

# Solidarity Trial Vaccines (STV) crisis communication planning guide[1]

World Health Organization

R&DBlueprint
Powering research
to prevent epidemics

# Contents



**1** Derived and adapted from Robinson, E.T., Baron D., Heise, L.L., Moffett, J., Harlan, S.V. (2011). Communications Handbook for Clinical Trials: Strategies, Tips and Tools to manage Controversy, Convey Your Message, and Disseminate Results. Microbicides, Media and Communications Initiative: Washington DC; Family Health International: Research Triangle Park, N.C.

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# Overview

All clinical trials occur in a context of risk and uncertainty. As with most trials, there is the potential for negative events to undermine trust in the Solidarity Trial Vaccines (STV) and to threaten an entire study.

This guide to crisis communication planning is built around three pillars: A Prevent a crisis; B Anticipate a crisis; and C Respond to a crisis.

It outlines communication principles to establish trust, transparency and common expectations with stakeholders – that will help prevent a crisis from occurring.

It gives steps for creating communication systems and structures in case a crisis emerges – that anticipate a crisis.

And it describes communication activities to be carried out if a crisis occurs – to respond to a crisis.

Here are the three steps in more detail:

**A. Investing from the outset in activities and principles that build trust and strong relationships will help prevent a crisis from occurring:**

- Build a foundation of trust
- Listen to communities and stakeholders
- Demonstrate appreciation
- Create unity and identification
- Demonstrate integrity
- Set expectations
- Inoculate against rumours and misinformation

**B. Putting in place communication systems and structures in case of a crisis will anticipate and mitigate a crisis:**

- Prepare the crisis team for their roles
- Brainstorm crisis scenarios
- Speed communication response by creating resources and expedited clearance ahead of time
- Engage in systematic issues management: analysis of media and community monitoring

**C. Following crisis response protocols will help de-escalate a crisis:**

- Day 1: Identify source of crisis, rapid information gathering, core team to conduct rapid assessment and action plan, share information, activate crisis communications plan and team, prepare for press conference
- Days 2-5 (or longer): Daily monitoring and analysis, create and release updated information, compile key messages
- After crisis: Conduct post-crisis debrief to learn lessons

The **Respond to a Crisis** section of the manual contains a list of invaluable and highly practical tips as well as day-by-day actions you should consider taking during a crisis.  We have marked these pages in orange on the right hand side so you can access them easily.

There is overlap as many of the principles described in the first section of this plan to **Prevent crises** are as important in engaging with stakeholders while 'responding' to a crisis, e.g. transparency, relational communication and unity.

We hope the guide is useful to you in helping prevent or manage any issues that may occur.

# Introduction

Possessing and delivering a strong, proactive crisis communication plan in place to maintain and restore public trust is central to the success of a vaccines trial.

### POTENTIAL CRISIS SCENARIOS

**Issues that can become crises inherent to clinical trials:**

- Safety concerns that can emerge when testing new vaccines
- Adverse reactions to the vaccine
- Unexpected trial closure

**Other crises that may occur in interactions between, or among, study staff, trial participants and hosts:**

- Disengaged/demotivated/unhappy staff or trial participants
- Charges of exploitation (including perception of colonial or imperialist attitudes/processes)
- Personal or political vendettas
- Unmet protocols
- Failure to follow through on promises or agreements
- Perceived disrespect and lack of appreciation

**Legal or financial matters that can fuel a crisis:**

- Disputes about information or data-sharing
- Breaches of contracts and memoranda of agreement
- Allegations of financial corruption

Negative events can emerge at any level or site of a trial's sponsoring or partner organisations and quickly affect any, if not all of its operations. Unless they are anticipated, mitigated and managed they can become highly visible negative events.

Communication alone cannot prevent a crisis from happening. But crises can only be managed successfully with a strategy to communicate rapidly and transparently with all stakeholders (including trial participants, staff, news media, affected and interested parties).[2] See **Appendix A Mapping potential stakeholders.**

# Aim of this document

This guide is for national focal points in the Solidarity Trial Vaccines. It sets out practical steps to help prevent, anticipate and respond to a crisis that could occur during each country's trial activities.

It is comprehensive and can be drawn on and implemented in different scenarios and stages both preparing for and in the event of a crisis.

It includes risk communication principles to establish trust, transparency and common expectations with stakeholders; steps for creating communication systems and structures in case a crisis emerges; and communication activities to be carried out if a crisis occurs.

National communication focal points are invited to use this guide as a resource to develop a crisis communication plan that meets the specific needs of the trial in their country. Plans should always be developed in collaboration with the trial's technical leadership and engagement focal points.

**2** Shepherd, M. (2005). Emergency risk communication. Presentation at Family Health International: Research Triangle Park, North Carolina, U.S.A.

The steps and tools described here must be adapted to meet the unique situation and capacity of a country's sites and stakeholders.

The document complements 'Good Participatory Practice (GPP) with trial populations for the Solidarity Trial Vaccines (STV)'[3] (hereafter referred to as the 'GPP Handbook').

Many of the planning and delivery engagement activities in the GPP Handbook will in turn help prevent and anticipate potential crises.

# Crisis communication team: Roles and responsibilities

The trial leadership responsible for crisis management should from the planning stage identify staff members who will perform the functions of crisis communication to support trial sites in their country—known as the "crisis communication team".

Some of the tasks of the crisis communication team will be similar to those performed by engagement focal points and other trial staff members who connect with local trial populations. Engagement focal points and other trial staff members may therefore be most suited to performing crisis communication.

The national communication focal point will lead the work of the crisis communication team. (The national communication focal point works closely with the trial's Principal Investigator (PI), the engagement focal point, and designated spokespersons).

The crisis communication team will work collaboratively with communication focal points across all organisational levels, sites and partners. Additional surge staff may also be needed during an actual crisis event, depending on the context, scale and scope of each country's trial and sites.

### Roles and responsibilities of the crisis communication team include:

- Listening and two-way engagement with stakeholders
- Monitoring issues that have the potential to become crises, through issues management processes
- Bringing emerging issues to the attention of trial leadership
- Coordinating communication planning, strategy development and implementation, between organisational levels of the trial, sites and partners
- Developing crisis communication materials and activities to anticipate and respond to an emergency
- Rapidly, and on an ongoing basis, releasing information through multiple channels and platforms about the crisis/crises
- Evaluating crisis communication response and development of lessons learned

For a full explanation of these and related functions see **Preparing the communication team** in the second section, **Anticipate a crisis**.

**3** World Health Organization. (2020). Good Participatory Practice (GPP) with trial populations for the Solidarity Trial Vaccines (STV).

# Effective crisis management: Prevent, anticipate and respond

This plan is built around the three pillars of "Prevent a crisis", "Anticipate a crisis", and "Respond to a crisis". It outlines activities for each of these. Much of the crisis communication work is done in advance to prevent and/or prepare for a crisis.

If steps are taken at the beginning of the trial to establish trust, transparency and common expectations (thus ''prevent a crisis"), most sites should not have to enact the activities described in the third part of the plan (i.e. "respond to a crisis").

