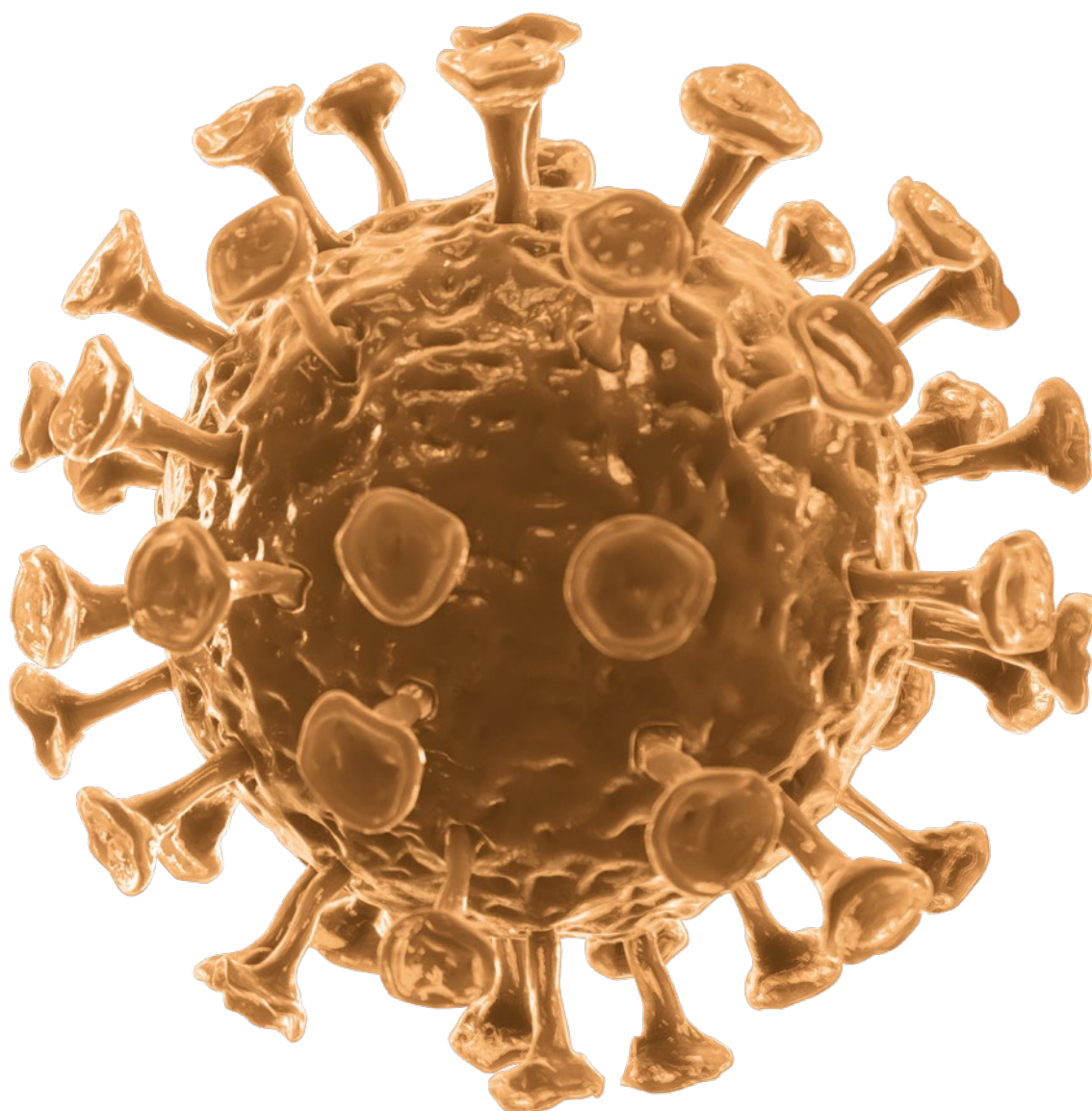


COVID-19 VACCINES:

**SAFETY
SURVEILLANCE
MANUAL**

**COVID-19 VACCINE SAFETY
COMMUNICATION**

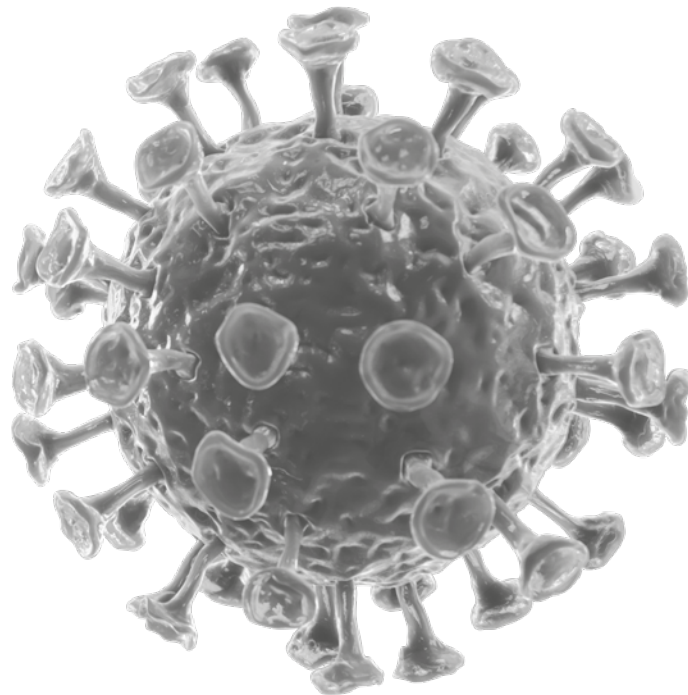


World Health
Organization

COVID-19 VACCINES:

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Organization**

Covid-19 vaccines: safety surveillance manual

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Key points

- Effective communication about COVID-19 vaccine safety, which will play a key role in maintaining the public's confidence in vaccination, will require planning and resources, that should be in place as early as possible, prior to deployment of COVID-19 vaccines.
- Vaccine safety perceptions are influenced by multiple factors, such as individual knowledge, attitudes and beliefs, social networks, messages about vaccine safety, communication environment, cultural and religious influences, organization of health services and expectations created by political leaders.
- The goal of vaccine safety communication should be to empower people to make evidence-informed choices about COVID-19 vaccination, to encourage trust in health authorities and those delivering vaccines and to facilitate access to timely, accurate and credible information about COVID-19 vaccination safety.
- Messages should be tailored to suit specific audiences, barriers and enablers, to ensure they are relevant and engaging.
- Messages should be pre-tested to assess their impact with people, even just a small group, who are representative of the target audience.
- The communications team should be integrated into vaccine safety planning and decision-making activities to facilitate appropriate and proactive communication activities.
- Partnerships should be established with other vaccine safety stakeholders to ensure coordinated information sharing and dissemination.
- It is important to identify and monitor for potential threats as a poorly managed incident concerning a COVID-19 vaccine safety issue will attract negative public attention.
- Establishing relationships with journalists and engaging with them regularly is important e.g., briefing them regularly and supporting their information needs around vaccine safety issues and concepts; this may help reduce sensationalist reporting.
- Social media should be used to communicate regularly to the public and give real-time updates about COVID-19 vaccine safety.
- Negative claims about COVID-19 vaccine safety are inevitable but the level and scale of response adopted should take into consideration resources and opportunity costs and the potential impact of the claim.

01 COVID-19 vaccine safety communication

Communication about COVID-19 vaccine safety will play a key role in maintaining the public's confidence in vaccination. Effective communication will require planning and resources, which need to be in place as early as possible before COVID-19 vaccines are available. This module provides guidance on communicating about COVID-19 vaccine safety from a programme perspective. It includes:

- a description of factors that influence people's perceptions of vaccine safety,
- case studies of past experiences with previous pandemics and vaccine safety issues,
- a synthesis of evidence and recommendations for communication from risk communication,
- hypothetical scenarios that apply these recommendations to the COVID-19 vaccine context, and
- criteria for prioritising responses to vaccine safety issues.

For more detailed, in-depth guidance, links to further resources, and answers to frequently asked questions about COVID-19 vaccine consult the appendices at the end of this document (see **Section 5**).

This module concerns communication at a programmatic level. It does not cover communication to support vaccine acceptance and uptake more generally; guidance is available here [placeholder for WHO acceptance and uptake doc]. Provider-patient communication is also not the focus of this document; guidance is available [here](#).

02 Factors influencing vaccine safety perceptions

Vaccine safety perceptions are influenced by multiple factors, such as individual knowledge, attitudes and beliefs, social networks, messages about vaccine safety, communication environment, cultural and religious influences, organization of health services and expectations created by political leaders.

2.1 Individual intentions towards COVID-19 vaccination

Understanding individuals' perceptions of COVID-19 vaccine safety is fundamental for effective communication as this will strongly influence their intention to be vaccinated. Adults are most likely to be the focus of early COVID-19 vaccination efforts in most countries, particularly those in high-risk professions, such as health care workers (HCWs). They will have diverse views on vaccination, ranging from those advocating for, or demanding, COVID-19 vaccines, through to those who reject them and a small group of anti-vaccine activists who will oppose COVID-19 vaccines. [Table 1](#) provides descriptions of these groups, and the related goals for vaccine safety communication. See [Appendix 5.1](#) for additional resources about these factors.

Results from early population-based polls and surveys during this COVID-19 pandemic showed that intentions to have a hypothetical COVID-19 vaccine among adults ranged from 87% in Australia to 37% in Poland.¹ Intentions *not* to be vaccinated ranged from 44% in Turkey to 2.6% in China. Individual factors associated with lower vaccination intentions include lower education and health literacy levels,² lower income and younger or older age.³ People are likely to shift their intentions over time as new information about COVID-19 vaccines becomes available. Interactions between groups, for example between activists and hesitant people, can also trigger changes in views on vaccination. Hence, individuals may change their intention over time.

-
- 1 Feleszko W, Lewulis P, Czarnecki A, Waszkiewicz P. Flattening the curve of COVID-19 vaccine rejection—a global overview (June 20, 2020). Available at SSRN: <https://ssrn.com/abstract=3631972> or <http://dx.doi.org/10.2139/ssrn.3631972>.
 - 2 Dodd RH, Cvejic E, Bonner C, Pickles K, McCaffery KJ; Sydney Health Literacy Lab COVID-19 group. Willingness to vaccinate against COVID-19 in Australia. *Lancet Infect Dis.* 2020;S1473-3099(20)30559-4. doi: 10.1016/S1473-3099(20)30559-4.
 - 3 COCONEL Group. A future vaccination campaign against COVID-19 at risk of vaccine hesitancy and politicisation. *Lancet Infect Dis.* 2020 Jul;20(7):769-770. doi: 10.1016/S1473-3099(20)30426-6.

Table 1: Descriptions of the range of COVID-19 vaccination intentions

Vaccination intention	Communication goals	Vaccine safety perceptions
Anti-vaccine activism	Reduce impact on other groups.	Activists may oppose all vaccination or just COVID-19 vaccination and engage in related activities such as protests. They are a small but vocal group and may attract public attention. They may source and share misinformation about vaccine safety, particularly via social networks. It is not possible to stop anti-vaccination activism, but its impact can be affected by the environment (see below).
Rejection	Minimize the size of this group by good management of vaccine safety issues.	A minority will reject COVID-19 vaccination, primarily based on safety concerns. However other factors such as experience, perceptions and values could be involved.
Hesitation	Listen to and address safety concerns transparently and effectively to support well-informed decisions. Facilitate access to reliable, evidence-based digital information at a country level (support from VSN*).	Some people will be hesitant to accept COVID-19 vaccination ^{2,4,5,6} due to factors such as the newness of the disease, use of novel vaccine platforms and uncertainty surrounding vaccine safety. This may change as they become more familiar with COVID-19 vaccination programmes. Hesitancy is dynamic and can be influenced by communication with a trusted health care worker.
Acceptance**	Address questions during vaccination encounters. Provide vaccine safety resources to share via social networks.	Most people will accept COVID-19 vaccines. Acceptance will depend on individual motivation to be vaccinated, social and professional influences and the availability of, and access to, a vaccine. Acceptors may have questions about potential side effects. Some, but not all, may want to understand the risk of more rare and serious potential adverse events by age or co-morbidity status.
Demande	Address questions during vaccination encounters.	Some people will absolutely want a COVID-19 vaccine. This has implications for vaccine programmes, prioritization, and health care worker interactions. High demand with low supply could lead to conflict and perceptions of 'favouritism' that may diminish trust in the overall programme.
Advocacy	Support constructive advocacy with tools that accurately and transparently address safety concerns.	Some people will be strong advocates for COVID-19 vaccination, motivated by a personal experience with COVID-19, or strong support of vaccination more generally. Advocates can be a key asset in safety communication, sharing information rapidly via their social networks, some of which can be large. ⁷

*VSN: *Vaccine Safety Net*, a global network of websites facilitating the access to reliable vaccine safety information⁸;

** to maintain this intention, access and other practical aspects should be facilitated.

- 4 Wong LP, Alias H, Wong PF, Lee HY, AbuBakar S. The use of the health belief model to assess predictors of intent to receive the COVID-19 vaccine and willingness to pay. *Hum Vaccin Immunother.* 2020;16(9):2204-16. doi: 10.1080/21645515.2020.1790279.
- 5 Barello S, Nania T, Dellafore F, Graffigna G, Caruso R. 'Vaccine hesitancy' among university students in Italy during the COVID-19 pandemic. *Euro J Epidemiol.* 2020;35(8):781-3. doi: 10.1007/s10654-020-00670-z.
- 6 Palamenghi L, Barello S, Boccia S, Graffigna G. Mistrust in biomedical research and vaccine hesitancy: the forefront challenge in the battle against COVID-19 in Italy. *Euro J Epidemiol.* 2020;35(8):785-8. doi: 10.1007/s10654-020-00675-8.
- 7 Dunn AG, Leask J, Zhou X, Mandl KD, Coiera E. Associations between exposure to and expression of negative opinions about human papillomavirus vaccines on social media: an observational study. *J Med Internet Res.* 2015;17(6):e144. doi: 10.2196/jmir.4343.
- 8 Vaccine Safety Net. Available at: <https://www.vaccinesafetynet.org/>. Accessed 23 October 2020.

