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**Accelerated Development of VAccine beNefit-risk
Collaboration in Europe**

Grant Agreement n°115557

**Deliverable 1.12
Developing communication strategies on vaccine
benefits and risks: Guidance for public-private
collaborations**

**WP1 – Best practice and code of conduct
for benefit-risk monitoring of vaccines**

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 ADVANCE IMI - 115557	Deliverable 1.12: Developing communication strategies on vaccine benefits and risks: Guidance for public-private collaborations		
	WP1. Best practice and code of conduct for benefit-risk monitoring vaccines	Version: 1 Final	
	Author(s): H Larson, E Karafillakis, A Yiangou, P Bahri, J Fogd, X Kurz, R Świerzewski, et al.	Security: Public	2/100

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ADVANCE vision is focused to deliver “best evidence at the right time to support decision-making on vaccination in Europe”. Our mission is to prototype a sustainable and compelling system that rapidly provides best available scientific evidence on vaccination benefits and risks post-licensure for well informed decisions. This will be achieved by developing and testing a code of conduct, rules of governance, technical infrastructures, data sources, methods, and workflows in a European network of stakeholders.

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DEFINITIONS

Participants of the ADVANCE Consortium are referred to herein according to the following codes:

- **AUH.** Aarhus Universitetshospital (Denmark)
- **AEMPS.** Agencia Española de Medicamentos y Productos Sanitarios (Spain)
- **ASLCR.** Azienda Sanitaria Locale della Provincia di Cremona (Italy)
- **CRX.** Crucell Holland BV (Netherlands)
- **ECDC.** European Centre for Disease Prevention and Control (Sweden)
- **EMA.** European Medicines Agency (United Kingdom)
- **EMC.** Erasmus Universitair Medisch Centrum Rotterdam (Netherlands)
- **GSK.** GlaxoSmithKline Biologicals, S.A. (Belgium) – EFPIA Coordinator
- **KI.** Karolinska Institutet (Sweden)
- **LSHTM.** London School of Hygiene & Tropical Medicine (United Kingdom)
- **OU.** The Open University (United Kingdom)
- **MHRA.** Medicines and Healthcare products Regulatory Agency (United Kingdom)
- **NOVARTIS.** Novartis Pharma AG (Switzerland)
- **PEDIANET.** Società Servizi Telematici SRL (Italy)
- **PFIZER.** Pfizer Limited (United Kingdom)
- **P95.** P95 (Belgium) - **Coordinator**
- **RCGP.** Royal College of General Practitioners (United Kingdom)
- **RIVM.** Rijksinstituut voor Volksgezondheid en Milieu * National Institute for Public Health and the Environment (Netherlands)
- **SP.** Sanofi Pasteur (France)
- **SP MSD.** Sanofi Pasteur MSD (France)
- **SSI.** Statens Serum Institut (Denmark)
- **SURREY.** The University of Surrey (United Kingdom)
- **SYNAPSE.** Synapse Research Management Partners, S.L. (Spain)
- **TAKEDA.** Takeda Pharmaceuticals International GmbH (Switzerland)
- **UNIBAS.** Universitaet Basel (Switzerland) - **Managing entity of the IMI JU funding**
- **UTA.** Tampereen Yliopisto (Finland)
- **WIV-ISP.** Institut Scientifique de Santé Publique (Belgium)


Grant Agreement. The agreement signed between the beneficiaries and the IMI JU for the undertaking of the ADVANCE project (115557).

Project. The sum of all activities carried out in the framework of the Grant Agreement.

Work plan. Schedule of tasks, deliverables, efforts, dates and responsibilities corresponding to the work to be carried out, as specified in Annex I to the Grant Agreement.


Consortium. The ADVANCE Consortium, comprising the above-mentioned legal entities.

Project Agreement. Agreement concluded amongst ADVANCE participants for the implementation of the Grant Agreement. Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement.

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EXECUTIVE SUMMARY

This report provides guidance for public-private collaborations (PPCs) on developing communication strategies on vaccine benefits and risks (BR), following a 4-step model. It is aimed at any institution part of a PPC that wishes to communicate new data or monitoring results about the BR of vaccines. It includes advice on defining the goals and objectives of a communication strategy (STEP 1), methods of mapping and engaging various stakeholders (STEP 2), developing the content and core components of the strategy (including selecting audiences, channels and messages) (STEP 3), and developing an implementation and monitoring plan (STEP 4). For each step, the report provides concrete examples as well as links to further resources. Detailed information is also provided about how to develop content for communication strategies related to BR and PPCs. Finally, two in-depth case studies based on the ADVANCE proof of concept study and the dashboard for monitoring vaccine BR are provided at the end of the report.

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1. Introduction


In the area of health protection, a strategic approach to communication was introduced in the 1980s with the objectives of strengthening health systems at population level and promoting healthy lifestyles and the use of healthcare services by individuals (1).

A specific area of health protection is pharmacovigilance, i.e. the safety surveillance and risk management of medicinal products with the overall aim of supporting safe use of medicines and preventing adverse patient outcomes due to exposure to medicines (2, 3). The need for effective communication in order to fulfil the aims of pharmacovigilance was globally acknowledged in the Erice Declaration of 1997 (4) and its follow-up publications (5-7). With a view to further progress, the strategic health communication approach was proposed for application in pharmacovigilance, including its integration with the risk assessment process (8).

Amongst medicinal products, vaccines are one of the most important product classes, used worldwide as highly effective interventions to control infectious diseases (9). For the implementation of vaccination policies, communication has always been an essential element (10-13). The need to communicate in the public domain more specifically about individual vaccine products, their effectiveness and safety profiles has developed more recently. This is related to an increasing public dialogue about vaccination and vaccines - on one hand in the context of the overall movement of shared decision-making in healthcare (14) and on the other hand because of vaccine hesitancy emerging in many countries worldwide (15). Most recently, the threats from the Ebola and Zika viruses have further increased public debate about vaccines. A major reason for vaccine hesitancy stems from concerns over their safety (15, 16) which often come with beliefs that vaccine-preventable diseases are not severe or cannot be easily transmitted. Given the globalisation of risk perception, a new model for vaccine risk communication has been called for, envisioning communication as an ongoing process for trust-building and managing of vaccine-related risks and risk perception (17).

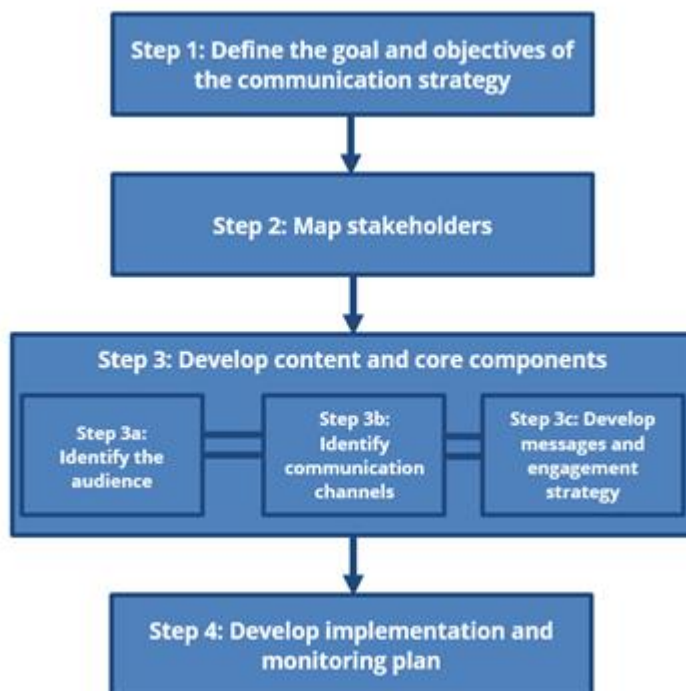
Hence, processes of benefit-risk (BR) monitoring of vaccines, including those applying methods for BR monitoring of vaccines as developed by the ADVANCE consortium for use in joint public-private undertakings (18), require communication processes. This report provides guidance for organisations part of public-private collaborations (PPCs) on developing communication strategies on vaccine BR. It includes advice on:

1. defining the goals and objectives of communication strategies (*see Step 1 in Figure 1 and section 2 of this document*)
2. methods of mapping and engaging various stakeholders (*see Step 2 in Figure 1 and section 3 of this document*)
3. developing the content and core components (including how to select appropriate audiences, channels, and messages) (*see Step 3 in Figure 1 and section 4 of this document*)
4. developing an implementation and monitoring plan (*see Step 4 in Figure 1 and section 5 of this document*)

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The report is structured according to those four steps that can be followed to develop communication strategies (Figure 1).


Figure 1: Steps of developing a communication strategy



This report finally provides two case studies (section 6) used to apply and test the steps described throughout the guidance. These case studies, coming from the ADVANCE project, include a proof of concept study about an electronic database and a dashboard presenting real time BR of vaccines. Small sections of what could be called “mock communication strategies” were developed by selecting a combination of different goals, target organisations, and communication audiences and channels.

1.1 Methods for the development of this report

This report constitutes deliverable D1.12 of the ADVANCE project: “*Developing communication strategies on vaccine benefits and risks: Guidance for public-private collaborations*”. It was developed using knowledge gathered for ADVANCE D1.4 (“*Analysis of public concerns and perceptions related to benefits and risks of vaccines*”) and ADVANCE D1.7 (“*Analysis of key issues and gaps about perception and knowledge on benefits and risks of vaccines*”). These deliverables explored public concerns about the BR of vaccines through a systematic literature review and media monitoring and analysis.

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Three reviews were also conducted to identify and map existing guidance documents on developing communication strategies. In a first instance, a review of research literature and experiences within the regulatory network of the European Union for medicinal products was performed by the European Medicines Agency (Annex B). LSHTM also coordinated a review of guidance documents used by ECDC's national immunisation focal points in EU Member States (Annex C). Finally, an overview of existing guidance documents on communication of BR of vaccines, including the report of the Working Group on Vaccine Safety of the Council for International Organizations of Medical Sciences (CIOMS), was compiled by LSHTM. Due to the abundance of existing guidance documents on the development of communication strategies, and to avoid duplicating this existing work, this report provides links to resources that provide more detailed information about specific areas.

All of these background studies and deliverables were used to develop a draft guidance which was presented during a joint public-private ADVANCE workshop and which was sent for consultation with all partners which were part of Working Group 1 of ADVANCE. Discussions and feedback received during the workshop and by email were used to revise the draft guidance and prepare the final report.


1.2 Scope

This guidance is for any institution (public health institutes, international health institutes, regulatory authorities, manufacturers, patient organisations, or academic research institutes) involved in a PPC on BR of vaccines. While some sections are common for all, other sections provide specific recommendations to different groups.

The guidance can be used to develop communication strategies when new information about vaccine benefits and/or risks comes out from PPCs. Any institution's communication team can apply it and adapt it to their existing communication strategies on vaccination. Once developed, some of the content or tools of the strategy will have to be regularly updated and adapted every time new information about a vaccine, safety concern, or BR monitoring result comes out. For instance, if a particular safety concern comes out related to the vaccination of pregnant women, the target audience, content, messaging and channels of communication would have to be adapted. Ideally, the strategy should therefore be designed in a way that allows adaptation to any situation.

1.3 System requirements for communication

A communication strategy needs a system in place to facilitate the professional and high quality development and implementation of the strategy, including the monitoring and evaluation of its activities. This includes the existence of a team of experts skilled in communication to coordinate and implement the different communication needs of organisation which should be addressed in the strategy. The CIOMS Guide on Vaccine Safety Communication provides recommendations to regulatory authorities on vaccine safety communication as part of vaccine pharmacovigilance. In addition to offering a communication

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plan template, the CIOMS report takes a clear position that a system must be put in place in order to professionally and at high quality prepare, implement and monitor/evaluate communication activities of a regulatory body.

More information about system requirements for communication strategy development can be found here:

- Council for International Organizations of Medical Sciences. CIOMS Guide to Vaccine Safety Communication. 2017. ([Link to document](#))

1.4 Developing a communication strategy from a user perspective

Communication is an iterative process that does not solely consist of messaging but also engaging with, and listening to the audience. Messaging activities part of communication strategies should be designed with an understanding of the audience's needs and expectations in order to achieve set goals and objectives. It is important to keep in mind that communication is about not only education or teaching but also, and mostly, about answering questions and needs raised by the public.

The user perspective should be taken into account from the development of the communication strategy until its implementation and evaluation. Additionally, if the strategy is communicating data based on a vaccine BR study or monitoring activity, the user perspective should also be incorporated into the design of these studies/monitoring activities. Figure 2 provides a schematic framework of the process of vaccine BR communication. It involves the process of BR monitoring, which goes from scoping to data gathering, assessment of results, and evaluation of a need for more monitoring analysis. Scoping will partly be influenced by the listening activities undertaken to explore the public's questions and needs. The listening process should make use of regular research reviews, media monitoring (in accordance with the D1.7 ADVANCE recommendations), and, if needed, direct stakeholder interactions. Messaging will also be influenced by those listening activities, from the design of messages and vaccination strategy to dissemination and evaluation of the communication strategy's goals and objectives. The framework therefore stresses the importance of linking the development of the communication strategy to BR monitoring as well as listening mechanisms aimed at understanding public knowledge and sentiments about vaccines.


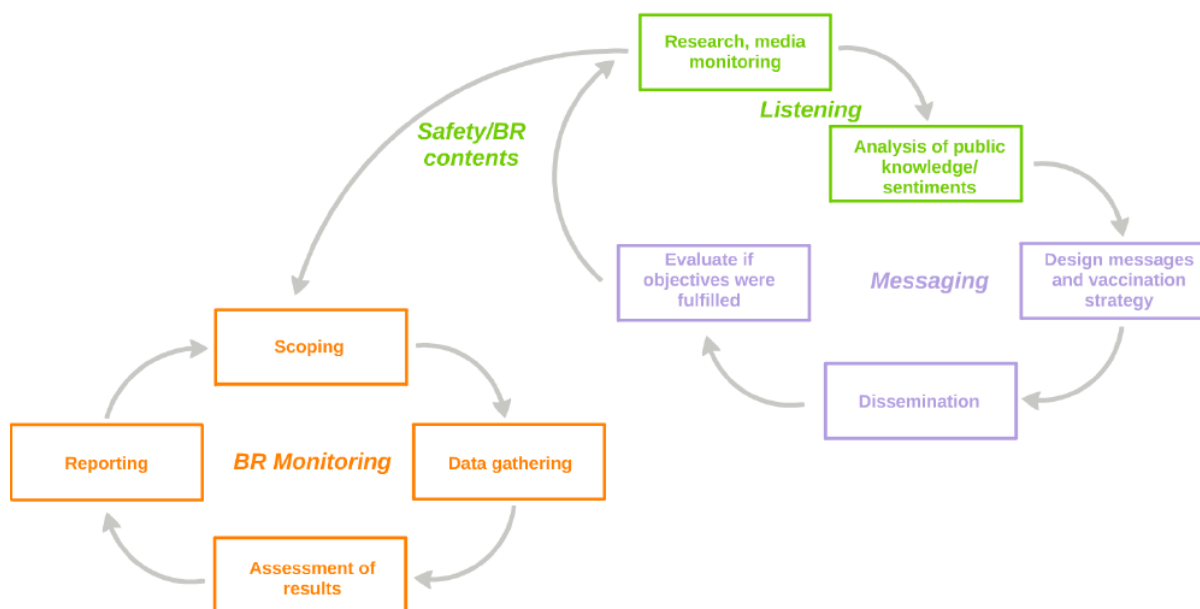
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Figure 2: A framework for the process of vaccines BR communication




Any communication activity also has to respect the public's interest in understanding how conflict of interests and bias are avoided in the BR monitoring, in particular given a context of a PPC. In the case of ADVANCE, this is achieved by referring in an understandable manner to the ADVANCE Code of Conduct and quality management processes (for more information, see sections 1.5 and 4.A).

1.5 The importance of building trust in PPCs

There is limited literature and data on public perceptions of PPCs. However, there is available literature on perceptions of the pharmaceutical industry, which reflect a state of distrust from the public. Public perception can be understood as the difference between an absolute truth based on facts and a virtual truth shaped by popular opinion. With the perception of the pharmaceutical industry being more negative than positive, building trust becomes increasingly difficult.

A study on British attitudes to the pharmaceutical industry stated that only 19% of those surveyed believed the industry to be 'trustworthy' (19). The study highlighted the public's concerns specifically about the industry being too profit-focused and not paying enough corporation tax. Additionally, there are beliefs of poor ethical standards on the interaction between doctors and pharmaceutical companies. Despite the low level of public trust in the pharmaceutical industry, there is a more positive perception of 'Joint Working' between the industry and the National Health Services (NHS) in the UK, with 45% in favour of the partnerships if there are clear benefits for the NHS. It should be noted that the survey did not state whether the subjects had experience working with PPCs or industry. However, when

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extrapolating from this information, PPCs themselves may invoke better perceptions from the public than the pharmaceutical industry working alone.

The study did however highlight an increase in concerns about ‘Joint Working’ in a sample that included NHS staff to 24% when compared to 17% in the general population. This disparity highlights the importance of trust building between the public and private entities involved in PPCs. Support from healthcare practitioners will also be important for building public trust in PPCs as public trust in hospitals, clinics and other medical care facilities is higher than trust in pharmaceutical and drug companies (20) and research has indicated that the level of trust in healthcare practitioners remains high (21). Consideration must also be given to the distrust practitioners have in the recommendations based on results from PPCs. As such, engaging and building trust healthcare practitioners should be a priority.


Building trust requires a delicate level of transparency. Whilst it is important to consider data protection for reasons of personal privacy of individuals, denying the public access from industry information and data can induce a sense of mistrust. Complete, objective and balanced information should be provided. People should be given the possibility to verify the information, for example by having access to the website of a trusted organisation or authority, and different channels providing the same message could be used. Hence, a balance between data protection and transparency must be identified. Furthermore, sharing information must be conducted in such a way as to avoid confusion, which in turn can lead to further mistrust. Increasing transparency in processes has been suggested as a tool to build trust (22). For example, this includes communicating the benefits of PPCs and how they ensure integrity and quality through strong governance models (including a code of conduct and quality management). Reassurance can also be provided when the public is aware of constant monitoring about the safety and benefits of vaccines.

More information about trust-building activities in communication can be found here:

- European Centre for Disease Prevention and Control. Communication on immunisation - building trust. Stockholm: ECDC; 2012. ([Link to document](#)) (23)
- YouGov. Report: British attitudes to the pharmaceutical industry. August 30 2013. ([Link to document](#)) (19)
- Calnan MW, Sanford E. Public trust in health care: the system or the doctor?. Quality and Safety in Health Care. 2004 Apr 1;13(2):92-7. ([Link to document](#)) (21)
- Edelman. 2016 Edelman Trust Barometer, Global healthcare sector trends. 2016 ([Link to document](#)) (20)

Benefits and risks of collaborations

Working Group 2 “Governance” of WP1 of ADVANCE has identified four main complementary roles of the public and private stakeholders in a PPC:


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- In terms of added values
 - more integrated and co-ordinated approach to public health needs
 - complementary use of existing resources and more particularly financial resources (funding), material resources (such as population, hospital or laboratory databases) and human resources (expertise and experience), and potential savings in using these resources
 - sharing of knowledge, good practice and information
 - co-ordination and mutual support between organisations.
- In terms of risks
 - risks for each individual organisation: public health institutes may be concerned by the perception of a loss of scientific independence if they collaborate with vaccine manufacturers, vaccine manufacturers may be concerned by their need to follow legal obligations and transparency rules as regards fund allocations; academic experts may be concerned by a potential loss of credibility and possible conflicts of interest with an advisory role to national and international bodies;
 - a complex and rigid structure may slow down the decision-making process and impact on working practices;
 - a complex and rigid structure may not be justified or necessary in terms of investment in time and resources;
 - conflicts between different perspectives and priorities and the time it takes to dissolve conflicts;
 - damage to reputation and waste of resources if the collaboration is unsuccessful;
 - loss of public trust.

