

Issues Management Guide

To support countries in preparing for unexpected situations with implications for public communications

This version has been adapted by the Pan American Health Organization/World Health Organization (PAHO/WHO) for the Region of the Americas, from the original document prepared by the communications sub-group of the Immunization Systems Management Group (IMG)/Global Polio Eradication Initiative (GPEI). IMG is responsible for the overall management of the activities under Objective 2 of the Polio Eradication & Endgame Strategic Plan 2013-2018.

For more information on the introduction of IPV, OPV withdrawal and strengthening routine immunization, see: www.paho.org/immunization/polio



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Acronyms

AFP	Acute flaccid paralysis
bOPV	Bivalent oral polio vaccine; containing serotypes 1 and 3
cVDPV	Circulating vaccine-derived poliovirus
DPT	Diphtheria-pertussis-tetanus vaccine
ESAVI	Event supposedly attributable to vaccination or immunization
IPV	Inactivated polio vaccine
mOPV	Monovalent oral polio vaccine
OPV	Oral polio vaccine
PAHO	Pan American Health Organization
SAGE	Strategic Advisory Group of Experts on Immunization of the World Health Organization
TAG	Technical Advisory Group on Vaccine-preventable Diseases of the Pan American Health Organization
tOPV	Trivalent oral polio vaccine
VAPP	Vaccine-associated paralytic poliomyelitis
WHO	World Health Organization

Purpose of this document

The objective of this document is to support countries so that they are ready to confront any unexpected situation or media crisis which could require a communication response or public information related to the introduction of the inactivated polio vaccine (IPV) and the withdrawal of the oral polio vaccine (OPV).

The purpose of this document is to help recognize and face any unexpected situations, to evaluate the possible impact, and to prepare an appropriate communication strategy, as well as minimize any potential negative consequences that could arise during a crisis (e.g., that could affect public confidence in immunization in general or IPV in particular).

Unpredictable and unexpected events can sometimes occur, as we all know. They generally occur at the most inopportune moment, leading to uncertainty, confusion, and an urgent need to prepare a response. Such events can generate public mistrust and disapproval of organizations, people, or immunization services. Having a crisis plan prepared in advance can help mitigate the negative impact of these events.

Introduction

Objective 2 of the Global Polio Eradication Initiative's (GPEI) Polio Eradication and Endgame Strategic Plan 2013-2018 calls for the introduction of at least one dose of inactivated polio vaccine (IPV) into routine immunization systems in preparation for the phased removal of oral polio vaccines (OPV). The introduction should be viewed as an opportunity to strength routine immunization (RI) programs.

Countries currently using OPV only are in the process of putting in place IPV introduction plans, to ensure this vaccine can be introduced into national routine immunization programs in 2015, ahead of the planned start of the phased removal of OPVs in 2016.

The IPV introduction plan should include communication initiatives and social mobilization activities at national and subnational levels so that target audiences are informed about the introduction of IPV into routine vaccination programs. The principal recipients of the messages are: parents and caregivers of children, medical professionals—especially pediatricians—, health personnel, and government authorities.

The communication plan should include messages and materials that respond to questions, concerns, or any information needs concerning: IPV introduction; the progressive withdrawal of OPV which starts by replacing the trivalent (tOPV) with the bivalent oral polio vaccine (bOPV) and events supposedly attributable to vaccination or immunization, known as ESAVIs.

This document presents hypothetical examples of situations that could require a rapid communication response and the implementation of effective informative measures concerning ESAVIs or other events that could compromise the credibility of the program. Furthermore, it includes a work protocol for the strategic management of possible media crisis situations.

It can also serve as a tool to promote cooperation with countries so that they are well prepared and have the technical and strategic resources to handle any potential “negative” unexpected events during the introduction of IPV and the progressive withdrawal of the oral polio vaccine.

Rationale for OPV cessation and IPV introduction

OPV is safe and effective at protecting children against lifelong polio paralysis. Over the past ten years, more than 10 billion doses of OPV have been given to nearly three billion children worldwide. More than 10 million cases of polio have been prevented, and the disease has been reduced by more than 99%. It is the appropriate vaccine through which to achieve global polio eradication.

