COVID-19 Vaccines: Safety Surveillance Manual

Module: COVID-19 vaccine safety communication

Contents

Abbreviations

AACVS	African Advisory Committee on Vaccine Safety
ACE	Angiotensin-converting enzyme
ADEM	Acute disseminated encephalomyelitis
ADRs	Adverse drug reactions
AEFI	Adverse event following immunization
AESI	Adverse event of special interest
ARDS	Acute respiratory distress syndrome
AVSS	Active vaccine safety surveillance
CEM	Cohort event monitoring
CEPI	Coalition for Epidemic Preparedness Innovations
CIOMS	Council for International Organizations of Medical Sciences
COVID-19	Coronavirus disease 2019
DCVMN	Developing Countries Vaccine Manufactures Network
DL	Data linkage
DNA	Deoxyribonucleic acid
EH	e-Health
EPI	Expanded programme on immunization
GACVS	Global Advisory Committee on Vaccine Safety
GBS	Guillain-Barré syndrome
GVAP	Global vaccine action plan
HCW	Health care worker
ICD	International classification of diseases
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
ISoP	International Society of Pharmacovigilance
ISRR	Immunization stress-related response
MAH	Marketing authorization holder
MedDRA	Medical dictionary for regulatory activities
MH	m-Health
MoH	Ministry of Health
mRNA	Messenger RNA
NIP	National Immunization Programme
NITAG	National Immunization Technical Advisory Group
NRA	National regulatory authority
PBRER	Periodic benefit-risk evaluation report
PHEIC	Public health emergency of international concern
PLSS	Post-licensure safety studies
PSUR	Product safety update report
PV	Pharmacovigilance
QPPV	Qualified person responsible for pharmacovigilance
RITAG	Regional Immunization Technical Advisory Groups
RMP	Risk management plan
RNA	Ribonucleic acid
SAGE	Strategic Advisory Group of Experts (for immunization)
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SKG	Significant knowledge gap
SIA	Supplementary immunization activities
SS	Sentinel surveillance
TGA	Therapeutic Goods Administration (Australian Ministry of Health)
VAED	Vaccine-associated enhanced disease
VLP	Virus-like particles
VPD	Vaccine preventable disease
WHO	World Health Organization

Glossary

Adjuvant	A pharmacological or immunological agent added to a vaccine to improve its immune response.
Adverse event following immunization (AEFI): general definition	Any untoward medical event that follows immunization and that does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.
• AEFI by cause: coincidental events	• An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety.
• AEFI by cause: immunization anxiety-related reaction	• An AEFI arising from anxiety about the immunization (see immunization stress related responses).
• AEFI by cause: immunization error-related reaction	• An AEFI that is caused by inappropriate vaccine handling, prescribing or administration, that, therefore, is preventable.
• AEFI by cause: vaccine product-related reaction	• An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product, whether the active component or one of the other components of the vaccine (e.g. adjuvant, preservative or stabilizer).
• AEFI by cause: vaccine-quality defect-related reaction	• An AEFI that is caused or precipitated by a vaccine due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer.
Adverse event of special interest (AESI)	A preidentified and predefined medically-significant event that has the potential to be causally associated with a vaccine product that needs to be carefully monitored and confirmed by further specific studies.
Causal association	A cause-and-effect relationship between a causative (risk) factor and an outcome. Causally-associated events are also temporally associated (i.e. they occur after vaccine administration), but events that are temporally associated may not necessarily be causally associated.
Causality assessment	In the context of vaccine AEFI surveillance, a systematic review of data about the AEFI case(s) to determine the likelihood of a causal association between the event and the vaccine(s) received.
Cluster	Two or more cases of the same or similar events related in time, geography (place), and/or vaccine administered. AEFI clusters are usually associated with a particular supplier/provider, health facility, and/or a vial of vaccine or a batch of vaccines.
Contraindication	A situation where a particular treatment or procedure, such as vaccination with a particular vaccine, must not be administered for safety reasons. Contraindications can be permanent (absolute), such as known severe allergies to a vaccine component, or temporary (relative), such as an acute/severe febrile illness.
Immunity	The ability of the human body to tolerate the presence of material 'indigenous' to the human 'body' (self) and to eliminate 'foreign' (non-self) material. This discriminatory ability provides protection from infectious diseases since most microbes are identified as foreign material by the immune system.
Immunization	Immunization is the process whereby a person is made immune or resistant to an infection, typically by the administration of a vaccine. Vaccines stimulate the body's own immune system to protect the person against subsequent infection