Before entering into the collaboration, each partner needs to weigh the potential BR of their participation and, at the same time, consider how their participation will be communicated to the public, which will also help addressing the question of whether the participation can be justified. Although statements published by different participating organisations should not contradict themselves, they may take into account their specific status and possible role in the collaboration (see section 2, STEP 1). Given that lack of trust towards health authorities has also been reported (24), these should also consider how the communication could influence the trust of the public.

1.6 Clarifications on the terminology used in the guidance

Audience. Targeted individuals or communities that the strategy will aim to communicate with through various channels for listening and messaging.

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Benefit-risk (BR) monitoring of vaccines. Data collection, both quantitatively or qualitatively and through passive or active mechanisms, and their assessment for evaluating the benefits of a vaccine in relation to its risks concerning quality, safety or efficacy as regards patients' health or public health

Crisis communication strategy. Plan describing the communication activities of an organisation in times of crisis. A crisis is defined as an event that occurs unexpectedly, that may be outside of the organisation's control, that required an immediate response, and that could pose a threat to public health. This could include public loss of confidence in vaccines and consequential decrease in vaccine uptake.

Governance. Set of processes for interaction and decision-making among partners involved in a project.


Pharmacovigilance. Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem (2). In line with this general definition, underlying objectives of pharmacovigilance in accordance with the applicable EU legislation are 1- preventing harm from adverse reactions in humans arising from the use of authorised medicinal products within or outside the terms of marketing authorisation or from occupational exposure; and 2- promoting the safe and effective use of medicinal products, in particular through providing timely information about the safety of medicinal products to patients, healthcare professionals and the public. Pharmacovigilance is therefore an activity contributing to the protection of patients' and public health. [EU-GVP Annex 1 on Definitions].

Public Private Collaboration. An engagement of public and private organisations to work together in a project because of common interests in public health. The roles and responsibilities of each partner organisation are agreed and formalised through a contract agreement in accordance with legal mandates and requirements. This could be a short-term (study specific) or a long-term broader project. The responsibility for the project can be attributed to either one stakeholder (who will be the decision maker) or shared between two or more partners (through a steering committee with representatives from the partner organisations and defined voting rights). (Note: there is no widely accepted definition and 'partnership' is also used as synonym elsewhere). (For more information about Public Private Collaborations, including a detailed model, please see ADVANCE WP1 White Paper).

Stakeholders. Any individual (e.g. public, vaccines, carers, health professionals, opinion leader) or institution organisation (e.g., national regulatory authority, national public health institute, academic research institution or foundation, CRO, vaccine marketing authorisation holder, patient association and civil society organisation) who has interests in the benefits and risks of vaccines and vaccination programmes.

Standard communication strategy. Plan describing the communication activities of an organisation in normal times (not affected by a crisis).

Study. Detailed investigation carried-out to answer a well-defined research question on vaccine benefit-risk monitoring in post marketing settings.

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Trust/confidence. Belief in the reliability, honesty, sincerity, or ability of someone (individual or institution) or something (information, vaccine)

Users. The institutions that will be using this guidance document to develop their own communication strategies.

Vaccine hesitancy group. Members of the public that encourage the delay in acceptance or refusal of vaccines despite national recommendations from authorities and availability of vaccine services.

2. STEP 1: Defining the goal and objectives of the communication strategy


The first step in developing a communication strategy about the BR of vaccines is to define the goal and objectives of the strategy. Both the goal and objectives should be designed to be specific, measurable, appropriate, realistic and time-bound (SMART). They should answer the questions of *what the target audience should know and wants to know after reading the information communicated about the BR of vaccines, how they should act or behave, and why this is important*. For some institutions, the goals could for example include sharing information about the benefits of a vaccine in a particular population, or the more challenging goals of maintaining or changing beliefs¹ and/or behaviours about the BR of vaccines. However, every organisation is expected to have different communication objectives, influenced by their available resources, budget, timeframe, and most importantly overarching institutional goals and missions. The goal and objectives development will also depend on the context and the current perception of vaccine BR in the population. Examples of objectives for research organisations, manufacturers, patient organisations, public health institutes, and regulatory authorities have been listed and described at the end of this section.

Institutions in charge of the communication strategy will also have to identify baseline indicators against which to measure or assess the achievement of their goals and objectives. Quantitative indicators for behaviour change could include an increase/decrease in vaccination coverage rates, an increase/decrease in information-seeking behaviour, or changes in the content and/or frequency of discussions with healthcare professionals (for more information, please see section 5). If the goal of an institution is to maintain or change public beliefs and behaviours, they will also have to conduct formative research including surveys and/or qualitative research to evaluate public beliefs and behaviours before and after communication has taken place.

Objectives related to these goals can then be developed according to the different audiences targeted by the communication strategy. The objectives will also have to be specific to the type of channels, actions and interventions used to communicate, which will differ across

¹ Belief is to be understood here in its cognitive sense: a consistent mode of thinking bringing together what is known, unknown, uncertain, and felt. See below reference.

25. Connors MH, Halligan PW. A cognitive account of belief: a tentative road map. *Front Psychol.* 2014;5:1588.

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different audiences. All stakeholders involved in the development of the communication strategy (identified in step 2, see section 3) should review and contribute to the definition of the goals and objectives of the strategy.

More information about the development of goals and objectives for communication strategies which can be applied to BR of vaccines can be found here:


- Fischhoff B, Brewer N, and Downs J. Communicating risks and benefits: An evidence based user's guide. Food and Drug Administration, US Department of Health and Human Services; 2011. ([Link to document](#)) (26)
- Bahri P. Public pharmacovigilance communication: a process calling for evidence-based, objective-driven strategies. Drug Saf. 2010; 33: 1065-1079. ([Link to document](#)) (8)
- The Health Communication Capacity Collaborative. The P-Process: five steps to strategic communication. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health Center for Communication Programs, 2013. ([Link to document](#)) (1)

2.1 Research organisations

Research organisations include academic as well as non-academic institutes, such as database custodians. The overarching mission of research institutes will often vary from one country to the next, depending on the national structure and organisation of the research and educational system as well as on the nature and scope of the organisation. However, research institutes in the field of public health commonly strive to contribute to society by conducting research, translating research into policy and practice, engaging with the world and communicating the benefits of science, and/or improving health and health equity.

When communicating about the results of PPC studies on vaccine BR, research organisations will often address the scientific community (e.g. through scientific journal articles), policy makers, health authorities and politicians (e.g. through reports or policy briefs), and/or the public (e.g. through interviews with the media). Goals and objectives for the communication strategy will vary depending on the audience (and corresponding channel).

For instance, when communicating to the scientific community, the goals of researchers might include sharing evidence and scientific information about the BR monitoring of vaccines (including study methods and designs) to improve the general state of knowledge and trigger further research to fill identified gaps. However, when communicating to policy maker, health authorities, and politicians, the goal of researchers will primarily be to translate research findings about the BR monitoring of vaccines into changes in policy and practice (if required). This means providing the required knowledge and evidence to policy makers such as immunisation managers in order to improve indirectly the health of the public.

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Finally, researchers might communicate directly to the public, for instance by giving media interviews, or indirectly by contributing to the research and development of effective communication materials to be distributed by health authorities. In such cases, their goals would be to:


- listen to the public's beliefs, opinions, and attitudes about the BR of vaccines in order to respond and communicate with them more appropriately and reduce the impact of safety-related crisis or other vaccine-related concerns
- improve the public's knowledge about the BR of vaccines for individuals and for the population, and correct this knowledge if new/conflicting information comes out from monitoring studies
- maintain or change beliefs and behaviours related to the BR of vaccines when new information becomes available (e.g. improve confidence and coverage rates for a vaccine if the BR balance is maintained or improved)
- demonstrate trustworthiness of scientific information coming from PPCs, for instance by communicating about the study methods and designs

2.2 International organisations: the example of ECDC

International organisations have a pivotal role in communication of BR of vaccines and vaccine safety. Particularly in the eyes of the public, they often represent a respected and authoritative voice in public health and can influence knowledge, behaviours and beliefs of populations on a large scale. This section uses the example of ECDC, as the most relevant one within the EU and as a direct partner involved in ADVANCE, however other organisations such as WHO (for instance through GVSI), WHO-EURO) or UNICEF will also have distinct aims and objectives when communicating about vaccine BR.

ECDC has a mission to communicate current and emerging threats to human health posed by infectious diseases, which includes communicating about the BR assessment of vaccines. The BR assessment of vaccines through post-authorisation passive and active monitoring and specifically designed studies are needed to monitor vaccine and vaccination programme safety, effectiveness, reduction/change in disease burden and vaccination coverage in order to support public health decision-making. These assessments are also needed to support national campaigns on immunisation, communication to the public and respond to anti-vaccine arguments.

Based on previous research and audience segmentation, ECDC has identified a number of target audiences for its communication, including health professionals, policymakers, health communicators and journalists. The general population is not a direct target audience for ECDC in its communication activities; however, transparency and an obligation to make its information public remain important goals in everything ECDC does. Therefore, all stakeholders can have access to this public information and communications.

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Multiple studies show that in all EU countries, healthcare professionals are identified as the most important and trusted source of information for people on how to be protected from vaccine-preventable diseases. This is particularly true for parents, who have the most questions and concerns. The personal credibility of healthcare professionals and their positions of trust place them in a unique position to help support parents in understanding vaccination and choosing to get their children protected. The typical goals of an ECDC communication strategy on BR assessment of vaccines would therefore be to develop approaches to reach healthcare professionals through the scientific community and representative professional groups, and also to share information and best practice communication strategies within their networks of national focal points, to give support to national health communicators. In this way, ECDC can empower vaccine experts, communicators and other professional stakeholders with information and knowledge to improve their local level campaigns and activities, and to facilitate their response to anti-vaccine arguments. Similarly, ECDC is also involved in improving vaccine confidence among healthcare professionals in Europe.


In an age where public information is so readily available on the internet (and contradictory information is abundant), the public needs to be certain that the authorities are working collaboratively and with the public interest in mind and can be trusted as a key source of accurate information on issues such as BR of vaccines, public health decisions and preventive methods.

2.3 Manufacturers

One of the missions of vaccine manufacturers is to enable better protection of individual and community health throughout life through existing vaccines as well as those in development¹. Manufacturers can communicate vaccine and vaccine preventable disease related information directly to the general public through different channels (i.e. media, websites (institutional or not), leaflets).

Depending on their type and content (either product-related or only disease-related), communication pieces have to undergo strict procedures, regulations and review processes, specifically when related to promotional purposes. These efforts are in place to ensure information is accurate, scientifically fair and balanced (not misleading), factual, objective, comprehensive, evidence-based, and in line with indications issued by appropriate regulatory authorities (on-label) and with local recommendations for use (issued by national public health institutes). All communications must also be properly referenced with recent and reliable scientific resources in a clear and visible manner. For transparency purposes, the manufacturers' logo or vaccine trade name (if applicable) should be added in a visible way on all company-sponsored communications. Minimal safety profile information and up-to-date patient leaflets, subject to regulatory approval, are also mandatory integrated parts of all product-related communications.

¹ <http://www.vaccines-europe.eu/about-vaccines-europe/mission/>

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Manufacturers can also collaborate with health authorities, scientific experts, professional and patient associations to indirectly communicate to the general public about vaccine preventable diseases and vaccination. Any communication related to a manufacturer-sponsored event needs to go through the above review processes and rules.


Real-time communication during safety crisis is of particular importance for manufacturers. It represents a real challenge, especially when uncontrolled, often emotional driven news and messages are largely and repetitively delivered in the media. Such events can have a large impact on existing vaccination program, lowering vaccine coverage rates, and potentially leading to the re-emergence of diseases previously under control. The historical case of MMR vaccine and autism in the UK is an important example: it took several years and substantial resources to restore adequate vaccine coverage rates in the UK. Building trust is difficult and it takes much longer to be re-built than to be lost. Communication from manufacturers, due to its commercial entity, has often been perceived by the general public as untrustworthy, selective, falsified, and manipulated to serve the best interest of the industry.

With the ultimate objectives of addressing current vaccine hesitancy, restoring public trust in vaccines and maintaining the optimal benefits of vaccination programs, it is primordial that manufacturers and other stakeholders (academic research institutes, patient or healthcare professional organisations, public health institutes, international organisations and regulatory authorities) stand together and have solid and transparent collaborations to effectively communicate to the general public. Although it is not the vaccine manufacturer's main goal to address vaccine hesitancy (and communication objectives therefore cannot be provided as such here), it is an outcome of the manufacturer's responsibility of providing good communication.

2.4 Patient organisations

2.4.1. Profiles of patient organisations in relation to vaccines

Non-governmental, patient organisations have been developing in Europe since almost 70 years. Although they have different missions, goals, objectives, aims, resources, range of operation (local, national, international), and ways of functioning, they have two basic common features: governance structure (board, staff, and audit committee) and the reason for their establishment – unmet needs in specific or general area in healthcare (therapeutic, legal, care-providing, vaccines safety). Usually such organisations are created as a response to a society lacking treatment or vaccines programmes, to address gaps in healthcare legislations, to monitor patient needs, or to monitor and observe specific therapeutic areas or medicinal products and their influence on patient safety or general public safety with regard to vaccines and vaccination programmes. The majority of patient organisations operate at local or national levels and work in disease-specific areas, focused on patient needs and direct patient care. Depending on the diseases (non-communicable, infectious, or genetic) that dictate the goals and mission of organisations, each patient organisation is involved in health-prevention programmes that include vaccination programmes created and tailored for specific needs. For instance, the National Organisation for Cervical Cancer Prophylaxis (Bulgaria) have an anti-

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HPV vaccination programmes, while The Meningitis Research Foundation (UK) does research and advocacy on meningitis and septicaemia.

Besides local and national patient organisations there are also European organisations operating at an international level, and focusing on regulatory activities and cooperation with European Union institutions and agencies. Such organisations are established as associations of national or local organisations. They include, for instance: Alzheimer Europe (AE), EURORDIS - Rare Diseases Europe, European Cancer Patient Coalition (ECPC), the European Patient's Forum (EPF), the International Association of Patients Organisations (IAPO), or the European Heart Network (EHN).

As part of their activities, patient organisations also very often cooperate with national and international organisations for health professionals. These include the International Epidemiological Association (IEA), the European Federation of Immunological Societies (EFIS), the European Society for Paediatric Infectious Diseases (ESPID), or the European Society of Clinical Microbiology and Infectious Diseases (ESCMID).


It is important to notice, that some local organisations are also active at an international level, as they have programmes focused on developmental issues and cooperate with stakeholders from different countries. Each of these organisations can be a social (mainly patients) representative partner in a PPC. The majority of patient organisations are focused and active in specific diseases areas e.g. cancer, rare diseases, heart diseases, lung-pulmonary diseases, immunological diseases.

2.4.2. Communication strategies for patient organisations within PPCs with regard to vaccines benefit-risk monitoring

Patient organisations belong to the institutions with the highest developed communication strategies. Independently of range of operation, goals, specificity, through last two decades, they developed strong cooperation with different stakeholders representing every area of life (e.g. local SMEs, local shops, restaurants, big companies, industry, agriculture, technological, media). This led to the development of specific communications strategies to communicate with patients and the general public. Currently, patient organisations are considered as the main bridge between healthcare regulators or healthcare professionals and the general public or – between the pharmaceutical industry and patients as representatives of the general public.

In many scientific, healthcare projects, patient organisations are responsible for elaborating communication strategies to disseminate information to the general public. In this case, the primary task for patient organisation is to provide support and expertise in translation of highly technical, scientific information into lay language, easy to understand for the general public or specific social groups e.g. children, their parents.

The studies and research programmes in vaccines BR monitoring shall be regarded as of special interest for the general public. Therefore, patient organisations as well as healthcare professional organisations with their broad networks of communication channels, are important to spread information to the public.

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While developing the communication strategy within PPCs on vaccines BR studies, it is important to prepare a short analysis of patient organisations that could be involved in the development of such strategy, not only with regard to disease-specific activities, but also the communication capabilities of the organisation.


2.5 Public health institutes and health authorities

Public health institutes (PHIs) exist to protect and improve the nation's health and wellbeing. A major role of most PHIs is to contribute to the gathering of information on the effects of routine vaccination programmes. In some countries, PHIs are part of Ministries of Health, while in others they advise the government and national health authorities on BR of vaccination programmes. This information is firstly used for immunisation policy, but also to support action to local health organisations and/or to health professionals and the general public. The BR assessment of vaccines through post-authorisation passive and active monitoring and specifically designed studies are needed to monitor vaccine and vaccination programme safety, effectiveness, reduction/change in disease burden and vaccination coverage in order to support public health decision-making. Depending on each country organisation, communication to the public is done by PHIs or is a task of national or regional health authorities. PHIs (or national/regional health authorities) should make sure that the public understands the aims and goals of a vaccination programme from a public health perspective (in a population context rather than only an individual perspective). In the process of communication from PHIs to the public, sustainability of trust of the public in the PHI is very important. One of the important communication goals for PHIs is being transparent. By being transparent, knowledgeable and being clear about the ultimate goal of strengthening public health, trust can be increased. Regarding transparency, it is important to be very clear about each stakeholder's role during the BR assessment of vaccines as concerns about perceived or actual conflicts of interest exist, especially among the public. The evidence on how best to communicate this is however still limited. Regarding being knowledgeable, it is important to have scientific up to date data on BR of vaccines and to base PHI's opinion on evidence.

Target audiences for communication for PHIs may include health organisations, health professionals, policymakers, health communicators, the public, and the media.

Multiple studies show that in all EU countries, healthcare professionals are identified as the most important and trusted source of information on vaccination for parents. The personal credibility of healthcare professionals and their positions of trust place them in a unique position to help support parents in understanding vaccination and advising to get their children protected. To this end it is important that PHIs provide the tools and training required for health professionals to underline the importance of the programme and to ensure they have sufficient time, knowledge and skills to communicate and discuss vaccination with parents.

The typical goal of a PHI communication strategy on BR assessment of vaccines would be to support the development of approaches to reach these target audiences through the scientific community, representative (professional) groups, websites, leaflets, (social) media, and also to share information and best practice communication strategies within country-specific

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networks. In this way, PHIs can empower them with information and knowledge to improve the local level campaigns and activities, and to facilitate decision-making among the public.

In an era where public information is so readily available on the internet (and contradictory information is abundant), the public needs to be certain that the authorities are working collaboratively and with the public interest in mind and can be trusted as a key source of accurate information on issues such as BR of vaccines, public health decisions and preventive methods.

2.6 Regulatory authorities

2.6.1 Considerations on communication by regulatory authorities about vaccines


The competent authorities in EU Member States and the European Medicines Agency (EMA) publish information about the medicinal products they authorise and oversee in accordance with their legal mandate. This means they provide to the public information about their assessments of the BR balances of these products, both in terms of procedure, evidence base and outcome. This information is published for transparency and accountability versus the public, to marketing authorisation holders to support implementing legally required regulatory decisions, and to inform patients and healthcare professionals.

Specifically for the safety and safe use of medicinal products, communication is needed to achieve the overall quality objectives of pharmacovigilance, which have been defined by the EU good pharmacovigilance practices (EU-GVP Module I) as follows:

- complying with the legal requirements for pharmacovigilance tasks and responsibilities;
- preventing harm from adverse reactions in humans arising from the use of authorised medicinal products within or outside the terms of marketing authorisation or from occupational exposure;
- promoting the safe and effective use of medicinal products, in particular through providing timely information about the safety of medicinal products to patients, healthcare professionals and the public; and
- contributing to the protection of patients' and public health.

More specifically for safety communication, the following objectives have been defined by the EU good pharmacovigilance practices (EU-GVP Module XV):

- providing timely, evidence-based information on the safe and effective use of medicines;
- facilitating changes to healthcare practices (including self-medication practices) where necessary;
- changing attitudes, decisions and behaviours in relation to the use of medicines;

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- supporting risk minimisation behaviour;
- facilitating informed decisions on the rational use of medicines.