2.2 Negative messages

Negative messages about vaccine safety can influence the public, particularly when shared in their social networks by people they trust. WHO is undertaking work on social listening to identify circulating messages about the safety of COVID-19 vaccines. Types of negative messaging include:

- misinformation – false or misleading information⁹
- disinformation – false information, purposely shared to mislead others^{9,10}
- conspiracy theories – explanations that allude to the hidden influence of powerful people¹¹
- fake news – fictitious information that imitates genuine news.⁹

Exposure to these types of negative messages, as well as negative opinions about vaccines, both in traditional and social media, has been associated with decreases in vaccine confidence and vaccine uptake.^{12,13,14,15,16} Viewing content that is critical of vaccines (even briefly) has been shown to increase people's perceptions of vaccines as risky;¹⁷ and exposure to negative claims has been shown to decrease people's certainty about vaccine safety.¹⁸ However, the environment can also influence how people respond to negative messages. See **Appendix 5.2** for detailed guidance on managing negative messaging.

2.3 Environmental influences

The 'environment' refers to the social, political and historical contexts that influence how people perceive vaccine safety issues. The wider contexts that influence vaccine hesitancy

-
- ⁹ Lazer DMJ, Baum MA, Benkler Y, Berinsky AJ, Greenhill KM, Menczer F, et al. The science of fake news. *Science*. 2018;359:1094-6. doi: 10.1126/science.aao2998.
 - ¹⁰ Wardle C, Derakhshan H. Information disorder: toward an interdisciplinary framework for research and policy making. Council of Europe; 27 September 2017. Available from: <https://rm.coe.int/information-disorder-toward-an-interdisciplinary-framework-for-research/168076277c>. Accessed 24 October 2020.
 - ¹¹ Sunstein CR, Vermeule A. Conspiracy theories: causes and cures. *J Polit Philos*. 2009;17:202-227. doi: 10.1111/j.1467-9760.2008.00325.x.
 - ¹² Larson HJ, Hartigan-Go K, de Figueiredo A. Vaccine confidence plummets in the Philippines following dengue vaccine scare: why it matters to pandemic preparedness. *Hum Vaccin Immunother*. 2019;15(3):625-7. doi: 10.1080/21645515.2018.1522468.
 - ¹³ Suppli CH, Hansen ND, Rasmussen M, Valentiner-Branth P, Krause TG, Malbak K. Decline in HPV-vaccination uptake in Denmark – the association between HPV-related media coverage and HPV-vaccination. *BMC Public Health*. 2018;18(1):1360. doi: 10.1186/s12889-018-6268-x.
 - ¹⁴ Gortz M, Brewer NT, Hansen PR, Ejrnæs M. The contagious nature of a vaccine scare: how the introduction of HPV vaccination lifted and eroded MMR vaccination in Denmark. *Vaccine*. 2020;38(28):4432-9. doi: 10.1016/j.vaccine.2020.04.055.
 - ¹⁵ Dunn AG, Surian D, Leask J, Dey A, Mandl KD, Coiera E. Mapping information exposure on social media to explain differences in HPV vaccine coverage in the United States. *Vaccine*. 2017;35(23):3033-40. doi: 10.1016/j.vaccine.2017.04.060.
 - ¹⁶ Hansen PR, Schmidtlaicher M, Brewer NT. Resilience of HPV vaccine uptake in Denmark: decline and recovery. *Vaccine*. 2020;38(7):1842-1848. doi: 10.1016/j.vaccine.2019.12.019.
 - ¹⁷ Betsch C, Renkewitz F, Betsch T, Ulshofer C. The influence of vaccine-critical websites on perceiving vaccination risks. *J Health Psychol*. 2010;15(3):446-55. doi: 10.1177/1359105309353647.
 - ¹⁸ Dixon G, Clarke C. The effect of falsely balanced reporting of the autism-vaccine controversy on vaccine safety perceptions and behavioral intentions. *Health Educ Res*. 2013;28(2):352-9. doi: 10.1093/her/cys110.

have been described extensively.¹⁹ Vaccine safety fears and subsequent rejection may be vehicles for the expression of deeper tensions. These may arise in situations where previous experiences may have compromised trust in governments and other institutions that promote and deliver vaccine programmes.²⁰

Some of the factors that may affect safety perceptions of COVID-19 vaccines are presented below.

Social, cultural, community and religious influences. Social norms and networks can greatly influence motivation to be vaccinated.^{21,22,23} People with shared values and beliefs may exist in tight-knit communities where ideas spread readily. For example, religious or community leaders with negative views on COVID-19 vaccine safety could be capable of changing the beliefs of those in their network.²⁴ Certain aspects of vaccines may clash with people's moral foundations.

Historical issues affecting trust. Lack of equity in health authorities' responses to the COVID-19 pandemic, or in previous immunization situations, could affect trust in COVID-19 vaccines among some historically disenfranchised groups. Groups most at risk may include people living on a low-income; ethnic, racial, indigenous, religious, sexual, and gender minorities; disabled; migrant; or members of communities with inadequate health service access or who have been disproportionately affected by the COVID-19 pandemic.^{25,26} Previous safety events related to other vaccines or vaccination programmes - whether real or rumours - may also impact on trust.

Organizational influences. Some individuals, such as HCWs, may be reached through workplace vaccination programmes. In some countries, mistrust has emerged among HCWs as a result of workplace COVID-19 infections and a perception of having been unsupported by governments in the face of overwhelming COVID-19 case numbers. This may reduce trust in communication about vaccine safety not only from governments but also from other community groups such as partners (UN agencies and NGOs) or schools.

Vaccination services. Previous negative experiences with health services may influence acceptance in adults.²⁷ Delivery of vaccination in large-scale clinics increases the chance of a clustered immunization stress-related response, where two or more vaccinees experience

19 Larson HJ, Jarrett C, Eckersberger E, Smith DMD, Paterson P. Understanding vaccine hesitancy around vaccines and vaccination from a global perspective: a systematic review of published literature, 2007–2012. *Vaccine*. 2014;32(19):2150-9. doi: 10.1016/j.vaccine.2014.01.081.

20 Wiley KE, Leask J, Attwell K, et al. Parenting and the vaccine refusal process: a new explanation of the relationship between lifestyle and vaccination trajectories. *Soc Sci Med*. 2020;263:113259. doi: 10.1016/j.socscimed.2020.113259.

21 Brewer NT, Chapman GB, Rothman AJ, Leask J, Kempe A. Increasing vaccination: putting psychological science into action. *Psychol Sci Public Interest*. 2017;18(3):149-207. doi: 10.1177/1529100618760521.

22 Leask J, Chapman S, Hawe P, Burgess M. What maintains parental support for vaccination when challenged by anti-vaccination messages? A qualitative study. *Vaccine*. 2006;24(49-50):7238-45. doi: 10.1016/j.vaccine.2006.05.010.

23 The Sabin-Aspen Vaccine Science and Policy Group. Meeting the challenge of vaccine hesitancy. 2020. Available from: https://www.sabin.org/sites/sabin.org/files/sabin-aspen-report-2020_meeting_the_challenge_of_vaccine_hesitancy.pdf. Accessed 24 October 2020.

24 Hussain RS, McGarvey ST, Fruzzetti LM. Partition and poliomyelitis: an investigation of the polio disparity affecting Muslims during India's eradication program. *PLoS One*. 2015;10(3):e0115628. doi: 10.1371/journal.pone.0115628.

25 Shadmi E, Chen Y, Dourado I, et al. Health equity and COVID-19: global perspectives. *Int J Equity Health*. 2020;19(1):104. doi: 10.1186/s12939-020-01218-z.

26 Reiter PL, Pennell ML, Katz ML. Acceptability of a COVID-19 vaccine among adults in the United States: how many people would get vaccinated? *Vaccine*. 2020;38(42):6500-7. doi: 10.1016/j.vaccine.2020.08.043.

27 Wheelock A, Parand A, Rigole B, et al. Socio-psychological factors driving adult vaccination: a qualitative study. *PLoS One*. 2014;9(12):e113503. doi: 10.1371/journal.pone.0113503.

the same adverse event at the same place and time, with the same vaccine. See [hypothetical scenario 5](#) for guidance on communicating in such a scenario.

Political influences. Leaders may create high expectations of COVID-19 vaccines. Overconfident communication could lead to mistrust if expectations are not met.^{28,29} Vaccine safety concerns may be a form of expression for wider political divisions and tension and thus, politicization of vaccination programmes is likely to do more harm than good.

28 Betsch C, Sachse K. Debunking vaccination myths: strong risk negations can increase perceived vaccination risks. *Health Psychol.* 2013;32(2):146-55. doi: 10.1037/a0027387.

29 Sandman PM, Lanard J. Part 2: Effective COVID-19 Crisis Communication. In *COVID-19: The CIDRAP Viewpoint* May 6, 2020. Available from <https://www.cidrap.umn.edu/sites/default/files/public/downloads/cidrap-COVID-19-viewpoint-part2.pdf>. Accessed 24 October 2020.

03 Recommendations for a vaccine safety communications approach

This section provides a summary of recommendations for communicating about COVID-19 vaccine safety, informed by risk communication principles. More detailed guidance is available in **Appendix 5.3**.

The goal of vaccine safety communication should be to empower people to make evidence-informed choices about COVID-19 vaccination. Any communication approach must encourage trust in health authorities and those delivering the vaccine, facilitate access to timely, accurate and credible information about COVID-19 vaccination safety via trusted channels and provide people with a means of asking questions and having their concerns addressed. The Vaccine Safety Net (VSN), established by WHO, is a worldwide network of websites that provide reliable information on vaccine safety online.⁸ VSN was established to counterbalance websites that published unbalanced, misleading and unreliable vaccine safety information. It aims to facilitate access to reliable, understandable, evidence-based information on the safety of vaccines for online users in various geographical locations and speaking different languages.

3.1 Plan and prepare prior to vaccine introduction

Planning and preparing to communicate about COVID-19 vaccine safety should take place as early as possible, ideally well in advance of the vaccines being deployed. Planning should include integration of the communications team (or equivalent) into any vaccine safety planning and decision-making activities to facilitate appropriate and proactive communication activities.

Establishing partnerships with other vaccine safety stakeholders will help coordinate information sharing and dissemination. Developing a communications plan — including activities such as designating responsibilities, nominating spokespeople, defining audiences or population groups, and developing materials — will help preparation for likely scenarios and develop mitigation measures. See **Appendix 5.3** and **Appendix 5.4** for more detailed guidance.

3.2 Set up lines of communication

Preparations should include setting up lines of communication, via trusted channels, with influencers and mobilizers, such as community, religious or cultural leaders, HCW associations, trusted journalists and other influential people. Engaging with them will help to identify and meet their information needs and offer opportunities to encourage

promotion of positive vaccination behaviour. Planning for and creating multiple forums for the public to ask questions or raise concerns, such as public meetings, website feedback forms, email, telephone hotlines, online chat, or a social media platform, should also be part of the preparation of communication pathways. See [Appendix 5.4](#) for more detailed guidance.

**Case study: Setting up lines of communication with local field workers—
Sierra Leone, 2015**

The use of local field workers can give credibility to engagement and help build public health capacity. Local field workers, who will remain part of a community long after external involvement has ceased, are accountable to local populations and understand the nuances of local needs and situations. During Ebola vaccine trials in Sierra Leone in 2015, researchers adopted a two-team approach, with both teams consisting primarily of local staff. One team liaised with the community, and their responsibilities included monitoring community concerns and addressing rumours. The other team undertook social science activities, such as assessing community perceptions, and their responsibilities included understanding trial participants' experiences by providing opportunities for them to give feedback. This feedback was then used to tailor and improve the vaccine trial processes.³⁰

3.3 Identify potential threats to confidence in COVID-19 vaccine safety

Various COVID-19 vaccine-related events could occur that may negatively influence perceptions of vaccine safety. These could include publication of new data on COVID-19 vaccines, and information about events such as a temporary vaccine suspension or recall, adverse events, negative messaging in the media, and community attitudes and beliefs. A poorly managed incident, for example a substandard or counterfeit vaccine, will also attract negative public attention. Identifying potential threats and monitoring for them will help to plan how, when and what to communicate and to whom. It is essential to communicate early and often (see case study below). See [Appendix 5.4](#) for more detailed guidance.

³⁰ Dada S, McKay G, Mateus A, Lees S. Lessons learned from engaging communities for Ebola vaccine trials in Sierra Leone: reciprocity, reliability, relationships and respect (the four R's). *BMC Public Health*. 2019;19(1):1665. doi: 10.1186/s12889-019-7978-4.

Case study: Communicate early, often, and with transparency—Sweden, 2010

The H1N1 vaccine, Pandemrix, was used in approximately 20 European countries but primarily in Finland, France, Germany, Ireland, Norway, Sweden and United Kingdom. Studies conducted in these countries confirmed an association between Pandemrix vaccination and narcolepsy.³¹ A meta-analysis of the studies showed that during the first year after vaccination, the relative risk of narcolepsy was increased 5- to 14-fold in children and adolescents and 2- to 7-fold in adults.³² Subsequent investigations indicated a possible genetic basis in affected individuals for this adverse event.^{33,34}

In Sweden, the country with the highest number of narcolepsy cases reported, Pandemrix vaccination coverage rates were high, with 60% of the population vaccinated against H1N1.³⁵ Initial communications about the vaccine had strongly emphasized vaccination for all Swedes as a measure to protect themselves and others, unless there were individual medical contraindications to vaccination. There was comparatively little communication around possible side effects in this newly developed vaccine.³⁶

There were several key lessons learned from these events in terms of communication. To maintain trust in a vaccination programme it is important to communicate early about possible side effects, listen to and involve those who are affected, rapidly investigate cases and transparently communicate results, as well as correct misleading information as soon as possible.³⁹ In addition, the Swedish investigation concluded that a glossary of key terms should be made available, e.g. via Internet, to allow people understand technical information.^{36,37}

3.4 Listen proactively

Listening proactively to the public, using multiple data sources, is essential to formulate tailored and targeted communications. Listening can help to:

- identify audiences and provide insights into what they are thinking, their concerns and questions;

31 European Medicines Agency. Twenty-second pandemic pharmacovigilance update - 19 August 2010. Available from: https://www.ema.europa.eu/en/documents/report/twenty-second-pandemic-pharmacovigilance-update_en.pdf. Accessed 24 October 2020.

