the group. The resistance results from a small proportion of susceptible individuals in a population making it difficult for the infectious agent to sustain circulation.

Herd immunity
A population with a high proportion of individuals with immunity to a particular pathogen, as a consequence of immunization or infection and recovery, may confer protection from infection on the small proportion of its non-immune members because there are too few susceptible people in the ‘herd’ for the infection to circulate.
**Herpes zoster**
An inflammatory disease, also known as the shingles, caused by the same virus that causes chicken pox. Some people exposed to this virus during childhood develop partial immunity. After the primary infection as chicken pox the virus becomes dormant, reactivating years or decades later as herpes zoster. It is characterized by painful skin lesions that occur mainly on the trunk (back and stomach) of the body but which can also develop on the face and in the mouth.

**HIV/AIDS**
Acquired immune deficiency syndrome (AIDS) is a collection of symptoms and infections resulting from the specific damage to the immune system caused by the human immunodeficiency virus (HIV).

**Holistic**
All embracing, taking into account all aspects of a situation; in healthcare, holistic usually refers to a commitment to consider all aspects of the patient’s situation, including social and psychological states as well as medical conditions.

**Hypersensitivity**
An excessive or abnormal sensitivity in a body tissue to an antigen or foreign substance.

**Hypertension**
High blood pressure.

**Hypotension**
Low blood pressure.

**Hypothesized associations**
Low blood pressure.

**Hypotonic hyporesponsive episode (HHE)**
A recognized serious reaction to immunization, especially pertussis-containing vaccine. It is defined as an acute loss in sensory awareness or loss of consciousness accompanied by pallor and muscle hypotonicity. No long-term sequelae have been identified in the small number of children who have had long term follow-up. HHE is not a contraindication for further doses of pertussis vaccine.

**Immune response**
The body’s defense against foreign objects or organisms, such as bacteria, viruses or transplanted organs or tissue.

**Immune system**
A complex system of organs and processes in the body responsible for fighting disease. Its primary function is to identify foreign substances in the body (including bacteria, viruses, fungi, parasites or transplanted organs and tissues) and develop a defense against them. This defense is known as the immune response.

**Immunity**
The body’s response mechanism for fighting against bacteria, viruses and other foreign substances. If a cell or tissue (such as bacteria or a transplanted organ) is recognized as not belonging to the body, the immune system will act against the “invader.” The immune system is the body’s way to fight external invasions.

**Immunization**
The process by which a person or animal becomes protected against a disease through an enhancement of their immune response. This term is different from vaccination which is a form of immunization where the body learns to recognize a particular foreign object (active immunization). Passive immunization can be provided by administering external antibodies that will temporarily help strengthen the body’s response without inducing memory against a specific foreign object.
**Immunization anxiety-related reaction**  
An AEFI arising from anxiety about the immunization.

**Immunization error**  
An AEFI classification that refers to events caused by errors in vaccine preparation, handling, or administration.

**Immunization safety**  
The process of ensuring and monitoring the safety of all aspects of immunization, including vaccine quality, vaccine storage and handling, vaccine administration, disposal of sharps, and management of waste.

**Immunocompromised (also immunosuppression)**  
Unable to mount a normal immune response. This condition can be genetic, or caused by disease (like HIV infection or cancer) by certain drugs (such as those used in chemotherapy and organ transplantation). Individuals whose immune systems are severely compromised should not receive LAV vaccines.

**Immunogenicity**  
The power of an antigen to induce an immune response.

**Inactivated polio vaccine (IPV)**  
An inactivated (killed) polio vaccine, developed in 1955 by Dr. Jonas Salk. Unlike oral polio vaccine (OPV), a LAV vaccine, IPV must be injected to produce the desired immune response.

**Inactivated vaccine (also known as killed vaccine)**  
A vaccine made from microorganisms (viruses, bacteria, other) that have been killed through physical or chemical processes. These killed organisms cannot cause disease.

**Incidence**  
The number of new cases (e.g., of a disease, adverse event) occurring in a defined population during a given time interval, often one year.

**Individual case safety report (ICSR)**  
A report received by a company or agency that describes an adverse event.

**Inflammatory bowel disease**  
A general term for any disease characterized by inflammation of the bowel; examples include colitis and Crohn’s disease. Symptoms include abdominal pain, diarrhea, fever, loss of appetite, and weight loss.

**Influenza**  
A highly contagious viral infection characterized by sudden onset of fever, aches and pains, and inflammation of mucous membranes.

**Informed consent**  
An ethical requirement that an individual who gives consent for an invasive medical procedure (e.g., a vaccination) is fully informed of all relevant risks and benefits of the procedure before making the decision to consent.

**Inoculation**  
The practice of intentionally exposing someone to matter from smallpox pustules in order to initiate a mild, protective response to the disease.

**Insulin**  
A hormone secreted by the islets of Langerhans and functioning in the regulation of the metabolism of carbohydrates and fats, especially the conversion of glucose to glycogen, which lowers the blood glucose level. It is also available as a pharmaceutical for the treatment of diabetes.
Intramuscular (IM) injection  
Administration of vaccine into the muscle mass. Vaccines containing adjuvants should be injected IM to reduce the depot effect and formation of granulomas.