Immunization safety	The process of ensuring the safety of all aspects of immunization, including vaccine quality, adverse event surveillance, vaccine storage and handling, vaccine administration, disposal of sharps and management of waste.
Immunization safety surveillance	A system for ensuring immunization safety through detecting, reporting, investigating, and responding to AEFI.
Immunization stress related responses (ISRR)	Stress response to immunization that may manifest just prior to, during, or after immunization.
Injection safety	The public health practices and policies dealing with various aspects of the use of injections (including adequate supply, administration and waste disposal) so that the provider and recipient are not exposed to avoidable risks of adverse events (e.g. transmission of infective pathogens) and creation of dangerous waste is prevented. All injections, irrespective of their purpose, are covered by this term (see definition of safe injection practices).
Mass vaccination campaign	Mass vaccination campaigns involve administration of vaccine doses to a large population over a short period of time.
Non-serious AEFI	An event that is not 'serious' and does not pose a potential risk to the health of the recipient. Non-serious AEFIs should also be carefully monitored because they may signal a potentially larger problem with the vaccine or vaccination or have an impact on the vaccination acceptability; in general.
Risk management plan (RMP)	A risk management plan is a document that describes the current knowledge about the safety and efficacy of a medicinal product. The RMP provides key information on plans for studies and other activities to gain more knowledge about the safety and efficacy of the medicine or vaccine. It also describes measures to be undertaken to prevent or minimise risks associated with the use of the product in patients.
Safe injection practice	Practices that ensure that the process of injection carries the minimum of risk, regardless of the reason for the injection or the product injected.
Serious AEFI	An event that results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. Any medical event that requires intervention to prevent one of the outcomes above may also be considered as serious.
Severe vaccine reaction	Vaccine reactions can be mild, moderate or severe. Severe reactions may include both serious and non-serious reactions.
Signal (safety signal)	Information (from one or more sources) that suggests a new and potentially causal association, or a new aspect of a known association, between an intervention and an adverse event or set of related adverse events, that is judged to be of sufficient likelihood to justify verification.
Surveillance	The continual, systematic collection of data that are analysed and disseminated to enable decision-making and action to protect the health of populations.
Trigger event	A medical incident following immunization that stimulates a response, usually a case investigation.
SAGE Values Framework	Values Framework, developed by WHO's SAGE, offers guidance globally on the allocation of COVID-19 vaccines between countries, and guidance nationally on the prioritization of groups for vaccination within countries while COVID-19 vaccine supply is limited
Vaccine	A biological preparation that elicits immunity to a particular disease. In addition to the antigen, it can contain multiple components, such as adjuvants, preservatives, stabilizers, each of which may have specific safety implications.

Vaccine-associated enhanced disease (VAED)	Vaccine-associated enhanced diseases are modified and severe presentations of clinical infections affecting individuals exposed to a wild-type pathogen after having received a prior vaccine against the same pathogen.
Vaccine pharmacovigilance	The science and activities relating to the detection, assessment, understanding and communication of AEFI and other vaccine- or immunization-related issues, and to the prevention of untoward effects of the vaccine or vaccination.
Vaccination failure	Vaccination failure can be defined based on clinical endpoints or immunological criteria, where correlates or surrogate markers for disease protection exist. Primary failure (e.g. lack of sero-conversion or sero-protection) needs to be distinguished from secondary failure (waning immunity). Vaccination failure can be due to (i) failure to vaccinate, i.e. an indicated vaccine was not administered appropriately for any reason or (ii) because the vaccine did not produce its intended effect
Vaccine reaction	An event caused or precipitated by the active component or one of the other components of the vaccine. It may also relate to a vaccine quality defect.
Vaccine safety	The process that maintains the highest efficacy of, and lowest adverse reaction to, a vaccine by addressing its production, storage and handling. Vaccine safety is a part of immunization safety.

1. 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 or 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 appendices at the end of this document:

- Appendix A: Spectrum of vaccination intentions for COVID-19 vaccines
- Appendix B: Managing negative messages (misinformation and anti-vaccine activists)
- Appendix C: Development of a COVID-19 vaccine safety communication plan
- Appendix D: Planning and preparing COVID-19 vaccine safety communication
- Appendix E: Guidance on social listening
- Appendix F: Development of evidence-based messages
- Appendix G: Responding to the needs of the media
- Appendix H: Communication on social media
- Appendix I: Frequently Asked Questions
- Appendix J: General resources.

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; detailed guidance is available here [placeholder for link to IVB group doc].

2. Factors influencing vaccine safety perceptions

Factors influencing vaccine safety perception include messages about vaccine safety and the communication environment, cultural and religious influences and expectations created by political leaders. See Appendix A for a more details about these factors and additional resources.

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 vaccination efforts in most countries, particularly those in high-risk jobs, such as healthcare 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.

Results from population-based polls and surveys early in the pandemic indicate intentions to have a hypothetical COVID-19 vaccine among adults. Intentions ranged from 87% in Australia to 37% in Poland. Intentions *not* to be vaccinated ranged from 44% in Turkey to 2.6% in China.[1] Studies describe individual factors associated with lower vaccination intentions including lower education and health literacy levels[2], lower income and young or old 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, some individuals may change their intention over time.

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

Vaccination intention	Communication goal	Vaccine safety perceptions
Anti-vaccine activist	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 managing vaccine safety issues well.	A minority will intend to reject COVID-19 vaccination, often based on safety concerns, however other factors such as experience, perceptions and values could be involved.

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[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.

Vaccination intention	Communication goal	Vaccine safety perceptions
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 a COVID-19 vaccine[4,5,6,7] 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 the vaccination programme. Hesitancy is dynamic and can be influenced by communication with a trusted healthcare 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.
Demander	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.
Advocate	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.[8]

48   *VSN: Vaccine Safety Net, a global network of websites facilitating the access to reliable vaccine
49   safety information[9]

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[4] 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.

[5] 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.

[6] Barello S, Nania T, Dellafiore 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.

[7] 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.

[8] 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.

[9] 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 information[10]
- disinformation – false information, purposely shared to mislead others[10,11]
- conspiracy theories – explanations that allude to the hidden influence of powerful people[12]
- fake news – fictitious information that imitates genuine news. [10]

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.[13,14,15,16,17] Viewing content that is critical of vaccines (even briefly) has been shown to increase people's perceptions of vaccines as risky[18]; and exposure to negative claims has been shown to decrease people's certainty about the safety of vaccines.[19] However, the environment can also influence how people respond to negative messages. See Appendix B for detailed guidance on managing negative messaging.