For vaccines, the EU good pharmacovigilance practices (EU-GVP P.I) confirms the above safety communication objectives, specifies that objectives in relation to vaccines may also aim at avoiding errors in vaccine handling, and recommends media monitoring especially for vaccines.

At global level, CIOMS in their report on vaccine safety communication has defined the following objectives for regulatory vaccine safety communication with stakeholders, which are in part similar to the EU good pharmacovigilance practices objectives defined above:


- understanding knowledge, attitudes, practices and related concerns and information needs of the audiences with regard to the vaccines;
- providing accurate and full information about the safety profiles and BR balances of vaccine products for supporting informed choice of individuals and policy-makers in relation to immunisation;
- facilitating changes to healthcare practices for safe and effective handling and use as well as prevention of harm;
- demonstrating trustworthiness of the vaccine safety surveillance system (pharmacovigilance) for trust-building;
- preventing and managing crisis situations due to safety concerns over vaccines.

It further defines as related sub-objective to provide the information in formats that may support healthcare professionals and vaccinators when communicating with individuals, such as (potential) vaccinees, carers and community leaders.

2.6.2 Communication objectives for regulatory authorities in relation to BR monitoring of vaccines in PPCs

Taking into account above considerations, the literature review performed by the LSHTM on vaccine sentiments in the EU (see ADVANCE D.1.4.) and the results on public concerns and information needs gained from the media monitoring conducted by the EMA on HPV vaccines (see ADVANCE D.1.7.), the following communication objectives for regulatory authorities in relation to BR monitoring of vaccines in PPCs are defined:

- understanding knowledge, attitudes, practices and related concerns and information needs of the general public and other stakeholders with regard to the vaccine under BR monitoring;
- providing accurate and full information about the BR monitoring and its impact on the safe and effective use in the context of the evidence-based BR balance of this

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vaccine product for supporting informed choice of individuals and policy-makers in relation to immunisation;

- facilitating changes to healthcare practices for safe and effective handling and use as well as prevention of harm;
- demonstrating trustworthiness of the regulatory pharmacovigilance system and the PPC;
- preventing and managing crisis situations due to safety concerns.

3. STEP 2: Mapping stakeholders involved in communication strategy development


Development of communication strategies in scientific projects depends strongly on proper identification and description of stakeholders and their involvement at different levels of project realisation. In this particular context, the term “*stakeholder*” refers to any individual or organisation with an interest in the BR of vaccines. It differs from the *users* of this guidance document, which are the institutions that will be using this guidance documents to develop their own communication strategies about BR of vaccines (described in more details in the introduction). It also differs from the *audience*, which are targeted individuals or communities that the strategy will aim to communicate with through various channels and messages (the identification and selection of the audience is described in more detail in step 3a).

In the case of such a broadly and publicly discussed area like vaccine BR, the identification of stakeholders involved in the development of a communication strategy should be regarded as a flexible process allowing for:

- a. adequate and fluent exchange of information between stakeholders directly involved in the BR monitoring;
- b. multi-channel, external outflow of knowledge and experiences resulting from the BR monitoring.

The most common practice used in stakeholder mapping is based on their involvement, not only in the development of the communication strategy but also in the BR monitoring/study (or project). With this approach, it is easy to distinguish four main groups of interest related to public-private collaborations (PPCs) in the area of vaccines BR studies:

- a. *project consortium*: pharmaceutical industry (vaccine manufacturers), public health institutes (responsible for vaccine safety monitoring), European medicines regulators, academia; (responsible for monitoring of the overall effect of the vaccination programmes);
- b. *project partners*: scientific organisations, PR, R&D companies, vaccine providers, scientific institutes, national healthcare institutions, national regulators (responsible for vaccine safety monitoring), vaccine providers;

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- c. *external partners*: scientific networks, patients' and consumers' organisations (national and international), other groups from different research projects developed in the same area, scientific and non-scientific media (journals, newspapers, other press, scientific channels on radio or TV, internet portals);
- d. *project beneficiaries*: broadly understood general audience (general public), including specified groups representation (i.e. general practitioners, immunologists, epidemiologists, school teachers, parent organisations, teenagers and young adult associations (including students and not only medical) etc.).

However, this preliminary division of stakeholders does not reflect the possibilities and needs for communication strategy development within the entire project. The communication strategy should be developed collaboratively between all possible stakeholders involved in the project and externally, through available and adequate channels (including the audience and/or general public). Hence, the process of stakeholder mapping and their involvement in communication strategy development can be executed in two different ways:

- a. *continuous process*: in parallel to the project timetable and stakeholder involvement in its realisation. In this case, the main emphasis in communication strategy development is put on stakeholders and their individual communication capabilities, project responsibilities and particularly defined objectives – each stakeholder or group of stakeholders (e.g. project consortium) creates their own mechanism for communication strategy development;
- b. *“step by step” process*: according to the projects' achieved milestones. In this case, the main emphasis in communication strategy development is put on specific outcomes received at different levels of the project realisation. Unlike with the parallel process (a), a defined group of stakeholders, involved in achieving a certain outcome, develops a common communication strategy.

The difference between these two approaches is shown in Figure 3 A and B.


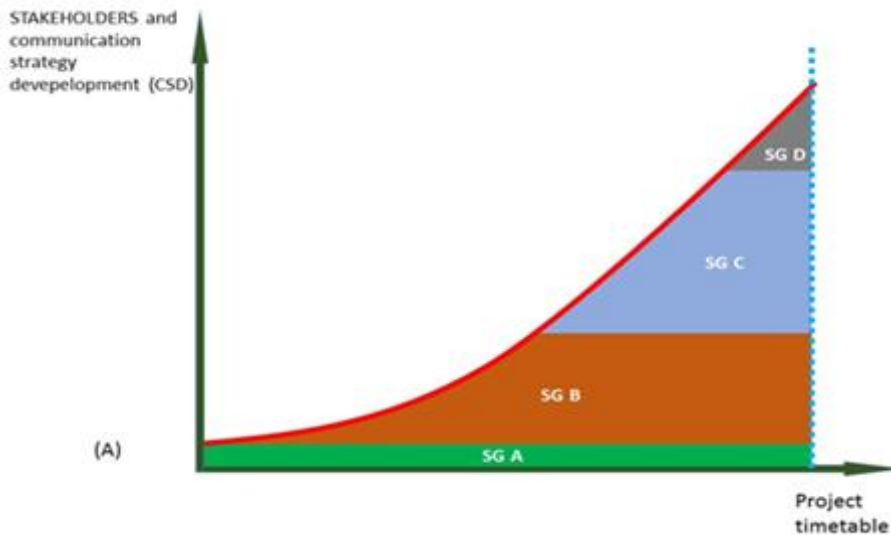
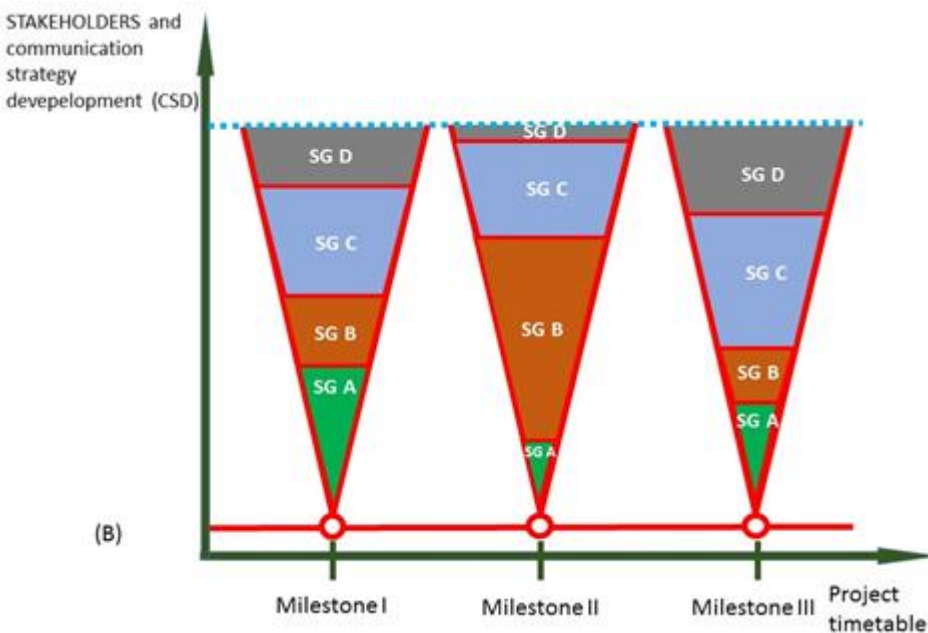
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Figure 3: Stakeholders and communication strategy development

A) Continuous process of communication strategy development: each stakeholder group (SG) A, B, C, D develops own structure of communication strategy, focusing on project timetable.



B) "Step by step" process of communication strategy development: stakeholder groups (A, B, C, D) cooperate on communication strategy development focusing on each milestone of the project.



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For both approaches of stakeholder mapping, the critical importance of the quality of information, the target group that particular information should reach and the appropriate methods used in communication strategy development should be emphasised.


Although general objectives of research projects devoted to vaccines BR monitoring and based on PPCs tend to be similar, the mapping of stakeholders involved in communication strategy development should be specified for each project separately. The main reason for this is the different types of healthcare systems in European Union Member States, which creates differences in healthcare organisation, policy (including insurance policy), healthcare payers, particular databases organisation and management, competences of national health institutes, vaccine authorisation bodies and, what is of great importance, differences in public perception of vaccination programmes, as well as public perception of studies on vaccines BR monitoring. In case of projects on vaccines BR monitoring realised at a national level, it is recommended to start a cooperation with an institution responsible for public opinion investigations.

It can be useful to create a map or list of relevant stakeholders with their potential roles and responsibilities, influence, and participation in the development of the strategy. A detailed contact list with stakeholder categories (e.g. research institute, opinion leader, patient organisation) can be developed and updated regularly. When creating a list of mapped stakeholders, they should be in agreement with the goals and objectives of the communication strategy. A proposed list of stakeholders and their characteristics and responsibilities in communication strategy development are presented in Table 1.


Table 1: Overview of potential stakeholders, and selection of their communication system's characteristics and responsibilities¹

STAKEHOLDER	CHARACTERISTICS OF COMMUNICATION SYSTEM	COMMUNICATION RESPONSIBILITIES
Vaccines manufacturers (pharmaceutical companies, including SMEs)	Usually well organised with own communication strategy development, specialised marketing and PR centres functioning at national and international levels, developed internal communication strategies and channels including social media; in case of SMEs: own communication strategy	Advisory in communication strategy development, possible adaptation of different, existing communication strategies for the project's needs (e.g. specific strategies for communication with PHIs; required channels for information flow between vaccine manufacturer and regulator) Legal responsibility for disseminating accurate product information


¹ This list of stakeholders, characteristics and responsibilities emerged as an outcome from the communication and governance workshops.

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	development focused at specific level (i.e. product target groups at national level)	
National Public Health Institutes	Usually no specified (unified) communication strategy, usually with single unit responsible for internal and external communication; communication department for health education / communication in general, separate departments for strategic objectives (i.e. departments of epidemiology, departments of environmental health etc.); however strong emphasis for external communication to general public	Communication strategy development for general public with different impact, dependent of the Institute competences and responsibilities; specific communication channels between PHIs and specialists e.g. epidemiologists and regulatory bodies (scientific conferences); integration of stakeholders at national level
European Medicines Agency (EMA)	Stakeholders and Communication Division in charge of communicating about benefit-risk evaluations, in accordance with legal communication and transparency provisions, and based on consultation with patient and healthcare professional organisations. Plans for communication are agreed within the EU regulatory network and as appropriate with marketing authorisation holders. developed communication channels, including own social media channels	Coherent, coordinated and consistent approach to stakeholder and partner relations management and communication in line with legal responsibilities


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National Competent Authorities (for vaccines authorisation)	Separate units for internal and external communication; own communications channels and strategies mainly directed to vaccines providers, and professional groups of interests	Communication between stakeholders at national level
National Health Ministries	Specialised departments; however one communication unit responsible for internal and external communication strategy development, one spokesperson	No specific role in communication strategy development, but of critical meaning as the decision-making body, regarding special communication channels e.g. press conferences
Academia (research institutes); Institutes for Epidemiology, Biostatistics	Specialised, scientific communication channels e.g. scientific journals; lack of separate communication strategy development for specific projects	Scientific approach mainly, dissemination of scientific information (specific studies, research results)
International institutes (e.g. European Centre for Disease Prevention and Control (ECDC))	Own health communication programs (scientific and public), hence own communication strategy development within own channels, own press room and social media channels	Advisory in communication strategy development, possible adaptation of different, existing communication strategies for the project's needs
Scientific organisations (national and international levels, including vaccine research networks) (i.e. International Epidemiological Association (IEA), European Federation of Immunological Societies (EFIS))	Own communication channels and communication methodologies	Dissemination of scientific information in limited of range, but large in members total amount

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Non-scientific organisations	Multi-channel, multi-stakeholder communication strategies	Dissemination of information (scientific and non-scientific, lay information)
Patient and Consumers Organisations including parental organisations, teenagers associations, students associations	Multi-channel, multi-stakeholder communication strategies; however main experience in lay-language communication hence: translation of scientific information into lay language	Dissemination of information to general public, elaboration of specific communication strategy development for targeted groups of recipients: children, parents, school teachers, young adults, general practitioners; effective in communication with regulatory bodies
Media (scientific and non-scientific): journalists representing newspapers, radio and TV health programmes, internet healthcare portals	Own communication channels and strategies	Dissemination of information to general public, large and different, non-specific audience; project promotion to general public
National Ministries of Education	Own communication channels and strategies	Dissemination of information to specific target audience: teachers
Healthcare professionals (general practitioners, hospital specialists)	Communication strategies only through specialised organisations	Dissemination of information to parents and children, assessment of particular needs, direct monitoring of benefits and risks of vaccines

Methods of engaging with stakeholders should be identified. They could include workshops to develop separate pieces of the strategy, interviews, core working groups, or reviews of the strategy after its development. Timelines for meetings and ways of keeping in touch should be agreed. Optimally, all stakeholders should agree on procedures for the development of the strategy, including governance and methods of dealing with new benefit and risk information. A group of experts responsible for speaking to the media and an official spokesperson should also be identified. The mapping of stakeholders should also include a plan of how to communicate with journalists and the media to ensure continued effective working relationships throughout the communication activities and in times of crisis.

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More advice on how to communicate with journalists can be found here:

- European Centre for Disease Prevention and Control. Communication on immunisation – building trust. Stockholm: ECDC; 2012. ([Link to document](#)) (23)
- World Health Organisation (WHO). Vaccine Safety Events: managing the communications response. A guide for Ministry of Health EPI Managers and Health Promotion Units. Copenhagen: WHO; 2013. ([Link to document](#)) (27)
- Sense about Science. Standing up for Science: A guide to the media for early career scientists. ([Link to document](#)) (28)
- Science Media Centre. Top tips for media work: a guide for scientists. ([Link to document](#)) (29)
- *Imperial College London. Do's and Don't's of talking about science to the media.* ([Link to document](#)) (30)

The communication strategy development should be coherent and transparent for all stakeholders involved. All stakeholders should agree on procedures used for communication strategy development, including the strategy governance - management and dissemination of information with special regard to new results from studies on vaccines BR monitoring. Detailed list of stakeholders and their categories linked to their role in the project should be updated regularly. Furthermore, the process of stakeholder mapping should also include an exploration of stakeholder viewpoints on the study findings on BR of vaccines. Conclusions from such evaluations could have a critical role in the communication strategy development.

Additional information about the process of stakeholder mapping for communication strategies can be found here:

- Kennon, N., Howden, P., & Hartley, M., (2009) Who really matters? A stakeholder analysis tool ([Link to document](#)) (31)
- European Centre for Disease Prevention and Control. Communication on immunisation – building trust. Stockholm: ECDC; 2012. ([Link to document](#)) (23)
- World Health Organisation (WHO). World Health Organization Outbreak Communication Planning Guide. Geneva: WHO; 2008 ([Link to document](#)) (32)

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Additional information on the behaviours and choices of different stakeholders can be found here:

- European Centre for Disease Prevention and Control. Let's talk about protection. Enhancing childhood vaccination uptake. Communication Action guide for healthcare providers. Stockholm: ECDC; 2013. ([Link to document](#)) (33)
- European Centre for Disease Prevention and Control. Let's talk about hesitancy. Enhancing confidence in vaccination and uptake. Practical guide for public health programme managers and communicators. Stockholm: ECDC; 2016. ([Link to document](#)) (34)

4. STEP 3: Identifying the content of the communication

4.1 Core component of the communication

4.1.1 Identifying the objective of the communication

While section 2 provided general guidance on developing communication goals and objectives, this section (4.1.1) provides more specific advice on communication objectives related to new information arising from a vaccine BR monitoring activity of the type developed in ADVANCE, such as the results of a post-authorisation study or of an active surveillance system. The objectives are discussed for communication to healthcare professionals and the public and are therefore particularly relevant for organisations that typically include healthcare professionals and the public as their audience.


In order to define the core components of the communication strategy, three main situations where communication may be needed should be considered, although they will be approached with different objectives by each organisation:

- Is the communication intended to assist healthcare professionals, individuals, or policy makers decision-making about vaccine BR?
- Does the communication need to convey study results that involve risks to the public, or may provoke public concerns?
- Is the communication intended to inform about ongoing investigations?

1) Is the communication intended to assist decision-making?

Healthcare professionals' perspective

Healthcare professionals may have multiple decisions to take in the context of an individual vaccination or of a vaccination programme, for examples to advise patients on the need to be vaccinated, to decide the vaccination schedule (e.g. administration of a booster dose), to administer a medicine preventing a possible adverse reaction (e.g. paracetamol to prevent

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fever, anti-histamines to prevent an allergic reaction), to inform patients about the likelihood of an adverse reaction or the expected effectiveness of the vaccine or to provide the patient with an alert card.

In this context, the objective of the communication to healthcare professionals may be *to help take the most appropriate decision* (for example, to recommend the vaccine, application of risk minimisation measures or a change into administration practices) or change their existing perception. If there is no clear basis for a recommendation, the objective will be *to communicate adequate information*. In these situations, the communication will need to include:

- An unambiguous recommendation, or a clear statement that is based on the information available or no recommendation can be expressed (for example if the decision needs to be taken based on patients' characteristics)
- A clear explanation of the scientific evidence and justifications underlying the recommendation; these explanations should be explained in an understandable language; the communication should include at least a section written in lay language to provide healthcare professionals with information they can directly communicate to the patients.
- If applicable, any follow-up action that has been initiated and that may lead to amend the recommendation or to communicate a more definitive view in the future.
- Any reference to a publication or preferably webpage where the results of the investigations or the reasons of the decisions are explained more extensively (with links to source documents, if appropriate) allowing the healthcare professional to seek additional information. For example, this information may include the link to the EU PAS Register (with the EUPAS number) where the study at the source of the recommendation may have been registered with the protocol.

The perspective of the general public

The most important decision that members of the public may need to take is whether or not to be vaccinated or to have a child or parent vaccinated. A key aspect is transparency. Clear and unambiguous statements and explanations based on scientific data and their interpretation need to be provided. Members of the general public should understand why a vaccine is recommended or required, from an individual as well as a public health perspective, and how to use it safely and effectively. The communication should make the public feel that they can trust that the recommendation is based on a fair and objective interpretation of the data (preferably by an independent scientific committee) and that no information has been hidden. The public should also have a clear understanding of both the available evidence and the unresolved uncertainties, and that both the evidence and the uncertainty were important in the decision.

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2) Does the communication need to convey study results that involve risks to the public, or may provoke public concerns?