Intranasal influenza  
A live attenuated influenza vaccine, administered through the nose. Advantages of this vaccine include easier and more acceptable administration than injection and possibly the stimulation of a broader immune response in some age groups.

Intussusception  
A potentially life threatening obstruction of the bowel. When the first rotavirus vaccine was licensed in 1999, it was withdrawn from the market following evidence linking it to a small increase in the risk of intussusception.

Japanese encephalitis (JE)  
A mosquito-borne viral infection, the leading cause of viral encephalitis in Asia.

Japanese encephalitis (JE) vaccine  
Two vaccines against JE are currently available internationally: the inactivated, mouse-brain derived JE vaccine and the live attenuated SA-14-14-2 JE vaccine.

Key message  
A key message gives the most important information that you want the public to know, for example in relation to a health education campaign on the benefits of vaccination.

Killed vaccine – See Inactivated vaccine.

Large linked databases (LLDBs)  
Administrative databases of relatively large size that were created separately from each other and linked to enable the sharing of data across platforms. Such linked databases have become popular in vaccine safety surveillance where specific disease's occurrence can be linked to a person's vaccination history.

Leukemia  
Any of a group of neoplastic diseases of the blood-forming organs, resulting in an abnormal increase in the production of leukocytes, often accompanied by anemia and enlargement of the lymph nodes, spleen, and liver.

Licensure  
The granting of a license to conduct a regulated procedure, for example, to conduct a trial of a new vaccine or to approve a vaccine for routine delivery to the public in a vaccination programme.

Live attenuated vaccine (LAV)  
A vaccine prepared from living micro-organisms (viruses, bacteria currently available) that have been weakened under laboratory conditions. LAV vaccines will replicate in a vaccinated individual and produce an immune response but usually cause mild or no disease.
Local (or localized)
Restricted or limited to a specific body part or region.

Lot (or lot-release)
Vaccines are produced in “lots” or batches. Prior to releasing a “lot” of vaccine for public use, the NRA provides a vital check on the manufacturer’s performance. As a minimum, lot release should be based on review of the summary lot protocols, which contain details of that particular lot. In addition, selected laboratory testing can be carried out. Lot release should be included in the regulations that cover biological products.

Lymphadenitis
Lymphadenitis is the inflammation and/or enlargement of one or more lymph nodes. Most cases indicate an immune response in the node to local infection or antigen stimulation, for example in a vaccine. Generalised lymphadenitis is a widespread inflammation of the lymph nodes due to systemic (circulating) infection.

Lyophilized
Freeze-dried; e.g. measles and BCG vaccines are transported as lyophilized powders which must be reconstituted with specific liquid diluents before use as injectable vaccines. Lyophilised vaccines must be discarded within 6 hours of reconstitution, or at the end of a vaccination session, whichever comes first.

Macrophagic myofasciitis
A disease causing muscle pain, joint pain, muscle weakness, fatigue, fever, and muscle tenderness. It is characterized by microscopic muscular infiltration with macrophages. Specific causes are unknown, but the disease has been associated with the persistence of aluminum hydroxide used in some vaccines. The diagnosis can only be confirmed through a muscle biopsy.

Malaria
An infectious disease caused by a parasite (plasmodium) that is transmitted from human to human by the bite of infected female Anopheles mosquitoes. Malaria is a leading cause of morbidity and mortality in sub-Saharan Africa.

Measles
A contagious viral disease marked by fever, the eruption of red circular spots on the skin that can be deadly to young and weakened individuals.

Measles vaccine
A preparation of live attenuated measles virus used to immunize against measles.

Meningococcal disease
Bacterial diseases caused by the meningococcus (Neisseria meningitidis). Meningococcal diseases include clinical forms of the disease, in particular meningitis, sepsis and pneumonia.

Microorganisms
Tiny organisms (including bacteria and viruses) that can only be seen with a microscope.

Minor (or mild) vaccine reaction
Vaccine reactions that usually occur within a few hours of injection, resolve after a short period of time, and pose little danger.
**MMR vaccine**
A preparation of live attenuated measles, mumps, and rubella viruses together in one vaccine, used to immunize against measles, mumps, and rubella.

**Monovalent vaccine**
A monovalent vaccine is designed to immunize against a single antigen or single microorganism whereas polyvalent vaccines aim to immunize against several strains of the same microorganism, or against several microorganisms.

**MR vaccine**
A preparation of live attenuated measles and rubella viruses together in one vaccine, used to immunize against measles and rubella.

**Multiple Sclerosis (MS)**
A disease of the central nervous system characterized by the destruction of the myelin sheath surrounding neurons, resulting in the formation of “plaques.” The cause of MS is unknown, although it appears to require a genetic susceptibility combined with an environmental ‘trigger’, possibly a viral infection. While extensively investigated, there is no epidemiologic evidence to support a link between vaccination and onset or recurrence of MS.

**Mumps**
An acute contagious viral illness marked by swelling, especially of the parotid glands.

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**N**

**National immunization programme (NIP)**
The organizational component of government Ministries of Health charged with preventing disease, disability, and death from vaccine-preventable diseases in children and adults. NIP is used interchangeably with the Expanded Programme on Immunization (EPI) that originally focused on preventing vaccine-preventable diseases in children.