## PREVENT A CRISIS

Building relationships and trust with relevant stakeholders is essential to preventing a negative event from escalating into a crisis. This should begin as soon as the vaccine trial team begins to engage with local hosts and potential trial participants.

Stakeholders include members of the local community (where trial volunteers are recruited), policy makers, advocacy groups, and other groups with an interest in the vaccines and the trial. See **Appendix A Mapping potential stakeholders.**

Preventing a crisis is the responsibility of all trial staff and leadership who communicate with stakeholders and not just engagement or communication focal points.

Communication principles and practices that should be integrated in all interactions and materials shared with stakeholders during the trial can also be found in the GPP Handbook.

### Communication objectives necessary to prevent a crisis include:

- Communicating and interacting with stakeholders in ways that establish and maintain trust
- Setting expectations clearly and early about the trial's purposes and protocols
- Setting expectations for change if an unexpected event does occur
- Establishing a sustained and regular two-way flow of information, opinions and concerns between trial staff, local hosts, participants, news media and other stakeholders
- Regularly and frequently communicating and showing appreciation to trial participants and local hosts
- Aligning the actions of trial staff with their words

### Build a foundation of trust

**(**Also see **Appendix B Trust-building practices)**

To increase trust, four practices should be consistently applied in all trial communications:

- Two-way communication
- Relational communication (respect, caring, appreciation and unity)
- Transparency
- Integrity

## Two-way communication

Two-way communication is the most effective way to build trust in situations of risk and uncertainty. Experts and lay people inform each other in back-and-forth sharing of information, concerns and reactions about a vaccine trial. This involves "listening" to communities and other stakeholders.

### Listening to communities

Two-way engagement activities with communities and research populations mean those stakeholders are more likely to feel understood and that their views, questions and concerns are being taken into consideration in trial planning.

These activities include group sessions with district leaders, civic, religious, cultural, local communities, key civil society groups, local engagement and social mobilisation actors. Community Advisory Boards (CABs), focus group discussions and other mechanisms ensure continuous input from local stakeholders throughout the trial.

### Listening to other stakeholders

Real-time in-person communication is the best way to engage with socio-cultural aspects relevant to trial development. However, other channels may be needed to understand attitudes, beliefs and behaviours. This includes when groups are geographically outside the trial community (the focus of engagement focal points), or there is distrust of trial officials, for example.

Social and news media can provide insights into the perspectives of government officials, journalists, general publics, and health/vaccine advocacy groups. However, monitoring of social and news media requires significant human resources.

National communication focal points may therefore need to create agreements with WHO headquarters and/or other partners to assist with frequent and regular computer-assisted scans of vaccine issues and trial events circulating in social media and news channels.

Local analysis focused at country and site level will provide relevant insights about topic trends and patterns that both reveal and influence stakeholders' beliefs, questions and concerns.

## Relational communication

Many people will pay more attention and listen more to communication from the trial if the staff and leadership show that they care about and respect those stakeholders they are communicating with.

Respect is shown in part by engaging in dialogue in the ways described above and in activities such as those outlined in the GPP Handbook. Other elements of communication include appreciation, and unity (identification).

Demonstrate appreciation. Showing appreciation for trial participants and local sponsors is critical to developing a trusting relationship with them. It is very important to acknowledge the altruism and courage of trial participants and local hosts supporting the trial. When people don't feel acknowledged, they are less likely to commit to the process and are more likely to become disengaged and demotivated.

The STV should look for all opportunities to show appreciation—thanking participants and local hosts frequently and regularly in trial leaflets, press events, town meetings, and one-on-one communication.

Create unity (identification). Communication can also build bonds of unity -- highlighting common ground between the trial and stakeholders. In general, people are more likely to trust those with whom they identify. To create unity:

- Use inclusive language and empathy ("we", "us", "our", etc.)
- Refer to trial goals, progress, accomplishments and consequences as shared by the trial staff and stakeholders
- Work with locally trusted leaders and channels to deliver information and gather stakeholder inputs (as described in the GPP Handbook)
- Introduce the whole site teams to trial participants in person if possible

The more stakeholders feel part of the trial team, and trial staff/leaders are part of their community, the more likely it will be that stakeholders trust the trial process and staff.

Engagement activities to establish community partnerships throughout the trial reinforce this goal (see GPP Handbook). Trust cements partnerships and can prevent problems from becoming crises.

Demonstrate integrity. Integrity is the final element of trust. Stakeholders understand integrity to mean the trial can be trusted to do what it says and "play fair". Integrity means following through on commitments and promises and aligning words and deeds. For example:

- Trial updates are made available at the time that it is said they will be communicated
- All staff follow and maintain with all stakeholders the steps outlined in protocols
- Agreements are equitably observed
- All trial participants are treated equally, with respect and without preference

### Transparency

Transparency and trusting relationships are intrinsically linked. If stakeholders believe that trial staff and leadership are sharing all that is known about the trials that can be legally shared, they will trust more. Where information must be withheld, legally and for purposes of scientific integrity, the trial should respectfully tell communities, the media and others that and why it is being withheld.

Transparency does not mean disseminating all relevant and shareable content through all means available at any time. Vaccine trials are complex undertakings: information about early testing stages, manufacturing processes and other information can be shared but may not be of equal interest or relevance to all stakeholders. Proactively distributing all available public information about the trial and related vaccines will overwhelm and confuse many stakeholders.

Instead, "filtering" and targeting information to different groups of stakeholders can ensure people have the information they most need to:

- Make informed decisions about how to protect themselves, their families and their communities from harm (including whether to participate in the trial)
- Comply with steps and procedures required of trial participants
- Abide by the legal requirements of the trial
- Maintain trust between stakeholders and the trial

A general principle for transparency is to post all available information in plain language on an accessible platform such as a website or Frequently Asked Questions (FAQs) board.

However, as well as making information available for those who seek it, it is as important to proactively target information and key messages so that they reach groups who do not seek them.

Transparency also means sharing information about unknowns and uncertainties. Stakeholders will want to know what health authorities know and also what is unknown or uncertain.

An integral part of transparency is to explain how the trial addresses unknowns, with a promise to share what can be shared when it is known. Communication of this kind will show that the trial is being honest and that it trusts stakeholders enough to share the uncertainties of evolving science. This can become an exercise in communicating the very nature of science.

Finally, information about financial benefits and rewards is especially important. Since trial volunteers will not receive remuneration, they are likely to be sensitive to information about financial benefits to other parties.

Perceptions of financial exploitation are more likely to develop if local hosts and trial participants learn about profits related to the trial after it is underway. It is therefore recommended that the trial is open about and makes available any information about financial gains related to the trial, and any special benefits that will be received by the government, for example.

## Set expectations

Setting stakeholder expectations is very important to prevent crises. Unmet expectations and assumptions can easily escalate into a crisis, especially if trust is lacking between the person whose expectations have not or are not felt to have been met, and those that they believe have broken a promise.

The best way to prevent such a situation from arising is to make explicit the trial protocols, procedures and assumptions in all encounters with participants and local hosts and in communication materials.

It is important to think through any gap in understanding that trial participants and local hosts may have. Even those issues that seem to be well-understood can be misinterpreted if they are not spelled out. Stakeholders may fill an 'information gap' with their own perceptions or understanding. They may feel hurt when actions by trial staff and leadership do not match their own expectations (even if these were never part of explicit communication from the trial).