OPV contains attenuated (weakened) polioviruses. On extremely rare occasions, use of OPV can result in cases of polio due to vaccine-associated paralytic polio (VAPP) and circulating vaccine-derived polioviruses (cVDPVs). cVDPVs are vaccine viruses, which through circulation in susceptible populations have mutated and regained the transmissibility and virulence properties of wild polio viruses (WPVs).

VAPP is a very rare vaccine adverse event in which the oral vaccine causes paralytic polio in the vaccine recipient or a close contact. Because of VAPP and cVDPVs, the global eradication of polio requires the cessation of all OPV in routine immunization as soon as possible after the eradication of wild poliovirus transmission. Since VAPP is rare and not widely transmissible, some countries have chosen not to focus discussions around VAPP, instead focusing on cVDPVs which have more of an impact on the public at large.

OPV is available in different formulations:

- Trivalent OPV – containing type 1, 2 and 3 serotype
- Bivalent OPV – containing type 1 and 3 serotypes
- Monovalent OPV – containing one serotype (i.e., type 1, 2 or 3)

Trivalent OPV is the only formulation used in routine immunization programs. Bivalent OPV is the most widely-used formulation during SIAs to more rapidly interrupt the remaining strains of WPV1 and WPV3 transmission – the only remaining WPV strains in circulation. WPV2 has been eradicated since 1999. The last case of WPV type 3 occurred in Nigeria in November 2012, however, it is too early to determine if it has been eradicated.

With WPV2 transmission already successfully interrupted, the only polio cases caused by the type 2 serotype are those related to the type 2 component of trivalent OPV. Over 90% of cVDPV cases are due to mutations in the type 2 component of the vaccine, which is also responsible for up to 38% of VAPP cases.

This why routine immunization programs will switch from trivalent OPV to bivalent OPV – even before WPV1 and WPV3 transmission are stopped. Following WPV1 and WPV3 eradication, use of all OPV in routine immunizations will be stopped.

To minimize the risks associated with the phased removal of OPV, countries must adequately prepare for the eventual switch from trivalent OPV to bivalent OPV (followed by the cessation of all OPVs altogether). The primary risk associated with the switch will be the increase in susceptibility to poliovirus type 2 in the population, which in turn would increase the risk of the emergence of cVDPV type 2 in the immediate period following withdrawal of trivalent OPV. Safely managing this risk will be key to a successful switch from trivalent to bivalent OPV.

To maintain immunity levels to type 2 polio, all countries should introduce at least one dose of IPV into routine immunization programs by 2015, as recommended by the Strategic Advisory Group of Experts on immunization (SAGE).

IPV mitigates or reduces the risk of cVDPV because it is a trivalent vaccine and uses inactivated, rather than weakened, viruses. IPV also strengthens the immune response to types 1 and 3. After the switch from trivalent to bivalent OPV, IPV will be the only vaccine with which to maintain immunity to type 2 polio.

Scenarios: Examples of situations where issues management may arise

There are a number of events related to IPV, IPV introduction and OPV withdrawal that could negatively affect a vaccination program and that may require a communication response and rapid provision of information. Listed below are some of the scenarios that could arise.

Scenario	Description of scenario
Wild polio cases or detection of wild polio viruses in a country or community	It is possible that after a country introduces IPV that wild polio viruses may be detected (e.g. in environmental surveillance) or that there may be a case or outbreak of polio in the country. It can be important to communicate that while IPV is an important vaccine for achieving polio eradication, the vaccine cannot prevent polioviruses from coming into a country. In the event of significant polio transmission in the post-eradication era, mOPV will be the vaccine of choice in trying to end transmission.
IPV vaccine supply shortages or delays	It is always possible that there can be shortages or delays in the availability of vaccines, including IPV. Even with the best planning, manufacturing or shipping delays, for instance, there could be temporary shortages or delays in the availability of IPV in some places. If there is or is going to be an IPV supply shortage or delay, it is often best to communicate that as soon as possible.
Vaccine-associated paralytic poliomyelitis	Very rarely, OPV vaccine can cause polio – this is one of the reasons for the transition to IPV. If a country or community has not experienced or is not aware of vaccine-associated paralytic polio (VAPP) it could be alarming. It can be helpful to provide information in advance on vaccine-associated polio, including letting the medical community know that it is rare.