**National immunization technical advisory groups (NITAGs)**
Advisory groups whose general objective is to guide national governments and policy-makers to develop and implement evidence-based, locally relevant immunization policies and strategies that reflect national priorities.

**National pharmacovigilance centre**
A governmentally recognized centre (or integrated system) within a country with the clinical and scientific expertise to collect, collate, analyze, and give advice on all information related to drug safety.

**National regulatory authority (NRA)**
The regulatory body that approves procedures to ensure that medicines, including vaccines, are of adequate safety and potency. The vaccine manufacturer is responsible for demonstrating that the vaccine batch produced meets the requirements, based on the test specifications given by the NRA. The NRA is also responsible both for the official vaccine lot release process, based on the data and information provided by the manufacturer and, eventually, for confirmatory testing.

**Necrosis**
The death of living cells or tissues.

**Neisseria meningitidis (aka meningococcus)**
A bacterium that causes meningitis, as well as infections elsewhere in the body.
**Neomycin**
A broad-spectrum antibiotic that is used in the manufacture of some vaccines.

**Neonatal tetanus**
Tetanus that occurs in a newborn infant.

**Neuritis**
Inflammation of the nerves.

**Neurodevelopmental disorders**
A disorder of neural development, an impairment of the growth and development of the brain or central nervous system.

**Neuropathy**
A general term for any dysfunction in the nervous system. Symptoms include pain, muscle weakness, numbness, loss of coordination, and paralysis. This condition may result in permanent disability.

**O**

**Oedema**
The presence of an excessive amount of fluid in or around cells, tissues, or serous cavities of the body.

**Options analysis**
A system for ranking multiple options in order to decide the best course of action in the prevailing circumstances.

**Oral polio vaccine (OPV)**
A preparation of live attenuated polio virus, used to immunize against polio and developed by Dr. Albert Sabin in 1961. OPV is administered orally (by mouth).

**Otitis media**
An inflammation of the middle ear usually caused by a virus or a bacteria. This condition usually occurs in conjunction with an upper respiratory infection. Symptoms include earache, high fever, nausea, vomiting, and diarrhea. In addition, hearing loss, facial paralysis, and meningitis may result.

**Oxytocin**
A hormone secreted by the posterior pituitary gland that stimulates contractions of the uterus and ejection of milk. As a pharmaceutical it is used in childbirth and lactation to cause muscles to contract in the uterus (womb) and mammary glands in the breast.

**P**

**Pan-American Health Organization (PAHO) Revolving Fund for Vaccine Procurement**
A mechanism developed by PAHO in 1979 for the purchase of vaccines, syringes/needles, and cold chain equipment for countries in Latin America and the Caribbean. Through a system of bulk purchasing, the Fund has secured for the past 30 years a supply of high quality vaccines for national immunization programs at affordable prices, and it has also allowed for the orderly planning of immunization activities.

**Pandemic**
An epidemic occurring over a very large area and affecting a large number of people.

**Paracetamol (also known as acetaminophen)**
A widely used over-the-counter analgesic (pain reliever) and antipyretic (fever reducer).
**Passive reporting** – See Passive surveillance.

**Passive surveillance (also known as spontaneous reporting)**
A surveillance system designed to collect adverse events that follow vaccination. This type of surveillance typically relies on health professionals noticing and reporting adverse events in individuals after vaccination to the NRA or appropriate authority.

**Pathogen**
Any disease-causing substance. Most commonly used for organisms (e.g., bacteria, viruses) and their biological products (e.g. toxins).

**Pertussis (also known as whooping cough)**
An infectious bacterial disease caused by Bordetella pertussis that produces violent, spasmodic coughing; also called whooping cough.

**Pertussis vaccine**
Two types of pertussis vaccines are currently available: the inactivated whole-cell vaccine (wP) and subunit protein-based vaccine (aP).

**Pharmacovigilance**
The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.

**Placebo controlled**
A randomized clinical trial may include controls in which some of the subjects receive a product which has no active ingredients, referred to as a placebo, e.g. a sugar pill or an injection of normal saline. None of the people in the clinical trial nor the clinical team administering the intervention know who was given the placebo, or the test product, or the best performing existing product. A placebo controlled trial enables researchers to evaluate whether the simple act of being given a pill or an injection has a beneficial effect.

**Plague**
A serious, potentially life-threatening infectious disease that is usually transmitted to humans by the bites of rodent fleas. It was one of the scourges of early human history.

**Pneumococcal conjugate vaccine (PCV-7, PCV-10, PCV-13)**
Three subunit polysaccharide-conjugate vaccines exist against pneumococcus. PCV-7 vaccine protects against seven serotypes and PCV-10 protects against ten serotypes of Streptococcus pneumoniae, and PCV-13 protects against 13 serotypes serotypes of Streptococcus pneumoniae most commonly isolated from young children.

**Pneumococcal disease**
Bacterial diseases caused by Streptococcus pneumoniae. Pneumococcal diseases include meningitis, sepsis, and pneumonia, all of which cause significant illness and death.

**Polioymyelitis (also known as polio)**
An acute infectious viral disease characterized by fever, paralysis, and atrophy of skeletal muscles. The Global Polio Eradication Initiative was launched in 1988 with the goal of eradicating polio from the earth through routine and mass polio vaccination programs.