[10] 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

[11] Wardle C, Derakhshan H. Information disorder: toward an interdisciplinary framework for research and policy making, Council of Europe; 27 September 2017. Available fromm: https://rm.coe.int/information-disorder-toward-an-interdisciplinary-framework-for-researc/168076277c. Accessed 24 October 2020

[12] 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.

[13] 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.

[14] Suppli CH, Hansen ND, Rasmussen M, Valentiner-Branth P, Krause TG, Mølbak 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.

[15] 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.

[16] 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.

[17] Hansen PR, Schmidtblaicher 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.

[18] Betsch C, Renkewitz F, Betsch T, Ulshofer C. The influence of vaccine-critical websites on perceiving vaccination risks. J Heal Psychol. 2010;15(3):446–55. doi: 10.1177/1359105309353647.

[19] 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.

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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 have been described extensively.[20]

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.[21]

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.[22,23,24,25] People with shared values and beliefs may exist in tight-knit communities where ideas spread readily. For example, a religious or community leaders with negative views on COVID-19 vaccine safety would be capable of changing the beliefs of those in their network.[26] 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 efforts, can 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.[27,28]

Organisational 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 government communication about vaccine safety.

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20 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.

[21] 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.

22 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.

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[24] 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.

[25] Wiley KE, Leask J, Attwell K, Helps C, Degeling C, Ward P, 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.

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[27] Shadmi E, Chen Y, Dourado I, Faran-Perach I, Furler J, Hangoma P, et al. Health equity and COVID-19: global perspectives. Int J Equity Health. 2020;19(1):104. doi: 10.1186/s12939-020-01218-z.

[28] 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.

Vaccination services

Negative previous experiences with health services may influence acceptance in adults.[29] Delivery of vaccination in large-scale clinics increases the chance of a clustered immunization stress-related response, where two or more vaccinees experience 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. Over-confident communication could lead to mistrust if expectations are not met.[30,31] 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.

3.   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 C.

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.[32] The VSN was established to counterbalance websites providing 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.

[29] Wheelock A, Parand A, Rigole B, Thomson A, Miraldo M, Vincent C, et al. Socio-psychological factors driving adult vaccination: a qualitative study. PLoS One. 2014;9(12):e113503. doi: 10.1371/journal.pone.0113503.

[30] 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

[31] 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.

[32] Vaccine Safety Net. Available at: https://www.vaccinesafetynet.org/. Accessed 23 October 2020

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 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 C and Appendix D for more detailed guidance.

3.2. Set up lines of communication

Preparations should include setting up lines of communication with influencers and mobilisers, 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 D 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 can 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. [33]

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

3.3. Identify potential threats to confidence in vaccine safety

Various COVID-19 vaccine-related events can occur that may negatively influence perceptions of vaccine safety. These may include publication of new data on COVID-19 vaccines, events such as a temporary vaccine suspension or recall, adverse events, negative messaging in the media, and community attitudes and beliefs. Identifying potential threats and monitoring for them will help plan how, when, what to communicate, and to whom. This is part of planning to communicate early and often (see case study below). See Appendix D for more detailed guidance.

> **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.[34] 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 - to 7-fold in adults.[35] Subsequent investigations indicated a possible genetic basis in affected individuals for this adverse event.[36,37]
>
> Sweden was the country with the most narcolepsy cases were reported, where there was high Pandemrix vaccination coverage rates, with 60% of the population vaccinated against H1N1.[38] Initial communications about the vaccine had strongly emphasised 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.[39]
>
> There were several key lessons learned in terms of communication from these events. 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.[39,40]

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[34] 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

[35] 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.

[36] 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.

[37] 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.

[38] 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.

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

[40] 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.

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; to identify community influencers and trusted sources; and to detect negative messaging and anti-vaccine activity. These insights may be specific to contexts and locations. Listening should be a continuous activity, as people's concerns and information needs will change as the pandemic evolves and as vaccines are deployed. 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 E for more detailed guidance.

Case study: Listen to community feedback—Guinea, 2014

In June-July 2014, the local population of a region of Guinea did not trust international teams deployed to try to control the Ebola outbreak, which hindered containment efforts. External agencies nominated community spokespeople, based on their assumed standing in the community. 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. [41]

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[41] 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.[42] Use these principles 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, without withholding any, even when the facts are yet to be fully established.[43] The assumption that the public will panic if they have access to accurate information in a crisis is not supported by evidence.[44] 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 specifics of an 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 general public. For example, describing how vaccines are tested and then monitored for safety. It is important to pay attention to health literacy when developing statements and materials.[45] 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.[46] 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.[47] See Appendix F for further information.

Accept and acknowledge uncertainty: Convey uncertainty about vaccine safety, when it exists, in a way that avoids over-confidence 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.[48] Identify likely scenarios the public may need to consider 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

[42] 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.

[43] 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.

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

[45] 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. Preprint available at: https://www.medrxiv.org/content/10.1101/2020.06.03.20121814v1.

[46] 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

[47] 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.

[48] 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.

193 be forthcoming with information as it becomes available. Leaving an information vacuum will allow
194 others with lower quality information or misinformation to fill it. Keep the public updated about
195 actions being taken by governments, in the event of possible adverse events following immunization
196 (AEFIs). If information is evolving, be transparent and say that. Partnering with the media can help to
197 disseminate information quickly and get key messages to the public. Social media may offer a useful
198 means of providing brief, frequent, and real-time updates, and can signal willingness to readily share
199 information.