Scenario	Description of scenario
Other events supposedly attributable to vaccination or immunization (ESAVIs)	<p>Immunization can be followed by an adverse event ESAVI, also called an event supposedly attributable to vaccination or immunization (ESAVI), which can be caused by the vaccine or by an error in the immunization process. It is also possible that people will believe a reaction was caused by a vaccine when it was not. Given the wide use of vaccines, coincidental health problems not caused by the vaccine could be blamed on the vaccine because the adverse event closely follows the vaccination in time.</p> <p>Uncertainty and fear about vaccine adverse events can quickly harm an immunization program so it is very important to communicate quickly should an ESAVI occur.</p> <p>In the event of an ESAVI, tell people what is known and what is being done to investigate and respond.</p> <p>It is also often helpful to be proactive to let local officials know what to expect (e.g., reports of ESAVIs may occur and that they are likely to be coincidental but a full investigation will be done).</p>
A new study or experimental data involving IPV	<p>New research about the benefits of vaccines is being published all the time. There can be a need to communicate when such research receives news media or public attention. Most research does not generate attention, but if the research involves vaccine safety there can be a need to communicate quickly.</p>
Activist criticisms or claims designed to stop introduction or decision to introduce IPV or criticize global involvement	<p>There are many claims an activist could make and steps they could take to slow or stop IPV introduction. Tactics that have been used include asking questions in parliament, bringing about a court case or otherwise blocking progress of introduction. Agreement amongst country and global stakeholders on a protocol for responding or not should be discussed prior to IPV introduction.</p>
A report in the news media or local rumor regarding IPV or OPV	<p>The media often has articles about vaccine safety or concerns that can grab public or parent attention. Often the stories involve anecdotes or unsupported claims. If the claim will reduce or harm public or parent confidence in IPV, there may be a need to respond or reassure the public.</p>
Temporary suspension of an IPV or OPV vaccine	<p>Temporary suspensions of a vaccine from public use, including in another country, can cause public attention and concern, particularly among individuals who were recently immunized or were planning to be immunized. In the case of IPV or OPV, it would be helpful to communicate quickly, including the reasons for the suspension and any public health advice to parents whose children were recently vaccinated.</p>
An IPV or OPV vaccine recall	<p>Very rarely, manufacturers may have to recall a vaccine for safety reasons. Recalls are often broadly publicized and therefore a communication response is often needed from public health officials. As with a temporary suspension, it will be important to provide information and guidance to parents and caregivers.</p>

Determining whether to respond or communicate

When an immunization program becomes aware of an event involving or affecting IPV or OPV vaccination, it must decide whether to communicate this information, how the information should be communicated, and with which groups and people to communicate. It also needs to decide what the public health messages and guidance will be. When programs inform health workers, the media, parents or the public about an issue involving a recommended vaccine, it is important to identify 1) why the information is being provided and 2) what should be done as a result of the information.

Whether real or perceived, any vaccine related event can become a crisis situation if it is not handled correctly. Informing health workers, the media, parents or the public in a timely manner can help maintain confidence in the vaccine and the immunization recommendation. Not promptly disclosing a potential problem can reduce trust and confidence and cause parents to delay vaccination.

In determining how and when to respond and communicate about an IPV-related event, below are some guidelines to consider. Immunization program managers should also consider whether the event will have a low, medium or high impact or risk to public health and/or the immunization program. Many events will be low impact if public health and immunization programs proactively address the issue before an actual event happens.

Best practices for developing a plan

Unexpected vaccine-related events are frequently marked by uncertainty, confusion and a sense of urgency. Effectively communicating around such events, including through mass media, can help minimize their impact, and can help maintain trust and confidence in organizations, persons or services (such as immunization). Key elements of conducting a 'best practice' communications approach to such events are summarized below. All are aimed at securing trust - the overriding goal in issues management communications is to help build, maintain or restore trust. Consequences of losing the public's trust can be severe, in particular around public health issues.