**Polysaccharide vaccine**
A vaccine that is composed of long chains of sugar molecules that resemble the surface of certain types of bacteria. Polysaccharide vaccines are available for pneumococcal disease, meningococcal disease, and Hib.

**Post-licensure surveillance (also known as post-marketing surveillance)**
Pharmacovigilance conducted after a product has been licensed and introduced for use in a population.

**Potency**
A measure of strength or immunogenicity in vaccines.
**Prequalified vaccine**
A vaccine that has been approved as acceptable, in principle, for purchase by United Nations agencies, such as WHO, after full assessment of all procedures involved in its production. The purpose of the assessment is to verify that prequalified vaccines: (a) meet the specifications of the relevant UN agency; and (b) are produced and overseen in accordance with the principles and specifications recommended by WHO, for good manufacturing practice (GMP), and for good clinical practice (GCP). This is to ensure that vaccines used in national immunization services in different countries are safe and effective for the target population at the recommended schedules and that they meet particular operational specifications for packaging and presentation.

**Preservatives**
Compounds that are added to multi-dose vaccine vials to prevent bacterial and fungal growth. The most commonly used product is called thiomersal, a mercury-containing compound.

**Priming**
The process of artificial induction of immunity, in order to protect against infectious disease. Priming the immune system involves sensitizing or stimulating an immune response with an antigen that can produce immunity to a disease-causing organism or toxin (poison). Vaccinations involve the administration of one or more of these antigens, which can be administered in several forms.

**Programme for International Drug Monitoring (PIDM)**

**Rabies**
A potentially fatal viral infection spread through the bite of certain warm-blooded animals. It attacks the central nervous system and, if left untreated, is highly fatal in animals.

**Randomized clinical trials**
A systematic study of medical interventions in human subjects (including patients and other volunteers) in which study subjects are randomly assigned to treatment and control groups. Used to discover or verify the effects of and/or identify any adverse reactions to investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the objective of ascertaining their efficacy and safety. Studies in which neither the investigator nor the study subjects know to which group, treatment or control, they have been assigned until the conclusion of the study are referred to as ‘double-blind randomized clinical trials’ and are considered the gold standard for drug and vaccine efficacy research.

**Reactogenicity**
Being able to produce adverse reactions.

**Reassortant vaccine**
A live attenuated vaccine in which attenuation is achieved by using virus strains in which some gene sequences have been rearranged (reassorted); for example, RotaTeq vaccine contains five reassortant rotavirus strains.

**Recombinant DNA**
A vaccine technology that uses genetic material from a disease-causing organism into a live vector, often a yeast cell, in order to replicate a protein antigens of the disease-causing organism. The proteins are then purified and used as vaccine.
**Reconstituted vaccine**  
The mixing of a powdered (usually lyophilized) form of a vaccine with a fluid called a diluent prior to injection.

**Retrovirus**  
An RNA virus (a virus composed not of DNA but of RNA). Retroviruses have an enzyme called reverse transcriptase that gives them the unique property of transcribing RNA (their RNA) into DNA. The retroviral DNA can then integrate into the chromosomal DNA of the host cell to be expressed there. HIV is a retrovirus.

**Risk**  
The probability that an individual will experience a certain event during a defined period of time.

**Risk-benefit analysis**  
Evaluation and assessment of the relative risks and benefits of an intervention, e.g. the potential benefit of protection from measles and its complications due to vaccination, relative to the potential risk of adverse reactions to the vaccine.

**Rotavirus**  
A group of viruses that cause diarrhea (rotaviral gastroenteritis) in children.

**Rotavirus vaccine**  
A preparation of live attenuated rotavirus used to immunize against infant rotaviral gastroenteritis.

**Rubella (German measles)**  
A viral infection that is usually milder than measles but can cause serious damage or death to a fetus when a pregnant woman is infected.

**Rubella vaccine**  
A preparation of live attenuated rubella virus used to immunize against rubella.

**Safety profile**  
A summary of the evidence on the safety of a medical product, such as a vaccine or drug, under ideal conditions of use, including the incidence of any adverse reactions relative to the number of doses given.

**Sciatic nerve**  
The largest nerve in the human body providing both motor and sensory control for much of the lower limbs. Vaccination of infants and children in the buttock is not recommended because of concern about potential injury to the sciatic nerve, which is well documented after injection into the buttock.

**Second opportunity**  
WHO recommends that all children receive two doses of measles vaccine, either through routine services or mass vaccination campaigns. Often when the second dose is delivered through campaigns, it is considered the second opportunity for measles vaccination.

**Seizure**  
Uncontrolled electrical activity in the brain, resulting in convulsion, physical signs, thought disturbances, or a combination of symptoms.

**Sensitivity**  
In the context of public health surveillance, the proportion of all incident cases of a health condition detected by a surveillance system.
Sepsis (also known as “blood stream infection”)
The presence of bacteria (bacteremia) or other infectious organisms or their toxins in the blood (septicaemia) or in other tissue of the body.

Serious adverse event
A regulatory term defined as any untoward medical occurrence that at any dose: results in death; requires inpatient hospitalisation or prolongation of existing hospitalization; results in persistent or significant disability/incapacity; or, is life-threatening. For more information, see http://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm.