Objectives of a communication strategy may include sharing of new information on BR, addressing inaccurate perceptions of vaccine BR or changing beliefs and attitudes about vaccines. As it is generally accepted that vaccine acceptance is in part associated with the amount and quality of information available, the communication objective of sharing new information on BR has become important over the last decade due to the development and increasing use of social media. Communication between members of the public was previously primarily based on “mouth-to-ear” communication within relatively narrow circles of familial and social relations. Social media now provides an opportunity for all individuals to communicate instantly to a large community. As highlighted in the review presented in Deliverable 1.7, social media is used as a resonance chamber to news, opinions and beliefs, irrespectively of their accuracy and the credibility of the messenger. The communication may therefore create a message that can be adapted and transmitted throughout the web by members of the public, including healthcare professionals. This function of the communication strategy will influence its content as the text must be accurate, based on facts, concise and written in lay language to allow its re-use and re-transmission, as well publication in the media. Precautions should be taken to avoid the possible modification of the content of the communication, which could lead to misunderstandings and misinterpretation of the original message.

Communications about results of a vaccine BR activity (such as observational study) will need to select the relevant information and express it in an understandable and concise manner, together with actions arising from the results. Elements of information should not only include the main results but also a brief description of the methods used and the source of the data. For example, if the study involves a PPC, this should be stated together with relevant statements on the respective roles of the private and public sectors (see section 4.1.4 below).

3) Is the communication intended to share information about ongoing investigations?

Emergence of a safety signal or new information about the effectiveness of a vaccine may lead public health institutions, regulatory authorities and vaccine manufacturers to initiate investigations on the possible individual or public health consequences of such information. In a preliminary stage, especially if the information has been the subject of media attention, communication may be needed to inform the public about the actions taken in relation to this investigation in order to provide reassurance that the regulatory system is managing this issue.

Although there may be no definite data to be presented, this type of communication should be as factual as possible. A provisional recommendation can be expressed together with timelines on when additional information will be available and/or communicated. The communication should also take into account uncertainties attached to incomplete data. The communication may also reflect that BR assessments are dynamic by nature because information itself changes over time. As time passes, more information is accrued particularly

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on safety data. However, for some vaccines (e.g. HPV), effectiveness data might come in later than safety data which could provide a temporarily incomplete and therefore flawed BR profile.

4.1.2 Communicating benefits and risks

The communication should normally be accompanied by a presentation of the vaccine and its indication, which diseases it aims to prevent, and accurate information on individual and public benefits. The general approach is to contextualise risk information with evidence on disease epidemiology, vaccine use/exposure rates and baseline rates of events that can occur with and without vaccination. The following questions need to be answered in an understandable and clear language:

- How frequent and how severe is the disease to be prevented?
- What is the risk for the population that is not vaccinated?
- How frequent and how severe is the risk induced by the vaccine?
- What is the aim of vaccination?

To simultaneously communicate benefits and safety information (especially when it arises from spontaneous reports early after marketing) is however difficult because of the inequality of the information: safety data are reported and made public at a much earlier stage than data on benefits¹. Effectiveness information on a specific vaccine may fail if it is not based on strong evidence, for two reasons:

- It may raise additional concerns about the BR of the vaccine if a safety issue has been shown in individuals but effectiveness has not been firmly established
- It may affect trust into the communicating organisation if it is perceived to hide uncertainties (see section 4.1.3).


A particular example of the difficulty of communicating about both benefits and risks is the HPV vaccine for which effectiveness data will emerge only several decades after its introduction. In its press release reporting the outcome of the EU referral on CRPS/POTS², the EMA used the wording “are expected to” in the information for patients³:

Information for patients: *HPV (human papillomavirus) is a major cause of cancer of the cervix (neck of the womb) and some other cancers, as well as other conditions such as genital warts. HPV vaccines are expected to prevent many cases of such conditions.*

¹ In the case of the H1N1 influenza pandemic vaccine, the first case of Guillain-Barré Syndrome was reported in October 2009 whilst the first preliminary data on effectiveness were made available to regulators in January 2010 after the peak of the vaccination campaign. See Kurz X. et al. Safety monitoring of Influenza A/H1N1 pandemic vaccines in EudraVigilance. *Vaccine* 2011;29(36):4378-87.

² CRPS: complex regional pain syndrome; POTS: postural orthostatic tachycardia syndrome

³ European Medicines Agency. HPV vaccines: EMA confirms evidence does not support that they cause CRPS or POTS. Reports after HPV vaccination consistent with what would be expected in this age group. Press Release. 20/11/2005. www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/11/news_detail_002436.jsp&mid=WC0b01ac058004d5c1

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Benefits and risks lack a common unit of assessment and cannot be easily compared. The “risk-risk” concept has therefore been proposed (35): benefits of being vaccinated could actually be understood as avoiding the harms and adverse experiences of a disease for oneself or for others. By expressing harms of the disease in terms of risks, the patients can weigh the risks, with inherent uncertainties, of adverse effects from a severe disease versus the risks (and inherent uncertainties) of experiencing adverse effects from the vaccine. This approach has two advantages:


- Disease epidemiology may be better known than vaccine effectiveness and stronger evidence can be provided.
- Many vaccine-preventable diseases have nowadays a low incidence and their signs, symptoms and severe manifestations are not well known by young people and young parents; the risk-risk approach allows communicating such information.

However this approach may not work in some cases, as these calculations and their understanding by the public may neglect the fact that vaccination rates (low or high) of a large proportion of the population changes the risk of vaccine-preventable diseases.

A widely accepted principle is that information on BR should be provided at individual as well as at population levels. Results of vaccine BR activities (e.g. pharmacoepidemiology studies) are most often expressed as statistical estimates applicable to a population. For example, an incidence rate of convulsions between the age of 1 month and up to pre-school booster pertussis vaccination or up to the age of 6 years was 2.6 per 1000 person-years in the THIN database (ADVANCE Deliverable 5.6, Table 24, page 133). This estimate applies to the population covered by THIN. However, for people whose child has experienced a convulsion or who know a family where a child has experienced a convulsion, this information is contradictory with their experience that if the family includes three children and all three have been vaccinated the risk is 1/3. There is therefore a need to take into account that for many people the data provided seem incoherent with their individual experience (35), and they may share this experience with others, especially with the rise of personalised medicine. A literature review also found that individuals often rely on information consisting of individual stories and narratives that influence fear and uncertainties (24). Standard methods exist to transform data expressed in the form of *incidence density* (e.g. 2.6 per 1000 person-years) into the form of an *individual risk* expressed as a frequency or percentage. This form of expressing risk should be used if possible.

Balancing what is known and unknown about the benefits, risks and uncertainties of a vaccine compared to the alternative (not being vaccinated) is a complex task. Patients and providers would benefit from receiving objective, quantitative information on BR of vaccines as well as clear statements about uncertainties. Conveying BR information in a quantitative format should therefore be considered, for example:

- Guillain-Barré syndrome (GBS) is a rare condition occurring with an annual frequency of 10 to 20 cases per 1 million adult population (36); a study on inactivated influenza vaccines found an increased risk of GBS among adult vaccinees of approximately 1 additional case per million persons vaccinated above the GBS annual frequency (37).

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- The risk of febrile seizures [following inactivated influenza vaccines] was estimated to be 5 to 9 per 1,000 vaccinated children less than 5 years old, and most seizures occurred among children less than 3 years old (38).

Although conveying information numerically (along with minimal background context) can provide greater clarity, it also presents its own challenges. Average results may not be sufficiently informative because individuals experience a range of vaccine effects varying widely from the average results (as example given earlier). Reporting variability may be useful to enrich the communication but may also be difficult to interpret by the public.

Specific information about BR of vaccines is not presented here. Reviews may be found in reference documents such as publications (9), textbooks (39), or on the WHO Global Vaccine Safety website (40).

4.1.3 Communicating uncertainty

Need to communicate uncertainty

Regulators or public health institutes/authorities may be reluctant to communicate uncertainty not only because explaining uncertainty is difficult and it may appear as if there is not yet anything concrete to tell the public, but also because it may undermine their credibility by exposing their lack of knowledge. This attitude may underestimate people's ability to understand uncertainty, which exists in many daily life activities. Communicating on uncertainties can lend additional credibility and trust to other aspects of the communication. Sharing uncertainty may be particularly important in the field of vaccines as it is intrinsic to this class of products at the time of approval:


- as a preventive measure for diseases with rare incidence, there is limited information on whether the vaccine will be useful for any given individual;
- there is an unknown risk of serious adverse reactions given the limitations of clinical trials and risks may depend on unknown individual characteristics;
- post-authorisation studies are frequently requested to confirm efficacy or safety, which may be perceived as an important sign of missing information and uncertainty.

Sources of uncertainties

Uncertainty does not only include statistical uncertainty but also lack of knowledge on safety and effectiveness of the vaccine or vaccination programme.

Several sources of uncertainties have been described (35):

- Human variability (due to heterogeneous real world populations)
- Methodological uncertainties:
 - in clinical trials: tightly controlled populations, short duration, small sample size; contradictions in results of multiple trials

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- in post-marketing data: varying levels of rigor and strength of evidence in the source of post-market data (e.g. observational studies, spontaneous reports, active surveillance, meta-analysis); contradictions in results of multiple studies; database heterogeneity; confounding can never be excluded in uncontrolled environments.
- Statistical uncertainty
- Unknowns: the limits in the scientific understanding of a disease (i.e. specifically for many auto-immune diseases), mechanisms of suspected adverse reaction or a physical process make it difficult to know what could be an important harm or vaccine characteristics that need further investigation.

Addressing uncertainty in communications

The first step is to identify and characterise the gaps in knowledge and the sources of uncertainties in order to provide fair and factual information. As the tolerance to uncertainty will depend on human judgment and past experience, the patient perspective should be addressed by including patients' and healthcare professionals' representatives in identifying the sources of uncertainties that will be useful to address and how they should be addressed. The dynamic nature and complexity of the evaluation and decision-making on BR may also be highlighted, including the unknowns of the available evidence.

If possible, access should be provided to additional information, such as assessment reports and meeting minutes, to allow the public to understand the data gathering, risk assessment and decision-making processes. Use of daily life uncertainties for comparison may also facilitate understanding of vaccination-related uncertainties.


4.1.4 Communicating about PPCs

The ADVANCE project was set-up to develop and test a framework that could provide robust post-marketing vaccine BR data to support decision-making in Europe. This was motivated by the recognition that formalised governance is needed at study and project levels to engage both public and private stakeholders in post-marketing vaccine BR monitoring studies or programmes thereby ensuring transparency in roles and responsibilities. The communication strategy should take into account that involvement of the private sector in PPCs is frequently a reason for the lack of confidence in results of vaccine BR activities. Trust into the organisation that communicates the results is an important factor to increase public confidence.

Components of a communication

The following specific aspects need to be addressed in a communication:

- the justification for the organisation to enter into a collaboration, the benefits and the potential risks;

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- if participation of (a) vaccine manufacturer(s) may be an issue, the justification, benefits and potential risks of such participation;
- given the above, measures taken to ensure the validity and credibility of the results.

An example may be the following:

These results come from a study lead by Organisation Y. The study was performed in collaboration with (vaccine manufacturers) who market the vaccine Z in Country. (The vaccine manufacturers) have funded the study and provided technical information on the vaccine and the study design. Organisation Y had the full responsibility to take decisions for the collection, analysis and interpretation of the data. Vaccine manufacturers were entitled to comment on the results and interpretation, all comments and responses were kept and are available for scrutiny. Additional information is available on the following website: XXX.

4.1.5 Formats of the communication on benefits and risks

General considerations


The perception of BR of vaccine has an influence on vaccine acceptance and attention should be given to the presentation of information on BR. Several aspects need to be considered:

- a minimum degree of health literacy and numeracy are necessary to understand health information and make informed decisions;
- verbal descriptions may be limited in its ability to communicate accurate information, hence numerical information and description of the context may be needed;
- words to describe uncertainty may have different meanings to different persons or to the same persons in different situations, and they should be quantified as much as possible.

The format of the communication should therefore also be targeted to the audience and it should simplify as much as possible complex information.

Experts in communication including patients' and healthcare professionals' representative as appropriate should be consulted for every communication as every communication presents differing issues and contexts to be taken into account. This section presents therefore only general considerations.

Different numerical and graphical formats have been proposed to display information on BR. The publicly available textbook "*Know Your Chances: Understanding Health Statistics*" is a useful tool to help anyone from the public to better understand health information, numbers and risk charts, but it does not provide recommendations on which format should be used to best communicate health information (41). The BR group of the Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium (PROTECT) project developed a set of practical recommendations for BR decision processes and supporting tools (<http://protectbenefitrisk.eu/>), including a review of visualisation formats

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(<http://protectbenefitrisk.eu/visualisations.html>) and a guide, developed in association with patients and healthcare professions' associations, providing definitions, explanations, recommendations and examples on the BR assessment (<http://protectbenefitrisk.eu/PPI.html>).

Several reviews of the literature have tried to identify which display formats should be recommended to communicate BR (42-45). A first finding is that the effect of a presentation format depend not only on the type of format but also on the context in which the format is used. A second finding is that few overall recommendations can be expressed, given the variability of the formats that were tested and of the methods used to measure their effectiveness.

Numerical representations


It is widely accepted that the format used to present health risks numerically influences the decision-making. Use of natural frequencies (for example, 2 in 1000 persons) has been generally accepted as the best method of communicating about absolute risks. However, a different conclusion was reached by a randomised clinical trial comparing comprehension of benefits and harms of treatments when absolute risks are presented as natural frequencies, percentages or both. Carried-out with 2,944 randomly selected adults aged 18 years of older, the trial showed that the percent format resulted in a better comprehension than natural frequencies. The percent format was notably better for the comprehension of absolute differences (46). The authors believed that the percent format was probably best because it is more succinct. The percent format is also simpler, is more widely used in the daily life, in the media for example, and indicates more directly whether a figure is higher than another one. In another study, risk perception varied by number format and numeracy, with less-numerate participants given risk information in a percentage format perceiving the medication as less risky than when given risk information in a frequency format (47). This shows that there is still inconclusive evidence on the best methods of presenting health risks to the public.

Graphical representations

A study with patients affiliated to a breast cancer patient association (52% had breast cancer) has found that numeracy was predictive of "graphicacy" (ability to read graphs), i.e. people may not better understand graphs if they do not understand numbers (48). Another study in prostate cancer patients found a large variation in the ability to comprehend graphs even among higher educated patients (49).

Several studies tested the influence of graphic display format on the interpretations of quantitative risk information, on health-related knowledge and treatment choices.

A trial in 120 adults with lower education and literacy compared two formats of pictographs and different bar chart formats across different orientations and numerator size. It concluded that for adults with low education and literacy, pictographs are likely to be the best format to use when displaying small numerators (<100/1000) and bar charts for larger numerators (>100/1000) (50).

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Another trial compared six graph formats describing the benefits of taking one of two drugs as well as the risks of experiencing side effects. Pictographs were found the best format for communicating probabilistic information to patients in shared decision-making environments, particularly among lower numeracy individuals (51).

An observational study compared different graphical display formats to communicate risk information and found that horizontal pictographs were perceived faster and more accurately than vertical format and that shaded and one-graph pictographs were preferred (52).

PROTECT conducted an online survey to evaluate the preferences of visual formats from people who are obese or had been obese in the past, and healthcare professionals (<http://protectbenefitrisk.eu/PPI6.html>). The survey asked questions on preferences for visual formats in connection to BR information related to weight loss interventions. It proved difficult to point at one individual visual format to be superior for BR communication. While there was a tendency favouring the bar chart and the table format for visual BR communication, it was concluded that much work is still needed to ensure a clear and understandable BR information about drugs to patients and public.

Formats displaying both benefits and risks


Communication of summary statistics incorporating both BR is still a domain of research. The European Medicines Agency is currently piloting use of effect tables as a tool to display such information in European Preliminary Assessment Reports but has not reached conclusions yet (53). PROTECT has tested a variety of display formats that can be used to communicate BR information graphically (see <http://protectbenefitrisk.eu/visualisations.html>) but currently their use in BR communication in regulatory setting or research environment is minimal.

Choosing between text, graphical and numerical messages

Texts and numerical values are used most commonly to communicate BR. There is currently no clear evidence about which numerical or graphical format would be best to help patients understand the information and take decisions, but it makes sense that the simple formats like percentages and pictographs have been judged most useful in a few studies, especially by people with low health literacy and numeracy. The addition of graphical representations to numerical values may be considered but their added value in view of the additional constraints they impose on the communication need to be taken into account. Display of summary information combining BR seem to be currently premature.

4.2 Organisation-specific component of the communication

The content and components of the communication strategy should be discussed and agreed by all relevant stakeholders mapped under STEP 2 (see section 3). Although the broader topic of communication will be around the BR of vaccines, including previous and new knowledge for different populations, vaccines, countries, and contexts; each communicating organisation will have to decide on the angle or focus their communication strategy will take. Deciding on which areas to focus on can be facilitated by conducting a situation analysis, systematically

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collecting study findings (about BR of vaccines), health, epidemiological and demographic data of affected populations, and contextual information (see section 4.1 for more information).

In addition to defining the areas the communication strategy will focus on, it is also important to review the social, economic, structural, cultural, and educational environments in which the communication strategy will be implemented. These will help design context-specific and targeted communication strategies that are adapted to local and cultural contexts. It is also useful to list the available financial and human resources that will be available to implement the communication strategy.

4.2.1 Principles on identifying the target audiences

Primary and secondary audiences


In developing the communication strategy, it is necessary to identify the target primary and secondary audiences of the communication. Primary audiences are individuals who are directly affected by the new information on BR of vaccines, or who are in the best position to make decisions based on this new information (such as parents, or healthcare professionals, immunisation policy makers). They are therefore individuals who will want to receive communication messages directly. Secondary audiences, sometimes called influencing audiences, are those who can influence the primary audience (such as community leaders or family members but also healthcare professionals) and who may indirectly receive communication material.

Primary and secondary audiences should have already been listed and identified by the stakeholder mapping exercise (STEP 2, section 3) but should be discussed and selected more precisely during this step by all stakeholders involved in the development of the communication strategy. As mentioned in section 3, the audience is not only a recipient of information but should also be listened to and should be an active stakeholder involved in the development of the communication strategy.

Examples of broad categories of primary or secondary audiences include (but not limited to):

- Populations or individuals targeted by vaccination programmes (i.e. parents, carers, adolescents, pregnant women...) – vaccinated or non-vaccinated
- Healthcare professionals (as receivers and providers of vaccination)
- Politicians and policy makers
- Scientific organisations and academia
- The media through journalists
- The general public

Healthcare professionals could be selected as the primary audience of the communication to fulfil two different objectives. They could receive the communication as a tool on how to communicate BR of vaccines with patients, and how to listen to them. In parallel, the strategy

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could also identify as a communication target population hesitant healthcare professionals refusing recommended vaccines for themselves (i.e. influenza vaccination), or their patients.

Developing the audience's profile

Formative/baseline research can be conducted to help develop their profile and identify the most appropriate primary and secondary audiences to focus on. This should aim to describe:


- Socio-demographic characteristics such as age, sex, religion, socio-economic status, or occupation
- Geographic characteristics including where the audience is located and how this might impact their response to the communication strategy
- Socio-cultural information such as language, culture, religion, ethnicity, social position
- The audience's behaviour, beliefs, knowledge, motivations, values, and attitudes
- Psychographic characteristics such as needs, hopes, concerns or aspirations
- Barriers and facilitators to change or that might contribute to adopting or maintaining certain beliefs and behaviours
- Effective communication channels to reach the audience and how the audience will respond to them

The formative research could include stakeholder meetings, collection of routine available data (population surveys, etc.), literature reviews, as well as short surveys, interviews, or focus groups. These profiles have to be developed for all population groups within the targeted audience, whether there are from different socioeconomic backgrounds, gender, or ethnic minorities. These data should be collected almost simultaneously with the BR monitoring studies and can help segmenting individuals and organisations into groups with similar characteristics, needs and preferences to facilitate the selection of the primary and secondary audiences.