Timing of public announcements

The timing, candor and comprehensiveness of a public announcement are critical, and may be the most important aspect of issues management communications. This is particularly critical given today's globalized, internet-connected world, where information can rapidly be transmitted in an uncontrollable manner. It is important that key internal partners are informed ahead of a public announcement.

Transparency

Communications should be conducted in an easy-to-understand, complete and factually accurate manner. As and when new and relevant information becomes available, this information should also be subsequently communicated.

Know your target audiences

Clearly identifying with whom you want to communicate and understanding their concerns will help ensure that the right messages are delivered by the right messengers through the right channels. This will enhance the impact of the message delivery.

Empathy and acknowledgement of the audience's concerns

As applicable, communications should be suitably understanding and compassionate in acknowledging and responding to the issue or event. It often helps to begin with acknowledging that people are concerned or have concerns

Planning

Communications should be an integral strategic part of the broader technical issues management control. Having a pre-prepared communications plan in place and trained spokespeople are key. Sensitizing the media in advance of an unexpected event can also be helpful, not only for the introduction of a new vaccine but also for understanding the contribution vaccines make to the health and well-being of children and the country overall.

Advance preparation is critical!

An issues management plan should be developed in advance of a vaccine introduction, ready to be adapted if an event occurs.

Monitoring of evolving situation

Monitoring and continually evaluating the situation will aid in further sensitizing and targeting a communications approach over time.

Guidelines to consider

- **Learn and Confirm** - The first step is to identify and confirm what has happened or what has been claimed to have happened. People will want to know the facts and it is important to be sure you have the correct information before you begin communicating.
- **Designate a spokesperson** – Identify a person to serve as the primary spokesperson for communicating with the media and public. This person should be known to be credible and trusted, have knowledge on the subject, and be prepared to communicate with the media.
- **If in doubt, communicate** – From a public and health worker trust standpoint, it is better to err on the side of too much communication, than too little.
- **Provide regular updates** – It can help to provide frequent updates to health workers, the media and the public, especially if the event affects whether or when IPV or OPV are given.
- **Let media and public know if you “don’t know”** – In the early stages of a vaccine-related event you likely will not have all the information and details. It can be helpful to let the public and media know that you do not currently have all the information needed. It is also important to let them know you are working on getting more information and to provide an idea of the time line.
- **Be flexible and ready to take more or new action** if events that initially seemed to have low impact on the vaccine program suddenly change to medium or high impact.
- **Be proactive with positive placements about the value of vaccines and the polio plan.** This will help counterbalance negative media and help reduce the credibility and importance of negative reports, especially those that involve anecdotes or unsupported claims.

Events supposedly attributable to vaccination or immunization (ESAVis): Essentials

- **Simplify complex information** – communicate in a way that everyone can understand.
 - Note that fear and anger are barriers to effective communication.
- **Communicate early and often** to health workers about the situation. Health workers need to be confident in vaccines and vaccination recommendations. They are also the people who will be talking with parents and caregivers. The medical community, including pediatricians, should be considered as they are often those speaking with the media and providing advice to parents.
- **Listen to what the public or parents are saying** and try to understand their concerns and the underlying reasons for their concerns. This includes understanding the local perception of the disease, perception of injections and perception of the vaccine.
- **Be as transparent as possible and proactively outline steps** taken by the government to strengthen routine immunization alongside the introduction of IPV.
- **If an ESAVI occurs, communicate as quickly as possible.** The public needs to know that you share their concerns, that the situation is being investigated and that you will keep them informed.
- **Make sure that all partners are giving out the same message**, but tailor explicit communication messages to the specific situation. It is useful to differentiate between the general public and the medical community and their respective information needs.
- **Risks perceived to be generated by a trusted source are more accepted** than risks perceived to be generated by an untrusted source, so have a trusted spokesperson deliver the message and be cautious about trying to discredit others. It is often best to take a positive approach and perpetuate a dialogue over unfounded or unsupported claims.
- **Risks perceived to have clear benefits are more accepted** than risks perceived to have little or no benefit. It is important to make sure families and communities understand the benefits and importance of vaccination.
- **Risks perceived to be familiar and understandable** are more accepted than risks perceived to be exotic. Avoid technical terms and long words or phrases when explaining.
- **Identify and meet the needs of the media.** Media can be the gateway to public opinion. Also remember that many or most journalists may not understand: 1) why vaccines are used; 2) how vaccines work; and 3) the difference between a report or claim of an adverse event following immunization and an actual or verified adverse event – many or most reporters may assume that if there is a report that it must be true that the vaccine caused the outcome.