32 Sarkanen TO, Alakuijala AP, Dauvilliers YA, Partinen MM. Incidence of narcolepsy after H1N1 influenza and vaccinations: systematic review and meta-analysis. *Sleep Med Rev.* 2018; 38: 177-186. doi: 10.1016/j.smrv.2017.06.006.

33 Partinen M, Komum BR, Plazzi G, Jennum P, Julkunen I, Vaarala O. Narcolepsy as an autoimmune disease: the role of H1N1 infection and vaccination. *Lancet Neurol.* 2014;13(6):600-13. doi: 10.1016/S1474-4422(14)70075-4.

34 Hallberg P, Smedje H, Eriksson N, Kohnke H, Daniilidou M, Öhman I, et al. Pandemrix-induced narcolepsy is associated with genes related to immunity and neuronal survival. *EBioMedicine.* 2019;40: 595-604. doi: 10.1016/j.ebiom.2019.01.041.

35 Lundgren B. 'Rhyme or reason?' Saying no to mass vaccination: subjective re-interpretation in the context of the A(H1N1) influenza pandemic in Sweden 2009-2010. *Med Humanit.* 2015;41(2):107-12. doi: 10.1136/medhum-2015-010684.

36 Fahlquist JN. Vaccine hesitancy and trust. Ethical aspects of risk communication. *Scand J Public Health.* 2018;46(2):182-8. doi: 10.1177/1403494817727162.

37 Feltelius N, Persson I, Ahlqvist-Rastad J, Andersson M, Arnheim-Dahlström L, Bergmanet P, al. A coordinated cross-disciplinary research initiative to address an increased incidence of narcolepsy following the 2009-2010 Pandemrix vaccination programme in Sweden. *J Intern Med.* 2015;278(4): 335-53. doi: 10.1111/joim.12391.

- identify community influencers and trusted sources; and
- detect negative messaging and anti-vaccine activity.

These insights may be specific to contexts and locations. Listening should be a continuous activity, as concerns and information needs will change as the pandemic evolves and as vaccines are deployed. Social listening may provide an additional avenue for surveillance for real or perceived AEFIs. Not listening proactively may result in incomplete or incorrect understanding of audiences and missed opportunities to respond to issues such as emerging misinformation or public outrage over a perceived vaccine safety issue.

Ways to listen to the public include:

- qualitative methods (interviews, focus groups, observations)
- tracking public opinion via surveys of representative samples
- insights from community and religious leaders and other influential people
- tracking calls to hotlines and other forms of public feedback
- monitoring traditional media
- digital and social media listening.

See **Appendix 5.5** for more detailed guidance.

Case study: Listening to community feedback—Guinea, 2014

In June-July 2014, the local population in a region of Guinea did not trust the international teams deployed to try to control the Ebola outbreak. This mistrust hindered containment efforts. The external agencies nominated community spokespeople, based on their assumed standing in the community. At the same time, a WHO anthropologist spent three days talking with the local people about who they would trust as spokespeople to raise their concerns. The spokespeople named by the local people were different from those nominated by the external parties. Once leaders respected by the community, such as those with traditional caring roles or religious duties, were given leadership roles, cooperation with outbreak measures increased notably. In other contexts, trusted spokespeople may include traditional practitioners, religious leaders, elders, and others.³⁸

³⁸ Wilkinson A, Parker M, Martineau F, Leach M. Engaging 'communities': anthropological insights from the West African Ebola epidemic. *Philos Trans R Soc Lond B Biol Sci.* 2017;372(1721):20160305. doi: 10.1098/rstb.2016.0305.

3.5 Communicate in ways that build understanding and trust

Communication that is transparent, timely, empathic and acknowledges uncertainty can help boost people's trust in health authorities, which in turn can positively influence people's willingness to be vaccinated.³⁹ These principles should be used to guide how, when, and with whom to communicate.

Communicate with openness and transparency: Be open and transparent about vaccine safety by providing access to all information, not withholding any, even when the facts are yet to be fully established.²⁹ There is no evidence to support the assumption that the public will panic if they have access to accurate information in a crisis.⁴⁰ Lack of honesty and withholding information can erode trust. Keep promises to share information and regularly update the public with new information. If specific information about vaccine safety is unavailable, communicators should say so and explain how they plan to get it. When it is not possible to share specific information about an on-going investigation, share information about the process and what is expected to take place. When details are scarce, communicating hope is appropriate.

Communicate with clarity: This includes demystifying vaccine safety for the public. For example, explaining how vaccines are tested and then monitored for safety. It is important to pay attention to health literacy when developing statements and materials.⁴¹ This is particularly important when considering equity of access to information. Plain language communication includes being clear about what people need to do in relation to vaccine safety, getting to the point quickly, and understanding audience information needs.⁴² Differing levels of numeracy should be accommodated when communicating probabilities, by communicating both qualitative (e.g., very low) and quantitative (e.g., 1 in every 100,000 people receiving the vaccine) estimates of risk.⁴³ See **Appendix 5.6** for further information.

Accept and acknowledge uncertainty: Convey uncertainty about vaccine safety, when it exists, in a way that avoids over- or under-confidence and will ensure informed decision making. Being over-confident, over-reassuring or minimising risks may reduce trust. On the other hand, evidence suggests that the communication of uncertainty about pandemic vaccines can reduce vaccine intentions.⁴⁴ Identify likely scenarios the public may need to consider

³⁹ Siegrist M, Zingg A. The role of public trust during pandemics: implications for crisis communication. *Euro Psychol.* 2014;19:23-32. doi: 10.1027/1016-9040/a000169.

⁴⁰ Seeger MW. Best practices in crisis communication: an expert panel process. *J Applied Comm Res.* 2006;34(3):232-44. doi: 10.1080/00909880600769944.

⁴¹ McCaffery KJ, Dodd RH, Cvejic E, Ayre J, Batcup C, Isautier JMJ et al. Disparities in COVID-19 related knowledge, attitudes, beliefs and behaviours by health literacy. 2020. medRxiv 2020.06.03.20121814; doi: 10.1101/2020.06.03.20121814.

⁴² World Health Organization. Tactics to apply to make your communications understandable. 2020. Geneva: World Health Organization. <https://www.who.int/about/communications/understandable/plain-language>. Accessed 4 November 2020.

⁴³ Trevena LJ, Zikmund-Fisher BJ, Edwards A, Gaissmaier W, Galesic M, Han PKJ, et al. Presenting quantitative information about decision outcomes: a risk communication primer for patient decision aid developers. *BMC Med Inform Decis Mak.* 2013;13(Suppl 2):S7. doi: 10.1186/1472-6947-13-S2-S7.

⁴⁴ Han PKJ, Zikmund-Fisher BJ, Duarte CW, Knaus M, Black A, Scherer AM, et al. Communication of scientific uncertainty about a novel pandemic health threat: ambiguity aversion and its mechanisms. *J Health Commun.* 2018;23(5):435-44. doi: 10.1080/10810730.2018.1461961.

and what decisions may need to be taken and when, and explain what is being done to reduce uncertainties.

Be responsive and timely with communications: If concerns about the safety of COVID-19 vaccines arise, do not wait to be certain before communicating. Anticipate concerns as much as possible and be forthcoming with information as it becomes available. Leaving an information vacuum will allow others with lower quality information or misinformation to fill it. Keep the public updated about actions being taken by governments, in the event of possible adverse events following immunization (AEFIs). If information is evolving, be transparent and say that. Partnering with the media can help to disseminate information quickly and get key messages to the public. Social media may offer a useful means of providing brief, frequent, and real-time updates, and can signal willingness to readily share information.

Act and speak with empathy: Speaking with empathy is not only important when addressing a press conference but also when participating in small meetings with community members or stakeholders. It may feel more comfortable to talk about vaccine safety by focusing on data and using impersonal and abstract language, but using personal language and showing concern helps to build trust. It is important to identify spokespeople whose manner and presence communicates both competence and empathy, not just with their words, but also with their non-verbal communication and their tone. Listen to, acknowledge, and respond to people's emotions about COVID-19 vaccines. Use genuine expressions of concern about issues and events related to vaccine safety.

Additional guidance on the principles of risk communication for a vaccine-related crisis can be found in the WHO publication [Vaccine safety events: managing the communications response](#) (p. 36). Information about other determinants of trust, such as competence, objectivity, fairness, consistency, sincerity, faith can be found in the WHO publication: [Vaccination and trust](#) (p. 25). Additional resources can be found in [Appendix 5.10](#).

3.6 Construct messages about COVID-19 vaccine safety using an evidence-based approach

Insights from health communication research can make vaccine safety messages more effective and acceptable to audiences. For example, keeping messages clear, short and simple, focusing on the positive opportunities for COVID-19 vaccines to improve health, rather than focusing on the risks of disease. Scientific consensus around vaccine safety should be emphasized. Messages should be tailored to suit specific audiences, barriers and enablers, to ensure they are relevant and engaging. Data should be clearly presented with the addition of visuals to clarify text. The messages should include positive narratives to model vaccination behaviour. The messages should be around specific actions that people can do to reduce harms, e.g. talk to your doctor. Although messages should be tailored to specific audience needs, they must remain consistent. These messages will also be useful when developing resources for advocates and other communicators. See [Appendix 5.6](#) for more detailed guidance.

Case study: Communicate in ways that build trust during a vaccine safety scare—Australia, 2010

In April 2010, Australia suspended seasonal influenza vaccine for children under 5 years of age following reports of an increased rate of adverse events following immunization. An initial investigation found that the safety signal was related to one brand of influenza vaccine only, and thus paediatric vaccination with other brands restarted.⁴⁵ The scare affected confidence in paediatric influenza vaccination and vaccination rates dropped from 45.5% in 2009 to 7.9% in 2010 in one Australian state that had a funded programme.⁴⁶ The media provided extensive coverage of the actual vaccine suspension event and some follow up from health authorities to family doctors. Moreover, studies conducted both at the time and subsequently found that some parents and providers were uncertain about the ongoing safety of the vaccine due to a lack of information provided.^{47,48}

Lessons learnt from this incident include:

- the need for public health authorities to be proactive during a vaccine safety incident and to engage with both, parents and providers;
- the need to give a name to the adverse event because not doing so can raise doubts;
- the need to provide information updates via trusted sources throughout the duration of a vaccine scare to avoid the development of information voids; and
- the need to acknowledge uncertainty and provide updates discussing what is known and unknown, using well-established risk and crisis communication principles.

Information should be disseminated via both traditional media sources and other trusted sources. This could be authoritative information from regulatory authorities or key health experts provided via government health websites, childcare centres and schools.⁴⁷

3.7 Pre-test messages with representatives of target audiences and adjust as needed

Public responses to COVID-19 vaccine safety messages may be unpredictable and not reflect previous experiences, so pre-testing messages is essential. In time- and resource-poor settings, testing with a small group is still useful. It is important to test the messages with people who

⁴⁵ Horvath J. Review of the management of adverse events associated with Panvax and Fluvax. Canberra, ACT: Australian Government Department of Health and Ageing; 2011. Available from: <https://www.health.gov.au/resources/publications/review-of-the-management-of-adverse-events-associated-with-panvax-and-fluvax>. Accessed 24 October 2020.

⁴⁶ Mak DB, Carcione D, Joyce S, Tomlin S, Effler PV. Paediatric influenza vaccination program suspension: effect on childhood vaccine uptake. *Aust N Z J Public Health*. 2012;36(5):494-5. doi: 10.1111/j.1753-6405.2012.00925.x.

⁴⁷ King C, Leask J. The impact of a vaccine scare on parental views, trust and information needs: a qualitative study in Sydney, Australia. *BMC Public Health*. 2017;17(1):106. doi: 10.1186/s12889-017-4032-2.

⁴⁸ Blyth CC, Richmond PC, Jacoby P, Thornton P, Regan A, Robins C, et al. The impact of pandemic A(H1N1)pdm09 influenza and vaccine-associated adverse events on parental attitudes and influenza vaccine uptake in young children. *Vaccine*. 2014;32(32):4075-81. doi: 10.1016/j.vaccine.2014.05.055.

are representative of the target audience to assess their impact, not with colleagues whose responses may not reflect those of the target audience.

Case study: Using positive narratives to model vaccinating behaviour—USA, 2009

In October 2009, the US implemented a vaccination programme against ‘swine flu’ caused by the H1N1 influenza virus. Due to an initial shortage, the vaccine was prioritized for risk groups, including young adults.⁴⁹ President Obama stated that he and his family would take the advice of health authorities as to when it would be appropriate for them to receive the vaccine.

The President’s daughters, Malia and Sasha, received the vaccine in October 2009 when it became available for school-aged children. The President and First Lady, Michelle Obama, received the vaccine in December 2009, when additional supplies became available and it was recommended more broadly for all adults. President Obama spoke in the media about his confidence in the safety of the vaccine and endorsed its use in both, children and adults.⁵⁰

A study of trust in government and H1N1 vaccination intent found that discussion by President Obama of his daughters’ H1N1 vaccination had a positive impact on vaccination decision making and uptake that was independent of political party association. This was seen to largely transcend politics and to be an example of a father trusting in the vaccine for his children.⁵¹ A subsequent photo of President Obama with rolled up sleeve about to receive the H1N1 vaccine provided an additional powerful positive role model image.⁵⁰

3.8 Work closely with the media

In many cases, the traditional media (television, radio, and print) will act as an important intermediary between health authorities and the public.⁵² Briefing journalists regularly, and supporting their information needs around vaccine safety issues and concepts, may help reduce sensationalist reporting. Establishing relationships with journalists and engaging with them regularly is important. It is recommended to develop mutually beneficial relationships with the media by being easily accessible and responding promptly to requests for information. Become a go-to source for vaccine safety information by providing clear and concise media

⁴⁹ Centers for Disease Control and Prevention. 2009 H1N1 Flu Vaccine. 2010. Available from: <https://www.cdc.gov/h1n1flu/vaccination/>. Accessed 24 October 2020.

⁵⁰ Lee, J. 2009. The President and First Lady get vaccinated. The White House blog. Available from: <https://obamawhitehouse.archives.gov/blog/2009/12/21/president-and-first-lady-get-vaccinated>. Accessed 24 October 2020.