Selection of the primary and secondary audiences

The selection of audiences will depend on various factors. Once the different potential audiences have been described, characterised, and segmented, the following questions should be discussed within stakeholder working groups to select the primary and secondary audiences:

- Will addressing this group be crucial to achieve the communication strategy objectives (and for the organisation in charge of communication)?
- Is this group most affected or at risk by the changes in BR of vaccines?
- Which groups make decisions or have influence on those affected?
- Are there sufficient resources available to focus on this group?
- Will this group change considerably within the timeframe of the programme?

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Those questions will also facilitate the prioritisation of audience segments within primary and secondary audiences to decide which audience to focus on. A phased approach can also be envisioned, where a high priority audience is reached in a first phase and other less critical audiences are reached in later phases.

Example of audience selection: the case of HPV vaccination


The example of a national public health institute wishing to communicate new results about the effectiveness of HPV vaccination (i.e. the vaccine being equally effective with one dose instead of two or three doses) can be taken to illustrate the process of audience selection. In such a scenario, the primary target groups could consist of:

- Parents of older children and teenagers, more particularly teenagers that have not received the first dose of the vaccine yet;
- Groups with more difficulties accessing vaccination, such as travelling communities, Roma populations, or certain religious communities;
- Healthcare professionals responsible for communicating and promoting HPV vaccination with their patients;
- Teachers or community leaders responsible for promoting or facilitating the delivery of HPV vaccination.

Secondary audiences that could influence the primary audience's perceptions and attitudes include paediatricians, school nurses, youth group leaders, general practitioners, gynaecologists, religious or community leaders, media professionals and journalists.

Additional information about the selection of audiences can be found here:

- The Health Compass. How to develop a communication strategy. Health compass; 2016. ([Link to document](#)) (54)
- The Health Communication Capacity Collaborative. The P-Process: five steps to strategic communication. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health Center for Communication Programs, 2013. ([Link to document](#)) (1)
- O'Sullivan, G.A., Yonkler, J.A., Morgan, W., and Merritt, A.P. A Field Guide to Designing a Health Communication Strategy. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs, March 2003. ([Link to document](#)) (55)
- European Centre for Disease Prevention and Control. Conducting health communication activities on MMR vaccination. Stockholm: ECDC; 2010 ([Link to document](#)) (56)
- Health communication capacity collaborative. Designing a social and behaviour change communication strategy. Johns Hopkins; 2016. ([Link to document](#)) (57)

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- Bingham A, Brawley M, Gopinath CY. Designing communication strategies that work: Implementing the SIM process. Nairobi, Kenya: PATH; 2009. ([Link to document](#)) (58)

4.2.2 Principles on identifying communication channels

Types and categories of communication channels


A first list of potential communication channels should have been identified during STEP 3a (section 4.2.1), while researching background information about habits and preferences of primary and secondary audiences.

Communication channels are typically divided into three groups:

Interpersonal channels refer to one-to-one contact between the audience and for instance healthcare professionals, vaccine providers, family member or peers. This type of communication is usually highly trusted by individuals as it involves face-to-face communication, and is engaging and participatory. However, it can be difficult to implement (timely and costly) and to control messages.

Community-based channels aim to reach a wider group of people within a geographic area or a community defined by a set of similar characteristics, but still have geographically a low reach. These communities can be reached through physical social networks such as community gatherings and activities (i.e. health fairs or cultural events) or through community-based media (i.e. local newspapers or radios, online social groups). Community-based channels are participatory and engaging and can be adapted to target local community needs. However, they can be costly to scale up, and need to be adapted for reaching multiple or wider communities.

Mass media channels are effective to reach a very large audience rapidly. TV and radio can be used to reach individuals, families and children or adolescents. They can facilitate discussion within groups (families or peers). They allow for larger creativity and can be repeated multiple times in local languages. Materials for TV-communication can be particularly expensive to produce and some audiences might be missed (those without access to TV or radio). Mass media channels also include the print media (newspapers or magazines), which can reach segments of the population based on their reading habits. These channels are less costly and timely but rely on audience literacy. Digital (i.e. websites and newsletters) and social media (i.e. blogs, YouTube, forums, Facebook or Twitter) are useful to reach particular groups of the population (i.e. young adults, adolescents) and allow longer messages (particularly on scientific websites) to be spread faster and more frequently. It can be participatory as well, but its trustworthiness can be questioned by some users.

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Selection of communication channels


Tools should be selected according to their effectiveness in increasing acceptance of the selected messages with the primary and secondary audiences based on formative research and reviews of existing data. They should aim to maximise impact while achieving scale and wider reach, especially when targeting the “general public”. However, channels will have to be selected based on the initial goals and objectives of the strategy, and more particularly by answering the following questions:

- is the goal to reach a lot of people quickly or to focus on a small section of the population over time?
- in the country/context where communication is taking place, which channel is used to reach a large number of people quickly?
- is this a one-off communication or does it require high frequency of messaging?

It is more effective to use a mix of channels, particularly interpersonal channels and community-level or mass media channels. This can help achieve objectives faster, through reaching a higher number of people (in different communities) more frequently. Exposure from multiple sources can also reinforce a particular message. A lead channel can be selected and then supplemented by a few supporting channels, especially when addressing different or large audiences.

Eventually, channels should be selected based on the:

- channels’ strengths and limitations (see some examples in the description of the different types of channels): a list of all potential channels should be created, with context-specific strengths and limitations, using experiences from previous communications, as well as feedback from stakeholders involved in the development of the communication strategy;
- audience habits and preferences: different target audiences might have different needs and concerns and might use different media channels or come into contact with different potential sources of communication. The selection of channels will also be affected by which sources or channels the audience sees as trustworthy, as this will impact their acceptance of the message;
- messages specificities: short messages or recommendations might work better for TV or mass media, while more in depth detailed information can be posted on professional websites or on leaflets available at doctor’s offices;
- available resources and accessible communication environment (based on financial resources, media production skills available, access to air-time, etc.): a comprehensive cost-analysis should be made, and compared to the strengths and limitations of each channel as well as their effectiveness in reaching a large number of people, reaching local communities, or being used frequently or over a long period of time (see questions related to objectives and goals above).

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- channels other organisations are using for similar communications

Finally, it is also important to determine at this stage the mediators of communication for each channel. The mediators might differ for each message and audience, and can include multiple players identified in the stakeholder mapping exercise (organisations or individuals). Mediators should be selected based on the audience trustworthiness of a particular institution, as well as their authority and expertise in the matter being discussed. In some cases, a message will be heard more strongly when coming from a peer (community representative) than from an expert scientific institute or spokesperson.


Selection of tools

Once lead and supporting channels have been identified, institutions in charge of developing the communication strategy should decide on the tools and materials that will be used to spread messages using those channels. These will be specific to the channel chosen.

For instance, for interpersonal communications, the tools used to communicate could be peer, family, or provider counselling using training or support materials. It could also include using posters, brochures, leaflets and factsheets in healthcare clinics to facilitate communication between patients and providers. Tools that could be used with community-based channels include community participation activities (using health fairs, theatre shows, or advocacy activities) or community media such as articles published in local community newspapers, or spots on local radios. Finally, for mass media channels, tools include advertising, publicity, advocacy or promotion using printed articles (press releases, advertisements, FAQ sheets), TV or radio spots (interviews with experts, advertisements, documentaries, press conferences), or website or blog pages and social media articles.

Example of channel selection: the case of HPV vaccination continued

In the case of new information about the effectiveness of HPV vaccination mentioned previously, the following channels could be considered if parents of teenagers are considered the primary target. As parents of older children might not visit their GPs or paediatricians as frequently as parents of young children do, vaccine providers would not be the idea channel. Instead, communicators could decide to reach parents through larger mass-media campaigns, for instance by organising TV or radio interviews with experts to announce the change in the vaccine effectiveness. This could be combined with a social media campaign aimed at young adults but also teenagers that could act as influencers on the primary audience. The social media campaign could include social media or blog articles sharing the news, with more in depth articles on official websites providing information that is more detailed. Finally, some interpersonal communication could take place at schools, with teachers or school nurses directly communicating to parents and teenagers, through one-on-one or group parent meetings.

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Additional information about channels required for effective communication can be found here:

- The Health Compass. How to develop a communication strategy. Health compass; 2016. ([Link to document](#)) (54)
- O’Sullivan, G.A., Yonkler, J.A., Morgan, W., and Merritt, A.P. A Field Guide to Designing a Health Communication Strategy, Baltimore, MD: Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs, March 2003. ([Link to document](#)) (55)
- European Centre for Disease Prevention and Control. Conducting health communication activities on MMR vaccination. Stockholm: ECDC; 2010 ([Link to document](#)) (56)
- Hyunyi Cho, Torsten Reimer, and Katherine McComas. The SAGE handbook of risk communication. SAGE publications; 2014. ([Link to document](#)) (59)

4.2.3 Principles on messaging and developing an engagement strategy


Key criteria of good messages

A message or set of messages for communicating new information about vaccines benefits and/or risk should follow good practice principles in order to be widely accepted by the public and effective in achieving the set goals and objectives of the communication strategy. First, messages should be adapted to fit to the audience’s needs and preferences.

Further principles of good messages include:

- each message should hold one main idea;
- simple and short messages or graphics are easy to understand and remember;
- language should be accessible, non-judgemental, persuasive and jargon-free with a tone suitable to the audience (e.g. parents vs. adolescents)
- messages should be based on the audience’s stage of change, and address their values, norms, beliefs as well as needs and priorities;
- clear messages and rationales for advice in case of significant side effects observed/reported;
- communicators should be transparent and provide clear and explicit information.

Finally, certain terms and concepts should be explained, such as “temporal association” and “safety concerns” to avoid any misunderstandings.

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Key messages

As messages should be tailored to the chosen target audiences and communication channels and multiple versions of the same messages might have to be developed to reach different audiences, it is important to outline the key message point that should be conveyed in all messages and activities, by all stakeholders. Key message contents can be delivered in different ways, depending on the channel or approach, but have to remain consistent to avoid any misunderstanding or confusion among the audience and to reinforce the message. This could be a specific vaccine risk and/or benefit identified in new studies. Key messages should typically include a call to action and address a behavioural determinant of interest. Therefore, the HPV example would include another key message such as “*Talk to your general practitioner about getting the HPV vaccine*”. Other important messages will then be added to the key message, such as an explanation of why it could be beneficial to reduce the number of doses in this particular case and for this particular vaccine (context).


Designing effective messages

Background and formative research should be conducted into what type of messages are most effective and appropriate to convey vaccine BR information to different audiences and through different channels. Messages should be developed to correspond to the audience’s needs and expectations, and should be adapted to the context in which it is being communicated. A message might be effective in one country or with one population but it may be detrimental in another. Message development should also be informed by the fact that messages can travel between different audiences, and between countries (especially on social media). It also requires media monitoring to understand how messages and vaccine-related information travels and is shared between different groups.

This stage should also include a decision about the frequency and length of communication, which will depend on the topic being communicated and the context in which communication is taking place. The right balance needs to be achieved and should be decided based on background formative research, as in some context, too much communication could be detrimental while in others, too little communication would be ineffective.

While the communication strategy stakeholders should be in charge of developing the messages respecting key criteria for effective communication - the actual design of the message should be done with the help of a creative team, including designers, artists, writers, producers, or broadcasters. Creative teams should be included in discussions with stakeholders as well as audience members, for instance by organising a design workshop. In the case of urgent information that needs to be communicated, certain pre-designed messages should be developed in advance and ready for use. When working across countries, it is important to include creative teams fluent in all languages and knowledge of local (sub)cultures to be used for the communication.

Finally, concepts and materials have to be tested with the intended audience and key decision-makers, revising them as necessary with the creative team and stakeholders before implementing the communication strategy.


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More information about the development of effective messages can be found here:

- The Health Compass. How to develop a communication strategy. Health compass; 2016. ([Link to document](#)) (54)
- O’Sullivan, G.A., Yonkler, J.A., Morgan, W., and Merritt, A.P. A Field Guide to Designing a Health Communication Strategy, Baltimore, MD: Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs, March 2003. ([Link to document](#)) (55)
- European Centre for Disease Prevention and Control. Conducting health communication activities on MMR vaccination. Stockholm: ECDC; 2010 ([Link to document](#)) (56)
- US Centers for Disease Control and Prevention. Crisis and emergency risk communication (CERC), 2014 edition. US: CDC; 2014. ([Link to document](#)) (60)
- Fischhoff B, Brewer N, and Downs J. Communicating risks and benefits: An evidence based user’s guide. Food and Drug Administration, US Department of Health and Human Services; 2011. ([Link to document](#))(26)
- Infanti J, Sixsmith J, Barry MM, Núñez-Córdoba J, Orovioigoicoechea-Ortega C, Guillén-Grima F. A literature review on effective risk communication for the prevention and control of communicable diseases in Europe. Stockholm: ECDC; 2013. ([Link to document](#)) (61)
- Public Health Agency of Canada. Canadian Immunisation Guide: Part 1: Key Immunisation Information 2016: Communicating effectively about Immunization. 2016 ([Link to document](#)) (62)
- British Columbia Centre for Disease Control (webpage). Immunization. British Columbia: Provincial Health Services Authority. ([Link to document](#)) (63)

4.2.4 Notes on differences between standard and crisis communication

As circumstances can influence the effectiveness of communication strategies, it is important to consider the context in which the strategy will be applied. The mechanisms of communication should therefore be context specific and when developing a standard communication strategy, attention should be given to its applicability and adaptability to times of crisis. In some instances, the vaccine hesitancy context can be perceived as a constant state of crisis, with peaks occurring following certain events, such as the publication of news articles. Priority should therefore be given to creating a strategy that is as effective as possible, as stronger and more proactive standard communication can help to prevent crisis or, if this is not possible, to alleviate concerns arising when crisis do occur. The standard communication strategy should include guidance and advice on what key messages should be communicated in times of crisis (different scenarios can be anticipated), by whom (including

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the selection of a spokesperson to speak to the media), and through which channels. Those messages should be communicated quickly after the onset of a crisis and the selection of communication channels should reflect this.

To avoid emphasis being placed on arguments that can undermine the effectiveness of a communication strategy during a crisis, it is important to communicate in front of anti-vaccine activists. When producing standard communication strategies, the consideration of alternative channels for communication that reach audiences before anti-vaccine activists will help to boost the effectiveness of the communication strategy during times of crisis. In the instances where anti-vaccine activists have reached audiences first, responding to them in an effective and appropriate manner is key. Consideration of responses to anti-vaccine activists during times of crisis is important, and can be supported by a strong response strategy during times of non-crisis.

Further information regarding managing communications in response to all types of vaccine related events can be found here:

- World Health Organization (WHO). Vaccine Safety Events: managing the communications response. A guide for Ministry of Health EPI Managers and Health Promotion Units. Copenhagen: WHO; 2013. ([Link to document](#)) (27)

Further information on crisis and emergency risk communication can be found here:


- US Centers for Disease Control and Prevention. Crisis and emergency risk communication (CERC), 2014 edition. US: CDC; 2014. ([Link to document](#)) (60)
- World Health Organization (WHO). World Health Organization Outbreak Communication Planning Guide. Geneva: WHO; 2008 ([Link to document](#)) (32)
- World Health Organization (WHO). World Health Organisation Vaccine Safety Supporting Document. Geneva: WHO; 2017 ([Link to document](#)) (64)
- World Health Organization (WHO). *How to Respond to Vocal Vaccine Deniers in Public*. Geneva: WHO; 2016 ([Link to document](#)) (65)

5. STEP 4: Developing an implementation and monitoring plan

5.1 Scope, objectives and planning components of monitoring and evaluation

Part of the communication strategy is a plan for monitoring the implementation of the communication intervention and for evaluating its outcome.

The monitoring should assess the adherence to the implementation plan and the strategy overall as well as the environment and impact of the implementation, both with a view whether adaptation of the implementation is needed to achieve the communication objectives.

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Monitoring is part of managing the implementation and focusses on logistics and immediate impact.

The evaluation should assess the effectiveness of a communication intervention, i.e. in how far the communication objectives have been achieved short-term and long-term, as well as at other (unintended) impact and the satisfaction of the own organisation and stakeholders with the process (including the monitoring) and outcomes, including their roles and engagement. Evaluation should conclude with specific recommendations about whether a new communication intervention is needed to correct or sustain the communication outcomes for the given vaccine safety topic, and generic recommendations which may be useful for future communication strategies for this or other vaccine safety topics.

Hence, monitoring and evaluation are the decisive steps for closing the implementation of a communication strategy or triggering a revision of the communication strategy to be implemented. This may be seen an ‘internal’ trigger and needs to be distinguished from ‘external’ triggers for revising a communication strategy, which are mainly new evidence or new concerns on the BR of a vaccine. The monitoring of a communication strategy may however identify new concerns and related communication needs in the public domain.

The monitoring and evaluation plan needs to define:


- Performance indicators;
- Methods;
- Responsible person and resources;
- Timings;
- Mechanism for notifying findings and recommendations to those responsible for follow-up action.

5.2 Overview of methods for monitoring and evaluation

Keeping oversight on the adherence to the implementation plan is a managerial task, supported by checking internal records.

The following quantitative or qualitative methods may be used to assess whether the communication objectives have been achieved or other impact has occurred:


Communication objective	Methods
Understanding knowledge, attitudes, practices and related concerns and information needs of the general public and other stakeholders	Focus groups with stakeholder groups Interviews with ‘information-rich’ representatives Knowledge-attitude-practice surveys Risk perception research

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	<p>News and social media monitoring and content analysis</p> <p>Analysis of enquiries from journalists and others</p>
<p>Providing accurate and full information about the benefit-risk monitoring and its impact on the safe and effective use for supporting informed choice of individuals and policy-makers</p>	<p>User testing of draft communication materials</p> <p>Feedback surveys in information recipients (e.g. parents, healthcare professionals, health policy makers, journalists)</p> <p>Risk perception research</p> <p>News media monitoring, dissemination and content analysis</p> <p>Monitoring of population and individual vaccination rates, vaccine efficacy, waning immunity, etc.</p>
<p>Facilitating changes to healthcare practices for safe and effective vaccine handling and use</p>	<p>Notifications of patient harm (patient safety incidences, vaccination errors, adverse reaction cases)</p> <p>Root-cause analysis of incidents/errors</p> <p>Knowledge-attitude-practice surveys</p> <p>Monitoring of vaccination rates</p> <p>Patient record analysis</p>
<p>Demonstrating trustworthiness of the regulatory pharmacovigilance system and the public-private collaboration</p>	<p>Focus groups with stakeholder groups</p> <p>Interviews with 'information-rich' stakeholder representatives</p> <p>News and social media monitoring and content analysis</p> <p>Public trust research</p>
<p>Preventing and managing crisis situations</p>	<p>Lessons learnt, reviews of (potential) crisis situations</p>

5.3 Consideration for method selection

According to the CIOMS Guide to Vaccine Safety Communication (66), the main challenge lies in finding methods and meaningful indicators, which can truly study change over time and causal relationships between communication interventions and the changes identified.

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5.4 Guidance for media monitoring and content analysis

Media monitoring and content analysis represent a specifically useful method, as a few persons can capture a wide range of countries and audiences in real time (67). Monitoring of the public debates in the media can happen daily using a defined list of newspapers in paper or online news media outlets, or through making use of a media intelligence service or academic research departments (66). The European Commission provides the media monitoring tool [MEDISYS](#) free of charge and social media can be screened additionally using other databases. ADVANCE deliverable D.1.7 reports on examples for both news and social media monitoring, and has provided some recommendations for media monitoring strategies. Although the impact on vaccine-related behaviours will be difficult to capture using media monitoring, the following can be monitored and analysed:

- Have the communicated messages been reported or discussed in the media?
- Which media have reported?
- Does the media content accurately reflect the communicated messages?
- What is the media content overall?