Developing key messages

Key messages are short statements designed to communicate essential information and points to the public, news media, or health workers. They reflect the essential information you want to convey and can also function as “sound bites” during media interviews. It is helpful to have developed key messages prior to communicating about vaccine-related events. Having key messages prepared in advance will allow you to communicate quickly and effectively.

Points to consider when developing key messages:

- List the 3-4 things you really want health workers, the public or the media to know, to consider, or to think about.
- Ensure the key messages:
 - Are specific, clear and concise
 - Use word and examples that your audience will understand
 - Avoid jargon and technical terms
 - Are positive – talk about what you are doing, and can and will do; not what you cannot
- Identify who is affected and let people know how they can determine if they were affected (e.g., by identifying the places and dates)
- Show compassion for anyone impacted by the event, even if there is no link to the vaccine
- Address the cause or potential cause of the event
- Provide guidance about what to do or what should be done going forward

Messaging for an example scenario: Contamination of multi-dose vials of IPV

See below some examples of key statements that could be used with the public or media to inform them about a contamination of multi-dose vials of IPV:

- We (health officials in country) learned yesterday that a number of vials containing IPV vaccine at a local clinic were found to have bacteria in them. [Note: if you can provide number do so]
- The problem was discovered after (three) children who received IPV vaccine at the clinic became ill. The children were vaccinated on (provide date).
- We are working to check on all the children who have received IPV vaccine at this clinic since (provide date). We want to know if they got ill and if so, how they are doing.
- The (three) children who received the bad IPV vaccine are (current health condition).
- Vaccine safety is very important and we are investigating this fully. We are also taking steps to make sure all clinics are properly handling and using IPV vaccines.
- We will make sure that all IPV vaccine given at this clinic is safe. To do that, we are (list the actions being taken).
- It is important to note that only IPV vaccines received at this clinic were affected. Other vaccines were determined not to be affected. We have no reports or concerns with IPV or other vaccines being provided at other clinics.

Standard procedures for reactive issues management

1. Establish a core communications team:
 - Consisting of communications professionals in relevant partner agencies (e.g., –PAHO/WHO)
 - The core communications team will liaise closely with technical counterparts in evaluating potential unexpected negative news or issues that may arise, and plan and implement an appropriate communications response, as necessary. Technical counterparts may include independent experts, pediatric associations, academicians as well as government and partners.
 - The team may also determine that proactive media training for spokespeople and/or journalist training is beneficial and should be included in response plans.
 - Determine timelines or schedules for providing information and situation updates.
 - Identify the sources of resources and capacity that may be needed to support the development and implementation of a issues management plan
2. Evaluate the situation: The core communications team, in liaison with technical counterparts should:
 - Assess the situation and its potential impact (i.e., reputational management issue, issue with vaccine safety or supply, epidemiological issue, political or societal issue, –ESAVI, etc.)
 - Evaluate the extent of news coverage and interest (i.e., one article, or extensive secondary media pick-up)
 - Determine ‘geographic’ impact (i.e., subnational, national, regional, global)
3. Determine actions: The core communications team, in liaison with technical counterparts:
 - Based on situation evaluation, should develop a reactive communications action plan strategy as necessary, in conjunction with technical counterparts as appropriate. (See ‘annex’ for example of a draft plan.)
 - This may require collaboration with regional and global teams, as necessary and appropriate.
 - Particular focus will be on ensuring potential political sensitivities are taken into account, and that partners are informed prior to dissemination of information to the public domain.