⁵¹ Quinn SC, Parmer J, Freimuth VS, Hilyard KM, Musa D, Kim KH. Exploring communication, trust in government, and vaccination intention later in the 2009 H1N1 pandemic: results of a national survey. *Biosecure Bioterror*. 2013;11(2):96-106. doi: 10.1089/bsp. 2012.0048.

⁵² Habersaat KB, Betsch C, Danchin M, Sunstein CR, Böhm R, Falk A. et al. Ten considerations for effectively managing the COVID-19 transition. *Nat Hum Behav*. 2020;4(7):677-87. doi: 10.1038/s41562-020-0906-x.

releases and background information and offering names of third parties for journalists to speak to about vaccine safety issues. See [Appendix 5.7](#) for more detailed guidance.

3.9 Build a social media presence

Social media offers significant potential for communicating about COVID-19 vaccine safety directly to the public. It is a convenient way to communicate regularly and give real-time updates. Some audiences may be using social media as a primary means of learning and communicating about COVID-19 vaccines. Anti-vaccine activists are certainly using social media to spread negative messaging about vaccines.

When communicating on social media, it is recommended to listen to what key audiences are saying and use this information to inform communications. Choose one or two platforms to communicate on; do not spread efforts too thinly across many platforms. Commit to two-way communication, including interacting, replying and conversing. Be active and interact regularly to build an online community. Use an authentic, personal approach and create safe spaces to encourage audiences to ask questions without fear of aggressive or hostile encounters. Regular interaction on social media requires substantial input, so allocate resources specifically for social media in the communications plan.

Using personal stories and other messages that elicit emotion can be useful for addressing emotional issues such as fear about vaccine safety. Personal stories can be part of an authentic, personal approach to communicating via social media.

See [Appendix 5.8](#) for more detailed guidance.

Case study: Using an authentic, personal approach via social media—Denmark, 2017

In 2013, the Danish media began to publish stories about young Danish women who experienced stress-related adverse events following HPV immunization. A television documentary, broadcast in 2015, brought attention to the experiences of girls with disabling symptoms. These stories were widely discussed in the media and concerns about vaccine safety were shared on social media. This negative attention was associated with a significant reduction in HPV vaccination uptake, although subsequent studies showed no association between the girls' events and HPV vaccination.⁵³

Danish health authorities responded with a national campaign in 2017, '*Stop HPV – Stop Cervical Cancer*', to rebuild trust and increase uptake. Based on formative research identifying mothers as key vaccination decision makers and Facebook as an important information source for this priority group, they developed a social media strategy to engage mothers who were hesitant about vaccinating their daughters. The campaign, which was primarily focused on a dedicated Facebook page, refocused attention on cervical cancer prevention by communicating evidence supporting HPV vaccine safety and personal stories of women with cervical cancer. HPV vaccine ambassadors helped spread these positive messages. Both uptake and Danish parent's trust in HPV vaccination increased. The campaign's wide reach and positive engagement with audiences may have contributed to these results. The campaign's success was in part attributed to the use of personal stories, which audiences engaged with more readily than factual posts, and which encouraged more positive dialogue.^{54,55}

3.10 Careful management of negative messages

While listening to and communicating with the public it is likely that negative messages about COVID-19 vaccine safety will be encountered. Negative messages include rumours, distorted, false or misleading opinions, misinformation and expressions of anti-vaccine sentiment. Not all negative messages warrant a response. Firstly, a vocal minority may generate a large proportion of the negative messages, which can then be amplified by social media algorithms and media attention. Responding to them could unintentionally add to this amplification and expose new people to them. Secondly, people may express fear and anxiety about vaccine safety, which is normal given the uncertainty around COVID-19 vaccines and their safety, particularly considering the accelerated development timeline. It is important not to assume these negative sentiments is simply misinformation, or other types of negative messages

⁵³ Suppli CH, Hansen ND, Rasmussen M, Valentiner-Branth P, Krause TG, Malbak K. Decline in HPV-vaccination uptake in Denmark - the association between HPV-related media coverage and HPV-vaccination. *BMC Public Health*. 2018;18(1):1360. doi: 10.1186/s12889-018-6268-x.

⁵⁴ Pedersen EA, Loft LH, Jacobsen SU, Søborg B, Bigaard J. Strategic health communication on social media: insights from a Danish social media campaign to address HPV vaccination hesitancy. *Vaccine*. 2020;38(31):4909-15. doi: 10.1016/j.vaccine.2020.05.061.

⁵⁵ Loft LH, Pedersen EA, Jacobsen SU, Søborg B, Bigaard J. Using Facebook to increase coverage of HPV vaccination among Danish girls: an assessment of a Danish social media campaign. *Vaccine*. 2020;38(31):4901-8. doi: 10.1016/j.vaccine.2020.04.032.

coming from anti-vaccine and other activists. It is recommended to respond with compassion by acknowledging people's concerns and providing information.

Listening will help to analyse the situation, determine whether it is appropriate to respond or not, and allow close monitoring of the popularity of the negative messages which can be used to inform a reactive strategy. Only respond to negative messages that have spread beyond the source community and are getting considerable reach and engagement from target audiences.

Responses should be directed to the audience when responding to negative messages. Do not argue with or try to convince the person spreading the negative message. Emphasize facts and content that trigger positive emotions, such as the health benefits of vaccines. Expose flawed arguments, explain why any misinformation is incorrect and, if possible, provide alternative explanations. The [Vaccine Safety Net website](#) provides criteria for good information practices that can be used to guarantee that website provides reliable, timely, accurate and evidence-based information on vaccine safety. Disseminating reliable information to and training relevant stakeholders, such as journalists, health authority staff, health care workers and factcheckers are key strategies for communicating. See **Appendix 5.8** for more detailed guidance.

Pre-prepared messages in the form of Frequently Asked Questions (FAQs) can be useful when responding. Listening is important to help identify appropriate and relevant questions. For example, videos containing misinformation or conspiracies may indicate people's questions (but not necessarily attitudes) and can be used in developing FAQs. Note that FAQs developed without good understanding of community knowledge and attitudes may not address people's real questions. See **Appendix 5.9** for more detailed guidance.

3.11 Criteria for prioritizing responses to vaccine safety issues

It is inevitable that anti-vaccine activists and some professionals will make negative claims about the safety of COVID-19 vaccines. While early and responsive communication is important, it is not possible or appropriate to respond to every new claim, particularly if there are many. Communicators must consider resources and opportunity costs in responding. Therefore, the level and scale of response should depend on the potential impact of the claim. Events that meet at least one of the following criteria will require a response. Further guidance can be found on page 17 of WHO's [Vaccine Safety Events: managing the communications response](#).

The AEFI is genuine. The primary role is to protect the health of the public. Responsiveness and expressions of empathy are essential. Misdiagnosing people's safety concerns as mere 'anti-vaccination' can lead to harms at population and clinical levels if the AEFI is not taken seriously and investigated.

The event or story is gaining attention. Via evidence from social listening or opinion monitoring, it is obvious that the event is gaining attention, particularly in the population groups prioritized for COVID-19 vaccination. The attention is the amount of exposure that the negative sentiment is getting, not the volume. Hence, some individuals, with only a few followers, may share a

large volume of messages but the amount of exposure will be low. Conversely, messages shared by influential individuals with many followers results in high levels of exposure by virtue of the number of their followers.

The alleged adverse event is unsubstantiated but publicised by a symptom/syndrome group. Safety concerns that reduced HPV coverage in Ireland and Denmark and those that changed HPV vaccine policy recommendations in Japan shared a common phenomenon: a group of individual parents were drawn together by a shared belief that the vaccine had caused their child's syndrome, condition or symptom cluster.

A respected opinion leader who is trusted in the community is advancing a view. A unique feature of vaccine safety scares is a medically-trained person publicly advancing a theory. They may influence HCWs and their confidence in recommending vaccination, and thus have an impact on the wider community.

The confidence of HCWs is likely to be affected. Vaccine safety concerns that amplify HCWs' existing hesitancy or trigger new concerns require rapid responses. Confident, committed HCWs are vital for the success of vaccination programmes. In the case of COVID-19 vaccines, HCWs are both recipients and recommenders of the vaccine.

The issue or event touches on moral foundations that are highly correlated with vaccine acceptance. Claims that touch on moral foundations associated with vaccine rejection may be more salient. Those found to have the strongest correlation with vaccine rejection include claims about the vaccine ingredients (purity/degradation) or where there is some level of coercion in vaccine programmes, either real or perceived (liberty).^{56,57}

⁵⁶ Amin AB, Bednarczyk RA, Ray CE, Melchiori KJ, Graham J, Huntsinger JR, et al. Association of moral values with vaccine hesitancy. *Nat Hum Behav.* 2017;1(12):873-80. doi: 10.1038/s41562-017-0256-5.

⁵⁷ Rossen I, Hurlstone MJ, Dunlop PD, Lawrence C. Accepters, fence sitters, or rejecters: moral profiles of vaccination attitudes. *Soc Sci Med.* 2019;224:23-7. doi: 10.1016/j.socscimed.2019.01.038.

Hypothetical scenarios

This section describes some hypothetical scenarios involving vaccine safety at different stages of COVID-19 vaccine development and provides practical advice on how to respond.

The pre-licensure phase, when phase I, II and III vaccine clinical trials are being conducted, is characterised by:

- early communication about COVID-19 vaccine safety
- demonstration of trustworthiness of vaccine safety and efficacy information collected during clinical trials and the decision-making processes
- collection of data on knowledge, concerns and information needs.

Hypothetical scenario 1: Early concerns among influential experts

An influential doctor with high-media reach shares concerns about alleged ‘shortcuts’ on safety for the COVID-19 vaccines, the number of adverse events of special interest (AESI) being monitored, and the ‘*too many uncertainties*’ about the vaccine’s safety. The general population hear these concerns in the media. Some of them share their views that COVID-19 is ‘the same as the flu anyway’ (see [example](#)).

Example response

Communicators should engage early with professional leaders, ideally prior to such events. Proactively communicate about the unique vaccine safety considerations for COVID-19 vaccines. Respond promptly with sufficient detail and do not be dismissive about concerns. Correct the false belief that shortcuts are being taken for the COVID-19 vaccine safety by providing information about how it is being assessed in phase I, II and III vaccine trials (see [Appendix 5.9](#) for responses to FAQ about safety and vaccine trials).

Directly and specifically address the differences between AESIs and adverse events following immunization (AEFIs), using the level of detail appropriate for the audience (See [Appendix 5.9](#) for responses to FAQ about AESIs). Associate discussions of vaccine safety with existing ideas people have about common medicines that may have common side effects and rare adverse effects.

Communicate about the clinical trial outcomes that are known, using appropriate, accessible formats. Engage with local expert advocates to broaden the coalition of voices addressing concerns. Communicate:

- what AESIs are and why they are listed and being monitored (see [Appendix 5.9](#)),
- the role of phase II and III trials in the evaluation of vaccine safety (see [Appendix 5.9](#)),
- what is known about safety, named AEFIs and their rates from COVID-19 vaccine trials so far
- what we know now, where uncertainty remains and what is being done to fill information gaps,
- plans for ongoing monitoring of AESIs and plans for detecting and managing safety signals,
- the potential benefits from a COVID-19 vaccine.

In some settings it may be reasonable to identify positive religious and community leaders as communication partners. Talk to them early about the upcoming vaccine programme. Ask them to be ready to be called if there are concerns about the vaccine to answer questions.

The pre-licensure phase, when phase I, II and III vaccine clinical trials are being conducted, is characterised by:

- early communication about COVID-19 vaccine safety
- demonstration of trustworthiness of vaccine safety and efficacy information collected during clinical trials and the decision-making processes
- collection of data on knowledge, concerns and information needs.

Hypothetical scenario 2: Rumours

A video about adverse events allegedly reported during phase II COVID-19 vaccine trials is shared via a local, known anti-vaccination Facebook group with 80,000 followers. Mainstream media organizations want to report the story.

Example response

Use the criteria in this manual to prioritise the level of response. Investigate the reach of the rumour. It may be possible to give trusted journalist(s) background information about the rumour and the potential harm in reporting it. If the rumour has been shared widely beyond original communities, address concerns on website or social media platform to enable advocates to respond. If the rumour has not been shared widely, not formally responding could be considered since responding may draw more attention to the topic. Avoid strategies that encourage polarization, such as entering into debates with those with strong beliefs. Debunk information with well-referenced facts. See [Appendix 5.2](#) for detailed guidance on managing negative messages.

Hypothetical scenario 3: Vaccine components

A group publicly expresses concern that a COVID-19 vaccine is made with new technology that modifies genes.

Example response

This issue will be specific to mRNA and DNA vaccine platforms. Governments should work with experts to rapidly produce information that answers FAQs about these vaccine platforms before the launch phase. Information should be specific to the vaccine(s) the country plans to introduce. See [Appendix 5.9](#) for responses for FAQs about new vaccine platform technologies.

Draft information about technically complex matters should be pre-tested on target audiences. Health literacy assessment tools like [PEMAT](#) can be used.

Governments should proactively provide information about the vaccine platforms and how different vaccines are produced.

Hypothetical scenario 4: Social media bombardment or attack

The Facebook page of a hospital recruiting for a candidate COVID-19 vaccine trial is attacked by anti-vaccine activists. The most frequent comments are: “COVID-19 is mutating”, “the vaccine will not work”; “we don’t know anything about COVID-19 so how can we make an effective vaccine”; “recruit politicians for vaccine trials and then we will trust you”; “let us live our lives, we don’t need vaccines (young people, not parents)”; “we will never accept mandatory immunization”.

The pre-licensure phase, when phase I, II and III vaccine clinical trials are being conducted, is characterised by:

- early communication about COVID-19 vaccine safety
- demonstration of trustworthiness of vaccine safety and efficacy information collected during clinical trials and the decision-making processes
- collection of data on knowledge, concerns and information needs.

Example response

Manage the immediate attack by banning offending individuals from the Facebook page and deleting false and offensive comments. Do not engage directly with the activists. Seek support from partners. See the [Anti-Anti-Vaxx Toolkit](#) for specific guidance on managing an activist Facebook attack.

Use listening techniques to determine whether these questions and concerns are more widespread and reflect target audiences' concerns. If so, communicate with broader audiences using other means. It is important not to argue with the people spreading the negative messages.