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

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

> **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 increase in the 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 alternate brands re-commenced.[49] The scare affected confidence
> in paediatric influenza vaccination and vaccination rates dropped in 2010 from 45.5% in 2009 to
> 7.9% in one Australian state that had a funded programme.[50] 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.[51,52]
> Lessons learnt from this incident include:
> - the need for public health authorities to be proactive during a vaccine safety incident and
>   engage with both parents and providers;
> - the need to give a name to the adverse event as 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

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[49] 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.

[50] 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.

[51] 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.

[52] Blyth CC, Richmond PC, Jacoby P, 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.

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- 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 heath experts provided via government health websites, childcare centres and schools. [51]

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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. Data should be clearly presented with the addition of visuals to clarify text. The messages should include positive narratives to model vaccinating behaviour. People should be provided with specific actions they can do to reduce harms. The messages must be consistent, although they should be tailored to specific audience needs. These messages will also be useful when developing resources for advocates and other communicators. See Appendix F for more detailed guidance.

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 that 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.[53] 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.[54]

A study of trust in government and H1N1 vaccination intent found that discussion by President Obama of his daughters' H1N1 vaccination particularly, 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 seen rather as an example of a father trusting in the vaccine for his children.[55] A subsequent photo of President Obama with rolled up sleeve about to receive the H1N1 vaccine provided an additional powerful positive role model image.[54]

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1.   [53] Centers for Disease Control and Prevention. 2009 H1N1 Flu Vaccine. 2010. Available from: https://www.cdc.gov/h1n1flu/vaccination/. Accessed 24 October 2020.

[54] 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.

[55] 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. Biosecur Bioterror. 2013;11(2):96-106. doi: 10.1089/bsp.2012.0048.

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

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[56] 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.

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.

See Appendix H for more detailed guidance.

> ### Case study: Using an authentic, personal approach via social media —Denmark, 2017
>
> 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.
>
> 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.[57]
>
> 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.[58,59]

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[57] 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..

[58] 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.

[59] 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.

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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 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. It is important not to assume these negative sentiments is simply misinformation or other types of negative messages coming from anti-vaccine and other activists. It is recommended to respond with compassion by acknowledging and informing people with concerns.

Listening will help 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 factual information and content that triggers 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 ensure your website provides reliable, timely, accurate and evidence-based information on vaccine safety. See Appendix H 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 the real questions people have. See Appendix I for more detailed guidance.

Criteria for prioritizing responses to vaccine safety issues

It is inevitable that 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 many arise. 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 is essential. Misdiagnosing people's safety concerns as mere 'anti-vaccination' can lead to harms at a population and clinical level 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

23

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

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

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

315 **The confidence of HCW is likely to be affected**. Vaccine safety concerns that amplify existing
316 hesitancy in HCWs or trigger new concerns require a rapid response. Confident, committed HCWs
317 are vital for the success of vaccination programmes. In the case of COVID-19 vaccines, HCWs are
318 both recipients and recommenders of the vaccine.

319 **The issue or event touches on moral foundations** that are highly correlated with vaccine
320 acceptance. Claims that touch on moral foundations associated with vaccine rejection may be more
321 salient. Those found to have the strongest correlation with vaccine rejection include claims about
322 the vaccine ingredients (purity/degradation) or where there is some level of coercion in vaccine
323 programmes, either real or perceived (liberty).[60,61]

324   − **Hypothetical scenarios**

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

327

[60] 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.
[61] 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.

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 the 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 I 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 I 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 I)
- the role of phase II and II trials the evaluation of vaccine safety (see Appendix I)
- 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 their 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 H 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 I 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 production.

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 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"* .

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 H for more guidance on managing negative messages.

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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 complain of headaches and dizziness after the vaccine was given, and some faint. The issue is 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 E). 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 F). Work with the media to disseminate information (see Appendix G). Engage audiences on social media, and counter negative messages as appropriate (see Appendix H and Appendix I).

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 C 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.

329

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. 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 E). 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 COVIID-19 vaccine safety. Confirm that messages are consistency with vaccine safety partners (see Appendix F).

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 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 E). 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.

330

331 # 4.   Appendices and additional resources

332

333 ## 4.1. Appendix A: Spectrum of vaccination intentions for COVID-19 vaccines

334 The spectrum of vaccination intentions to receive a COVID-19 vaccine appears in Figure 1. This
335 representation adapts other work in the area, for example the WHO spectrum of positions on
336 childhood vaccination.[62] The figure accounts for emerging studies on COVID-19 vaccine intentions,
337 issues known to be unique to new vaccine programs, and experiences with past pandemic and
338 epidemic vaccines (e.g., H1N1 and polio). This figure serves as a diagrammatic rather than
339 proportional representation of motivational states, which will be highly dependent on context.

340 Figure 1. Spectrum of intentions related to COVID-19 vaccines.

341

342 **Further resources**

Name of resource	Language	Source	About
CERC: Psychology of a Crisis	English	CDC, US DHHS	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	Vaccine Virtual Days	Assessing vaccine safety and confidence in the COVID-19 era (access available on request).

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[62] World Health Organization. Report of the SAGE Working Group on vaccine hesitancy. 01 October 2014.
https://www.who.int/immunization/sage/meetings/2014/october/1_Report_WORKING_GROUP_vaccine_hesitancy_final.pdf

Immunization stress related responses	English	WHO Health Product Policy and Standards	Guidance for prevention, identification and response to stress-related responses following immunization.