Severe vaccine reaction
This is not a regulatory term. It refers to vaccine reactions that usually do not result in long-term problems, but can be disabling and, rarely, life threatening. Severe reactions include serious reactions but also include other severe reactions.

Side effect
Any unintended effect of a pharmaceutical product (including vaccines) occurring at a dose normally used in man.

Signal
Reported information on a possible causal relationship between an adverse event and a drug, the relationship being previously unknown or incompletely documented. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information.

Simple message
A simple message is ‘jargon free’ and easy for the general public to understand – it ‘translates’ complex concepts and information into readily accessible ideas and examples.

Smallpox
An acute, highly infectious, often fatal disease caused by a variola virus and characterized by high fever and aches with subsequent widespread eruption of pimples that blister, produce pus, and form pockmarks. Declared eradicated by the World Health Assembly in 1980.

Sorbitol
An alcohol used in the manufacture of some vaccines.

Specificity
In the context of surveillance, the measure of the degree to which cases detected through a surveillance system actually have the disease.

Spontaneous reporting – See Passive surveillance.

Stabilizers
Compounds that are used to help vaccine maintain its effectiveness during storage. Vaccine stability is essential, particularly where the cold chain is unreliable. Factors affecting stability are temperature and pH.

Standard case definition
A common, formal definition for the health-related event under surveillance. The case definition of a health-related event can include clinical manifestations (i.e., symptoms), laboratory results, epidemiologic information (e.g., person, place, and time), and/or specified behaviors, as well as levels of certainty (e.g., confirmed/definite, probable/presumptive, or possible/suspected). The use of a standard case definition increases the specificity of reporting and improves the comparability of the health-related event reported from different sources of data, including geographic areas.
Strain
A specific genetic grouping of an organism. Many organisms, such as viral influenza, pneumococcus and meningococcus, have multiple strains that cause disease.

Stridor
A whistling sound generated when breathing (usually heard on inspiration) that indicates obstruction of the trachea or larynx.

Subcutaneous (SC) injection
Administration of vaccine into the subcutaneous layer above the muscle and below the skin.

Subunit conjugate vaccine
A vaccine in which two compounds (usually a protein and polysaccharide) are joined together to increase the vaccine’s effectiveness.

Subunit polysaccharide vaccine
A vaccine that uses portions of bacteria that are composed of long chains of sugar. Polysaccharide vaccines are available for pneumococcal disease, meningococcal disease and Hib.

Subunit protein-based vaccine
A vaccine made from fragments of viruses or bacteria that involve a protein to increase the vaccine’s effectiveness.

Subunit vaccine
A vaccine made from components of viruses or bacteria instead of the whole organism.

Sudden Infant Death Syndrome (SIDS) (also known as “crib” or “cot” death)
The sudden and unexpected death of a healthy infant under one year of age. A diagnosis of SIDS is made when an autopsy cannot determine another cause of death. The cause of SIDS is unknown.

Suppurative lymphadenitis
This is a common adverse reaction to tuberculosis (BCG) vaccine and involves the inflammation of the lymph nodes associated with skin ulceration.

Surfactant
A chemical agent capable of reducing the surface tension of a liquid in which it is dissolved.

Surveillance
The systematic collection, analysis, interpretation, and dissemination of health data on an ongoing basis, to gain knowledge of the pattern of disease occurrence and potential in a community, in order to control and prevent disease in the community.

Surveillance system
The systematic collection, analysis, interpretation, and dissemination of health data on an ongoing basis, to gain knowledge of the pattern of disease occurrence and potential in a community, in order to control and prevent disease in the community.

Synthetic vaccine
A vaccine consisting mainly of synthetic peptides or carbohydrates as antigens. They are often considered to be safer than vaccines from bacterial cultures.

Systemic
Relating to a system, or affecting the entire body or an entire organism (e.g., fever).
Tachycardia
A heart rate that exceeds the normal range for a resting heart.

Td vaccine
A preparation of tetanus and diptheria toxoids together in one vaccine used to immunize adults against diptheria and tetanus. This vaccine contains a reduced amount of diptheria toxoid used in the DT preparation for children. When given to women of childbearing age, vaccines that contain tetanus toxoid (TT or Td) not only protect women against tetanus, but also prevent neonatal tetanus in their newborn infants.

Temporal association
Two or more events that occur around the same time. The preceding event may or may not be causally related to the later one.

Tetanus
A disease caused primarily by toxigenic C. tetani. The rare but often fatal disease affects the central nervous system by causing painful muscular contractions.

Tetanus toxoid (TT) vaccine
A preparation of tetanus toxoid used to immunize against tetanus. When given to women of childbearing age, vaccines that contain tetanus toxoid (TT or Td) not only protect women against tetanus, but also prevent neonatal tetanus in their newborn infants.

Thiomersal
Thiomersal is a mercury-containing preservative that has been used in some vaccines and other products since the 1930's. While there is no evidence that the low concentrations of thiomersal in vaccines have caused any harm other than minor reactions like redness or swelling at the injection site, in July 1999 the US Public Health Service, the American Academy of Pediatrics, and vaccine manufacturers agreed that thiomersal should be reduced or eliminated from vaccines as a precautionary measure. Today, all routinely recommended childhood vaccines manufactured for the US market contain either no thiomersal or only trace amounts.