Counter any widespread negative messages by providing clear and simple explanations and exposing flawed arguments by providing evidence-based information. Emphasize the scientific consensus on COVID-19 vaccine safety. Provide opportunities for people to ask questions. Foster the audiences' trust by addressing concerns promptly, being transparent, and not over-reassuring. See [Appendix 5.8](#) for more guidance on managing negative messages.

Launch phase—After licensure, vaccination programmes for those eligible for vaccination will be implemented. This phase is characterised by:

- providing information on the safety profiles and risk-benefit balances of the different vaccine platforms (and individual products)
- ongoing monitoring of local knowledge, attitudes, concerns and information needs among the public and health care workers.

Hypothetical scenario 5: Cluster of immunization stress-related responses

A COVID-19 vaccine that caused moderate pain at the injection site in 10% of vaccine recipients in phase III trials is given in a mass vaccination campaign. At one clinic, there were long queues waiting to be vaccinated on a particular afternoon, a group of vaccine recipients complained of headaches and dizziness after the vaccine was given, and some fainted. The issue was reported widely in the media that evening.

Example response

Anxiety associated with shared beliefs about the cause of symptoms can spread easily and quickly, especially via the media or social media. This ‘contagion’ of fear can interfere with immunization programmes.

Spokespeople should acknowledge the symptoms and the distress experienced by the vaccine recipients and state that the causes are being investigated. They should identify the process for investigation and what others should do in the meantime. They should be available to update journalists on the incident.

Public sentiment should be monitored using listening techniques (see [Appendix 5.5](#)). Local leaders and health care workers should be engaged to reassure the community. Health care workers should be provided with messages and communication materials that explain acute stress responses (including syncope or fainting) (see [Appendix 5.6](#)). Work with the media to disseminate information (see [Appendix 5.7](#)). Engage audiences on social media, and counter negative messages as appropriate (see [Appendix 5.8](#) and [Appendix 5.9](#)). Communicate and address concerns promptly and transparently.

Prior to launching an immunization programme, develop a plan to respond to stress response clusters, including pre-testing messages in potential priority groups, nominating spokespeople and points of contact for the media, and training spokespeople and health care workers in communication. See [Appendix 5.3](#) for developing a communications plan. See also Section 5 and 7 of WHO’s [Immunization stress-related responses manual](#).

Hypothetical scenario 6: A community with questions

An influential community leader is urging people not to be vaccinated, saying that the vaccine is not safe, “it is a conspiracy and it is being given to people in lower-income countries to control fertility”.

Example response

The National Immunization Programme manager can provide information about vaccine safety and the importance of vaccination to community leaders before the launch. Vaccine safety communication resources tailored to the local needs and culture can be proposed, with support from the [Vaccine Safety Net](#) or the [Vaccine Safety Communication e-library](#). If vaccination resistance develops during the launch, work with positive influencers to engage with the resisting religious and community leaders. For example, it will be helpful to provide a simple one-page guideline on vaccine safety for these leaders, and to share information about how other leaders have previously dealt with such issues.

Vaccine roll-out—This is when the vaccine program is becoming established and larger number of the population receive it. This phase is characterised by:

- Staged communication as more evidence becomes available
- Communication of situational AEFI signal versus perceived but unsupported AEFI
- Communication integrated in AEFI management

Hypothetical scenario 7: Safety signal

An AEFI signal for one COVID-19 vaccine is being investigated. Regardless of the outcome, it has the potential to undermine confidence in other COVID-19 vaccines although no AEFI signal has been detected for the other vaccines.

Example response

Implement a vaccine safety communication plan (see **Appendix 5.3**). Use the criteria described in this module to prioritise the level and scale of response. Assess community sentiment and concerns using listening techniques (see **Appendix 5.5**). Prepare and pre-test messages, if possible, prior to vaccination campaign in anticipation of this issue. Tailor these messages to questions and concerns of different audiences, as needed.

Messages about vaccine safety should come from knowledgeable people (such as the National AEFI Committee spokesperson) with good communication skills. They should convey clear information about differences between the COVID-19 vaccines and focus on the benefits of COVID-19 vaccination. Messages should be short and simple, emphasizing evidence-based information and scientific consensus on COVID-19 vaccine safety. Confirm that messages are consistency with vaccine safety partners (see **Appendix 5.6**).

If the AEFI safety signal receives widespread media or public attention, communicate promptly and transparently. Brief journalists. Communicate and interact with audiences on social media. Provide health care workers with communication materials to respond to people's concerns. Continue to update audiences on the progress of the investigation and recommend what actions individuals should take in relation to the incident (e.g., continue to be vaccinated, continue to be vaccinated with other available vaccine(s)).

Hypothetical scenario 8: False rumour

A rumour is circulating that a COVID-19 vaccine has caused a spike in the incidence of a specific autoimmune disorder common in one of the groups of adults with comorbidities that is a COVID-19 vaccination priority target group. Investigations have shown the link is not plausible and no safety signal has been detected in AEFI monitoring. Some health care workers and a prominent immunologist are giving support to the rumour. A significant number of health care workers are refusing vaccination, stating their concerns about 'reactions'.

Example response

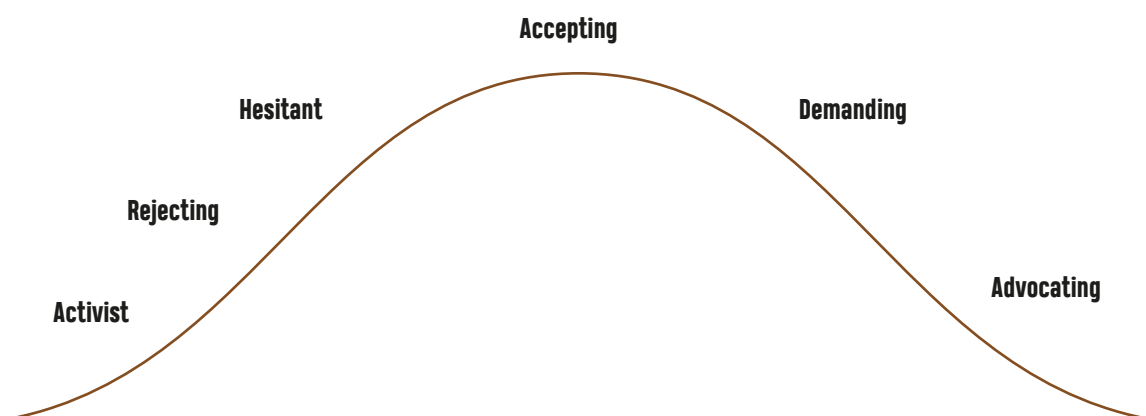
Respond rapidly with sufficiently detailed, frank information to address the claims. This can be done by a professional with sound and relevant knowledge in immunology or vaccine safety and could be in the form of an online statement that can be shared by relevant professional networks.

Assess whether more proactive modes of response are needed via listening for sentiment and spread of rumour among health care workers (see **Appendix 5.5**). Develop and, if possible, pre-test messages tailored to the concerns and information needs. Messages should explain why the rumour is incorrect, what is known about the vaccine's safety in that group and expose flawed arguments. Recruit respected opinion leaders, advocates and other influencers within health communities and professional societies to disseminate information to disprove the rumour. Initiate dialogue with health care workers to allow them to ask questions and have their concerns addressed.

Appendix 5.1: Spectrum of vaccination intentions for COVID-19 vaccines

The spectrum of vaccination intentions to receive a COVID-19 vaccine, adapted from other work, for example, WHO spectrum of positions on childhood vaccination, is represented below.⁵⁸ This takes into account results from recent studies on COVID-19 vaccine intentions, issues known to be unique to new vaccine programmes, and experiences with past pandemic and epidemic vaccines (e.g., H1N1 and polio). This figure serves as a diagrammatic rather than proportional representation of motivational states, which will be highly dependent on context.

Spectrum of intentions related to COVID-19 vaccines.



⁵⁸ World Health Organization. Report of the SAGE Working Group on vaccine hesitancy. 01 October 2014. Available from: https://www.who.int/immunization/sage/meetings/2014/october/1_Report_WORKING_GROUP_vaccine_hesitancy_final.pdf. Accessed 4 December 2020.

Further resources

Name of resource	Language	Source	About
CERC: Psychology of a Crisis	English	Centers for Disease Control and Prevention (CDC)	How people take in, process, and act on information in a crisis
WHO Euro vaccination and trust	English, Russian	WHO Regional Office for Europe	p. 9 How people make decisions about vaccination
The Science of Science Communication	English	The Cultural Cognition Project at Yale Law School	How people process information about science
Vaccine safety and confidence	English	Excellence in Pediatrics Institute (EPI) Vaccine Virtual Days	Assessing vaccine safety and confidence in the COVID-19 era (access available on request)
Immunization stress related responses	English	WHO Health Product Policy and Standards	Guidance for prevention, identification and response to stress-related responses following immunization

Appendix 5.2: Managing negative messages (misinformation and anti-vaccine activists)

Responding to negative messaging will be a key communications activity⁵⁹, that requires a considered approach. Here are some steps to take and things to consider when encountering negative messaging. Listening will help analyse the situation, determine whether it is appropriate to respond or not and closely monitoring the popularity of negative messaging will help to inform a timely reactive strategy.

- **Prepare a response**, regardless of plans to respond publicly. Use the principles of constructing evidence-informed messages, and work with stakeholders to ensure consistency.
- **Try to understand context of negative messages.** Sometimes, by the time the negative message has reached you, it has been decontextualized, i.e. key details about where and why it was spread and by whom and why are missing. Attempt to track down details that help clarify the content of the message, as well as why it may have spread, such as where the article clip or featured image came from.
- **Try to work out how far negative messages have already spread**, and the nature of that spread. Where did the negative message appear? Was it in a known anti-vaccine or fringe group on social media, or in an environment with a larger and more general audience? Has the media reported on it? Only respond to negative messaging that has spread beyond the source community.

⁵⁹ Habersaat K, Betsch C, Danchin M, Sunstein CR, Böhm R, Falk A, et al. Ten considerations for effectively managing the COVID-19 transition. *Nature Human Behav.* 2020;4(7):677-687. doi: 10.1038/s41562-020-0906-x.

- For negative messaging on social media, **consider the number of negative posts as well as the reach of and engagement with these posts**. People may be posting large volumes of negative messages on social media but have hardly any followers and thus have minimal influence. Try and work out how many people are being reached by and are engaging with (and therefore spreading) the message, and whether this has changed over time. If an individual or page is posting messages of interest, look at their number of followers to assess their influence, as well as the number of people engaging with or sharing this message.
- **Are target audiences engaging with and discussing the message?** What is the content and tone of their engagement? Just because a target audience is engaging does not mean they support the negative messaging. The target audience may be responding to and countering negative messaging on their own, which can be an effective strategy.
- **Is the audience asking questions or expressing concerns** in response to the negative messaging? This is where providing answers and assurance may be especially valuable.

Negative messaging that has spread beyond the source community and is being engaged with and discussed in non-fringe environments may warrant response. Here are some recommendations for responding to negative messaging:

- **Remember the audience is the people who are listening**, *not* the person or organization spreading the negative message. This is equally true when pitted against an anti-vaccine activist in a TV broadcast, responding to a critical remark from the crowd in a town hall meeting, or responding to a post on social media. Craft your response for the audience, not to argue with or convince the person spreading the negative message.
- **Emphasize factual information** when refuting negative messages. Too much focus on the misinformation may strengthen the falsehood in people's minds.
- **Create content that triggers positive emotions**, such as the health benefits of vaccines. This type of content is important to counteract negative messaging on vaccines based on emotional values and will complement information based on data and evidence.
- **Emphasize scientific consensus**, such as "90% of clinicians agree that this vaccine is safe"
- **Warn the audience** by explicitly signposting repeated misinformation, e.g., "There are many myths about COVID-19 vaccine safety. This myth, for example, is about..."
- **Explain why the misinformation is incorrect** and if possible, provide an alternative explanation. This is more effective than simply saying something is incorrect. Provide links to reputable sources where appropriate.
- **Expose any flawed arguments** by pointing out the techniques the person spreading the negative message is using, such as selective use of evidence, using fake experts, referring to conspiracy theories, false logic.
- **Avoid hostile interactions** with anti-vaccine activists. If you engage in arguments, you may be signalling to your audience that there is disagreement around what you are saying.
- **Do not refer to activists using imprecise collective nouns**, i.e. the anti-vaccine community or anti-COVID-19 vaccine groups. This can imply they are larger and more organised than they really are, may confer them more perceived power and influence, and get them more followers. If necessary, refer to activists as individuals, e.g., Joe Bloggs has posted this falsehood about...

Further resources

Name of resource	Language	Source	About
The Debunking Handbook 2020	English	PDF available	Guidance for debunking misinformation
How to respond to vocal vaccine deniers in public	English	WHO Regional Office for Europe	Algorithm for responding to anti-vaccine activists
Anti-anti-Vaxx Toolkit: A Strategy Guide to Prepare For, Defend Against, and Clean Up After a Facebook Anti-Vaxx Attack	English	Kids Plus	Guidance on preparing for anti-vaccine activist attacks on social media
Vaccine safety events: managing the communications response	English, Russian	WHO Regional Office for Europe	Chapter 11 (p. 43) – Dealing with rumours
Coronavirus disease (COVID-19) advice for the public: myth busters	English	WHO	Information for the public on various myths associated with COVID-19
Social Media Response Assessment and Management Guide	English	American Academy of Pediatrics	Guidance on whether and how to respond on social media, as well as resources for multiple platforms

Appendix 5.3: Development of a COVID-19 vaccine safety communication plan

A vaccine safety communication plan does not eliminate risk, but will help to prepare to communicate more effectively with the public, and collaborate with partners and the media in the face of risks. The plan may include the following activities:

- **Designate responsibilities.** These may lie within the coordination mechanism, i.e. vaccine communication group. Responsibilities may include scientific subject matter experts, media liaisons, spokespeople, and research or listening. Identify lines of responsibility, especially authority to sign-off/information clearances. This activity will also help to identify any training needs, e.g. media training, social media listening and analysis.
- **Nominate spokespeople.** A spokesperson should be someone trusted by the community. If health authorities are experiencing complex socio-political relationships with the public, it may be helpful to team up with an academic or scientific spokesperson outside the government to connect with the public and help rebuild trust. Members of National Immunization Technical Advisory Groups (NITAGs) may be able to act as sources of trusted expertise. Identify and meet any training needs for spokespeople in advance, e.g. media training.
- **Develop a decision tool to help determine your communications response to a vaccine-related event.** Responses must be context specific, based on your assessment of the potential impact of an event on confidence in vaccine safety. A decision tool will help

you assess the type of event and its potential impact (low, medium, high), and choose the appropriate communications response. See further resources for examples.