**Early communication with stakeholders should make clear:**

- What is expected of trial participants
- What and when information will be released concerning trial results
- What and why information cannot be shared with trial participants and other stakeholders
- What happens if another vaccine candidate tested at a different site is effective and becomes available
- Protocols if an adverse event (or some other deviation from expected actions related to the trial) occurs
- What participants should do if something does not happen in the way they expected
- How trial officials would investigate a safety issue or negative event

Information about these topics should be made available to all stakeholders. But once again, tailoring and proactive outreach concerning them depends upon stakeholders' level of involvement and interest in the trial. So for example, trial recruits will need detailed and proactive messaging about activities expected of participants, as outlined in the informed consent process; meanwhile social media influencers representing national organisations are likely to require less detail.

## Inoculate against rumours and misinformation

See **Appendix C How to deal with circulating rumours and misinformation**

Misinformation and rumours about the trial can escalate into a crisis. The impact of this and other misinformation can be mitigated by forewarning and preparing stakeholders for such an occurrence.

Most research on combatting misinformation concurs that the best way to address rumours, conspiracy theories, and other misinformation is to "inoculate" against it.[4] Inoculation means helping stakeholders

anticipate and recognise misinformation. Inoculation is not the same thing as refuting misinformation. Instead it helps stakeholders anticipate that they might hear or see misinformation and what to do if this occurs. The best time for inoculation is when trial staff provide volunteers or potential recruits with contact information for participants' questions. This should:

- Reinforce the mutual goal that the vaccine trials and their results are based on the best and most accurate information.
- Ask that any questions or concerns locals might have are brought to the point of contact (POC) and that information is sought using designated official channels.
- Explain that participants might hear or see information from other sources that is different from what they have received from the STV. Indicate that different information might be a misunderstanding or could even be a deception.
- Ask that if participants come into contact with information that is different from trial sources, they share it with a trial contact, but not with others.

If/when reports of misinformation are brought to trial staff, staff members should present the correct information but not repeat the rumour.

These elements of rumour inoculation create an opening where corrective information is more likely to be accepted if people subsequently encounter misinformation.

In addition, trial staff members should avoid escalating misinformation by staying alert for any stakeholder who is deeply entrenched in anti-vaccination opinions. In such a case the staff member should decline to debate vaccine harm/benefits with them. Such stakeholder can be provided with the official, accurate written materials about the relevant topic from the trial.

**4** Lewandowsky, S., Ecker, U.K.H, Seifert, C.M., Schwartz, N., and Cook J. (2012). Misinformation and Its Correction: Continued Influence and Successful Debiasing. Psychological Science in the Public Interest, Volume: 13 issue: 3, page(s): 106-131. https://journals.sagepub.com/doi/10.1177/1529100612451018; Bavel, J.J.V., Baicker, K., Boggio, P.S. et al. Using social and behavioural science to support COVID-19 pandemic response. Nature Human Behavior 4, 460–471 (2020). https://doi.org/10.1038/s41562-020-0884-z

## ANTICIPATE A CRISIS

The second section, "Anticipate a crisis", describes structures and systems that need to be established ahead of and in preparation for a crisis event:

- Prepare the crisis communication team to respond to issues that have the potential to become crises.
- Create contact lists and coordination systems to unify the response with internal and external partners who will need to be notified in case of escalation.
- Develop communication messages and materials ahead of time that will be needed if a crisis develops.
- Engage in continuous listening and monitoring for problems or issues that could escalate.
- Engage in systematic issues management to prevent escalation.

### Prepare the crisis communication team for their roles

The crisis communication team should convene early in the trial and meet frequently throughout to prepare for potential crises. The team's orientation should include learning about the activities related to each function; creating systems and practices to ensure activities can be performed, and practicing exercises in which they perform the activities.

### Learning about activities related to crisis communication roles

| | Crisis communication activities to be performed throughout the trial | Notes |
|---|---|---|
| A | Communication coordination task | |
| 1. | Identify points of contact for rapid internal notification and communication collaboration when crisis emerges among different WHO levels, manufacturer/s, local hosts and trial sites (as relevant). | Note: This list should be comprehensive. During an actual crisis-based notification, it will serve as a menu, from which relevant POCs will be selected. See **Appendix D Internal points of contact notification list template.** |
| 2. | Conduct or attend crisis communication coordination meetings with relevant points of contact (POCs). | Meetings should be held periodically throughout the trial for crisis planning and shared updates on potential issues. Meetings should be held more frequently during an actual event. |
| B | Public release of information | |
| 3. | Create systems for rapid dissemination and sharing of public information about crises with stakeholders, including order and timing of notices and updates. | Systems should include translation/tailoring process for different stakeholders, distribution mechanisms and channels, and criteria for order of notification. |
| 4. | Create and update contact information for key POCs for public release of information (channels, reporters, influencers, community POCs, healthcare providers, donors, etc.).<br>Note: These activities may be divided between engagement focal points for community POCs and other crisis communication team members who conduct outreach to stakeholders outside the community (international press, donors etc.). | The list created at the beginning of the trial should be comprehensive including channels, reporters, influencers, community POCs, healthcare providers, donors, etc. See **Appendix E Communication points of contact for public information releases.**<br>During crisis response, the crisis communication team will select the recipients of public releases based on topic and scope of crisis. |

| | Crisis communication activities to be performed throughout the trial | Notes |
|---|---|---|
| C | Monitoring, listening and two-way engagement | |
| 5. | Engagement focal points conduct two-way communication with trial community to monitor anxieties, concerns, rumours, response to any crises as outlined in the GPP Handbook. | Reports from community monitoring should be routinely shared with crisis communication team as part of issues management process. |
| 6. | Conduct and analyse results of news and social media monitoring for misinformation and potential crisis issues. | Local, national, and international monitoring is needed. A combined effort of community team, national team and WHO headquarters is recommended. |
| 7. | Analyse as a whole the results of social media, news media and community monitoring for emerging issues. | For detail about the process of analysis see section, **Analysis of media and community monitoring for issues management**, below. |
| 8. | Report potential issues to trial leadership team. | A synthesis of local, national and international monitoring should be shared with trial leadership as relevant to their sites. |
| D | **Crisis communication materials development** | |
| 9. | Develop, as possible, response materials ahead of a crisis. Create "shell" and "evergreen" documents for potential use in most likely crisis scenarios. (For details, see section, **Speeding communication response,** below). | Based on brainstorming sessions related to potential crisis scenarios, identify materials likely to be needed during a crisis. In coordination with engagement focal points, review public-facing materials described in GPP Handbook to identify topics and content that might be needed as background during a crisis. Determine if pre-crisis formatting of existing material is needed. |
| 10. | Conduct notification of relevant internal partners during unfolding crisis. Increase frequency of crisis communication coordination meetings. | Selected from list of pre-crisis notification POCs in **A1** above. Step-up frequency of crisis communication coordination meetings to create unified strategy and implement it across organisational levels and with relevant partners. |
| 11. | Conduct focused monitoring of community, social media and news media on crisis issue. Pre-existing monitoring systems should be requested to focus on crisis issue. | As part of their preparation national communication focal points should pre-arrange for transitions to crisis issue with monitoring groups. |
| 12. | Media relations and engagement. Conduct frequent and regular engagement with news media and social media influencers as needed to support crisis communication strategy. Briefing and preparing spokespersons for engagement with press and other platforms. | Tasks include briefing and preparing spokespersons for engagement with press and on other platforms. See **Appendix F Early announcement of negative event (holding statement) template.** This can be used for early announcements to press/media or as an outline for opening statements at a press conference. |
| 13. | Refining and creating communication materials and activities to support crisis communication response and updates. | Drawing upon materials created pre-crisis, as identified in D9 above, fill in "shell" documents, reformat "evergreen" materials as needed, and create new products and activities to support evolving crisis communication strategy. |