4.2. Appendix B: Managing negative messages (misinformation and anti-vaccine activists)

Responding to negative messaging will be a key communications activity[63], but 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 monitor the popularity of negative messaging to timely inform a 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 point the negative message has reached you, it has been decontextualized, lacking key details about where and why it was spread and by whom and why. Attempt to track down details that help clarify the content of the message as well as why it may have gained resonance, 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.

- 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 doesn't 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 assistance 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 organisation 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.

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[63] 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.

381 - **Emphasize factual information** when refuting negative messaging. Too much focus on the
382 misinformation may strengthen the falsehood in people's memories.

383 - **Create content that triggers positive emotions**, such as the health benefits of vaccines. This type
384 of content is important to counteract negative messaging on vaccines based on emotional
385 values, and will complement information based on data and evidence.

386 - **Emphasize scientific consensus** ("90% of clinicians agree that this vaccine is safe…")

387 - **Warn the audience** by explicitly signposting repeated misinformation. ("There are many myths
388 about COVID-19 vaccine safety. This myth, for example, is about…")

389 - **Explain why the misinformation is incorrect** and if possible provide an alternative explanation.
390 This is more effective than simply saying something is incorrect. Provide links to reputable
391 sources where appropriate.

392 - **Expose any flawed arguments** by pointing out the techniques the person spreading the negative
393 message is using, such as selective use of evidence, using fake experts, referring to conspiracy
394 theories, false logic, etc.

395 - **Avoid hostile interactions** with anti-vaccine activists. If you engage in arguments, you may be
396 signalling to your audience that there is dispute around what you are saying.

397 - **Don't refer to activists using imprecise collective nouns**, i.e. "the anti-vaccine community" or
398 "anti-COVID-19 vaccine groups". This can imply they are larger and more organised than they
399 really are, may confer them more perceived power and influence, and garner them more
400 followers. If necessary, refer to activists as individuals ("Joe Bloggs has posted this falsehood
401 about…").

402 **Further resources**

Name of resource	Language	Source	About
The Debunking Handbook	English	J Cook, S. Lewandowsky	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: Mythbusters	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.

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4.3.   Appendix C: Development of a COVID-19 vaccine safety communication plan

A vaccine safety communication plan does not eliminate risk, but will help 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.** Any response 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 enact 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 challenging 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. Healthcare workers will also be influential in the dissemination of vaccine safety information. They may need training; guidance on interpersonal communication will help them 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

448 target groups who are not easily reached through these channels. Strategies may include access
449 through immunisation providers and community health workers, social mobilizers, and civil
450 society organisations.

451 - **Seek input from key stakeholders** when developing your vaccine safety communications plan,
452 especially those representing audiences who have specific information needs or concerns, i.e.
453 older people, healthcare workers.

454 - **Agree on procedures to coordinate information dissemination** with partners, including who
455 releases what, when, and how. This may be led by government. Clarify approval processes,
456 especially if information needs to be disseminated quickly in event of a crisis.

457 - **Create contact lists** of key individuals in your organisation, the media and strategic partners.

458 - **Create key messages and communication materials** to disseminate through the planned
459 communication channels. These might be developed in anticipation of identified threats
460 occurring and include holding statements (a brief, simple statement that acknowledges an event
461 such as a safety signal, helps avoid 'no comment' responses), template media releases,
462 Frequently Asked Questions (for example explaining vaccine safety concepts like AEFIs or AESIs),
463 and talking points for spokespeople.

464 - **Determine training needs**, for example media and de-escalation training for spokespeople, who
465 often can become the focus of public anger and concerns and must perform well under pressure
466 to be effective. Healthcare workers will also be on the frontline of communicating about COVID-
467 19 vaccine safety. Supporting them with resources and training on how to have conversations
468 about vaccination can help improve their confidence and effectiveness as communicators.

469 - **Develop strategies to monitor and evaluate communications**. These may include evaluating the
470 effectiveness of communications, documenting challenges and lessons learned, identifying gaps
471 in skills and resources, and identifying any actions to improve communications in the future.
472 Evaluate communications using various tools, including social media listening, media monitoring
473 and monitoring at the community level via health workers, community-based mobilisers or social
474 mobilizers, seeking feedback from community and faith leaders, and civil society organisations.
475 Input from strategic partners will also be useful. Evaluation of communication activities including
476 effectiveness of vaccine safety communication could be integrated into vaccine Post-Introduction
477 Evaluations (PIE). Your evaluations should inform ongoing communications responses.

478 The Covid-19 safety communication plan should not be overly long. This plan will need regular
479 revision, especially after any vaccine related events to incorporate lessons learned and to keep
480 contact lists up to date.

481 **Further resources**

Name of resource	Language	Source	About
Guidance on developing communications plans			
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)
Decision tools for responding to vaccine-related events			
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)
Determining target audiences			
RCCE Action Plan Guidance. COVID-19 preparedness and response	English	WHO Global	Defining and prioritising your RCCE audiences and other stakeholders (p.20)
Training for spokespeople and other ambassadors			
SKAI eLearning module	English	NCIRS	Training for healthcare providers on conversations about immunisation with patients.
SKAI Resources for healthcare providers	English	NCIRS	Discussion guides and other resources to support healthcare providers' conversations about immunisation with patients.
Tips for spokespersons	English, Russian	WHO Regional Office for Europe	Principles for successful communication during a crisis.
Determining key communication channels			
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)
Evaluation			
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)
Preparedness checklists			

Name of resource	Language	Source	About
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 healthcare workers, influencers, the media and the public.
Other			
Crisis communication templates and tools	English	CDC CERC	A range of templates and tools to prepare and communicate during a crisis.