- **Identify and secure resources required to perform the plan.** Resources are both human and financial, and might include a budget for research and listening, training, equipment, and spaces. List the number of people and skills needed. If possible, include a budget to employ people dedicated to managing specific channels, e.g. social media, and specific areas of work such as social data collection and social listening. If possible, secure resources in advance.
- **Define target audiences** and audience segments. Segments are those people who share similar knowledge and concerns, or are reached through similar channels. Use listening and social media analytics, including content analysis, to identify and understand audiences and assess your reach. Special outreach may be needed for groups who are at higher risk or are traditionally more difficult to reach.
- **Identify key influencers and ambassadors.** These may include digital or social media influencers, for example a blogger or Instagram profile with many followers, as well as community and religious leaders, high profile health experts, educators, and other people with a large audience. Influencers can help spread your messages. Health care workers will also be influential in the dissemination of vaccine safety information. They may need training and guidance on interpersonal communication to help them to be effective in passing on vaccine safety information (see further resources below).
- **Determine key communication channels,** e.g. the lead organization and stakeholder websites, social media platforms, media releases, local/national media, brochures or handouts, public forums, schools and other educational institutions. Key channels will be where target audiences are seeking health information or talking about vaccine safety. Include strategies to access any target groups who are not easily reached through these channels. Strategies may include access through immunisation providers and community health workers, social mobilizers, and civil society organizations.
- **Seek input from key stakeholders** when developing your vaccine safety communications plan, especially those representing audiences who have specific information needs or concerns, i.e. older people, health care workers.
- **Agree on procedures to coordinate information dissemination** with partners, including who releases what, when, and how. This may be led by government. Clarify approval processes, especially if information needs to be disseminated quickly in the event of a crisis.
- **Create contact lists** of key individuals in your organization, the media and strategic partners.
- **Create key messages and communication materials** to disseminate through the planned communication channels. These might be developed in anticipation of identified threats and include holding statements, i.e., a brief, simple statement that can acknowledge an event such as a safety signal, which will avoid a 'no comment' response, template media releases, Frequently Asked Questions (e.g., explaining vaccine safety concepts like AEFIs or AESIs), and talking points for spokespeople.
- **Determine training needs,** such as media and de-escalation training for spokespeople, who often can become the focus of public anger and concerns and must perform well under pressure to be effective. Health care workers will also be on the frontline of communicating about COVID-19 vaccine safety. Supporting them with resources and training on how to have

conversations about vaccination can help to improve their confidence and effectiveness as communicators.

- **Develop strategies to monitor and evaluate communications.** These may include evaluating the effectiveness of communications, documenting challenges and lessons learned, identifying gaps in skills and resources, and identifying actions to improve communications in the future. Evaluate communications using various tools, including social media listening, media monitoring and monitoring at the community level via health care workers, community-based mobilizers or social mobilizers, seeking feedback from community and religious leaders and civil society organizations. Input from strategic partners will also be useful. Evaluation of communication activities including effectiveness of vaccine safety communication could be integrated into vaccine post-introduction evaluations. Your evaluations should inform ongoing communications responses.

The COVID-19 safety communication plan should not be overly long. This plan will need to be regularly revised, especially after any vaccine-related events; to incorporate lessons learned and to keep contact lists up to date.

Further resources

Name of resource	Language	Source	About
<i>Guidance on developing communications plans</i>			
Crisis Communication Plans Manual	English	CDC CERC	Guidance on developing and applying a crisis communications plan
Communication Plan checklist	English	CDC CERC	Checklist for creating a communication plan
Vaccine safety events: managing the communications response	English, Russian	WHO Regional Office for Europe	Guidance on developing a media communications plan (p. 18) Communications plan template (p. 51)
<i>Decision tools for responding to vaccine-related events</i>			
How to ensure a context-specific response	English, Russian	WHO Regional Office for Europe	An algorithm for analysing vaccine safety events and determining appropriate communications response
Vaccine Safety Events: managing the communications response	English, Russian	WHO Regional Office for Europe	Appropriate responses to low, medium and high-impact vaccine-related events (p. 49) Guide timeline for responses (p. 54)
<i>Determining target audiences</i>			
RCCE Action Plan Guidance. COVID-19 preparedness and response	English	WHO Global	Defining and prioritising your RCCE audiences and other stakeholders (p. 20)
<i>Training for spokespeople and other ambassadors</i>			
SKAI eLearning module	English	NCIRS	Training for health care workers on conversations about immunisation with patients

Name of resource	Language	Source	About
SKAI Resources for healthcare providers	English	NCIRS	Discussion guides and other resources to support health care workers' conversations about immunisation with patients
Tips for spokespersons	English, Russian	WHO Regional Office for Europe	Principles for successful communication during a crisis
<i>Determining key communication channels</i>			
Vaccine safety events: managing the communications response	English, Russian	WHO Regional Office for Europe	Guidance on choosing key communication channels (p. 25)
RCCE Action Plan Guidance. COVID-19 preparedness and response	English	WHO Global	Choosing channels (p. 21)
<i>Evaluation</i>			
New vaccine post-introduction evaluation (PIE) Tool	English, French	WHO Department of Immunization, Vaccines and Biologicals	Guidance on evaluation as part of PIE (p. 17)
Vaccine Safety Events: managing the communications response	English, Russian	WHO Regional Office for Europe	Guidance on communications evaluation (p. 59)
<i>Preparedness checklists</i>			
Checklist for preparedness	English, Russian	WHO Regional Office for Europe	A checklist to prepare for events that may erode trust in vaccines
New vaccine introduction: Checklist for planning communication and advocacy	English, Russian	WHO Regional Office for Europe	Checklist of communication and advocacy strategies for working with health care workers, influencers, the media and the public
<i>Other</i>			
Crisis communication templates and tools	English	CDC CERC	A range of templates and tools to prepare and communicate during a crisis

Appendix 5.4: Planning and preparing COVID-19 vaccine safety communication

Planning and preparing to communicate about COVID-19 vaccine safety should take place as early as possible, ideally well in advance of vaccines being deployed and should include:

- involving the communications team in vaccine safety work,
- establishing strategic partnerships,
- setting up communication pathways with the public,
- identifying potential threats to confidence in vaccine safety.

Developing a vaccine safety communications plan is covered in [Appendix 5.3](#).

(i) Integrate communications team into vaccine safety work

As soon as the organization starts planning for and making decisions about vaccine safety work, the communications team⁶⁰ should be involved. This principle applies at all levels of organizations, from national to local area levels. Communications should not be brought in at the last minute, when leadership and technical experts are ready to implement decisions or in the event of a crisis. Vaccine safety risk communications considerations should be included in preparedness assessments and planning meetings before the introduction of COVID-19 vaccines.

This approach will support effective communication that will be considered, appropriate, and proactive, rather than reactive. As a result, decisions about vaccine safety will be more likely to take into account the needs and perceptions of key audiences. The communications team will also have a better understanding and ability to communicate about technical aspects of vaccine safety.

(ii) Establish strategic partnerships

Establishing strategic partnerships with other vaccine safety stakeholders will improve information sharing and coordination of vaccine safety information dissemination. Coordination will help reduce the possibility of disseminating contradictory messages and advice, which can create confusion and distrust.

In the context of COVID-19 vaccine safety, key stakeholders might include:

- national and regional health authorities and other government bodies;
- National Immunization Technical Advisory Groups (NITAGs);
- regulatory agencies;

⁶⁰ Various people may be responsible for communications in different countries, this may be the manager of the Expanded Programme on Immunization (EPI) or the National Immunization Programme (NIP), a designated team under the responsibility of the local COVID-19 response team, e.g., the emergency response controller, or public health lead, a communication expert from a United Nations or a funded technical support organization in partnership with the EPI/NIP manager.

- United Nation bodies and other international organizations;
- professional associations, for example representing health care workers or welfare associations working for elderly populations;
- private sector organizations with a role in immunization, e.g. workplace immunization, local branches of pharmaceutical companies, vaccine manufacturers;
- research scientists, and educational institutions at all levels;
- nongovernmental organizations (NGOs);
- religious organizations;
- community groups, e.g. representing key population groups such as culturally and linguistically diverse communities, and those committed to vaccine advocacy; and
- science journalists, the media, national science media centre if available.

Develop a network of stakeholders as early as possible. Partners may exist across disciplinary and geographical boundaries. It may be possible to leverage existing networks, such as regional surveillance networks, coordination mechanisms, and groups of key stakeholders. Consider seeking inclusion in the [WHO Vaccine Safety Net](#). Linking with partners on social media may be a useful way to network and may also enhance your ability to reach wide audiences and increase your mutual credibility.

Activities between strategic partners will involve:

- agreeing on shared communications objective;
- developing processes for sharing and coordinating information dissemination, for example who releases what, when, and how;
- standardizing messages; and
- identifying and training spokespeople.

Governments, who lead AEFI communication at the country level, may be best positioned to coordinate vaccine safety communications between stakeholders and lead the response in the event of a crisis. Non-government voices, however, still have an important role in reassuring the public about the systems in place to investigate safety issues and respond appropriately.

Respected public health voices can also provide comments to the media and offer a supportive perspective. Certain partners, like community groups and health care workers, may act as advocates, mobilizers and peer educators for vaccine safety issues. Journalists and social media influencers can be potential partners in information dissemination as their reports can have an important impact on public trust. Partnerships with the media are discussed in more depth in **Appendix 5.7**.

Further resources

Name of resource	Language	Source	About
Stakeholder management	English, Russian	WHO Regional Office for Europe	List of key vaccine-related stakeholders, and principles for establishing and maintaining relations with them
Template terms of reference for a vaccine communication working group	English, Russian	WHO Regional Office for Europe	Advice on creating working groups with partners
Vaccine safety events: managing the communications response	English, Russian	WHO Regional Office for Europe	Guidance on building partnerships (p. 40)
Risk communication and community engagement (RCCE) action plan guidance. COVID-19 preparedness and response	English	WHO Global	Defining and prioritising RCCE audiences and other stakeholders (p. 20)

(iii) Setting up communication pathways with the public

The ‘public’ is anyone who has an interest in, or is affected by, decisions about COVID-19 vaccine safety, including health care workers. Engaging the public as legitimate partners can help to build trust and create a sense of shared responsibility for managing vaccine safety risks.

Public engagement means continuously listening to people’s concerns about vaccine safety, and actively engaging people in dialogue; not just informing the public about vaccine safety, risks, and benefits.

Public engagement can be facilitated by:

- offering multiple ways for the public to ask questions or raise concerns directly, e.g., via public forums, website feedback forms, email, hotlines, online chat, or through social media;
- scheduling regular meetings with stakeholders, community and religious or cultural leaders, health care workers and others to provide a forum for discussing and addressing vaccine safety concerns; and
- partnering with community influencers and mobilisers to disseminate information.

These actions signal an acknowledgement of people’s right to know about COVID-19 vaccine safety, vaccination risks and benefits, and acceptance of their concerns as legitimate.

(iv) Identifying potential threats to confidence in vaccine safety

Identifying potential threats to people’s confidence in vaccine safety can guide how and with whom to communicate and also help to shape messages. In a COVID-19 vaccination safety context, anticipated threats, sometimes called ‘vaccine-related events’, may include:

- adverse events following immunization (AEFIs), either connected or perceived to be connected with vaccination, or adverse events of special interest (AESIs);
- new scientific data on COVID-19 vaccines benefits and risks;
- events such as a temporary suspension of a vaccine, vaccine recall, change in vaccine or introduction of a new vaccine;
- negative messaging, e.g. news and other media reports, misinformation, or the actions of anti-vaccine activists, including social media;
- community attitudes and beliefs, including any pre-existing vaccine hesitancy, may also threaten confidence in COVID-19 vaccine safety; and
- low acceptance of the COVID-19 vaccines that may affect confidence in other vaccines.

Track anticipated threats using a tool such as a ‘risk register’, which lists each threat and related information i.e., description of the threat, category (type of ‘vaccine-related event’ as above), probable settings and populations, likelihood and potential impact (e.g. low, medium, high), response strategies, and risk ‘owner’ or manager.

Threats posed by negative messaging, and community attitudes and beliefs will often be specific to contexts and locations. Research and listening methods can help to detect and understand issues related to vaccine safety.

Further resources

Name of resource	Language	Source	About
Vaccine Safety Events: managing the communications response	English, Russian	WHO Regional Office for Europe	Definition and explanation of vaccine-related events (p. 12)
TIP Tailoring Immunization Programmes	English, Russian	WHO Regional Office for Europe	Guidance for understanding barriers to vaccination
WHO tool for behavioural insights on COVID-19	English, Russian	WHO Regional Office for Europe	Rapid, flexible and cost-effective monitoring of public knowledge, risk perceptions, behaviours and trust to make their COVID-19-related response relevant and actionable, includes vaccination

Appendix 5.5: Guidance on social listening

An overabundance of information and misinformation about the COVID-19 pandemic, especially online, called an ‘infodemic’, can lead to a range of poor outcomes. The infodemic makes it difficult for individuals to know where to seek credible information. Concerns and negative messaging circulating online and on social media may affect public perceptions of COVID-19 vaccine safety and lead to behaviours that do not protect people’s health.

Listening using multiple data sources is essential for formulating a tailored response. Listening can help to:

- identify audiences, including specific audience segments;
- understand what audiences are thinking, what information they need, and what actions they want to see happen;
- identify community influencers and trusted sources of information;
- adapt messages, prepare and disseminate targeted communications; and
- detect negative messaging.

Listening should be part of preparations to communicate about vaccine safety, as well as a continuous activity. People's concerns and information needs will change as the pandemic evolves and as vaccines are deployed in different populations and contexts. Inadequate listening activities can lead to incomplete understanding of audiences. Missed opportunities to respond may include issues such as emerging misinformation or public outrage over a perceived crisis before it becomes widespread.