To enable the crisis communication team to rapidly convene during a negative event, a 24/7 contact information list should be developed, which includes each team member's primary role. (See **Appendix G Contact form for crisis communication team**). This list should be regularly updated to include new team members and transitioning roles. All members of the team, the PI and the designated spokespersons should receive updated copies.

Working directly with the PI and other trial leadership, the team should adapt crisis communication response protocols to the situation at their site. The protocols are found in the section, **Respond to a crisis,** below.

### Brainstorm crisis scenarios

At pre-crisis meetings, the crisis communication team should brainstorm most likely scenarios as part of their preparation. Engagement focal points should attend brainstorming sessions to provide a community perspective on each potential event.

These include:

- Safety concerns that can emerge when testing new vaccines
- Adverse reactions to the vaccine (potentially including severe injury or death)
- Unexpected trial closures caused by safety concerns or scientific reasoning that a trial should not continue
- Disengaged/demotivated/unhappy staff or trial participants
- Charges of exploitation
- Personal or political disputes
- Breaches of protocols
- Perceived disrespect and lack of appreciation among trial participants/stakeholders
- Disputes about information or data-sharing
- Breaches of contracts and memoranda of agreement
- Allegations of financial misconduct

Brainstorming session agendas should include:

- Development of a brief description of the scenario and how it might unfold
- Identification of groups who could be put at risk (threats to health, property, reputation)
- Identification of organisational levels and internal partners that would need to be notified for communication coordination (See **Appendix D Internal notification points of contact**)
- Communication materials that would be needed in the first several days of a response

### Orient the onsite trial team: Crisis communication is everyone's job

As well as assigning specific roles on the crisis communication team, all trial staff should receive training on their role in preventing crises. Their interactions should also be monitored for any issues that might become a crisis. Training should happen before the onsite trial begins, and include:

- Key concepts of communicating trust, setting expectations, transparency, and "inoculation" in interactions with all stakeholders.
- Signs of issues that could become a crisis. Trial staff should be on the lookout for any issue that could escalate from a disagreement or complaint into something more serious.
- How to report issues to management, including when an event causing harm has occurred.
- How to direct inquiries and how information will be communicated to outside stakeholders during a crisis.

## Prepare resources and expedite clearance

Stakeholders are most likely to remember and believe the information they hear first about a crisis. In a negative event, the STV will want to rapidly engage stakeholders and be the primary source of information. But bad news has a way of spreading quickly through news and social media and other personal and professional channels. Public health organisations and governments often struggle to get out in front of bad news.

There are steps that the trial can take to communicate as quickly as possible. To increase the speed of its response, the trial can prepare materials and systems ahead of a time, including a system of rapid clearance.

### Communication materials

During its crisis scenario brainstorming sessions, the crisis communication team should develop a list of materials (press packs, talking points, factsheets, Q&As) that would be needed early to respond to each possible scenario. Some materials (such as an initial press release or "evergreen" factsheets) would be needed straightaway in most situations.

These materials should be outlined at the beginning of the trial; some can be completed and cleared in advance (factsheets and basic talking points about the trial, vaccines, etc. that will not change no matter what the crisis is). Others can be developed as "shell" documents that can be filled in with specifics if and when a crisis occurs.

"Shell" documents. Most content for communication products depends upon the specific crisis event. But some of it can be written in advance in a shell document and quickly completed as details emerge. This will better position the trial to be the first and primary source of information.

Examples include:

- Press release or holding statement announcing crisis event (See Appendix F Early announcement of negative event)
- Facebook post describing negative event
- Statement refuting circulating misinformation (see Appendix H: Template for early announcement addressing misinformation)
- Text messages notifying trial participants of adverse events (see Appendix I: Early announcement of adverse event)

"Evergreen" documents. Other core materials that can be prepared in advance are short, concise factsheets that include basic information about subjects that could be relevant in a crisis. Some may have already been prepared by engagement focal points (as outlined in the GPP Handbook for the public and trial recruits).

These can be used and/or reformatted as materials to provide background for other stakeholders during a crisis. Other material could be generated from scenario brainstorming exercises. This includes:

- Basic facts about the trial
- Contents of the vaccine candidates
- Results of Stage 1 and 2 trials
- Shareable elements of the agreement between national government, local hosts, WHO and manufacturers
- Activities required of trial participants

These basic materials should be cleared in advance of any crisis where they may be needed.

### Develop a rapid clearance process

Clearance protocols can be complex and lengthy procedures: experts from all relevant technical areas, organisational levels and partners often need to be consulted before information and messages can be shared publicly. This ensures scientific accuracy and protects the sensitivity of relationships between partners. At the same time, it can delay the release of information.

In the event of a crisis, it is essential that clearance is faster than for routine procedures. Otherwise, other information sources are likely to dominate the agenda and the trial will struggle to have an influence.

The crisis communication team should first work with trial technical experts and their communication counterparts at other trial sites and organisational levels to create shortcuts in the clearance process. First the team should identify the regular operating clearance process, then agree shortcuts, for example:

- Set expectations among the clearance points that clearance is an around-the-clock, everyday activity. Clearance points should be expected to monitor their emails or phones continuously for any urgent clearance request.
- Limit to as few as possible the number of clearance points needed before public sharing of information.
- Designate clearance points by function rather than individual names. For example, several experts on adverse reactions might be able to serve clearance points for a technical perspective, rather than a specific individual who might not always be available.
- Set time limits for clearance and a protocol that if there is no response beyond a certain time, this is interpreted as meaning approval.
- Set up categories of materials that can be cleared at the local, national and regional levels, with other levels only given "notice" (versus those that need clearance at all levels).

## Engage in systematic issues management

Issues related to potential crises are identified through systematic monitoring of news and social media; mechanisms used by engagement focal points to identify community concerns, anxieties, and questions; and reports of negative encounters or misinformation reported by any trial staff.

### Analysis of media and community monitoring

The crisis communication team should compile inputs from all monitoring sources and conduct an analysis of inputs weekly, or more often, depending on the volume of problems/concerns raised in the reports.