Thrombocytopenia
A severe decrease in the number of blood platelets, the cells involved in clotting. Thrombocytopenia may stem from failure of platelet production, splenic sequestration of platelets, increased platelet destruction, increased platelet utilization, or dilution of platelets.

Thrombocytopenic purpura
Severe thrombocytopenia characterized by mucosal bleeding and bleeding into the skin in the form of multiple petechiae (small purplish spot), most often evident on the lower legs, and scattered small bruises at sites of minor trauma. In children, idiopathic thrombocytopenic purpura is usually self-limited and follows a viral infection.

Time to onset
The period of time between an intervention (in this case, a vaccination) and the onset of an adverse reaction to the vaccine.

Toxic shock syndrome
A rare serious adverse event resulting from improper vaccine preparation and injection practices. It is a life-threatening illness that is caused by toxins (poisons) that circulate in the bloodstream. Bacteria that have infected some part of the body release these toxins. People with toxic shock syndrome develop high fever, rash, low blood pressure, and failure of multiple organ systems in the body.
**Toxoid**
Inactivated or killed toxin (poison) used in vaccine production.

**Toxoid vaccine**
A vaccine made from a toxin (poison) that has been made harmless but that elicits an immune response against the toxin.

**Tuberculosis (TB)**
A disease caused by the bacterium Mycobacterium tuberculosis. The bacteria usually attack the lungs. But, TB bacteria can attack any part of the body such as the kidney, spine, and brain. If not treated properly, TB disease can be fatal.

**Tuberculosis vaccine (Bacillus Calmette-Guérin, BCG vaccine)**
A vaccine against tuberculosis that is prepared from a strain of the live attenuated bovine tuberculosis bacillus. Tuberculosis vaccine is used in many countries with a high prevalence of tuberculosis to prevent childhood tuberculous meningitis and miliary disease. It is administered intradermally and often leaves a scar.

**Typhoid (typhoid fever)**
A serious disease caused by a bacteria called Salmonella Typhi. Typhoid causes a high fever, weakness, stomach pains, headache, loss of appetite, and sometimes a rash. If it is not treated, it can kill up to 30% of people who get it. There are different vaccines to prevent typhoid: inactivated vaccines that require injection, and live attenuated vaccines that are taken orally (by mouth).

**U**

**Uppsala Monitoring Centre (UMC)**
An independent centre which receives adverse drug reactions from national pharmacovigilance centres in WHO member countries and generates signals of possible side-effects. For more information, see http://www.who-umc.org.

**Urticaria (also known as hives)**
The eruption of red marks on the skin that are usually accompanied by itching. This condition can be caused by an allergy (e.g., food, vaccine, drugs), stress, infection, or physical agents (e.g., heat, cold).

**V**

**Vaccination**
Inoculation with a vaccine for the purpose of inducing immunity.

**Vaccine**
A material containing live attenuated or inactivated (killed) microorganisms, or constituents of microorganisms, capable of eliciting protection against infection.

**Vaccine Adverse Event Reporting System (VAERS)**
A passive surveillance system in the US intended to collect reports of reactions to vaccines. Under the aegis of the US Centers for Disease Control and Prevention and the US Food and Drug Administration.

**Vaccine effectiveness**
The probability that a vaccine, when used in the field under routine vaccination circumstances, confers immunity in a population. Expressed as a percent.

**Vaccine efficacy**
The potential of a vaccine to protect from a disease in controlled clinical trials. Expressed as a percent.
Vaccine pharmacovigilance
The science and activities relating to the detection, assessment, understanding and communication of adverse events following immunization and other vaccine- or immunization-related issues, and to the prevention of untoward effects of the vaccine or immunization.

Vaccine reaction (also referred to as adverse vaccine reaction or adverse reaction)
A classification of AEFI referring to events caused or precipitated by the vaccine when given correctly, caused by the inherent properties of the vaccine.

Vaccine safety
The process of ensuring and monitoring the safety of vaccines through their life cycle.

Vaccine safety surveillance – See AEFI surveillance.

Vaccine-associated neurotropic disease
A very rare disease of the nervous system that follows vaccination against yellow fever.

Vaccine-associated paralytic poliomyelitis (VAPP)
A very rare risk of paralytic polio resulting from oral poliomyelitis vaccine (OPV). Associated with approximately one in every 2.5 million doses of OPV. VAPP is not a risk with IPV.

Vaccine-associated risk
The probability of an adverse or unwanted outcome occurring, and the severity of the resultant harm to the health of vaccinated individuals in a defined population, following immunization with a vaccine under ideal conditions of use.

Vaccine-associated viscerotropic disease
A disease that presents with fever, liver damage and blood disorders that very rarely results from vaccination against yellow fever.

Vaccine-derived poliovirus (VDPV)
Where polio vaccine coverage rates decline but OPV use continues, person-to-person spread of vaccine polioviruses can lead to increased virulence that resemble the wild virus.

Vaccine-preventable diseases
Diseases for which vaccines exist that can confer partial or complete protection.

Vaccinee
The individual receiving a vaccine.

Valent
The number of types of a microorganism that are covered in a vaccine product (e.g. seasonal influenza vaccines that typically cover three virus types are called tri-valent).