Media monitoring and content analysis can identify:


- Information on the communicated messages which requires correction;
- Concerns and information needs in the public domain to be addressed by communication;
- Audiences which may not be reached by the media which have reported the communicated messages;
- Communication channels which have to be used in order to reach so far missed audiences;
- Opinion leaders or sub-populations to engage with.

6. Case studies from ADVANCE

6.1 ADVANCE Proof of Concept study: testing a system to generate evidence on the BR of vaccines

6.1.1 Introduction to the ADVANCE Proof of Concept study

ADVANCE seeks to address the feasibility of establishing a PPC to respond/evaluate relevant public health questions associated with the examination of BR of vaccines in a timely and efficient manner. Specifically, the ADVANCE vision is to deliver ‘best evidence at the right time to support decision-making on vaccination in Europe’, and its mission is to establish a prototype of a sustainable and compelling system that rapidly provides the best available scientific evidence on post-marketing vaccine BR for well informed decisions. Consequently,

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ADVANCE involves the creation and assessment of an infrastructure (i.e. system) which could bring together different stakeholders and data sources in Europe.

The first ADVANCE Proof of concept (POC) study was aimed at testing the system and the diagnosis of potential issues that would be encountered in a PPC with a distributed network model approach to estimate vaccine coverage, benefits, risks, and carry out a BR analysis using electronic healthcare databases.

Pertussis-containing vaccines was chosen as the test case for the first POC study. The following research question was addressed: *'has the initial BR profile of pertussis vaccines been maintained after the switch from whole cell pertussis (wP) to acellular pertussis (aP) vaccines in children prior to receiving their pre-school-entry booster?'*


This first POC study was designed using a 'pillar' approach where each pillar was under the responsibility of its own principle investigator. There were four pillars: coverage, benefits, risks and BR analysis. A multiple pillar approach was chosen so that as many individuals as possible could be involved and trained and also to allow databases to participate in different studies based on data eligibility, with further integration of activities within each team.

The objectives of the POC were to determine the feasibility of using pre-identified electronic healthcare databases in order to identify and operationalise each pillar's specific outcomes (i.e. coverage for the coverage pillar, pertussis and pertinent clinical sequelae following pertussis for the benefit pillar and potential safety events for the risk pillar) and to estimate the corresponding prevalence or incidence rates associated with these outcomes. The goal of the BR pillar was to use the information derived from the other three pillars, wherever feasible, in BR analyses and to perform a multi-criteria decision analysis (MCDA) using solicited preferences.

From the 19 databases in 8 countries available to or owned by ADVANCE partners, that were initially considered for the POC studies, 7 databases from 4 countries (Denmark (AUH and SSI), Italy (PEDIANET), Spain (SIDIAP and BIFAP) and UK (THIN and RCGP)) were ultimately included in the POC studies. These databases were selected based on the pre-specified scientific criteria as well as operational considerations including but not limited to the timely ethics committee approvals and database holders/custodians review process.

Overall, for the study period specified for the POC studies, these seven databases included data from more than 38 million subjects. The total study cohorts in each pillar varied in size because of the differences in the inclusion and exclusion criteria relevant for each pillar's research questions. Hence the study cohort for the coverage pillar included around 4.5 million children; the study cohort for the benefit pillar included 3 million children and 5 million children for the risk pillar.

Data on coverage, BR could be generated in each of the seven databases, and a BR analysis could be conducted on real world data. Overall, the primary objective of this first POC, i.e., to test a system to generate evidence on the BR of vaccines, was achieved. The generation of evidence using a 'known test case' was successful.

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One of the major accomplishments of this POC was the transparent multi-stakeholder collaboration and capacity building. The POC studies were executed by four different study teams and included 68 epidemiologists, vaccinologists, medical doctors, computer programmers and 10 statisticians. All ADVANCE partners/stakeholders were active participants with roles and responsibilities shared in an open and synergistic manner. All participants worked according to the ADVANCE code of conduct, with full transparency of conflicts of interest (providing declaration of interests, competencies (providing curriculum vitae) and input (all contributions by stakeholders toward the protocols, statistical analysis plans and report development were tracked). This represents a true multi-stakeholder, PPC with public and private partners in study teams sharing responsibilities.

This POC study was successful and promising for the ADVANCE concept and that future POC studies should aim at reducing the delay from the time the research question is generated to data access and results being available as well as on near real time monitoring. The POC study therefore constitutes a good concrete example of a situation in which the guidance for the development of a communication strategy described in this report could be applied and tested. Although the actual testing and development of a mock communication strategy would be too time- and resource-consuming and would not be feasible within the scope of ADVANCE WP1, this section provides examples of how the different steps described in the report could be applied in preparation for a first workshop aimed at developing the communication strategy. The example describes how a communication strategy about vaccine BR results from multi-country electronic healthcare databases would be developed. It does not describe how the results from the testing of the ADVANCE POC would be communicated as this is outside the scope of this report, and would fall under the scope of project communication.

6.1.2 Description of the organisation developing the communication strategy: national public health institutes

National public health institutes are governmental organisations that exist to protect and improve a nation's health and wellbeing. They provide science- and evidence-based leadership and policies in public health and collaborate with other institutions on surveillance systems, epidemiological and public health investigations, response to public health emergencies, as well as vaccine research, including benefit and safety studies.

As a partner in ADVANCE, national public health institutes have contributed to the ADVANCE EHD system but would additionally be a relevant stakeholder to communicate significant results about vaccine BR originating from the system.

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6.1.3 Mock communication strategy: Draft for 1st Workshop

STEP 1: Defining the goals and objectives of the communication strategy

The goal of this communication strategy is to “*provide information about new insights regarding vaccine BR to inform the public, to sustain trust in the programme and to facilitate decision-making*”.

Specific objectives based on this goal are to:

- inform the target audience about new vaccine BR data and what this data means for public health
- explain in a clear and understandable way how the data was obtained by describing the EHD system
- ensure transparency by informing the target audience of the PPC cooperative and collaborative aspects of the EHD system and how conflict of interests were managed (description of the code of conduct and governance)
- provide recommendations in the form of active actions the target audience can take in response to this new data (either continue or stop vaccination depending on the data).

The goal and objectives in this step were designed during an initial meeting of the team in charge of communication within the public health institute and were based on the institution’s overall mission and values as well as the context of its country and the available budget, resources and timeframe.


Although the goals and objectives are specific to the public health institute, inputs and feedback from other stakeholders involved in the development of the communication strategy will be sought during a first workshop. The workshop will also be used to identify indicators to measure monitor the success of the communication strategy.

These goals and objectives will have to be reviewed and adapted once an audience and channels have been selected.

STEP 2: Mapping stakeholders

The following list of stakeholders was drawn based on their potential interest in BR information as well as the ADVANCE-EHD system:

- International, national and/or regional public health agencies
- Academic and non-academic research institutes, including database custodians such as The Health Improvement Network database (THIN)
- International and national regulatory agencies
- Vaccine manufacturers
- Patient/end users groups/civil society representatives

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These stakeholders will be invited to the first workshop to discuss the development of the communication strategy and to identify potential other stakeholders which could be involved in the development of the strategy. More specifically at the workshop, it will be decided if, how and when the ministries of health, WHO, the European Parliament, members of ECDC's management board, EMA's Pharmacovigilance Risk Assessment Committee, healthcare professionals' organisations, vaccination, health, or child focused non-governmental organisations, as well as members of the public including patient representatives or civil society representatives and individuals opposed or hesitant to vaccination should be consulted on the draft strategy. During this workshop, a list of all stakeholders will be finalised with the following tabulated information:

- Name of stakeholder/institute
- Category of stakeholder
- Contact person and contact details (phone, email)
- Characteristics and description of involvement in the project (if any) and viewpoints about the project (formative research might be needed to develop this)
- Responsibilities for the communication strategy (these should be discussed during the workshop and agreed based on each organisation's competencies and interests)

STEP 3: Identifying the content of the communication

A second workshop will be organised with the stakeholders taking part in the development of the communication strategy, to discuss the content of the communication. The content will be chosen based on the broader national public health institutes' institutional mission and values, the data identified through the EHD-system and its meaning, and the goals and objectives of the strategy. This will be explained to the different stakeholders, who will be asked for inputs and comments. The following content was identified and will be revised during the workshop:

- Description of the benefits of the vaccine in consideration (for individuals and for the population) and the side effects of the vaccine in consideration (presentation, occurrence, frequency, individuals at risk, etc.)
- Description of the BR balance, and why it is either negative or positive – if there is a change, explanation of why the balance has changed (and what it means for people who had already received the vaccine)
- Explanation of how the EHD can be used to obtain data and to perform a BR analysis as well as how it was developed
- The usefulness of systems like the ADVANCE EHD, which provide a platform for the rapid generation of evidence on BR of vaccines across member states

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- Transparent and clear description of the stakeholders involved in the EHD system (public and private) and how they work together under the PPC (including how conflict of interests are managed and the governance framework used)

STEP 3a: Identifying the audience

The following primary audiences were selected based on the list of stakeholders identified in STEP 2, their goals and objectives, and the content of the communication strategy:

- National health authorities (if PHIs not part of them)
- Healthcare professionals and vaccine providers (including pharmacists, nurses, school healthcare personnel as a sub-audience)
- Policy makers
- The public (including parents and groups expressing hesitancy to vaccinate as a sub-audience)
- The media

Secondary audiences selected include: national public health institutes, ECDC, patient organisations, healthcare professional associations, research networks, and non-governmental organisations working on immunisation, vaccination, health, or child focused.

STEP 3b: Identifying the channels of communication


The vaccine providers themselves should be given sufficient information from national public health institutes to facilitate their discussions with patients. They should have a variety of materials available with different details of information that they can choose from such as: leaflets, reports, FAQ and fact sheets, scientific articles, websites, or meetings/conferences. If necessary, they should also be offered training resources on interpersonal communication skills. They should be given an opportunity to contact relevant people at the national institute of public health if they have any questions or if they need any clarifications.

The public should also be reached via other channels, such as internet and social media updates (depending on the urgency of the new information identified), TV/radio interviews with spokespersons, leaflets or posters, and parent group meetings (for instance through schools).

STEP 3c: Developing the message and engagement strategy

Another workshop will be organised with creative teams and key stakeholders, including representatives of the public and vaccine providers. Findings from the formative research will inform the selection of effective ways of formulating the content of the communication during this workshop.

The key messages - which would be present in all communications - will be related to (1) the change in the BR balance, (2) the ADVANCE EHD-system, and (3) the PPC.

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These messages will be tested with a sample of representatives from the primary audiences before adapted if needed and implemented. Some important words should also be defined in lay language before communication such as PPC, EHD-system, or BR. The understanding of this list of words will be tested by members of the public.

STEP 4: Implementing and monitoring the communication strategy

Implementation plan with agreed communication tools, messages and dissemination timetable and mechanism, as well as monitoring and evaluation plan. Monitoring of implementation progress at three levels:

- management: is the strategy being implemented by the national public health institutes' communication team according to the initial plan?
- process: are stakeholders taking their responsibilities and acting as expected?
- end of process: did the public and the vaccine providers receive the communication and were the goals achieved?


Indicators will for instance include the number of audience members who can correctly describe the new vaccine BR information, or who have successfully implemented the recommended actions (i.e. getting vaccinated), as well as assess the audience's trust in the information provided in relation to the PPC and their understanding of how conflict of interests were managed in producing the data. Indicators will be measured both before and after communication has taken place.

6.2 Near-real time monitoring: a dashboard for vaccine benefit-risk monitoring

6.2.1 Introduction to the ADVANCE dashboard

At the core of the mission of ADVANCE and many of its stakeholders is the concept of BR monitoring. Monitoring should be understood as periodic checks on several key parameters of the benefits and the risks of vaccines (such as vaccine coverage, incidence of adverse events, incidence of the preventable disease) to trigger an alert if and when there would be suspicion that the BR profile in the population may be different from initial expectations. This alert would generate a further, subsequent and possibly more formal analysis and assessment. Monitoring should start as soon as a new vaccine is used in a given country. The target should be near real-time information, meaning possibly weekly refresh of data that would only be a few days old, and in parallel with the rollout of a vaccination programme.

There are several, and typically not integrated, sides of post-licensure or post-marketing vaccine surveillance; the surveillance of vaccination uptake and compliance with the recommended vaccination schedule, safety, vaccine effectiveness and impact. To date, post-marketing vaccine surveillance has focused primarily on vaccine safety, with an enhanced interest in near real-time surveillance using electronic healthcare databases. Although formal BR assessments, by which the benefits of a medical intervention are offset against its risks at

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one point-in-time, are increasingly performed, post-marketing (integrated) monitoring of coverage, benefits, risks, and BR is not yet implemented in practice. ADVANCE explores methodology for near real-time BR monitoring of vaccines using electronic healthcare databases. A visualisation of key data for monitoring vaccination coverage, benefits, and safety is being proposed; that are then combined into composite measures of the vaccine BR profile as it evolves over time. To facilitate the monitoring, a visual dashboard was developed. The dashboard is illustrated using simulated data reflective of the introduction of the rotavirus vaccination in the UK.

6.2.2 Description of the organisation developing the communication strategy: vaccine manufacturers

For vaccine manufacturers the quality, safety and effectiveness of their products are of utmost interest and importance, always with the safety and improved health of vaccinated individuals in mind. This is also reflected in their legal obligations (such as by the EU GVP) to 'monitor' the BR of the vaccines. A dashboard allows almost instant view of how a new vaccine would be working in the real world (as opposed to clinical trials), from the first week of use. This would allow rapid detection of a potential issue, real or not, to trigger appropriate further investigations and measures. If no issue is detected, the public and regulators will still benefit from the reassurance that there is constant monitoring in place about the safety and the benefits of vaccines. Therefore proper communication on the dashboard is important, to explain the reasons to set it up, the methodology and data sources, the limitations, and the process in case of an alert.


6.2.3 Mock communication strategy: Draft for 1st Workshop

STEP 1: Defining the goals and objectives of the communication strategy

The goal of the communication strategy for vaccine manufacturers is to “*improve understanding of how near-real time monitoring of vaccine BR is achieved through the ADVANCE dashboard*”. Specific objectives are to:

- explain what the dashboard is and how it was developed
- describe how data on BR is created with the dashboard
- explain how the dashboard can be used to monitor BR of specific vaccines
- describe the PPC cooperative and collaborative aspects of maintaining the dashboard, taking required actions, and communicating to various audiences

The goal and objectives in this step were designed during an initial meeting of the team in charge of communication within the vaccine manufacturer’s company and were based on the institution’s overall mission and values as well as the available budget, resources and timeframe.

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Although the goals and objectives are specific to vaccine manufacturers, inputs and feedback from other stakeholders involved in the development of the communication strategy will be sought during a first workshop. The workshop will also be used to identify indicators to measure monitor the success of the communication strategy.

These goals and objectives will have to be reviewed and adapted once an audience and channels have been selected.

STEP 2: mapping stakeholders


The following stakeholders with an interest in the dashboard and part of the ADVANCE PPC were identified:

- National or regional public health agencies
- Academic and non-academic research institutes, including database custodians such as The Health Improvement Network database (THIN)
- International and national regulatory agencies
- Other vaccine manufacturers
- International public health institutes
- Patient/end users groups/civil society representatives

These are the internal project stakeholders. A first workshop will be conducted with those ADVANCE partners, partly to discuss other stakeholders, external to the project, which might or should be involved in the development of the communication strategy. These could include healthcare professionals' organisations, vaccination, health, or child focused non-governmental organisations, as well as members of the public including patient representatives or civil society representatives.

During this workshop, a table with the list of external and internal stakeholders will be created with the following information:

- Name of stakeholder/institute
- Category of stakeholder
- Contact person and contact details (phone, email)
- Characteristics and description of involvement in the project (if any) and viewpoints about the project (formative research might be needed to develop this)
- Responsibilities for the communication strategy

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STEP 3: Identifying the content of the communication

A second workshop will be organised with all the stakeholders taking part in the development of the communication strategy, to discuss the content of the communication based on the project, and the goals and objectives of the strategy. The following draft of the communication content was developed and will be further reviewed:


- what the dashboard is in the particular context of ADVANCE, and the reasons for its set up and use
- the methodology and data sources behind it, including the inherent limitations
- the process in case of an alert (with a definition of what is meant by an alert): specific communication (content and channel), to which specific audiences, and potential actions (why whom, how)
- the PPC cooperative or collaborative aspects of (i) maintaining the dashboard (ii) taking required actions (iii) communicating to various audiences

STEP 3a: Identifying the audience

The primary audience for this communication strategy are regulatory authorities (national and international). The audience was selected as they had been identified in STEP 2's identification of stakeholders with an interest in the dashboard and as due to important trust issues, vaccine manufacturers cannot aim to communicate directly with any stakeholder, particularly the public. Addressing regulatory authorities is crucial to achieve the communication strategy objectives of sharing knowledge about how to use the dashboard to monitor BR of vaccines. Regulatory authorities can also use the dashboard to communicate directly to other groups and have a greater impact and influence on those immediately affected by changes in BR: the public.

Other stakeholders that might be reached indirectly (secondary audience) include:

- International (CDC, ECDC) and national public health institutes
- Associations of patients or health professionals
- Vaccine providers (GPs, pharmacists, nurses, school healthcare personnel)
- Research networks working on immunisation, sentinel disease surveillance networks
- Vaccination, health, or child focused non-governmental organisations
- Members of the public including patient representatives or civil society representatives
- Groups expressing hesitancy to vaccinate

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STEP 3b: Identifying the channels of communication

Vaccine manufacturers have an established and formal communication channel to regulatory authorities, which are limited and highly regulated. Therefore, the channels for this communication strategy consist of a mix of protocol and study result disclosures/posting to websites (companies' data disclosure websites, CT.gov, ENCePP register etc.), companies' social media pages, and peer-reviewed journals. Those channels will be used to discuss and agree on some public statements, which will then be made into press releases. Regulatory authorities will then have to decide how they wish and how it is appropriate for them to communicate to other stakeholders.

STEP 3c: Developing the messages and engagement strategy

A third workshop will be organised with creative teams, key stakeholders and representatives of regulatory authorities to discuss and agree on the messages of the communication strategy.

The key messages - which will be present in all communications - are related to (1) the benefits of using the dashboard, and (2) its development by a PPC. Examples of such messages include:

- “The vaccine BR monitoring dashboard, developed by the ADVANCE public-private collaboration, can be used to follow near-real time safety and benefit data”
- “The vaccine manufacturers have funded the development of the dashboard and provided technical information on how to collect the data. Partnership X had the full responsibility to take decisions for the collection, analysis, and interpretation of the data” (see section 4.1.4)


These messages will be refined further in the workshop and will be tested with a sample of representatives from the audience before fully implemented and adapted if needed.

STEP 4: Implementing and monitoring the communication strategy


The communication strategy will be implemented according to the implementation plan. The vaccine manufacturers will also have to monitor its progress on three levels:

- management: is the strategy being implemented by the vaccine manufacturers communication team according to the initial plan
- process: are stakeholders taking their responsibilities and acting as expected
- end of process: did the regulatory authorities receive the communication and were the goals achieved

Indicators to measure and monitor the success of the communication strategy in achieving the goal and objectives are focused on improvements in knowledge and understanding of the targeted audiences. Examples of indicators include the number of audience members who

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can correctly describe what the dashboard is or who are able to use the dashboard as well as an assessment of a more general understanding of the different concepts. A survey will be set up to measure the audience's knowledge of similar dashboard before the communication takes place and after.

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ANNEXES

Annex A: List of identified guidance documents for communication strategy development

Guidance, recommendations and practical tools to develop communication strategies

Bahri P. Public pharmacovigilance communication: a process calling for evidence-based, objective-driven strategies. Drug Saf. 2010; 33: 1065-1079.