Examples of items to consider when evaluating if an issue requires or would benefit from a communications response (and scale of response) include:

- Can the issue have significant potential fall-out, i.e. affect confidence in immunization, in IPV, or in the Ministry’s ability to deliver services?
- Who is most likely to be affected by this issue? Parents, communities, medi-

cal professionals, partners, donors, the government

- What type of messages might they need? For example, key messages on safety of IPV such as:
 - IPV is a safe vaccine, whether used alone or in combination vaccines
 - IPV vaccine has not been associated with any serious adverse events in [the country]
 - Minor side effects include minor local reactions such as pain and redness at injection site
 - IPV has been used extensively around the world for more than 60 years
 - Strong and rigorous quality control standards are in place to ensure the safety of IPV
- Consider proactive communication
 - Positive communications about the impact of immunization or stories about the introduction with well-informed journalists can help build support for immunization and the introduction of IPV
 - Spokesperson and journalist training should be considered
 - Providing information and stories to trained journalists can help ensure more balanced reporting should an incident arise

4. Steps in producing materials:

- Agree who will take lead in producing which materials
- Develop initial draft
- Share with relevant technical counterparts to ensure technical accuracy
- Share with broader core communications team for input
- Finalize draft and circulate for internal approval as appropriate
- Translate into local/other languages as necessary

5. Monitor evolving situation:

- Establish clear mechanisms and systems to monitor the evolving situation, and to evaluate the impact of communications activities, including over time (i.e., media monitoring, assessments of views among key target audiences, etc.)
- Adapt and further tailor the communications strategy based on outcomes

Additional resources

- [GPEI Polio Eradication and Endgame Strategic Plan 2013-2018](#)
- [PAHO/WHO Final report of the XXI Technical Advisory Group \(TAG\) Meeting on Vaccine-preventable Diseases](#)
- [PAHO/WHO Practical Guide: Inactivated Poliovirus Vaccine \(IPV\) Introduction](#)
- [PAHO/WHO Polio Field Guide, Third Edition, \(2006\)](#)
- [PAHO/WHO Immunization Polio Webpage](#)
 - [FAQs on the Introduction of Inactivated Poliovirus Vaccine \(IPV\)](#)
 - [Background and Technical Rationale for Introduction of one dose of Inactivated Polio Vaccine \(IPV\) in Routine Immunization Schedule](#)
 - [Brief on IPV Introduction, OPV Withdrawal, and Routine Immunization Strengthening](#)

Annex: Example of a reactive communication strategy

- Development of objectives: Clearly identify and state the aims the communications strategy will seek to achieve.
- Identification of target audiences:
 - Internal audiences, e.g. national and sub-national staff in partner organizations and Ministries
 - Professional audiences, e.g. NITAGs, pediatric associations, medical doctors, nurses
 - Broader audiences, e.g. health workers, communities, parents
 - Media, e.g. general media, scientific media
- Development of key messages: Tailored towards each target audience's needs, concerns and likely questions
- Identification of spokespersons and training on messaging as appropriate: Partner agency and Ministry spokespersons, independent experts, caregivers and parents
- Monitoring of impact: As necessary, based on the evolving situation, additional activities may be implemented to ascertain the impact of the issue, such as: knowledge, attitudes and practices (KAP) evaluations among specific audiences (caregivers, communities, parents, medical professionals, etc.)
- Project management example for implementation of activities: Successful implementation of activities can be assured through effective project management. A simple table can help in this process, as outlined below.

Activity	Status	Next steps	Responsibility	Date
Internal staff briefing	<ul style="list-style-type: none"> ■ Book meeting room ■ Invitations to all staff sent out ■ Speakers identified and invited 	<ul style="list-style-type: none"> ■ Brief speakers ■ Prepare talking points and PowerPoint slides ■ Ensure AV support available 	Lucas,	15 Feb
Fact sheets and reactive Q&As	<ul style="list-style-type: none"> ■ Initial draft developed 	<ul style="list-style-type: none"> ■ Forward to technical colleagues to ensure accuracy ■ Share with partner focal points for input ■ Finalize incorporating comments ■ Post on website and distribute to key partners 	Maria,	20 Feb
Etc...	Etc...	Etc...	Etc...	Etc...