Validity
The degree to which an estimate reflects the true value of what it purports to measure.

Varicella (also known as chickenpox)
An acute contagious disease characterized by papular and vesicular lesions.

Vasculitis
Refers to a heterogeneous group of disorders that are characterized by inflammatory destruction of blood vessels that cause a visible rash.

Vasovagal syncope
A neurovascular reaction that leads to fainting.
Virus
An ultramicroscopic infectious agent that consists of genetic material surrounded by a protein coat. A virus can replicate themselves only within cells of living hosts.

Whole cell pertussis (wP) vaccine
A preparation of inactivated whole cell pertussis bacterium, used to immunize against pertussis.

Wild poliovirus
A strain of poliovirus that occurs naturally, as opposed to vaccine-related strains.

World Health Organization (WHO)
A United Nations specialized agency established to coordinate international health activities and to help governments improve health services.

Yellow fever
An infectious viral tropical disease transmitted by mosquitoes and characterized by high fever, jaundice, and gastrointestinal bleeding.

Yellow fever vaccine
A preparation of live attenuated yellow fever virus, used to immunize against yellow fever. A single dose provides protection against the disease for at least ten years and often for 30 years or more.
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Module 1

Question 1
Answer A and D are correct.

Eradication refers to the complete and permanent worldwide reduction to zero new cases of the disease through deliberate efforts.

If a disease has been eradicated, no further control measures are required.

Elimination refers to the reduction to zero (or a very low defined target rate) of new cases in a defined geographical area.

Elimination requires continued measures to prevent re-establishment of disease transmission.

Question 2
All the answers are correct.

The initial EPI goals were to vaccinate every child against tuberculosis, polio, diphtheria, pertussis, tetanus and measles by the time they were one year of age, and to give tetanus toxoid vaccinations to women to protect them and their newborns against tetanus.

Question 3
Answers A and D are correct.

An AEFI is any adverse event observed following immunization. Some may be due to the vaccine, some due to error in the administration of the vaccine, and some are the result of unrelated coincidence.

An adverse vaccine reaction is a subset of AEFI. It refers to a vaccine-related event caused or precipitated by a vaccine when given correctly. Note that the rate of adverse vaccine reactions is very much lower than the rate of health-damaging complications resulting from the disease in unvaccinated individuals.

Question 4
All answers are correct.

All of the listed components can contribute to the risk of an adverse reaction.

Question 5
Answer D is wrong.

An event that occurs in 2 out of a thousand persons is regarded as uncommon (infrequent). Please compare the frequency and the Percentage of persons vaccinated in the table above.
Module 2

Question 1

Answers A and D are correct.

Answer B: Allergic anaphylactic reactions are more likely to occur after receipt of the second dose of measles vaccine.

Answer C: Pertussis (wP) is an inactivated vaccine. Live vaccines include:
- Tuberculosis (BCG),
- Oral Polio Vaccine,
- Measle,
- Rotavirus,
- Yellow Fever.

Question 2

Answer C is incorrect.

Inactivated vaccines can be considered safer than live vaccines, which, however, comes with a reduced effectiveness of the vaccine. Inactivated vaccines should not be seen as ineffective – the immunization schedule foresees repeated doses to ensure adequate immune responses in patients.

Live vaccines on the other hand should not be seen as unsafe – their production is usually done with meticulous quality checks ensuring their safety. It is rather important to have well trained health staff screening patients for counter indications to the vaccines.

Question 3

Answer D is incorrect.

Measles vaccine is a live vaccine, not a conjugate vaccine.

Question 4

This pentavalent vaccine combines five ('penta') antigens in one formulation: diphtheria toxoid, tetanus toxoid, whole-cell pertussis, hepatitis B and Haemophilus influenzae type b.

Question 5

Answer B is incorrect.

Aluminium salts primarily slow the escape of the antigen from the site of injection. As the exposure between the antigen and the immune system, they increase the effectiveness of the vaccine.
Module 3

Question 1
This statement is true.

Events that are life-threatening or result in the death of a patient are defined as "serious".

Question 2
Answer C is correct.

Incorrect storage can lead to reconstitution errors: The drug may be given to the client in mistake for a vaccine or may be used instead of the correct diluent to reconstitute a freeze-dried powder vaccine.

Question 3
Answer A is correct.

The number of expected infant deaths occurring the day after DTP immunization would total 2,421.

Question 4
Answer B is correct.

The vaccine attributable rate is 0.2:1,000 or 2 additional cases of convulsions in infants in every 10,000 vaccinations, compared with the background rate.

Module 4

Question 1
Parents may be anxious about immunization because they are voluntarily exposing their healthy children to the risk of an adverse reaction. Any benefit from the vaccination is not immediate and can only be imagined in terms of protection from future disease.

Question 2
Pharmacovigilance authorities concluded that the original clinical trial contained too few vaccinees to detect the real incidence of such a rare adverse event. As a consequence, subsequent rotavirus vaccines were subject to clinical trials containing at least 60,000 infants. This example illustrates why signal detection, hypothesis generation and testing are vital in post-licensure pharmacovigilance of vaccines.

Question 3
Answers B and C are correct.

Answer A: According to the Brighton Case definition, fever higher than 40.5 degrees Celsius is "extreme".