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4.4. Appendix D: 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. Thorough preparations will include (i) involving the communications team in vaccine safety work; (ii) establishing strategic partnerships; (iii) setting up communication pathways with the public; and (iv) identifying potential threats to confidence in vaccine safety. Developing a vaccine safety communications plan is covered in Annex C.

(i) Integrate communications into vaccine safety work

As soon as the organisation starts planning for and making decisions about vaccine safety work, the communications team* should be involved. This principle applies at all levels of organizations, from national to catchment area level. 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. Include vaccine safety risk communications considerations in preparedness assessments and planning meetings before the introduction of COVID-19 vaccines.

This approach will support effective communication that is 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 stronger understanding of and ability to communicate about technical aspects of vaccine safety.

*A range of people may be responsible for communications; in some countries, this may be the Expanded Programme on Immunization (EPI) Manager, in others a designated team under the head of the local COVID response, for example the Emergency Response Controller, or Public Health Lead. In some countries, a communication expert from a UN or a funded technical support organization prepares the communication plan, in partnership with the EPI manager.

(ii) Establish strategic partnerships

Establishing strategic partnerships with other vaccine safety stakeholders improves information sharing and coordination of vaccine safety information dissemination. Coordination will help reduce the possibility of disseminating contradictory 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)

− regulators

− UN bodies and other international organisations

− professional associations, for example representing health care providers or welfare associations working for elderly populations

− private sector organisations with a role in immunization, e.g. workplace immunisation, local extensions of pharmaceutical companies, vaccine manufacturers

− research scientists, and educational institutions at all levels

− nongovernmental organizations (NGOs)

522   –   religious organisations

523   –   community groups, e.g. representing key population groups such as culturally and
524   linguistically diverse communities, and those committed to vaccine advocacy

525   –   science journalists, the media, national science media centre if available

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

532 Activities between strategic partners will involve:

533   –   agreeing on shared communications objectives,

534   –   developing processes for sharing and coordinating information dissemination, for example
535   who releases what, when, and how,

536   –   standardizing messages, and

537   –   identifying and training spokespeople.

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

542 Respected public health voices can also provide comment to the media and offer a supportive
543 perspective. Certain partners, like community groups and healthcare providers, may act as
544 advocates, mobilisers, and peer educators for vaccine safety issues. Journalists and social media
545 influencers can be potential partners in information dissemination; their reports can have an impact
546 on public trust. Partnerships with the media are discussed in more depth below.

547 **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).
RCCE Action Plan Guidance. COVID-19 preparedness and response	English	WHO Global	Defining and prioritising your RCCE audiences and other stakeholders (p.20)

548

549 (iii) Set up communication pathways with the public

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

553 Public engagement means not just informing the public about vaccine safety, risks, and benefits, but
554 also continuously listening to people's concerns about vaccine safety, and actively engaging people in
555 dialogue.

556 Public engagement can be facilitated by:

557 — Offering multiple ways for the public to directly ask questions or raise concerns, for example
558 via public forums, website feedback forms, email, a hotline, online chat, or through social
559 media.

560 — Scheduling regular meetings with stakeholders, community and religious or cultural leaders,
561 health workers and others to provide a forum for discussing and addressing vaccine safety
562 concerns.

563 — Partnering with community influencers and mobilisers to disseminate information.

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

566

567 (iv) Identify potential threats to confidence in vaccine safety

568 Identifying potential threats to people's confidence in vaccine safety can guide how and with whom
569 to communicate, and will help shape messages down the track. In a COVID-19 vaccination safety
570 context, anticipated threats, sometimes called 'vaccine-related events', may include:

571 — adverse events following immunisation (AEFIs), either connected or perceived to be
572 connected with vaccination, or Adverse Events of Special Interest (AESIs)

573 — new scientific data on COVID-19 vaccines benefits and risks

574 — events such as a temporary suspension of a vaccine, vaccine recall, change in vaccine or
575 introduction of a new vaccine

576 — negative messaging, e.g. news and other media reports, misinformation, or the actions of
577 anti-vaccine activists, including social media

578 — community attitudes and beliefs, including any pre-existing vaccine hesitancy, may also
579 threaten confidence in COVID-19 vaccine safety.

580 — low acceptance of the COVID-19 vaccine that may affect confidence in other vaccines

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

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

588 **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

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590

4.5. Appendix E: 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 (See Section 9.3).

Listening using multiple data sources is essential to formulate a tailored response. Listening can help with the following:

– 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

– 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. If listening activities are insufficient, the understanding of audiences may be incomplete. 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 gaining traction

- **formative research** to gather insights directly from local populations. This is sometimes called a situational analysis; Tailoring Immunization Programmes describes the process in-depth. You can use a variety of methods such as interviews, focus groups, and observations. Your 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 for example 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

- **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. See below for more information on listening online and on social media.

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

633 Listening can be a time-consuming and expensive activity. If possible, earmark resources in the
634 communication plan to employ people with dedicated listening responsibilities. Share listening
635 insights with strategic partners to amplify collective listening capacity. Sharing can also help tune in
636 to a greater diversify of voices. Depending on available skills and resources, you may need to seek
637 external help to gather these insights.