This article describes a strategic health communication approach to communicate information on the effective and safe use of medicines, including vaccines. It includes “agreeing measurable communication objectives through shared problem ownership of all concerned parties, evidence-based design and a cyclic process for planning, implementation, and evaluation of communication as a public health intervention”. It discusses the participation of medicine users in the risk management process in the form of a two-way communication system to “inform risk assessment as well as the analysis of risk minimization options, allow for agreement upon communication objectives and enable understandable, attractive communication materials to be designed”. The article advises the use of mixed media and repetition of messages, as well as cooperation within healthcare and medical information systems.

[Link to document](#)

British Columbia Centre for Disease Control (webpage). Immunization. British Columbia: Provincial Health Services Authority

Webpage with infographics and information about vaccination for healthcare professionals. The website also provides a link to an [immunization communication tool](#) for immunisers, as well as posters and reference cards. This tool recommends the A-S-K approach to healthcare professionals (Acknowledge your client’s concerns; steer your conversation; know the facts well). It provides answers to questions about vaccination both for healthcare professionals and for patients. Examples of questions for vaccine safety include: Are vaccine safe? How are vaccines approved in Canada? How is vaccine safety monitored in Canada? Who makes recommendations for vaccine use in Canada? How was the HPV vaccine approved in Canada? It also answers questions on multiple injections, on vaccine misconceptions, the safety of vaccine components, natural immunity versus vaccine immunity, the necessity of vaccines, whether vaccines work, and whether a healthy lifestyle is sufficient protection.

[Link to webpage](#)

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Cairns G, MacDonald L, Angus K, Walker L, Cairns-Haylor T, Bowdler T. Systematic literature review of the evidence for effective national immunisation schedule promotional communications. Stockholm: ECDC; 2012.

A systematic literature review examined the published evidence on the effectiveness of European promotional communications for national immunisation schedule (NIS) vaccinations. The review was commissioned by the European Centre for Disease Prevention and Control (ECDC) and conducted by the Institute for Social Marketing at the University of Stirling.

[Link to document](#)

Erice Statement 2009: communication, medicines and patient safety. Br J Clin Pharmacol. 2010; 69: 207-208.

The document provides an update on the Erice declaration, to adapt to a changed landscape in pharmacovigilance. It explains that safety communication needs to be focused on creating dialogue and that there are new ways of cooperating with the media.


[Link to document](#)

European Centre for Disease Prevention and Control. Communication on immunisation – building trust. Stockholm: ECDC; 2012.

This guide highlights the importance of trust and credibility for public health organisations in order to communicate effectively on immunisation. The document aims at supporting Member States in planning and implementing communication initiatives on vaccination, by presenting an overview of the main issues that public health institutions need to consider in relation to building and maintaining trust.

Transparency and trust are parameters to work with – before and while undertaking any communication activities – to ensure that information on immunisation is acknowledged by the public and advice is followed. Undertaking the different steps for preparing and implementing a communication programme will increase effectiveness of immunisation campaigns. This includes managing stakeholders, selecting priority audiences and assessing their knowledge, attitudes and behaviours, selecting the most appropriate communication channels to reach them, as well as formulating key messages, being consistent and creating materials that address the information needs and concerns of the priority audiences.

[Link to document](#)

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European Centre for Disease Prevention and Control. Conducting health communication activities on MMR vaccination. Stockholm: ECDC; 2010.

This guide provides an overview of health-communication-related obstacles to measles, mumps and rubella (MMR) vaccination. It provides assistance in the planning and implementation of national communication initiatives on MMR vaccination.

[Link to document](#)

European Centre for Disease Prevention and Control. Let's talk about hesitancy. Enhancing confidence in vaccination and uptake. Practical guide for public health programme managers and communicators. Stockholm: ECDC; 2016.

This guide provides practical evidence-based and peer-reviewed advice for public health programme managers (PHPMs) and communicators involved with immunisation services. It identifies ways to enhance people's confidence in vaccination and addresses common issues which underlie vaccination hesitancy. This guide serves as a supplement to the ECDC guide Let's talk about protection.

[Link to document](#)

European Centre for Disease Prevention and Control. Let's talk about protection. Enhancing childhood vaccination uptake. Communication Action guide for healthcare providers. Stockholm: ECDC; 2013.


This guide provides practical peer-reviewed advice and evidence-based guidance for healthcare professionals involved with vaccination services on ways to increase childhood vaccination uptake. The advice aims to help HCPs gain insights into the behaviours and choices of different stakeholders and identify ways to better address concerns and obstacles to vaccination uptake. It gives perspectives from parents and caregivers; social marketers, health promoters and media specialists; vaccination experts and providers; and hard-to-reach populations. It also provides support material for conversations with stakeholders with ways of making the case for protection, useful hand-outs to support conversations with parents, frequently asked questions, and useful links.

[Link to document](#)

European Centre for Disease Prevention and Control. Measles and rubella elimination: communicating the importance of vaccination. Stockholm: ECDC; 2014.

The goal of this project is to support EU Member States in their fight against measles and rubella. More specifically, this project aims to:

- dispel the myths about measles vaccination;

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- offer scientific, evidence-based corrections of misperceptions on measles
- inform about rubella infections in pregnancy; and
- discuss the BR of vaccination against rubella for women of childbearing age.

This report should enable Member States to engage in effective, evidence-based risk communication. Information on measles and rubella is presented in a modular fashion, so it can be easily used in customised leaflets, flyers, or web pages. The facts presented in this report are intended to lower the barriers to measles and rubella vaccination and raise awareness for congenital rubella syndrome (CRS), including awareness for ante-natal screenings and post-partum vaccination.

[Link to document](#)

European Centre for Disease Prevention and Control. Rapid literature review on motivating hesitant population groups in Europe to vaccinate. Stockholm: ECDC; 2015.


Literature review on determinants of vaccine hesitancy in Europe and strategies to address them. The articles selected for review recommend every communication intervention to be based on clear and comprehensive frameworks combining an array of concepts: knowledge, attitudes, acceptance, perceptions, beliefs, or behaviour. They advise prioritising interventions that can target the most common population groups and behaviour, and leave smaller scale interventions to fill the gaps and address specific hesitant populations. Various studies agree that messengers have to be perceived as credible and trusted sources by hesitant populations and this trust needs to be reinforced by using effective and transparent arguments. Ideally, vaccine providers are to be used as advocates of vaccination, but interventions can use a range of stakeholders as long as they have expertise in communication design, delivery, and evaluation. They also mention that optimally, healthcare professionals are to be included as receivers of information, training and education.

[Link to document](#)

European Medicines Agency (EMA) and Heads of Medicines Agencies. Good pharmacovigilance practices for the European Union (EU-GVP). London: EMA; 2012-2016.

These guidelines, developed by EMA and HMA provides guidance on good pharmacovigilance practices in the EU and include a section on communicating vaccine safety information. It provides recommendations on key concepts and values of vaccine safety communication, transparency, content of communication, collaboration with other partners, responses to public health emergencies, preparation and testing of communication, collection of evidence, proactive and reactive communication, media monitoring, and adaptation to different contexts and countries.

[Link to document](#)

	Deliverable 1.12: Developing communication strategies on vaccine benefits and risks: Guidance for public-private collaborations		
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	Author(s): H Larson, E Karafillakis, A Yiangou, P Bahri, J Fogd, X Kurz, R Świerzewski, et al.	Security: Public	72/100

Hyunyi Cho, Torsten Reimer, and Katherine McComas. The SAGE handbook of risk communication. SAGE publications; 2014.

The SAGE handbook of risk communication provides theories, current research, practise, and effective communication strategies for risk situations in varied contexts. It provides integrative knowledge about the models, audiences, messages, and the media and channels required for effective risk information.

[Link to document](#)

Infanti J, Sixsmith J, Barry MM, Núñez-Córdoba J, Oroviogoicochea-Ortega C, Guillén-Grima F. A literature review on effective risk communication for the prevention and control of communicable diseases in Europe. Stockholm: ECDC; 2013.

This review examines the current body of literature on risk communication related to communicable diseases, focusing on: (i) definitions and theories of risk communication; (ii) methodologies, tools and guidelines for risk communication research, policy and implementation; and (iii) implications, insights and key lessons learned from the application of risk communication principles in real-world settings.

[Link to document](#)


Larson H. The globalization of risk and risk perception: why we need a new model of risk communication for vaccines. Drug Saf. 2012; 35: 1053-1059.

Article portraying the complexity and globalisation of risk communication for vaccines. It calls for a new, more holistic model of risk assessment, risk communication, and risk mitigation, embedded in an ongoing process of risk management for vaccines and vaccination programmes. The article describes risk communication as an ongoing process that requires trust-building activities as well as operational and policy strategies to address vaccine-related risks and perceptions of risks.

[Link to document](#)

Public Health Agency of Canada. Canadian Immunisation Guide: Part 1: Key Immunisation Information 2016: Communicating effectively about Immunization. 2016.

In addition to describing vaccine hesitancy and the principles of effective communication (adopt a vaccine recipient-centred approach, respect differences of opinions about immunisation, represent the benefits and risks of vaccines fairly and openly, and clearly communicate current knowledge using an evidence-based approach), this guide from the

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Public Health Agency of Canada provides examples of immunization facts that can be communicated.

[Link to document](#)

Shimp L. Strengthening immunization programs: the communication component. Arlington, VA: Basic Support for Institutionalizing Child Survival Project (BASICS II) for the United States Agency for International Development; 2004.

This report, published by the Basic Support for Institutionalising Child Survival Project, discusses the importance of communication in vaccination programmes. It provides an overview of communication activities for immunisation and describes how to use it to improve vaccination programmes in developing countries. Communication is discussed as a complement to a wider programme of immunisation planning, activities, and partnerships. The target audiences are immunisation technical experts and communication specialists. The report describes the role of communication in vaccination programmes, challenges to immunisation communication, partners and coordination in immunisation communication, fundamentals of immunisation communication for national EPI programmes, and immunisation communication practices.

[Link to document](#)


The Health Communication Capacity Collaborative. The P-Process: five steps to strategic communication. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health Center for Communication Programs, 2013.

The P-Process is a tool to develop strategies for evidence-based health communication for behaviour change programmes. It has three cross-cutting concepts (social and behaviours change communication theory, stakeholder participation, and continuous capacity strengthening) and consists of five steps: Inquiring, designing a strategy, creating and testing, mobilising and monitoring, and evaluating and evolving.

[Link to document](#)

Uppsala Monitoring Centre (UMC). Dialogue in pharmacovigilance. Uppsala: UMC; 2002.

The UMC has published a collection of writings about communication entitled Dialogue in Pharmacovigilance - more effective communication. This 140-page book contains a wealth of material for anyone interested in how to improve the current state of communications in pharmacovigilance. The book includes sections on: principles in good communications in pharmacovigilance; description of players - their activities, interests and needs; the role of the mass media in public drug education; academic journals; general public drug education, profession education; prescribing information; pharmacovigilance information for patients;

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communication on ADRs occurring with marketed medicines; crisis and recall; and legal concerns.

[Link to document](#)

Uppsala Monitoring Centre (UMC). Effective communication in pharmacovigilance: the Erice Report. Uppsala: UMC; 1997.

Report on the International Conference on Developing Effective Communications in Pharmacovigilance held in Erice, 24-27 September 1997, organised by the UMC, the World Health Organization, the University of Verona, the International School of Pharmacology, the Ettore Majorana Centre for Scientific Culture and supported by EQUUS Communications.

[Link to document](#)

US Department of Health and Human Services, Food and Drug Administration. Communicating risk and benefits: an evidence-based user's guide. Silver Spring: US Department of Health and Human Services, Food and Drug Administration; 2011.


This guide summarises the latest research on risk communication and provides evidence-based recommendations to improve health provider risk communication with the public. It provides information on how communication can be evidence-based, consistent with science, and how it should be evaluated. The guide discusses the goals of risk communications, methods for evaluating them, standards for assessing their adequacy, and the language they use. They also describe the audience and others with communications.

[Link to document](#)

US Centers for Disease Control and Prevention. Crisis and emergency risk communication (CERC), 2014 edition. US: CDC; 2014.

Crisis and Emergency Risk Communication is an approach to communicating effectively during emergencies. These principles are used by public health professionals and public information officers to provide information that helps individuals, stakeholders, and entire communities make the best possible decisions for themselves and their loved ones. CERC recognizes that during emergencies, we work under impossible time constraints and must accept the imperfect nature of our choices. CERC draws from lessons learned during public health emergencies and research in the fields of public health and emergency risk communication. Other resources available on the [CDC website](#).

[Link to document](#)

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Waisbord S, Larson H. Why invest in communication for immunization: evidence and lessons learned. Baltimore, MD, New York, NY: Health Communication Partnership based at Johns Hopkins Bloomberg School of Public Health / Center for Communication Programs, United Nations Children's Fund; 2005.

This report explains why it is important to invest in communication for immunisation. It discusses communication as a broad concept, including “advocacy, social and community mobilisation, and information, education and communication activities”. The document discusses challenges of communication for immunisation, evidence-based communication activities, lessons learnt, and the contribution of communication to strengthened vaccination programmes. Some of the successful communication activities listed include restoring quality-interaction between health providers and caregivers, training and supervising health providers, using mass media, continuous activities to build and maintain confidence, communication strategies to respond to controversies, communication activities with local influential leaders, and the use of community networks to promote immunisation.

[Link to document](#)

World Health Organization (WHO). How to Respond to Vocal Vaccine Deniers in Public. Geneva: WHO; 2016


This guidance document provides basic, broad principles for a spokesperson of any health authority on how to behave when confronted by and how to respond to vocal vaccine deniers.

[Link to document](#)

World Health Organization (WHO). The importance of pharmacovigilance: safety monitoring of medicinal products. Genève: WHO; 2002.

This WHO report was designed to explain the importance, growth, and impact of pharmacovigilance for safety monitoring of medicinal products, including vaccines. It discusses communication of safety information and the development of the 1998 Erice Declaration on Communicating Drug Safety Information. The document also explains that information and data from national pharmacovigilance centres, and drug information and poison centres can be used to disseminate drug alerts and drug safety information to health professionals. Regulatory authorities also have communication mechanisms (websites, videos, television programmes) to inform the public and encourage reporting of safety events. It stresses the importance of collaboration between regulators, manufacturers, consumers, and the media.

[Link to document](#)

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World Health Organization (WHO). *Strategies for addressing vaccine hesitancy: a systematic review (WHO-SAGE report)*. Geneva: WHO; 2014.

Systematic review of implemented and evaluated strategies and interventions addressing vaccine hesitancy across diverse global contexts. Few strategies explicitly address vaccine hesitancy, and even fewer have been evaluated. Multicomponent interventions and/or those with a dialogue-based approach were found to perform better. Interventions which could successfully address vaccine hesitancy include social mobilisation, mass media, communication tool-based training for HCWS, non-financial incentives, and reminder-recall activities.


[Link to document](#)

World Health Organization (WHO). *Vaccine Safety Events: managing the communications response. A guide for Ministry of Health EPI Managers and Health Promotion Units*. Copenhagen: WHO; 2013.

This WHO guide provides strategies and tools to plan and manage effective communication in response to vaccine safety related events (VRE). The target audience are vaccination programme managers who require adaptable tools to increase public trust and confidence in vaccination while minimising the negative impact of VRE. The report provides background information on the media, concerns about vaccination, communication, and vaccine related events. It also comprises of advice regarding the following:

- Understanding and using the media
- Identifying target audiences and spokespersons
- Developing messages to communication complex information (risk communication, developing key messages, etc.)
- Channels to communication about immunisation
- Writing a media communication plan/strategy (steps and template)
- Routine communication activities
- Responses and activities in response to crisis, rumours, VREs, and AEFI reporting
- Partnership building for effective communication
- Specific communication preparations required for special immunisation events (i.e. mass campaigns)
- Timeline for communication actions and best communication practices
- Evaluation of communication strategies and activities

[Link to document](#)

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World Health Organization (WHO). World Health Organization Outbreak Communication Planning Guide. Geneva: WHO; 2008

WHO guide to help national authorities apply the WHO Outbreak communication principles (trust, announcing early, transparency, listening, planning) to their outbreak planning and preparation activities. The guide describes the 7 steps of planning for national public health authorities: assessment; coordination; transparency; listening during outbreaks; communication evaluation; constructing an emergency communication plan; and training.

[Link to document](#)

World Health Organization (WHO). World Health Organisation Vaccine Safety Supporting Document. Crisis Communications Plan Template. Geneva: WHO; 2017

This document provides guidance on the essential elements of an immunization communications plan, with special emphasis on elements that relate to crisis communication. Developing an immunization communications and crisis communications plan allows you to build and maintain trust in vaccines and demand for vaccination and prepare for vaccine safety events and crises.

[Link to document](#)

Documents with information about BR and vaccine confidence

Andre FE, Booy R, Bock HL, Clemens J, Datta SK, John TJ, Lee BW, Lolekha S, Peltola H, Ruff TA, Santosham M, Schmitt HJ. Vaccination greatly reduces disease, disability, death and inequity worldwide. Bulletin of the WorldHealth Organization. 2008; 86: 140-146.


This article communicates the benefits of vaccination, as they could be shared as part of a wider communication strategy on the BR balance of vaccines.

[Link to document](#)

Edwards A, Elwyn G. Shared decision-making in healthcare: achieving evidence-based patient choice. Oxford: Oxford University Press; 2009.

Book examining patient choice and clinical decision-making. Evidence-based medicine is deeply ingrained in the practice of modern medicine, while patient choice is increasingly high on the political agenda. "Shared Decision Making" has developed in response to the sometimes-uneasy relationship between a patient's right to input into their treatment options, and a clinician's responsibility to provide the best evidence-based healthcare.

[\(Book – no link available\)](#)

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	Author(s): H Larson, E Karafillakis, A Yiangou, P Bahri, J Fogd, X Kurz, R Świerzewski, et al.	Security: Public	78/100

Larson H, de Figueiredo A, Xiahong Z, Schulz WS, Verger P, Johnston IG, Cook AR, Jones NS. *The state of vaccine confidence 2016: global insights through a 67-country survey.* *EBioMedicine*; 2016.

This article describes a large-scale, data-driven study on worldwide attitudes to immunizations to examine perceptions of vaccine importance, safety, effectiveness, and religious compatibility among 65,819 individuals across 67 countries. It found that overall sentiment towards vaccinations is positive across all 67 countries; however, there is wide variability between countries and across world regions. Vaccine-safety related sentiment is particularly negative in the European region, which has seven of the ten least confident countries, with 41% of respondents in France and 36% of respondents in Bosnia & Herzegovina reporting that they disagree that vaccines are safe (compared to a global average of 13%). The oldest age group (65+) and Roman Catholics (amongst all faiths surveyed) are associated with positive views on vaccine sentiment, while the Western Pacific region reported the highest level of religious incompatibility with vaccines. Countries with high levels of schooling and good access to health services are associated with lower rates of positive sentiment, pointing to an emerging inverse relationship between vaccine sentiments and socio-economic status. The article recommends regular monitoring of vaccine attitudes together with monitoring of local immunisation rates at national and sub-national levels to identify populations with declining confidence and acceptance.

[Link to document](#)

Larson H, Schulz W. *The State of Vaccine Confidence 2015.* London: London School of Hygiene & Tropical Medicine.

This report provides an overview of the state of vaccine confidence in the world in 2015. It describes historical examples of loss of confidence in vaccination and their resolutions. It also offers methods for the measurement of vaccine confidence and describes the results of a survey comparing vaccine hesitancy in five countries (Nigeria, Pakistan, India, Georgia, and the UK).


[Link to document](#)

Webpages with links to useful resources, information about vaccination

Communication tools (webpage). ECDC.

ECDC webpage with links to toolkits and guidance materials on communication. It provides links to communication materials described in this list.

[Link to webpage](#)

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Immunisation (webpage). UK Government

Webpage with infographics and information about immunisation for healthcare professionals. Includes training material for healthcare professionals.

[Link to webpage](#)

Risk Communication (webpage). World Health Organisation.


Webpage with links to documents and guidance on risk communication, including a [toolkit](#) for behavioural and social communication in outbreak response; a [participant handbook](#) for effective communications; and a [handbook](#) for effective media communication during public health emergencies.