The analysis should draw attention to:

- Any negative coverage of trial topics or related COVID-19 vaccine issues that are frequently the subject of posts, stories or journalist inquiries
- Circulating misinformation about the trial and specific sites
- Complaints about the trials (staff or procedures)
- Highly emotional content and comments related to the trial or COVID-19 vaccines more generally
- Persistent questions about the trial
- Declining participation or reluctance among participants
- Reports from trial site staff based on interactions with local hosts and trial participants

These items should be summarised and prioritised. Any issue that has the potential to impact on WHO, the Ministry, manufacturers, the trial and/or its participants should be flagged for response. Those that have the potential for high impact, and that could attract opposition from stakeholders, should be prioritised.

High-priority emerging issues should be shared with trial leadership and with communication staff at other levels of the organisation, who may see similar patterns in their monitoring. It is important to share the results of the analysis during a crisis communication coordination call to develop a broad picture of what is circulating locally, nationally and internationally—since crises can emerge from issues percolating at any level and the combined levels may create a pattern that is missed by looking at one level only.

## Proactively manage and track issues[5]

High-priority issues should be the subject of discussion at regular trial leadership meetings. Discussion should include approaches to resolve priority issues; assignment of staff to try to resolve an issue; timeline; and projection of how an issue might emerge as a crisis.

The crisis communication team should start and maintain a record of the high-priority issues. The document could look like the example given below.

| ISSUES MANAGEMENT LOG: Example | | | |
|---|---|---|---|
| **Date initiated** | **Example of issues** | **Example of resolutions** | **Status** |
| | News coverage and advocacy group social media are posting stories alleging that squalene from shark livers is being used in the vaccine candidate being tested at [insert site]. The misinformation has been circulating for 2 weeks and is increasing in volume. | Communication team is clearing statement to release to media and post on Facebook describing ingredients of the vaccine [if possible, legally to share them]. NOTE: do not repeat the content of the misinformation in the statement [insert name of the responsible communication team member and time for release]. | Open. |
| | Several complaints from trial participants that a staff member has been disrespectful of them during the recruiting process. | [Member of leadership team] to speak with staff member and complaining volunteers to resolve tension [insert date for contacts to be completed]. | Interviews with participants are scheduled for [insert date]. |
| | Advocacy group post false story about early results of the trial at [insert site location]. | Press statement reinforcing the timing of results was issued to journalists and posted on Facebook. The release pointed to trial communications previously given to participants and community leaders that stated how and when results would be released. | Resolved — no further stories from advocacy group or news coverage. |

See **Appendix J Issues management template**

The issues management log should be maintained and reviewed regularly by trial site managers to ensure issues are being managed to reduce the likelihood they could escalate and become crises.

Records of all issues, resolution steps, status and date of resolution should be maintained throughout the trial. Description of resolved issues should be maintained among the tracking records for purposes of future reference or re-emergence of the issue.

**5** Model derived from Centers for Disease Control and Prevention. (2006). CDC Unified Process Practice Guide: Issues Management. Accessed on November 15, 2020 at https://www2a.cdc.gov/cdcup/library/practices_guides/CDC_UP_Issue_Management_Practices_Guide.pdf

## RESPOND TO A CRISIS

The third section, "Respond to a crisis" is operational, describing crisis communication activities using systems and structures that have already been established.

Despite efforts to communicate in ways that create trust, transparency and shared expectations, STV sites could still find themselves in a crisis situation. This may mean sustained negative community or media interest intensifies the focus on the trial or one of its partners, and stakeholders demand immediate information. In this scenario, the structures created and activities undertaken to anticipate a crisis should position the trial to respond rapidly and reduce negative impact of various crisis scenarios.

### Crisis communication response protocols[6]

The following steps should help the STV leadership and staff members respond when issues have escalated into a crisis.

### Day 1

1. Trial staff members learn of a problem or identify an unresolved issue that has escalated to crisis status including the following dynamics:

- Growing public attention
- Negative characterisation of the trial, including implications that undermine its credibility
- Harmful impact on the trial, its participants and/or other stakeholders/partners
- Potential to seriously disrupt the trial or any of its sites

2. The source of information about the crisis issue shares it with the PI, communication crisis team leader, and other relevant organisational leadership. Note that awareness of the crisis could enter the trial's management from any organisational level or through any onsite team or staff member.

3. Rapid information-gathering – PI gathers additional information rapidly, as available and needed. If the problem has emerged from media or other communication monitoring, the crisis communication team leader gathers most up-to-date and relevant record(s) of monitoring and analysis and any relevant input from engagement focal points. Communication lead draws on results of preparedness scenario planning and relevant communication materials that have already been prepared.

4. The PI, crisis communication team lead and designated spokesperson conduct a rapid assessment and initial plan of action based on gathered resources and new information. The discussion should cover:

- What has happened and its significance for the trial
- Who should be informed
- Action to be taken (including communication functions)
- Everyone's roles and responsibilities
- Who should be informed immediately among the vaccine trial sponsors and hosts for purposes of coordinated response? (Drawing upon list of crisis notification partners identified when the team filled in **Appendix D Internal points of contact notification list**):
  - Sponsoring organisations
  - Research teams and communication officers at site level
  - Ministries of Health, local government officials, and ethics committees, where relevant
  - Donors
  - Manufacturer
  - Others

**6** These protocols have been modified and adapted from: PATH, Rotavirus Vaccine Program. Clinical trial communication to manage risks. Washington (DC): PATH; 2007.

5. Designated trial staff share initial information with technical and communication point persons from partners and other organisational levels (Ministry, WHO headquarters/regional/country levels, manufacturer, and/or donors) for coordination of initial response and communication. When filled in, **Appendix D Internal points of contact list** will have contact information for comprehensive list of possible POCs.

6. Crisis communication plans and teams are activated. Based on Steps 1-5 above, the team should:

- Rapidly define communication objectives
- Decide process for dissemination of first public announcements among various options. For example, based on earlier decisions about criteria for order of release:
  - If the crisis involves an adverse event, or any safety concern related to the trial, trial participants must be notified before any wider public announcement (see **Appendix I Early announcement of adverse event**)
  - Wide announcement must notify press, community contacts, advocacy groups simultaneously.
  - Roll-out: notify most affected groups first, followed by news media and others
  - Roll-out to press: brief first those journalists who have provided fair and accurate accounts about vaccines in the past, followed by expected interview requests from other reporters and influencers
- Fill in template (**Appendix F**) for initial press release or holding statement adding the following specific content:
  - What has occurred
  - What the trial and/or partners a doing to resolve the situation at the moment (WHO, Ministry, other partners)
  - [If relevant] What should trial participants do related to the negative event
  - What is being done to find answers that are currently unknown
  - Expression of empathy and solidarity
  - Where/when will more information will be provided
  - Name and contact information for the media contact for the trial
  - What is currently known and what is unknown about each bullet (for transparency)
- Create initial talking points based on press release or holding statement, adding in background
- Activate the rapid emergency communication clearance process
- Identify relevant pre-developed and "shell" l documents related to the crisis topic, fill in "shell" documents and prepare to post or highlight background documents relevant to the crisis

7. Initial plan of action and related materials are shared by PI and crisis communication team with POC colleagues identified in Step 4 above.

8. Spokespersons are prepared for press conference, community meetings or anticipated interviews with journalists. Crisis communication team generates anticipated Q&A, including challenging questions, and practises with spokespersons.