638 Listening online and on social media

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

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

650 Here is some guidance for listening manually.

651 - **Generate a list of keywords and hashtags** relevant to COVID-19 vaccine safety. These may
652   change frequently.

653 - **Find out when particular keywords appear online** on web pages, in news, blogs, etc. by setting
654   up notifications via Google Alerts. You can receive these as it happens, daily, or weekly.

655 - **Track trending Google searches of keywords** by country via Google Trends. Set up weekly or
656   monthly notifications via 'Subscriptions'.

657 - **Search for keywords or hashtags on social media platforms** using platform search tools, for
658   example via Twitter advanced search or Reddit search. Facebook search allows exploration of
659   public posts in public groups or pages. Instagram search allows searching for people or hashtags.
660   Facebook, Instagram and YouTube are also searchable using Google.

661 - **Track multiple keywords or hashtags** using tools like social media aggregators, e.g. Tweetdeck
662   for Twitter. This will help partially automate monitoring.

663 - **Use free tools to search and analyse listening data. For example,** Onemilliontweetmap provides
664   a real-time geographic map of geolocated tweets with specific search terms or hashtags. Media
665   Cloud provides analysis of digital news media, including some social media shares. WhatsApp
666   monitor supports searching WhatsApp public groups in Brazil, India and Indonesia.

667 - **Generate a list of key individuals, groups, or websites** that may be useful to track. This might
668   include influential individuals, community groups or other groups representing target audiences.
669   For listening to negative messaging, develop a list of individuals, groups or websites that

670   generate or share misinformation or negative sentiment about COVID-19 vaccine safety. Track
671   these actors.

672 -   **See how often links have been shared** on Facebook, Instagram, Twitter and Reddit using Chrome
673   browser plugin [CrowdTangle Link Checker](). This tool also shows associated posts (limited to
674   public pages or accounts) and engagement data.

675 -   It is important to **work out how many people being reached by and engaging with messages of
676   interest**. Counting the number of messages posted on a particular topic gives a false impression
677   of message influence. People may be posting a large volume of messages on social media but
678   have hardly any followers, and therefore little influence. If an individual or page is posting
679   messages of interest, look at their number of followers to assess their influence. Look at the
680   number of people engaging with or sharing this message.

681   Note that the information gathered can be useful for understanding what people are saying about
682   vaccine safety on social media, but may or may not correspond with vaccination sentiment in any
683   population or groups more broadly, especially those who do not have digital access. Also use other
684   means of listening, such as monitoring mainstream media and community conversations.

685 **Further resources**

686 While many of these resources were designed for journalists, they contain relevant information
687 anyone listening on social media, including health authorities and other people working in vaccine
688 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.
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.

4.6. Appendix F: Development of evidence-based messages

Whether developing a media release, talking points for spokespeople, or a post for social media, it will be necessary to develop messages about COVID-19 vaccine safety.

Vaccine safety information 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 AEFI and AESIs. Through listening, it is possible to identify commonly asked questions to address.

Here are some tips from health communication research to help make these messages more effective and acceptable to your audiences. The next section provides specific scenario-based examples of good messages.

- **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 to 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'). ("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 avoid an over-emphasis on vaccine safety issues and unintentionally triggering concerns in people seeking other types of information.

- **Emphasize scientific consensus,** for example "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 information about specific actions they can do to reduce harms.** In uncertain situations, such messages can give people a sense of control. ("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[64]. For example, use frequencies (1 out of 100) rather than percentages (1%) or abstract terms ('common'). Use the same denominator when comparing risks. Use absolute, not relative risks.

- **Use illustrations and visuals.** Visuals can clarify text and data, but 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[65]. See this example about COVID-19 from Stanford Medicine.

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[64] Trevena LJ, Zikmund-Fisher BJ, Edwards A, 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-S7.
[65] 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).

725   -   **Use personal stories about vaccination and other messages that elicit emotion.** Negative
726   narratives about vaccine safety can have a powerful influence on how people perceive vaccine
727   risk. Positive, emotive narratives can help model vaccinating behaviour and are often more
728   memorable than factual information (WHO Europe, 2017). Narratives are effective for addressing
729   emotional issues and overcoming resistance[66]. See this example of President Obama receiving his
730   H1N1 vaccine in 2009. Social media users may want to share their own positive stories of
731   vaccination via your pages or posts; allowing them to do this also demonstrates trust in your
732   online community.

733   -   **Pre-test your messages** with representatives of target audiences and adjust as needed. How the
734   public responds to COVID-19 vaccine safety messaging may be unpredictable and not reflect
735   previous experiences.

736   -   **Consistency of messages is important**. Use and reuse the same messages in all channels and
737   platforms without much deviation to avoid confusion.

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[66] Cawkwell PB & Oshinsky D. Storytelling in the context of vaccine refusal: a strategy to improve communication and immunisation. *Med Humanit*. 2016; 42: 31-35.

738 **Further resources**

Name of resource	Language	Source	About
Guidance on developing messages			
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.
Tools for developing messages			
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.
Pre-prepared messages on vaccine safety			
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 (in various languages) 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.
Presenting data			
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, US Dept of Health and Human Services	Presenting quantitative data (p.53)
Reporting the findings: Absolute vs relative risk	English	Health News Review	Using absolute versus relative risk.

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4.7.   Appendix G: 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 (Habersaat 2020). 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; 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[67].

-   **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 in understanding and translating technical concepts.