Methods for listening

Methods for listening to the public include:

- media monitoring to understand how the media covers issues related to vaccine safety and what narratives seem to be listened to;
- formative research to gather insights directly from local populations. This is sometimes called a situational analysis; [Tailoring Immunization Programmes](#) describes the process in-depth. There are a variety of methods such as interviews, focus groups, and observations that can be used. Strategic partners, other vaccine safety stakeholders, community and religious leaders and other influential people may have access to a range of different audiences and can also help gather insights;
- tracking public opinion e.g., via surveys;
- speaking to community and religious leaders and other influential people;
- tracking calls to hotlines and other forms of public feedback to identify community questions and concerns around safety; and
- digital and social media listening. For an example, see the [EPI WIN COVID-19 Infodemic Digital Intelligence reports](#). The [Vaccine Safety Net](#) has also initiated global digital and social media listening activities on vaccine safety.

If possible, monitor places where people actively search for information and converse about vaccine safety. This may be at public events such as seminars or town hall meetings, in the comments sections of news articles, in online discussion forums, or on social media. Digital and social media listening is covered in more detail below.

Listening can be a time-consuming and expensive activity. If possible, allocate specific resources to employ people with dedicated listening responsibilities in the communication plan. Share listening insights with strategic partners to amplify the collective listening capacity. Sharing

can also help to hear from a greater diversity of voices. Depending on available skills and resources, external help might be needed to gather these insights.

Listening online and on social media

Listening online and on social media can improve understanding of the online audience, identify influencers, adapt messages to formulate targeted communications, and detect negative messaging.

Depending on the social media platform, content and associated engagement may be public or private or a combination of both. For example, Twitter, Reddit, Instagram, YouTube and TikTok host predominantly public content (although some also allow private content), while Facebook has some public pages and groups. Commercial monitoring tools or services are useful for monitoring public content but may require substantial resources and specialized expertise to analyse. Monitoring services based on natural language processing will likely become increasingly popular. These services, including their algorithms and the transparency of the data they monitor, should be evaluated before use to ensure their outputs are correctly applied.

Here is some guidance for listening manually:

- **Generate a list of keywords and hashtags** relevant to COVID-19 vaccine safety. These may change frequently, so will have to be updated.
- **Find out when particular keywords appear online** on web pages, in news, blogs, etc. by setting up notifications via [Google Alerts](#). You can set the parameters to receive alerts instantly, daily, or weekly.
- **Track trending Google searches of keywords** by country via [Google Trends](#). Weekly or monthly notifications can be set up via 'Subscriptions'.
- **Search for keywords or hashtags on social media platforms** using platform search tools, e.g., via [Twitter advanced search](#) or [Reddit search](#). [Facebook search](#) that can explore public posts in public groups or pages. [Instagram search](#) can be used to search for people or hashtags. Facebook, Instagram and YouTube are also searchable using Google.
- **Track multiple keywords or hashtags** using tools like social media aggregators, e.g. [Tweetdeck](#) for Twitter. This will help to automate the monitoring partially.
- **Use free tools to search and analyse listening data. For example, Onemilliontweetmap** provides a real-time geographic map of geolocated tweets with specific search terms or hashtags. [Media Cloud](#) provides analysis of digital news media, including some social media shares. [WhatsApp monitor](#) supports searching WhatsApp public groups in Brazil, India and Indonesia.
- **Generate a list of key individuals, groups, or websites** that may be useful to track. This might include influential individuals, community groups or other groups representing target audiences. For listening to negative messaging, develop and track a list of individuals, groups or websites that generate or share misinformation or negative sentiment about COVID-19 vaccine safety.

- **See how often links have been shared** on Facebook, Instagram, Twitter and Reddit using Chrome browser plugin [CrowdTangle Link Checker](#). This tool also shows associated posts (limited to public pages or accounts) and engagement data.
- It is important to **determine how many people are being reached by and are engaging with messages of interest**. Counting the number of messages posted on a particular topic gives a false impression of message influence. People may post a large volume of messages on social media but have hardly any followers, and therefore little influence. If an individual or page is posting messages of interest, look at the number of followers and the number of people engaging with or sharing the message to assess their influence.

Note that the information gathered can be useful for understanding what people are saying about vaccine safety on social media, but may or may not correspond with vaccination sentiment in broader populations or groups, especially those who do not have digital access. To broaden the information gathered other means of listening, such as monitoring mainstream media and community conversations should be used.

Further resources

While many of these resources were designed for journalists, they contain relevant information anyone listening on social media, including health authorities and other people working in vaccine safety.

Name of resource	Language	Source	About
RCCE Action Plan Guidance. COVID-19 preparedness and response	English	WHO Global	Tools for formative research: — COVID-19 Rapid Qualitative Assessment Tool (p. 8) — COVID-19 Rapid Quantitative Assessment Tool (p. 14)
How to monitor public opinion	English, Russian	WHO Regional Office for Europe	Tools to monitor public opinion on vaccination
CERC Messages and Audiences	English	CDC CERC	Guidance on gathering audience insights (p. 9)
Essential Guide to Newsgathering and Monitoring on the Social Web	English	First Draft	Monitoring best practices across major platforms and online services
How to begin to monitor social media for misinformation	English	First Draft	Strategies to monitor Reddit, 4chan, Twitter and Facebook (Part one)
Monitoring social media for misinformation, part two	English	First Draft	Free tools to monitor social media (Crowdtangle, 4chan, Tweetdeck) (Part two)
How to investigate health misinformation (and anything else) using Twitter's API	English	First Draft	Guide to collecting data from Twitter

Name of resource	Language	Source	About
Speed up your social newsgathering with these Twitter search shortcuts	English	First Draft	Guide to monitor tweets (including using Tweetdeck) using search operators
Closed Groups, Messaging Apps & Online Ads	English	First Draft	Monitor groups and closed messaging apps
RCCE Action Plan Guidance. COVID-19 preparedness and response	English	WHO Global	Guidance on learning about audiences (p. 25)
The 101 of disinformation detection	English	Institute for Strategic Dialogue	Toolkit for detecting disinformation online via listening

Appendix 5.6: Development of evidence-based messages

It will be necessary to develop messages about COVID-19 vaccine safety for a variety of uses, such as media releases, talking points for spokespeople, or posts for social media. The type of COVID-19 vaccine safety information that the public may seek, or you may wish to communicate could include: vaccine risks and benefits, information about vaccine safety regulatory processes and surveillance systems, and vaccine safety concepts such as AEFIs and AESIs. Through listening, it is possible to identify commonly asked questions that can be addressed.

Here are some tips from health communication research to help make these messages more effective and acceptable to your audiences.

- **Keep messages clear, simple and short.** Avoid using vaccine safety jargon or technical terms like ‘AEFIs’ or even ‘adverse events’. These terms are not part of most people’s everyday language.
- **Convey balanced, evidence-based information** that communicates potential risks to a level of detail appropriate for the audience.
- **Explain the costs and benefits of vaccination, but focus on the positive** opportunities for COVID-19 vaccines to improve health (‘gain frames’) rather than on the risk of disease (‘loss frames’). Example: vaccinate against COVID-19 and protect our community’s health.
- **Balance messages about vaccine safety with more general COVID-19 vaccine information.** This may help to avoid over- emphasizing vaccine safety issues and unintentionally triggering concerns in people seeking other types of information.
- **Emphasize scientific consensus**, e.g., “90% of clinicians agree that this vaccine is safe” and develop straightforward consistent terms to use when presenting the limits of scientific confidence.
- **Provide people with specific actions they can do to reduce harms.** In uncertain situations, such messages can give people a sense of control e.g., “Get vaccinated”, “Talk to your doctor about COVID-19 vaccines” or “Ring this number to find out more”.

- **Shape messages to suit specific audiences.** This means considering cultural differences, literacy levels, or the specific communication needs of particular groups. Audiences on digital and social media may be particularly fragmented and require messages tailored specifically to their needs.
- **Present data clearly** to support audience comprehension.⁶¹ For example, use frequencies, 1 out of 100, rather than percentages, 1% or abstract terms, such as 'common'. Use the same denominator when comparing risks. Use absolute, not relative risks.
- **Use illustrations and visuals.** Visuals can clarify text and data, but they should be closely related to what is said in the text, to be effective. Using visuals on their own can make messages accessible by overcoming language, cultural and literacy barriers.⁶² See this [example about COVID-19 from Stanford Medicine](#).
- **Use personal stories about vaccination and other messages that elicit emotion.** Negative narratives about vaccine safety can have a powerful influence on how people perceive vaccine risk. Positive, emotive narratives can help model vaccination behaviour and are often more memorable than factual information.⁶³ Narratives are effective for addressing emotional issues and overcoming resistance.⁶⁴ See this [example of President Obama receiving his H1N1 vaccine](#) in 2009. Social media users may want to share their own positive stories of vaccination via your pages or posts; allowing them to do this also demonstrates trust in your online community.
- **Pre-test your messages** with representatives of target audiences and adjust as needed. How the public responds to COVID-19 vaccine safety messaging may be unpredictable and not reflect previous experiences.
- **Consistency of messages is important.** Use and reuse the same messages in all channels and platforms without changes to avoid confusion.

⁶¹ Trevena LJ, Zikmund-Fisher BJ, Edwards A, Gaissmaier W, Galesic M, Han PK, et al. Presenting quantitative information about decision outcomes: a risk communication primer for patient decision aid developers. *BMC Med Inform Decis Mak* 2013;13 Suppl 2(Suppl 2):S7. doi: 10.1186/1472-6947-13-S2-S7.

⁶² Adam M, Barnighausen T, McMahon SA. Design for extreme scalability: A wordless, globally scalable COVID-19 prevention animation for rapid public health communication. *J Global Health*. 2020;10(1):010343. doi: 10.7189/jogh.10.010343.

⁶³ World Health Organization. Vaccination and trust. 2017. Available from <https://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/publications/2017/vaccination-and-trust-2017>. Accessed 18 November 2020.

⁶⁴ Cawkwell PB, Oshinsky D. Storytelling in the context of vaccine refusal: a strategy to improve communication and immunisation. *Med Humanit*. 2016;42(1):31-35. doi: 10.1136/medhum-2015-010761.

Further resources

Name of resource	Language	Source	About
<i>Guidance on developing messages</i>			
Vaccination and Trust: How concerns arise and the role of communication in mitigating crises	English, Russian	WHO Regional Office for Europe	Guidance on creating effective vaccine messaging (p. 30)
Vaccine Safety Events: managing the communications response	English, Russian	WHO Regional Office for Europe	Guidance on developing vaccine message content (p. 20)
CERC Messages and Audiences	English	CDC CERC	Guidance on developing messages (p. 6)
International Patient Decision Aid Standards (IPDAS) criteria	English	IPDAS Collaboration	Criteria for assessing the quality of patient decision aids
<i>Tools for developing messages</i>			
How to prepare a message map	English, Russian	WHO Regional Office for Europe	Tool to develop and pre-test messages
Message Development for Communication Worksheet	English	CDC CERC	Worksheet to develop six basic emergency message components
Everyday Words for Public Health Communication	English	CDC	Index of plain language alternatives for public health jargon
<i>Pre-prepared messages on vaccine safety</i>			
Vaccine safety messages	English, Russian	WHO Regional Office for Europe	Pre-prepared messages on vaccine safety and AEFIs
Societal benefits of immunization	English, Russian	WHO Regional Office for Europe	Information on wider social benefits of vaccination, for use in messaging, talking points
List of Vaccine Safety Net websites	Various	Global Vaccine Safety Initiative, WHO	List of websites that provide credible vaccine safety information
RCCE Action Plan Guidance. COVID-19 preparedness and response	English	WHO Global	List of COVID-19 information sources for generating content (p. 23)
Country & Technical Guidance - Coronavirus disease (COVID-19)	Various	WHO Global	Technical guidance on COVID-19
<i>Presenting data</i>			
Key principles for presenting data	English, Russian	WHO Regional Office for Europe	Principles for presenting numbers about vaccination to the public
Communicating Risks and Benefits: An Evidence-Based User's guide	English	FDA	Presenting quantitative data (p. 53)
Reporting the findings: Absolute vs relative risk	English	Health News Review	Using absolute versus relative risk

Appendix 5.7: Responding to the needs of the media

In many cases the traditional media (television, radio, and print) will act as an important intermediary between the communicating organization and the public.⁶⁵ For certain communities, radio may be particularly useful given its reach and availability. Several specific actions can develop mutually beneficial relationships with the media.

- **Establish relationships with journalists.** Initiate these connections early and engage regularly. Many journalists use social media to source stories and contacts so you may be able to initiate a relationship through platforms such as Twitter.
- **Be easily accessible and available** for interviews, including after hours. Ensure journalists can readily contact you.⁶⁶
- **Respond promptly** to requests for information. The media needs to turn information around quickly, often within a few hours.
- **Provide clear and concise media releases** that explain complex information in straight forward language. Avoid jargon or technical terms. Media releases should lead with the most important information, and include who, what, where and when.
- **Provide background material** if the issue to discuss is complex, for example explaining AEFIs versus AESIs, rapid authorization, emergency and compassionate use. Background knowledge may improve reporting.
- **Work with the media to decrease sensationalism.** Brief journalists regularly and provide support for understanding vaccine safety issues and concepts. Relationships with specialist health reporters can be especially useful as they often have skills to understand and translate technical concepts into lay language.
- **Identify potential spokespeople** from your organization as early as possible, preferably as part of your communications plan, and organize media training to help them prepare to interact with the media.
- **Become a 'go-to' source** for vaccine safety information. Offer names of third parties for journalists to speak to about vaccine safety issues.
- **Be guided by values and actions that foster public trust** when talking with the media (see above). Be honest and open with information. Do not minimise risks or make over-reassuring statements about COVID-19 vaccine safety. If you do not know the answer to a question, acknowledge the uncertainty and say what you are doing to find the answer. Do not refuse to answer or say 'no comment'.

⁶⁵ Habersaat KB, Betsch C, Danchin M, et al. Ten considerations for effectively managing the COVID-19 transition. *Nat Hum Behav.* 2020 Jul;4(7):677-687. doi: 10.1038/s41562-020-0906-x.