9. Approved initial announcement is released to stakeholders in order determined in Step 6 above.

10. Transitions daily monitoring reports to focus on crisis issue and requests engagement to monitor community for inputs on crisis issue.

## Days 2-5 (or longer, depending on sustained attention by community/media)

11. Conduct daily analysis of monitoring reports for community, news/social media; and consider amount and types of reporter requests coming in to trial communication staff. Use key interviews and inputs from community meetings and leaders to understand and respond to community concerns.
12 Based on reviews of news/social media and community response, adjust communication objectives as needed.
13. Create and release updated information including new information related to the crisis issue and that which responds to questions and concerns found in monitoring reports. Address any rumours or misinformation on channels in which they appear. See **Appendix C How to deal with circulating rumours and misinformation.**
14. Make sure that spokespersons are available to reporters. If experts are not available to answer questions, people will seek information from less informed and perhaps adversarial sources.
15. Agree between the crisis communication team and coordinating partners which external partners should have journalists referred to them, and what content should be shared with other key people in the wider community (including researchers or key people in the field, as relevant to the topic of the crisis). Ensure these colleagues have necessary background information and related current material on the status of the trial.
16. Compile key messages document including original content of holding statement and all updates and background materials. Create these as bullet points that are easy to extract and use for talking points, social media posts, or new products. Time and date stamp each subsequent version. Regularly update and distribute, highlighting changes in each version disseminated. Distribute this document as updated to spokespersons and all agencies coordinating communication coordination with the trial.
17. Depending upon direction of community and media response, escalate dissemination of accurate information and updates through additional press conferences, community meetings and social media outlets. Request that other organisational levels, responding partners and engagement focal points distribute through their channels and contacts, as relevant.
18. Conduct frequent crisis communication coordination calls with POCs at other organisational levels, Ministry of Health, manufacturer and donor organisations, as relevant.

### Repeat Steps 5-18 until crisis has declined

19. As the crisis evolves, the crisis communication team continues to meet regularly to discuss:

- Progress in mitigating the crisis and reaching communication objectives
- Results of news and social media and community monitoring for reaction
- How inquiries from reporters, community and other stakeholders are being handled
- Any additional steps needed to keep all stakeholders informed

As new information emerges, the crisis communication team develops, clears and distributes new materials and messages to all stakeholders in sessions and channels where two-way communication is facilitated.

### After the crisis:

20. The crisis communication team should be monitoring and adjusting the volume and frequency of stakeholder engagement as the crisis declines. Signs of resolution include:

- Decreasing requests about the crisis issue from reporters
- Fewer social media posts about the issue
- Fewer news media stories about the issue
- Narrowing of public channels focused on the issue
- Fewer complaints filed about the issue
- Decreased proportion of community or town meeting time spent responding to questions on the issue
- Increase in attention to a different emerging issue

21. Evaluate the implementation of the crisis plan.

22. Advocate for any necessary improvements.

22. Update the plan to improve future response.

## Additional tips for communicating during a crisis[7]

The principles described in the first section of this plan to 'Prevent a crisis' are equally important guidelines for engagement with stakeholders while responding to a crisis. Now is the time to double-down on activities that build trust (transparency, relational communication and unity).

Transparency is essential now. During a crisis, there is a tendency for organisations to want to focus only on the positive elements of a situation. But it is essential to deliver an honest message that contains both good and bad, what is known and, as yet, unknown and/or uncertain.[8]

In addition, the trial must demonstrate its reliability by sharing information when and where it previously indicated it would do so.

### Communicate as early and regularly as possible about new developments[9]

- Being first to communicate bad news puts you in control of the message.
- Early communication is most likely to be remembered. Any addition or challenge to early information is not as likely to be recalled. Being first to communicate means that accurate information will be more likely to be acted upon.
- Communication decreases perception that the trial might be hiding something.
- Communicating early increases the likelihood that the trial will be the primary source of information on the crisis.

**7** Adapted from Health, R.L., (2006). Best practices in crisis communication: evolution of practice through research. *Journal of Applied Communication Research*. 34(3): 245-48.
**8** Reynolds, B. Crisis & Emergency Risk Communication for Leaders. U.S. Department of Health and Human Services. Accessed October 2020 at https://emergency.cdc.gov/cerc/resources/pdf/leaders.pdf
**9** Shepherd M. Emergency risk communication. Presentation at Family Health International, May 2005, Research Triangle Park, NC.

### Continue to listen to the community and respond with empathy

- Acknowledge the emotion behind community concerns, questions and demands during a crisis. Even if you disagree with their interpretation, or their perceptions are based on inaccurate information, acknowledging their feelings increases people's feelings of being heard and respected. "I hear how concerned you are . . .", "We share your frustration. . .", "I wish we knew more right now as well . . .".
- Avoid using scientific jargon and make communication simple and straightforward.
- Don't talk "down" to community members or other stakeholders—this can create barriers and jeopardise the carefully developed trusting relationships the trial has been working to create.
- Choose communication approaches that suit the situation. The more hostile the group your research team is dealing with, the greater the need for face-to-face communications. Meeting with people in person shows that you care about their concerns and take them seriously.

For additional tips on messaging during a crisis see **Appendix K Basic messaging checklist for crises**.

## Appendix A Mapping potential stakeholders

| Stakeholder category | Individuals and organisations | Why engage them | How to engage them |
|---|---|---|---|
| **Government officials and policy actors** | Governors | | |
| | Mayors | | |
| | National executing entities | | |
| | Intersectoral commissions | | |
| **Trial participants*** | | | |
| **Community leaders*** | Community action organisations | | |
| | Cooperatives and associations | | |
| | Indigenous associations | | |
| | Women's groups | | |
| | Leaders of religious communities | | |
| **Academia** | Universities | | |
| | Practice committees | | |
| | Scientific societies | | |
| | Research centres | | |
| **Journalists (local*, national, international)** | Radio | | |
| | Internet | | |
| | Newspapers | | |
| | TV | | |
| | Social media influencers | | |
| **"General publics"** | People living around study (not directly involved, but interested) | | |
| **Local* and national health and care providers** | Networks of health-related associations | | |
| | Community nurses | | |
| | Physicians | | |
| **National/international advocacy groups** | | | |
| **Civil society organisations and relevant NGOs** | Donors | | |
| | United Nations agencies | | |
| | Relevant foundations | | |

* These groups are identified as stakeholders for engagement focal points as part of communities from which trial participants are drawn. Other groups identified in this chart must also be considered stakeholders for the trial and involved in trust-building, expectation-setting, crisis management, etc.

## Appendix B Trust-building communication practices

### Engage in dialogue with stakeholders (two-way communication)

- Gather information about local communities' culture, concerns, beliefs, questions, norms and opinions.
- Listen to news and social media for concerns, questions, misinformation shared by communities and other stakeholders (local/national government, healthcare workers, advocacy groups, journalists, general publics, etc.).
- Incorporate what you learn into communication activities and products.
- Answer questions from these monitoring activities at the next opportunity in meetings, press events, interviews, and other messaging opportunities.