Answer D: To be due to DTP vaccination, encephalopathy symptoms should occur within 48 hours of vaccination.
Question 4

The case was isolated and clinical & laboratory investigations were carried out. A brain biopsy was collected immediately after the child’s death and sent for culture, microscopy and electronic microscopy. It was determined that herpes virus was responsible for the clinical picture. This example shows, that it is critical to take additional information into account.

Apart from the additional information that was made available, one has to be aware, that the nature of the problem is also a potential factor:

- Disease level and incidence – is this a common vaccine-preventable condition (e.g. measles) or relatively rare (e.g. diphtheria)?
- Is this a crisis situation – for example, a life-threatening vaccine reaction or a threat to the continuation or success of the immunization programme?
- Is the risk caused by an immunization error that can be identified and corrected, or is it an unavoidable and inherent risk?
- Why has concern been raised about the risk and by whom?

Module 5

Question 1

Answer C is correct.

For infants known to be HIV infected, the risks linked to the vaccination outweigh its benefits with or without signs and symptoms.

They should not be immunized.

For infants with unknown HIV status who have signs and symptoms of infection and are born to infected mothers the risks usually outweighs benefits.

They should not be immunized. If infection status can be established early (virology), BCG may be administered once HIV infection ruled out.

For infants born to women of unknown HIV status the benefits outweigh the risks.

These infants should be immunized.

For infants whose HIV status is unknown and who demonstrate no signs or reported symptoms suggestive of HIV infection but who are born to known HIV-infected women benefits usually outweigh the risks.

These infants should be immunized after consideration of local factors (details in guideline).

Question 2

Answers A and D are correct.

Pooling and analysing data from several countries provides additional statistical power for identifying rare adverse events, such as intussusception following rotavirus vaccination. It could reduce the time taken to investigate and establish a causal association between the AEFI and the vaccine and take appropriate action.
Module 6

Question 1

The AEFIs are due to an immunization error as the investigation revealed that unsterile needles had been used.

To avert this practice, WHO recommends the use of sterile, disposable auto-disable (AD) syringes with attached needles for all vaccine injections; AD syringes cannot be used a second time because the plunger “locks” when it has been pushed forward to deliver the vaccine and it cannot be pulled back.

Note how the key messages are listed to support the main message of the statement:

- Information specifying the event,
- Possible cause of the AEFI,
- Scientific evidence on the disease,
- Scientific evidence on the vaccine,
- Response undertaken to respond to the event.

Question 2

All of the statements above are correct.

Relevant tools include discussions on social media channels, e.g. Facebook, Twitter; blogs (diaries, opinion pieces and commentaries on news and events written by members of the general public as well as journalists and all kinds of experts); or Wikipedia, the online encyclopaedia, with content freely created by its worldwide contributors.

All these forms of communication can be harnessed to deliver correct health messages on vaccine safety and to counteract misleading or health-damaging information that is causing concern locally or nationally.

Question 3

A, C and D are correct.

The best means of communicating with a nervous young mother may be a one-to-one interview in a room where you will not be disturbed and the conversation is private. Take time to listen to her concerns and reassure her that they are understandable. Use simplified messages in language that she can understand and do not overload her with too much technical detail. Leaflets that provide additional information to read later may serve well to reinforce your messages.

Communication with teachers at a large school can take place in a group meeting, so that your message can influence many of them at the same time. The room should be large enough to seat everyone comfortably, so they can all see you. Make, however, sure that the group is small enough that they can be heard by everyone if they ask questions. Use display materials (e.g. posters, video, slides) and provide hand-outs to read later to reinforce your messages.

Question 4

All of the statements above are correct.
Question 5

Statements B and C are correct.

A vaccine reaction or immunization error means that a previously healthy person was subjected to some form of harm as a result of the immunization. By contrast, medical drugs are given to people who are already sick, to make them better. This difference results in a much lower public tolerance to adverse reactions of vaccines than there is to the side-effects of drugs.

Most vaccine recipients are babies and young children who were vaccinated with their parents’ consent; any harm that occurs following an immunization is seen as “avoidable” by parents because the vaccine could have been refused. There is much less tolerance for instances of avoidable harm than there is for adverse events that could not be avoided.

Due to a decline of childhood infections in industrialized countries the threats to health and life posed by once-common vaccine preventable diseases (measles, polio, pertussis, diphtheria and tetanus) is low. The benefits of vaccination are no longer being reinforced by directly experiencing the diseases that vaccines prevent.

Question 6

Statements A, B, C, D, and E are correct.

Your key message should be a simple explanation of the situation: If there is no evidence that the death was caused by the vaccine itself, state this. If there is an investigation ongoing, say this.

As with any new vaccine, health authorities closely monitor adverse events following the vaccination, so that any safety issues are quickly identified and followed up. State how many people have been vaccinated with this vaccine, how many serious adverse events have been reported, and how many of those have proven to be related to the vaccine itself, to put this particular event into perspective. For example, state how many people die or are seriously ill each year as a result of influenza.

If you do not have information to respond to a journalist’s request, offer the journalists to share the information with them later, or refer them to the specialist who has this information available. After the interview, provide the offered information to the journalist in a timely manner.

Question 7

Sequence: D: 1, A: 2, C: 3, B: 4.

(other sequences are possible).