⁶⁶ Leask J, Hooker C, King C. Media coverage of health issues and how to work more effectively with journalists: a qualitative study. *BMC Public Health.* 2010;10:535. doi: 10.1186/1471-2458-10-535.

Further resources

Name of resource	Language	Source	About
Setting the media agenda	English, Russian	WHO Regional Office for Europe	Guidance on working with the media on vaccination issues
Guide to being a media officer	English	Stempra	Practical advice on: <ul style="list-style-type: none"> — developing media releases (p. 14) — pitching to journalists (p. 19) — targeting journalists (p. 23) — press briefings (p. 25) — using spokespeople (p. 27)
Top tips for media work: a guide for scientists	English	Science Media Centre	Practical advice on preparing to interact with the media
Vaccine safety events: managing the communications response	English, Russian	WHO Regional Office for Europe	Guidance on: <ul style="list-style-type: none"> — interacting with the media (p. 29) — writing media releases (p. 52) — typical media questions (p. 62) — responding to typical journalist tactics (p. 64)
How to prepare a press release	English, Russian	WHO Regional Office for Europe	Key elements of a press release
How to prepare a message map	English, Russian	WHO Regional Office for Europe	Tool to develop messages and help prepare spokespeople for interviews
The questions journalists always ask in a crisis	English, Russian	WHO Regional Office for Europe	Sample questions asked by journalists in a crisis
Tips for spokespersons	English, Russian	WHO Regional Office for Europe	Principles for successful communication during a crisis, useful for spokesperson training and to prepare for an interview or press conference

Appendix 5.8: Communication on social media

Social media has significant potential for communication about COVID-19 vaccine safety directly to the public.⁶⁷ Some audience may be using social media as a primary means of learning and communicating about COVID-19 vaccines. Anti-vaccine activists are certainly using social media to spread negative messaging about vaccines. Social media offers a convenient way to communicate regularly and give real-time updates. Here are some tips.

- **Listen to what key audiences are saying** through social media listening and use this information when developing your communications.

⁶⁷ Veil SR, Buehner T, Palenchar MJ. A work-in-process literature review: incorporating social media in risk and crisis communication. *J Conting Crisis Man.* 2011;19(2):110–22. doi 10.1111/j.1468-5973.2011.00639.x.

- **Decide what content may be attracting attention on social media.** Identify the most popular topics online and their associated keywords. Listening is also useful for identifying any gaps in messages.
- **Decide on the platform/s.** This decision will depend on where the key audiences are. Note that spreading efforts too thinly across many platforms may be ineffective. Top ranking social media platforms globally include Facebook, YouTube, Instagram, TikTok (Douyin), Weibo, Reddit, SnapChat, Twitter, Pinterest and Kuaishou. Consider those most likely to be used by the groups you want to target.
- **Decide on the format.** Although text is almost always appropriate, the use of multimedia, including podcasts, which are increasingly popular, may enhance the virality of messages.
- **Consider the available audience.** Certain groups defined by age, culture, language and gender may be more likely to use certain platform or not at all. Choose language and content that matches the platform and speaks to audiences using the platform.
- **Commit to two-way communication,** including interacting, replying and conversing. This is a rich opportunity to develop relationships and trust with audiences. Posting and responding to audience comments shows you are listening and actively responding to people's needs and concerns. However, it is not necessary to respond to every comment or to unfounded criticisms.
- **Be active and interact regularly** to build your community of followers and your credibility, such as hosting livestreams, live Q&As or Ask Me Anything (AMA) threads. Chatbots designed for interactions on COVID-19 could supplement, but not replace, your communication activities. Examples include [WHO's Facebook Messenger COVID-19 Chatbot](#) (a version of its WHO Health Alert platform) and [Healthbuddy](#).
- **Monitor the impact of your messages.** Simple metrics and more sophisticated tools for getting analytics may be useful to continuously monitor the number of individuals and their interactions (number of visits and time spent in reading). Monitoring may be helpful to refine original messages and improve understanding what works best.
- **Create safe spaces** for audiences to ask questions and to encourage dialogue, such as offering more private ways to seek advice. Encourage individuals to post questions publicly to benefit others who may have similar concerns. Respond promptly and protect the space by removing aggressive or hostile posts. Make community management expectations clear from the outset and choose moderators who commit to maintaining a civil discussion.
- **Remember that many individuals may be cautious about making themselves publicly visible** on social media. They may be 'silent', i.e. observing but not openly commenting, liking or sharing posts.⁶⁸ Design messaging with this audience in mind, not just as a response to the most vocal and active users on social media.
- **Use an authentic, personal approach** rather than impersonal statements. If possible, post as an individual with a first name rather than as an anonymous organization. Social media users expect human conversations with real people, so offer a way for them to connect to with a real person, whether through the chat function on a social media platform or connecting them to a hotline.

68 Steffens, M. S., Dunn, A. G., Wiley, K. E., Leask, J. How organisations promoting vaccination respond to misinformation on social media: a qualitative investigation. *BMC Public Health*. 2019;19(1),1348. doi: 10.1186/s12889-019-7659-3.

- **Amplify reach** to wide and diverse audiences using two-way communication. An active community of followers can also help disseminate your posts. Paid posts or campaigns can also be useful.
- **Identify influential and credible users** who can help spread your messages. These might be for example health care workers⁶⁹ or others with widely followed Facebook pages or Instagram accounts that already act as trustworthy and influential sources of information.
- **Interact with partners** to share information and increase your mutual credibility. Creating a collective presence on social media will amplify balanced, pro-vaccine voices and can act as a counterbalance to anti-vaccine voices.
- **Allocate resources** specifically for social media in your communications plan. Listening and regular interaction on social media requires substantial input. Dedicated social media staff will be useful for this.
- **Make a policy of avoiding hostile interactions** to preclude being drawn into protracted dialogue with anti-vaccine activists.
- **Use a considered approach** when responding to negative messaging.

Note that social media will not reach everyone, such as unnetworked people in vulnerable or poor communities, particularly in developing countries. The traditional media, alongside interpersonal communication, can be better used to reach such communities.

Further resources

Name of resource	Language	Source	About
Guide to being a media officer	English	Stempra	Developing social media campaigns (p. 35)
Setting the media agenda	English, Russian	WHO Regional Office for Europe	Guidance on setting the vaccination social media agenda
CERC social media and mobile media devices	English	CDC CERC	Guidance on using social media in a crisis
Social media fact sheet	English	Pew Research Center	Social media patterns and trends (US data)
The 2020 social media demographics guide	English	Khoros	Social media demographic information
More than half of the people on earth now use social media	English	DataReportal	Information on global social media use and top-ranking social media platforms
Digital 2020	English	DataReportal	Global digital trends
140+ Social media statistics that matter to marketers in 2020	English	HootSuite	Sociodemographic data on users of various social media platforms

⁶⁹ Eghtesadi M, Florea A. Facebook, Instagram, Reddit and TikTok: a proposal for health authorities to integrate popular social media platforms in contingency planning amid a global pandemic outbreak. *Canadian J Public Health*. 2020;111(3):389-391. doi: 10.1186/s12889-019-7659-3.

Appendix 5.9: Frequently Asked Questions

Note that these questions and answers will require pre-testing with target audiences, and revision as new information becomes available.

1. How are we ensuring that the COVID-19 vaccines are safe?

Even though researchers are developing COVID-19 vaccines quickly, they are checking their safety very carefully. Safety checks are done in the laboratory, in clinical trials, and when vaccines are used in the population.

Clinical trials assess vaccines in people to see if they work to prevent COVID-19 and are safe. Clinical trials have three parts, called phases. In phase 1, the vaccine is given to a small number of people. In phase 2, the vaccine is given to hundreds of people. Finally, in phase 3, the vaccine is given to many thousands of people. Researchers are able to observe potential reactions by including lots of people in clinical trials.

If the clinical trials show the vaccine is safe, the government regulatory agency checks the safety information. They also check the way vaccines were developed in the laboratory. The government regulator is independent, which means they are separate from the researchers who develop the vaccine, and from the manufacturers who make the vaccine.

If the government regulator agrees the vaccine is safe, the manufacturer can start supplying doses of the vaccine for those who need it. The government and manufacturers continue to monitor the safety of the vaccine when people are being vaccinated in the community.

All these steps have been and will be followed for the development of COVID-19 vaccines to make sure they are safe. It might look like shortcuts are being taken, but this is not so, these steps are just happening faster than usual. People are joining the clinical trials more quickly than usual and funding and approval steps have been fast-tracked. Also, researchers; manufacturers and government regulators are working together to check vaccine safety information from clinical trials more rapidly than usual.

2. How are we going to monitor for COVID-19 vaccine safety when they are given to the community?

After the clinical trials are finished, governments, manufacturers and researchers will keep looking for rare or unexpected reactions to COVID-19 vaccines. One way of doing this is to make a list of uncommon health problems that could occur in those that are vaccinated. These problems might happen to someone by chance, or they might be caused by the vaccine. These are called 'adverse events of special interest' (AESIs). These might include things like allergic reactions (anaphylaxis) or other health conditions that may not have an obvious cause. These health issues might be so rare that researchers can only see if they occur in vaccinated people by looking at very high numbers of people.

If researchers find any possible rare reactions, they do specific studies to find out if the vaccine is causing them. If the studies show the vaccine is causing rare reactions, the government

regulator will act. They look at benefits of the vaccine, as well as the risks, to make their decision. The decision could include changing advice about how we use the vaccine, or in certain cases, even stopping vaccinations.

3. Will it be worth having a COVID-19 vaccine?

COVID-19 can be an extremely serious disease. A vaccine will reduce the risk that you get the disease or pass the infection on to others.

Many people with COVID-19 have a fever, dry cough and feel tired, but some people have trouble breathing and need to go to hospital. Some people die from the disease. Older people and people with health problems like high blood pressure or diabetes are more likely to become seriously sick, but anyone can get very sick from COVID-19. Some people have symptoms that last for many months. The virus can damage your lungs, heart, and brain.

Anyone of any age can be infected and spread the virus to others, even if they do not show signs of disease. Vaccinations help stop the spread of the virus, especially those more vulnerable to severe disease or dying.

4. I've heard that there are some vaccines using new technologies. How can we know these are safe?

All new vaccine technologies are being put through stringent testing and quality checks to make sure they are safe. This is the same for all COVID-19 vaccines, no matter what technology they use.

RNA vaccines are a new vaccine technology. We have successfully used RNA to target cancer cells, but using it to protect against infectious diseases like COVID-19 is new. RNA vaccines have a different way of working than traditional vaccines. Traditional vaccines imitate a viral or bacterial infection to train your immune system to rapidly respond if you come into contact with them. RNA vaccines contain instructions (or a code) that direct your body to make the disease antigen itself. Your immune system then responds to that antigen by making protective antibodies against the disease.

RNA vaccines do not introduce any actual parts of the virus into your body. RNA vaccines only deliver instructions that allow your body to make a protective response. These vaccines are sometimes called mRNA or messenger RNA vaccines. This name reflects the RNA vaccine's role in delivering instructions or a 'message', rather than the actual disease antigen.

5. Can a COVID-19 vaccine give me COVID-19?

Almost none of COVID-19 vaccines in development are 'live' vaccines. This means they do not include any weakened form of the SARS-COV-2 virus that causes COVID-19. This means you cannot get COVID-19 from the vaccine.

COVID-19 vaccines teach your immune system to recognise the SARS-COV-2 virus and make protective antibodies against it. If you are exposed to the SARS-COV-2 virus after getting a vaccine, you will already have protective antibodies in your body to fight the virus.

A small number of COVID-19 vaccines in development use live virus, but this live virus has been weakened (attenuated). This means the live virus in the vaccine is strong enough to teach your immune system to make protective antibodies, but too weak to give you the actual disease. We already use live virus vaccines to protect against measles, mumps, rubella and chickenpox.

All COVID-19 vaccines will undergo stringent clinical trials, testing and quality checks before health authorities approve them for use.

Appendix 5.10: General resources

Name of resource	Language	Source	About
The Vaccine safety communication eLibrary	Various	WHO	Open-source library of tools and resources for vaccine safety communication
Vaccine safety communication: Guide for immunization programme managers and national regulatory authorities	English	WHO Western Pacific Region	Guide for immunization programme Managers and national regulatory authorities
Vaccine safety basics learning manual	English	WHO	Manual to accompany eLearning course on vaccine safety basics . Guidance on communicating vaccine safety is covered in Module 6 (Communication, p. 145)
CIOMS Guide to vaccine safety communication	English	Council for International Organizations of Medical Sciences (CIOMS)	Recommendations for vaccine safety communication with a specific focus on regulatory bodies and authorities
Communicating risks and benefits: an evidence-based user's guide.	English	United States Food and Drug Administration, US Dept of Health and Human Services	Scientific base for effective communication
Vaccine safety communication library	English, Russian	WHO Regional Office for Europe	A library of guidance for national health authorities and others who communicate about vaccine safety
CERC Templates and tools	English	CDC CERC	Crisis and Emergency Risk Communication tools to help agencies prepare and communicate before, during, and after an emergency

Name of resource	Language	Source	About
<u>COVID-19. Guidelines for communicating about coronavirus disease 2019</u>	English	Pan American Health Organization & WHO Regional Office for the Americas	Guidance, principles and templates for risk communication in relation to COVID-19
<u>The COVID-19 risk communication package for healthcare facilities</u>	English	WHO Regional Office for the Western Pacific	Risk communication information, procedures, and tools for health care workers and healthcare facility management
<u>RCCE action plan guidance. COVID-19 preparedness and response</u>	English	WHO Global	Action plan for effectively with the public, engaging with communities, local partners and other stakeholders
<u>COVID-19 Vaccine Questions and Answers for Healthcare Providers</u>	Various	CANVAX	Answers to questions pertaining to COVID-19 vaccine safety prior to, and during the vaccines roll out to 1) facilitate scientific discussion between stakeholders, including front line health workers with potential vaccine recipients and 2) increase comprehension and transparency of information to facilitate acceptance and uptake of the vaccines
<u>CERC in an infectious disease outbreak.</u>	English	US-CDC	Discussion of principles of communication in an infectious disease outbreak

COVID-19 VACCINES:

SAFETY SURVEILLANCE MANUAL