-   **Identify potential spokespeople** from your organisation as early as possible, preferably as part of your communications plan, and organise media training to help you 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 to the media (see above). Be honest and open with information; don't minimise risks or make over-reassuring statements about COVID-19 vaccine safety; if you don't know the answer to a question, acknowledge the uncertainty and say what you're doing to find the answer. Don't refuse to answer or say 'no comment'.

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[67] 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.

773 **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 • 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: • 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.

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4.8. Appendix H: Communication on social media

Social media has significant potential for communicating about COVID-19 vaccine safety directly to the public[68]. 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 for you 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.

Decide which 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 they 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 vaccine target groups.

- **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 one platform over another or not at all. Choose language and content that matches the platform and speaks to audiences use of 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 involved and their interactions (number of visits and time spent in reading). Monitoring may be helpful to refine original messages and better 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 readily, 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.

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[68] Veil SR, Buehner T, Palenchar MJ. A Work-In-Process Literature Review: Incorporating Social Media in Risk and Crisis Communication. *J Contin Cris Man.* 2011;19(2):110–22

814   -   **Remember that many individuals may be cautious about making themselves publicly visible** on
815   social media. They may be 'silent', i.e. observing but not openly commenting, liking or sharing
816   posts[69]. Design messaging with this audience in mind, not just as a response to the most vocal
817   and active users on social media.

818   -   **Use an authentic, personal approach** rather than impersonal statements. If possible, post as an
819   individual with a first name rather than as an anonymous organisation. Social media users expect
820   human conversations with real people. Offer a way for social media users to connect to a live
821   human, whether through the chat function on a social media platform or connecting them to a
822   hotline.

823   -   **Amplify reach** to wide and diverse audiences using two-way communication. An active
824   community of followers can also help disseminate your posts. Paid posts or campaigns can also
825   be useful.

826   -   **Identify influential and credible users** who can help spread your messages. These might be for
827   example healthcare workers[70] or others with widely followed Facebook pages or Instagram
828   accounts that already act as trustworthy and influential sources of information.

829   -   **Interact with partners** to share information and increase your mutual credibility. Creating a
830   collective presence on social media will amplify balanced, pro-vaccine voices and can act as a
831   counterbalance to anti-vaccine voices.

832   -   **Allocate resources** specifically for social media in your communications plan. Listening and
833   regular interaction on social media requires substantial input. Dedicated social media staff will be
834   useful here.

835   -   **Make a policy of avoiding hostile interactions** to preclude being drawn into protracted dialogue
836   with anti-vaccine activists.

837   -   Use a considered approach when responding to negative messaging (see below).

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

841 **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.

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[69] 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.

[70] 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: 389-391.

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

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4.9. Appendix I: 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 the 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 test 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 find 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 many doses of the vaccine for those who need it. The government and researchers still monitors the safety of the vaccine while people are being vaccinated.

Researchers are following all these steps to develop COVID-19 vaccines and make sure they are safe. It might look like they are taking shortcuts, but 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 and government regulators are working together to check vaccine safety information from clinical trials more rapidly than before.

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 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. These might happen to someone by chance, or they might be caused by the vaccine. These are called 'Adverse Events of Special Interest' (AESI). 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 large numbers of people.

If researchers find any rare possible reactions, they do special studies to find out if the vaccine is causing them. If the studies show the vaccine is causing rare reactions, the government regulator will take action. This could include changing advice about how we use the vaccine, or rarely, stopping vaccinations. They look at benefits of the vaccine, as well as the risks, to make their decision.

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

884 COVID-19 can be a very serious disease. A vaccine will reduce the risk that you get the disease or pass
885 the infection on to others.

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

891 Anyone of any age can be infected and spread the virus to others. Vaccinations help stop the spread
892 of the virus, especially those more vulnerable to severe disease or dying.

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

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

896 RNA vaccines are a new vaccine technology. We have successfully used RNA to target cancer cells,
897 but using it to protect against infectious diseases like COVID-19 is new. RNA vaccines work differently
898 to traditional vaccines. Traditional vaccines use antigens from the virus or bacteria to train your
899 immune system to rapidly respond if you come into contact with them. RNA vaccines contain
900 instructions (or a code) that direct your body to make the disease antigen itself. Your immune system
901 then responds to that antigen by making protective antibodies against the disease.

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

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

907 Almost all COVID-19 vaccines in development are not 'live' vaccines. This means they don't include
908 any weakened form of the SARS-COV-2 virus that causes COVID-19. This means you cannot get
909 COVID-19 from the vaccine.

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

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

917 All COVID-19 vaccines will undergo stringent clinical trials, testing and quality checks before health
918 authorities approve them as safe to use.

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4.10. Appendix J: 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.
COVID-19. Guidelines for communicating about coronavirus disease 2019	English	Pan American Health Organization & WHO Regional Office for the Americas	Guidance, principles and templates for risk communication in relation to COVID-19.
The COVID-19 risk communication package for healthcare facilities	English	WHO Regional Office for the Western Pacific	Risk communication information, procedures, and tools for healthcare workers and healthcare facility management.
RCCE Action Plan Guidance. COVID-19 preparedness and response	English	WHO Global	Action plan for effectively with the public, engaging with communities, local partners and other stakeholders.

Name of resource	Language	Source	About
COVID-19 Vaccine Safety Answers document	English	CANVAX, member of VSN	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.
CERC in an infectious disease outbreak.	English	US-CDC	Discussion of principles of communication in an infectious disease outbreak

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