### Build a relationship with stakeholders

- Thank trial participants and local hosts for their support and participation at every opportunity.
- Create special opportunities to express appreciation.
- Acknowledge hardships that stakeholders have undergone to support the trial.
- Create a sense of unity between trial staff and stakeholders by:
  - Using unifying language ("we", "us", "our")
  - Referring to shared goals and accomplishments
  - Inviting stakeholder representatives to speak at press events and other communication activities
- Demonstrate integrity by:
  - Keeping promised schedules (for delivering information and other updates)
  - Treating everyone fairly, equitably and respectfully

### Be transparent

- Make available all relevant information about the trials that can legally be shared.
- Proactively disseminate information that is needed to:
  - Make informed decisions about the trial (stakeholders)
  - Comply with trial steps and protocols
  - Maintain trust between stakeholder and the trial
  - Abide by legal requirements of the trial
- Say what is known and unknown about the trial and/or outcomes.

Any violation of these practices has the potential to create distrust, making it more likely that problems emerging during the trials could escalate into crises.

## Appendix C How to deal with circulating rumours and misinformation

The crisis communication team should monitor news, social media and trial site communities for all types of misinformation, rumours, visual deceptions, false connections, manipulated content, fabricated content, and even humour/parody with the potential to confuse and obscure the facts.

Not every rumour or conspiracy theory should be addressed. But those with the potential to harm the trial, its local hosts, participants or the sponsors should be monitored closely. If misinformation spreads widely, persists for more than several days, and has journalists and local communities inquiring about it, the misinformation should be addressed. Below are best practices for addressing misinformation.

### NEVER REPEAT MISINFORMATION—even to refute it

Two important psychological principles support this point:

- Processing fluency (ease of recall). The more you hear misinformation, the more familiar it is and the easier it is to recall. This partly explains why rumours and deception persist.
- Negative tags, "fade away" in memory. When people say misinformation is not true, those who recall the refutation only remember the misinformation content and forget the negation. So any refutation that includes the misinformation just serves to reinforce inaccurate information as true.

Avoid "myth busters" that repeat misinformation and then label it as wrong.

Over time, readers only remember the "myth," and the correction fades away. (For example, "You can be infected with COVID-19 by the trial vaccine. WRONG!" People will remember the message about the vaccine and forget about the "WRONG" or negative tag).

Avoid putting a question that raises doubt about facts into a headline.

A question established doubt about information, but many people will not read past the header to find the answer. All the reader will recall is an area where there is doubt.

### Points to consider when addressing misinformation

- Identify and share correct information without repeating corresponding misinformation.
- Share relevant correct information using the same channels on which misinformation is being shared.
- Use sources for correct information that are part of the community or group in which the misinformation is circulating. They will be more trusted than non-members.
  - For example for rumours circulating in WhatsApp groups, in-group "explainers" can respond when bad information is posted, explaining or debunking it.
- Keep corrections simple. "Over-explaining" can make you seem less credible.
- Find ways to make correct information interesting, novel or emotional. People are more likely to pay attention to and share such information (research has shown that rumours with these qualities are shared more than accurate information that is neutral).
- If the misinformation is part of a larger narrative with causal relationships between untrue information and consequences, make sure the correction does not leave a gap in the story. People are less likely to believe a correction if it causes disruption in the mental model they have created to make sense of events.

### Always be respectful of people who believe misinformation

As part of rumour monitoring, notice the context in which misinformation is spread, paying attention to any political or social narratives in which it appears. Misinformation may be part of a larger world view or cultural system. Attempts to correct believers in this circumstance must avoid offending them, which would not only fail to "correct" their beliefs, but also decrease their trust in health officials for the future.

- Avoid using authoritarian types of rebuttal to correct misinformation. People resist being told what to do and believe.
- Use empathy and identify common ground as you engage people about rumours and misinformation they believe.
- Present corrective information in a way that is consistent with the world view of the audience. Know the audience's value system and frame accurate facts in a way that aligns with it. (For example, some people may be suspicious of scientific process, but may be highly connected to family values. Information about vaccine trials can be framed by family benefits).

### Recognise when it is counterproductive to directly debunk misinformation

- If people uncritically accept their own belief in misinformation, but actively use counter-arguments to deride accurate information, realise that your efforts may be backfiring.
- The more you challenge, the more strongly some believers will hold to their own positions.
- Direct refutation may lead to polarisation between believers and those with opposing views on the same issue, thus damaging cooperation on other issues.

## Appendix D Internal points of contact notification list

| Who | Role title/ unit clearance role | Who will contact | Contact Information work/after hours |
|---|---|---|---|
| WHO HQ technical contact | | | |
| WHO HQ communication contact | | | |
| WHO Regional Office (PAHO) technical point of contact | | | |
| WHO Regional Office (PAHO) communication point of contact | | | |
| WHO Country Office technical contact | | | |
| WHO Country Office communication contact | | | |
| Ministry of Health technical point of contact | | | |
| Ministry of Health communication contact | | | |
| **Manufacturer** | | | |
| Manufacturer technical point of contact | | | |
| Manufacturer communication point of contact | | | |
| **Donor** | | | |
| Donor leadership | | | |
| Donor communication | | | |
| Local hosts trial hosts | | | |
| Leadership point of contact | | | |
| Communication point of contact | | | |

## Appendix E Communication points of contact for public information releases

| Who | Organisation/role | Who will contact | Contact information |
|---|---|---|---|
| **Community contacts** | | | |
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| **Journalists** | | | |
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| **Advocacy groups** | | | |
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| | | | |
| **Local government officials** | | | |
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## Appendix F Early announcement of negative event (holding statement) template

The purpose of this initial press statement or holding statement is to answer the basic questions: What has occurred? What are the trial and its partners doing to resolve the situation at the moment? What is being done to find answers that are currently unknown? Where/when more information will be provided?

This statement should also provide whatever guidance is possible and relevant at this point to trial participants, local hosts, and/or the community, express solidarity and empathy for any concerned and affected groups, and detail how and when further information will be disseminated. If possible, the statement should give phone numbers or contacts for more information or assistance. Please remember that this template is meant only to provide you with guidance. One template will not work for every situation.

**FOR IMMEDIATE RELEASE**

**CONTACT: (name of contact)**

**PHONE: (number of contact)**

**Date of release: (date)**

### Headline—Insert your primary message to the public

Dateline (your location)—Two-three sentences describing current situation

Insert quote from an official spokesperson demonstrating solidarity with and concern for victims or others affected.

Insert actions *currently* being taken by the trial, Ministry or other relevant partner to resolve the issue.

List actions *that will* be taken.

Insert quote from an official spokesperson and [if possible trusted community leader] providing reassurance.

List contact information, ways to get more information, and other resources.

Derived from U.S. Centers for Disease Control and Prevention, 2014. *Crisis + Emergency Risk Communication, 2014 Edition.* U.S. Department of Health and Human Services: Washington DC.

## Appendix G Contact form for crisis communication team

| Name (alphabetical order) | Crisis communication role | Work phone or preferred contact method | After hours phone or preferred contact method | Notes |
|---|---|---|---|---|
| **Example** | | | | |
| Harriet Alvarez | Conducts reviews of social and news media for emerging issues | Mobile: XXX XXXX Email: XXX XXXX Text messages work best | Mobile : XXX XXXX Use phone after hours | Works remotely from [insert place]. Not on site |
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## Appendix H Early announcement addressing misinformation template

This template can be used as the content of a press release or as the outline for talking points addressing rumours or other misinformation. It is intended to be used as an early response to misinformation that is circulating and threatens to spread.

The Global Solidarity Trail [and partners?] have become aware that misinformation about topic [insert topic, but not content of the rumour] that is circulating.

**[DO NOT REPEAT the MISINFORMATION, even to "debunk it." Repeating it cements it further in the minds of stakeholders]**

The STV recognises that misinformation like this can be confusing. So we want to make sure you have the best and most accurate information available about [insert topic, not rumor itself].

Here is the correct information about [topic]:

- Provide correct information
- Include what is known and what is unknown

We are dedicated to providing you with good information about every aspect of the trial.

When stakeholders can expect updates [If this is an ongoing and evolving situation].

You can find more information about [topic] at (Website, on bulletin boards, Facebook, etc.).

## Appendix I Early notification to trial participants of adverse event template

### Sample script for notification to trial volunteers

The Solidarity Trial Vaccines (STV) and Ministry of Health [or other relevant local health authorities] are aware of a vaccine trial participant at [insert trial site] who has developed a serious illness in the period following vaccination with a COVID-19 vaccine [insert type].

The name of the affected volunteer and details of the illness cannot be shared due to privacy reasons. However, there is no indication that the illness is connected in any way to the vaccine. The [insert name of vaccine candidate] has a strong safety record in Phase 1 and 2 trials. Even so, the trials at [insert places] have been paused in order to evaluate the data and assess any risk.

The STV at [site] is communicating with all trial sites administering [insert the vaccine name], the manufacturer and the Ministry of Health and Social Protection to review all safety records and potential risks. The vaccine manufacturer [insert name] will continue to communicate with the key sites, and the trials will continue to be carried out in strict accordance with good clinical practice requirements.

All staff involved in the trials express their deepest sympathy to the volunteer who is ill and express wishes for the volunteer's complete recovery.

We recognise the concern that volunteers might have about the situation. We all wish that we knew more right now. But we will let you know as soon as more information is available.

If any trial volunteer is experiencing fever or . . . please contact . . .

More information is expected following a review of [insert relevant info here, for example: the volunteers' medical history and an external review of the trial's safety data to date]. It will be disseminated to trial participants through telephone voicemail [or other].

## Appendix J Issues management template

| Initiation date | Issues: Brief description | Actions to resolve (including responsible party and date completed or expected) | Status: Not addressed, in process, closed |
|---|---|---|---|
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## Appendix K Basic messaging checklist for crises

Use this checklist to review messages to be used when responding to crises.

- Present short, concise, and focused messages.
- In a heightened state of concern, it's difficult for people to take in lots of information. Limit the amount of information you share in any single event or communication product.
- Between three and seven bits of new information is a realistic limit for people to memorise and recall, especially when they are stressed. For example, practise these 4 key steps to prevent COVID-19 infection: stay 6 feet away from people, wash your hands frequently, wear a mask, and avoid touching your face.
- Make the most important information easy to remember.
- Create acronyms or rhyme (for example: "Stop/drop and hold" in case of an earthquake).
- Get the most important point out first. Don't start with background or establishing your organisations credentials or role.
- Give action steps in positive terms, not negative ones (e.g. "call XXX-XXXXX..... if you are experiencing joint pain", is a positive messages. A negative message is "Don't panic").
- Repeat the message frequently—repetition reflects credibility and durability.
- Use personal pronouns for the organisation. "We are committed to . . ." or "We understand the need for . . .". Personal pronouns make your organisation more human.
- Use simple, easy-to-understand language.
- Avoid technical terms and professional jargon and euphemisms; they imply insecurity and lack of honesty.
- Only promise what you know you can deliver. Otherwise, promise to remain committed to solving the problem until it is resolved.
- Avoid using humour. When people feel fearful, angry, or concerned, they aren't like to think a situation is funny. Even humour about topics which don't seem sensitive can be offensive in some cultural contexts. What is funny to one person, may be an insult to someone else.
- Take care to avoid appearing condescending or judgmental ("I know it's hard to understand the science behind this, but I will try to explain it to you. . .").
- When explaining an issue, attack the problem, not people or organisations. Your audience or the community you are engaging may identify with the groups that you think are behind the crisis.

Derived from: Centers for Disease Control and Prevention. (2006). Crisis and Emergency Risk Communication for Leaders. Washington DC: U.S. Department of Health and Human Services) (https://emergency.cdc.gov/cerc/resources/pdf/leaders.pdf)

## Appendix L Practical guidance for conducting a press conference

At a press conference, you invite a group of journalists by video conference, telephone or in person (with physical distancing) to hear a prepared statement and ask questions.

You should consider calling a news conference to:

- Ensure that all media receive the same information at the same time
- Make important announcements, such as a premature trial closure or an adverse event
- Respond to criticism that has appeared in the media
- Correct circulating misinformation
- Save time: you can answer a lot of questions at the same time and avoid many individual phone calls

News conferences can be very useful to share accurate information, lay out next steps and set expectations about an escalating issue. They can clarify misinformation, but they can also be difficult and risky. You need to plan news conferences and manage them carefully.

When deciding to hold a press conference to manage escalating issues, you should think like a media editor. Ask yourself:

- Why should I send a reporter?
- What kind of story will the reporter get?

If the answers are not positive, then do not call a news conference.

A number of practical activities must be done before, during and after a news conference to ensure a media event goes well.

### Before the news conference

#### Plan

- Ensure that systems are in place so that journalists can see and hear the speakers
- For video/audio conferences, verify sound and video platforms for two-way communication with the journalists
- Make sure there is electricity with enough multi-way adapters onsite
- For in-person conferences:
  - Provide a speakers' table, podium or platform so everyone can see and hear the speakers
  - Provide enough space for the people you expect to attend in person to maintain physical distancing
  - 1–2 hours before the start, check the venue. Is the equipment working?

## During the news conference

### Manage time

Allow time at the beginning for latecomers to arrive, but make your announcement within 30 minutes of the starting time. If you wait too long, the busiest reporters may have left.

Keep the number of presenters to a minimum. Make sure their prepared remarks are short and to the point. Put a large-type name card in front of each speaker. Have someone introduce each speaker and manage the questions afterwards. Prepare speakers ahead of time for tough questions.

Have a facilitator chair the news conference and invite questions from individual journalists. Ensure that the speaker does not get into an argument with a journalist. It is normal to allow one question and a follow-up from a journalist before moving to the next question. Make sure that as many different journalists as possible have a chance to ask questions.

Forty-five minutes is long enough for a statement and questions. Many news conferences at larger events (such as international conferences) take place during the lunch break.

Provide press/media materials in person, downloadable on web, or by email:

- Copies of the speeches or statements to be made
- A factsheet about the trial
- Information about other relevant activities or products
- Have more than enough materials to go around: journalists are competitors, so do not expect them to share

Derived from: Food and Agriculture Organization, Working with the Media. Accessed on November 29, 2020 at http://www.fao.org/docrep/014/i2195e/i2195e01.pdf