[Link to webpage](#)

The Vaccine Confidence Project (webpage). London: London School of Hygiene & Tropical Medicine.

The website of the Vaccine Confidence Project provides regularly updated information on crisis of vaccine confidence and allows mapping issues of confidence around the world.

[Link to webpage](#)

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Annex B: Report for IMI ADVANCE WP 1 WG 4 on guidance documents on vaccine communication used by regulatory competent authorities in Member States

A survey was conducted by the EMA (Priya Bahri) in 2015, (draft survey questionnaire had been consulted with Heidi Larson and Emilie Karafillakis) and the following report of 27 May 2015 was circulated to ADVANCE:

Introduction

In support of the ADVANCE project, namely to collect background information for deliverable D.1.12., the European Medicines Agency (EMA) contacted the competent authorities responsible for authorisation of medicinal products in Member States by means of a Non-Urgent Information request (NUI). The NUI consisted of two sets of questions, one relating to guidance on vaccine communication, the other relating to media monitoring practices. More specifically, the first set of questions solicited whether and which guidance documents competent authorities use themselves or request marketing authorisation holders to use when communicating about vaccines, or which they are otherwise aware of or feel they should be developed. The NUI also stated that the report for ADVANCE will not contain the competent authorities' individual responses, but summary information (see Annex 1 for the NUI).

This report summarises the responses to the first set of questions and lists all guidance documents used with a view to supporting the development of deliverable D.1.12., i.e. a strategy for public communication in the context of vaccine BR monitoring.


Summary of responses

Response rate

Sixteen competent authorities out of the 28 Member States responded to the NUI, namely the agencies from Bulgaria, Denmark, Finland, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, Portugal, Romania, Slovakia, Slovenia and Sweden. In addition, the Norwegian agency responded, as an EEA country but not an EU Member State.

Guidance documents used by competent authorities in Member States

Seven Member States stated that they use the Considerations P.I on Vaccines, part of the EU Good Pharmacovigilance Practices (GVP), which includes sections on communication specific to vaccines, and refer to the GVP Module XV on safety communication about medicinal products in general. GVP P.I was published as final in December 2013 and applies to the EMA, the competent authorities in Member States and marketing authorisation holders in the EU. While the EMA and other regulatory bodies worldwide had previously published general

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principles and processes for communicating about safety of medicines including vaccines, issuing regulatory guidance on specific aspects relevant to the communication of vaccines was new. The fact that only seven out of the 16 Member States describe use of GVP for vaccine communication may reflect that not yet all assessors and communication officers are aware of this new guidance.

Out of the seven positive responders, three Member States stated that in addition to GVP, they use WHO guidance. While two did not specify which WHO guidance documents they use, one described using the WHO webpage dedicated to vaccination campaigns. Further, out of these seven, one Member State stated to use national guidance in addition to GVP and WHO guidance; one Member States uses national guidance in addition to GVP; one Member State uses mainly national guidance, but with GVP awareness; and one Member State stated to use only national guidance.

The NUI also solicited feedback on the usefulness of the GVP on vaccine communication, and out of the seven, only one Member State responded with a specific case when GVP was used and one Member State confirmed to use it, but gave no further details. The specific case provided referred to communication of a signal of increase in the reported number of BCG vaccine-related supportive lymphadenitis, in particular severe cases that required surgical intervention. For interpreting the responses it again to be noted that the GVP on vaccine communication is still rather new. The guidance was presented at a number of meetings (Conference of the International Society for Pharmacoepidemiology 2013, training session at Annual Meeting of International Society of Pharmacovigilance 2014, training session at Pharmacovigilance Course of Uppsala Monitoring Centre 2014, meeting of WHO Global Vaccine Safety Initiative 2014) and received very positive feedback and follow-up interest.


Four Member States mentioned that they have guidance on communication processes for medicinal products available, which they also apply to vaccines; and out of these four, one Member States intends to update its general guidance with vaccine-specific aspects.

One Member State passed on a response from the public health authority in its Member State, which uses only WHO guidance, in particular those issued by WHO-EURO.

It should be noted that a number of Member States mentioned that communication on vaccines in their Member States is mainly enacted by the public health authorities rather than the competent authorities for authorising medicinal products.

Guidance documents requested by competent authorities in Member States to be used by marketing authorisation holders

Three Member States state to request explicitly marketing authorisation holders to use GVP. It should be noted however that GVP applies in any case to marketing authorisation holders in the EU, and that this does not require specific endorsement through Member State guidance. Interestingly, out of these three, one Member State states to request marketing authorisation holders to use GVP while it does not state for itself to use GVP; and maybe less

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interestingly, given that GVP applies to all marketing authorisation holders in the EU anyway, one Member State states to use GVP itself but does not state to request marketing authorisation holders explicitly to do so.

Guidance needs identified by competent authorities in Member States

Three Member States expressed the need for further guidance on vaccine communication, mainly for interacting with journalists. More in detail, out of these three, one asked for further guidance on “*vaccine communication targeted to different stakeholders including journalists for enhancing the awareness of benefits that immunization provides versus risks and use in dialogue with vaccination opponents*”, one for guidance on “*agreements with journalists and involved institutions in the vaccine field about timings of publication, the management and spread of information concerning a vaccine in order to avoid the circulation of incorrect news*”, and one for “*evidence-based guidance about vaccines*” which may be used when interacting with journalists and the public as a “*tool to calm down the anti-vaccination front endangering the fairly good domestic vaccination coverage rate*”. The latter need did actually not originate from a competent authority, but was passed on from the public health authority in the same Member State. It is interesting, but not surprising to note that the main concern of competent authorities in relation to vaccine communication is to provide accurate BR information in the context of anti-vaccination sentiments.

Other guidance and initiatives competent authorities in Member States are aware of


It was also solicited whether competent authorities are aware of guidance documents they do not currently apply but could find useful, or whether they are aware of relevant initiatives.

Regarding other guidance documents, one Member State passed on information from its public health authority about ECDC guidance.

One Member State responded that it is aware of training courses held by journalists for epidemiologists and other experts from the Ministry of Health in that Member State on how to communicate on vaccines including sensitive information on adverse events following immunisation (AEFIs).


One competent authority in another Member State responded that the public health authority in its Member State is currently involved in a project aiming to identify relevant public attitudes and national key information channels that should provide insight in the “general status of public knowledge, practice and position on the topic, to enable sustainable long term activities for protection of the population against communicable diseases by vaccination”.

The competent authority in Hungary mentioned in its response that the Hungarian National Centre for Epidemiology (NCE) is associated partner of ADVANCE.

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List of guidance documents referred to in the responses

- EU Good Pharmacovigilance Practices (GVP) Module XV on Safety Communication (accessible here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp&mid=WC0b01ac058058f32c)
- EU Good Pharmacovigilance Practices (GVP) Considerations P.I on Vaccines (accessible here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp&mid=WC0b01ac058058f32c)
- Hungarian National Centre for Epidemiology (NCE) guidance (accessible here: www.oek.hu, www.vacsatc.hu)
- Hungarian Office of the Chief Medical Officer (OCMO) guidance on media relations (not published)
- Irish National Immunisation Office guidance (accessible here: <http://www.hse.ie/eng/health/immunisation/>)
- Swedish National Board of Health and Welfare national communication strategy for vaccine programs (<http://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/19588/2014-11-6.pdf>)
- Slovenian public health authority guidance on managing immunisation
- ECDC technical report Health Communication and its Role in the Prevention and Control of Communicable Diseases in Europe (<http://ecdc.europa.eu/en/publications/Publications/health-communication-communicable-disease-europe.pdf>)
- ECDC technical report Communication on Immunisation – Building Trust (<http://ecdc.europa.eu/en/publications/Publications/TER-Immunisation-and-trust.pdf>)
- WHO guidance documents (unspecified)
- WHO information for immunization campaigns (accessible here: <http://www.who.int/campaigns/immunization-week/2015/en/>)
- WHO-EURO Guide to Tailoring Immunization Programmes (http://www.euro.who.int/__data/assets/pdf_file/0003/187347/The-Guide-to-Tailoring-Immunization-Programmes-TIP.pdf?ua=1)
- WHO-EURO guide Adverse Safety Events-Managing the Communication Response (http://www.euro.who.int/__data/assets/pdf_file/0007/187171/Vaccine-Safety-Events-managing-the-communications-response-final.pdf?ua=1)”

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Text of the Non-Urgent Information request (NUI) to Competent Authorities in Member States [text deleted in D.1.12, only questions maintained]

ADVANCE Survey on guidance documents used by competent authorities in Member States regarding communication to/with the public¹ about safety concerns or the risk-benefit balance of vaccines

PLEASE READ FOOTNOTES FIRST.

QUESTION 1. Do you apply, at your agency, any specific guidance/principles/procedures/templates when communicating about vaccines, either drawn up by yourself or another organisation in your Member State, another country, at EU or international level? If so, please provide titles and copies (indicate if internal or public) and links if published on the internet.

QUESTION 2. Have you issued specific guidance on vaccine communication for MAHs or do you have otherwise voiced expectations towards them about how to communicate (e.g. reference to guidance issued by others)?


QUESTION 3. Do you already have any experience with the communication guidance in GVP P I on vaccine pharmacovigilance issued about a year ago? If yes, please provide feedback.

QUESTION 4. Are you aware of any guidance you do not use but think could be useful?

QUESTION 5. Do have any relevant initiatives ongoing or planned in terms of guidance development, supporting research, stakeholder cooperation or similar?

QUESTION 6. Do you have any comment you want to add, e.g. about guidance needs, their usefulness, major academic publications, guides for journalists, opinions from others?"

¹ Communication with the public here refers to informing stakeholders like the general public/sub-populations, healthcare professionals or the media about BR data/conclusions on vaccines. It also refers to receiving information or questions from such stakeholders. It does not refer to adverse reaction reporting or communication within/between authorities or between authorities and MAHs.

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Annex C: Report for ADVANCE WP 1 WG 4 of results of media monitoring and communication guidance survey with national immunisation focal points in EU Member States

Introduction and methods

In June 2015, national public health institutes from all 28 European Member States were sent a request by ECDC under scope of ADVANCE WP1 WG4 to take part in a short survey about their use of media monitoring tools to detect adverse events following immunisation (AEFIs) and concerns over the risk-benefit (RB) balance of vaccines in the population. Media monitoring is the active monitoring of online media channels to collect information about an organisation or a specific issue. Different tools or systems have been created to facilitate the monitoring of a variety of online media channels, from blogs to forums or newspapers. This allows public health institutions to track what the population is saying about specific topics, such as vaccination, and respond to potential concerns or interact with the public. The aim of this survey was to map out, analyse and compare media monitoring systems currently in place in Europe to detect and monitor AEFIs and concerns over the RB balance of vaccines in the population.

The second part of the survey enquired about the use of guidance documents on communication to/with the public about safety concerns or the RB balance of vaccines. “Guidance” was meant in its broadest sense, from key principles or templates to detailed guidance, academic recommendations, descriptions of communication tools or even standard operating procedures, either published or internal. They may be addressed to competent authorities and/or marketing authorisation holders, or support others (i.e. healthcare professionals or journalists) in their communication efforts. Communication with the public referred to informing stakeholders like the general public/sub-populations, healthcare professionals, or the media about BR data and/or conclusions on vaccines. It also refers to receiving information or questions from such stakeholders, but does not refer to adverse reaction reporting or communication within/between authorities.

A total of 11 countries responded to the survey: Czech Republic (Department of Public Health Protection), Hungary (National Centre for Epidemiology), Ireland (Health Services Executive, Health Protection Surveillance Centre), Latvia (Centre for Disease Prevention and Control of Latvia), Lithuania (Ministry of Health), Malta (Medicines Authority), the Netherlands (RIVM), Norway (Norwegian Institute of Public Health), Poland (National Institute of Public Health, National Institute of Hygiene), Portugal (Directorate General of Health), and Sweden (Public Health Agency of Sweden).

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Results part 1: Media monitoring systems

Media monitoring systems for AEFIs and/or RBs

Of the 11 organisations which responded to the survey, five discussed existing media monitoring tools used in their countries (at national or organisational levels) to monitor and detect AEFIs and concerns over RBs in the population: Hungary, Ireland, Latvia, Lithuania and the Netherlands.


Table 1 – Media monitoring tool (MMT) for AEFIs and/or RB

	CZ	HU	IE	LV	LT	M T	NL	NO	PL	PT	SE
Media monitoring tools to monitor and detect AEFIs	No	Yes	No	Yes	Yes	No	Yes	No	No	No	No
Media monitoring tools to monitor and detect concerns over RB balance of vaccines	No	Yes	Yes	No	Yes	No	Yes	No	No	No	No
Other tools to monitor and detect AEFIs	Yes	No	Yes	No	Yes	No	Yes	Yes	No	No	Yes
Other tools to monitor and detect concerns over RB balance of vaccines	Yes	No	No	No	No	No	Yes	No	No	No	Yes
General media monitoring tool within which vaccines could be added	Yes	No	Yes	No	No	No	No	Yes	Yes	No	Yes
Other European tool	No	No	No	No	No	No	No	No	No	No	No

In Hungary, the Office of the Chief Medical Officer is responsible for monitoring reports of AEFIs and concerns over the RB balance of vaccines in the population at a national level. The National Centre for Epidemiology monitors newspapers, TV channels, and online and medical portals on a daily basis to detect reports of AEFIs and concerns about the RB balance of vaccines at a national level. The search is performed in Hungarian, using RSS feeds and manual screening (no search terms) to look for online news. Information collected from the monitoring tool is stored in MS outlook and is disseminated by a plain e-mail daily. Results are used to prepare for planned communication interventions, but does not include a data analysis component. The monitoring system is managed by Public Health authorities at the national level. The tool has not been evaluated.

In Ireland, the Health Protection Surveillance Centre discussed use media monitoring to identify up to date information and articles on immunisation/vaccines. The tool collects national and regional daily information from online news and newspapers to detect any stories related to immunisation or vaccination. The service is provided by a private company (Kantar Media), and is stored on email. The results from the monitoring are reviewed and used to prepare for planned communication interventions but it does not include an analysis component. It is managed by the National Immunisation Programme and has not been evaluated to date.

In Latvia, the Centre for Disease prevention and Control uses media monitoring to monitor and detect AEFIs in the population. A private organisation monitors all the media and social media daily at a national level in Latvian and Russian. The organisation (LETA) sends results by email daily, which are stored on computer hard drives. Results from the monitoring are reviewed but the tool has not been evaluated. It is a general health-monitoring tool, which covers various topics, including immunisation.


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In Lithuania, the Ministry of Health monitors the media to detect reports of adverse events following immunisations and/or concerns over the risk-benefit balance of vaccines. Its aim is to analyse all possible challenges in healthcare and respond to them, as well as to analyse opinion of the general public about different health issues. It is used to plan communication activities and has a national and regional scope.

In the Netherlands, RIVM uses a media-monitoring tool to monitor and detect AEFIs and RBs in the population at a national and regional level. The tool monitors news about vaccination and collects information on content (title and summary), sentiment (positive, negative, neutral), source, data and time of message, and URL. Social media, websites, and online newspapers are collected in Dutch daily using the search terms “National immunisation program” (NIP) and all diseases included in the NIP. It is collected by a private company (Howardshome), which generates daily reports automatically and a person at RIVM is in charge of reviewing tweet desk continuously as well. Results from the tool are used to prepare for planned communication interventions and ad hoc reactions if necessary. The tool does not include a data analysis component and is managed by Public Health authorities at the national level. It has not been evaluated. Plans include to monitor weekly volume of online media (overall NIP and specific VPDs) and to conduct more in-depth systematic content analysis in case of increase in volume. Plans for potential automatic analysis of the content and sentiment of online media are also being evaluated.

Table 2: Existing media monitoring tools for AEFIs and/or RB detailed information

	HU	IE	LV	LT	NL
Management	Office of the Chief Medical officer (PH authority)	National Immunisation Programme	LETA (private organisation)	Ministry of Health	RIVM (PH authority)
Scope	National	National and regional	National	National and regional	National and regional
Purpose	Monitoring	Identification of articles on immunisation/vaccines in the media	Private organisation (for profit). They monitor all media and offer to sell media monitoring in specific fields, such as public health	Analyse challenges in healthcare and react to them, helps plan all communication activities in time, helps analyse opinion of the general public about different health issues	Using one digital system to monitor news about vaccination (do not register whether it is about an adverse event or a risk benefit)
Data collection	RSS feeds and manual screening, disseminated by email	Website search and emails received	Media monitoring sent daily by email from private company	---	Howardshome and one person keeps an eye on Tweetdesk daily
Search terms	---	---	None used	---	National immunisation program and the diseases included in it
Languages	Hungarian	---	Latvian, Russian (for Russian media in Latvia)	---	Dutch


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Websites	Newspapers, TV channels, online and medical portals	http://www.kantarmedia.ie provides this service	All media channels, including social media	---	Twitter, all types of websites and social media, online newspapers
Frequency	Daily basis	Daily basis	Daily basis	---	Daily basis – daily reports automatically generated by Howardshome
Storing	In MS outlook	On email	---	---	Yes – can download data from a half year ago
Information collected	---	Daily information on online news and newspapers for any story concerning vaccines or immunisation	All media publications	---	Content (title and summary message), sentiment (positive, negative, neutral – automatically done by the company and based on positive and/or negative words), source, date and time of message and URL
Data analysis	Not coded, no analysis	Not coded, no analysis	Don't know	---	Not coded, no analysis
Follow up	Using results to prepare for planned communication interventions	Results are reviewed, and used to prepare for planned communication interventions	Results are reviewed	---	Using results to prepare for planned communication interventions and ad hoc reactions if necessary
Evaluation	No	No	No	---	No

Other tools

Other tools were mentioned by respondents as being used to monitor and detect AEFIs and RB concerns in the population were:

- The department of public health protection in the Czech Republic mentioned using general media monitoring.
- In Ireland, the Irish Regulatory Authority for Medicines (HPRA) is responsible for monitoring adverse events following immunisation
- In Lithuania, a questionnaire available on the website of the Ministry of Health is used to detect AEFIs in the population
- In the Netherlands, reports of AEFIs are collected by the Netherlands Pharmacovigilance Centre Lareb (passive and active surveillance system). Surveys are also being conducted in the population to monitor acceptance of vaccination.
- In Norway, AEFIs are monitored by NIPH and the Norwegian Medicines Agency.
- In Sweden, the Medical Product Agency received online reports from patients and health professionals about AEFIs and concerns over the BR balance of vaccines.

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Respondents also suggested other existing general media surveillance or monitoring tools within which monitoring in relation to vaccines could be added:

- The “Newton media monitoring” tool was mentioned in Czech Republic.
- Ireland mentioned that the Communication office of the Health Services Executives has a system to monitor routinely the general media (newspapers and TV).
- In Norway, vaccine information monitoring could be added to a current monitoring tool (private company Opoint) used by NIPH for daily monitoring of the trigger word NIPH.
- In Sweden, the Public Health Agency of Sweden performs a manual scan of the media and scientific literature and via Pubcrawler and a news agency in order to produce a weekly vaccine newsletter.

No respondent was aware of tools being used in other European countries.


Results part 2: guidance documents

All respondents except for Hungary and Poland stated using some type of guidance documents when communicating about vaccines in their organisations. National guidance documents mostly came from the Ministry of Health, national public health institutes, or immunisation committees and institutes. Respondents also declared using guidance from other countries (US, UK, Australia, Canada, etc.) and international organisations (ECDC, EMA, WHO, UNICEF).

Only four respondents had experience with the “Guideline on good pharmacovigilance practices (GVP) on vaccines for prophylaxis against infectious diseases (PI)”, issued in 2014 (GPV PI): Ireland, Malta, Portugal, and Sweden. Respondents from Malta explained that their experience with the GVP is still too recent to provide robust feedback at this stage. Portugal mentioned that their experience was not with the GVP published in 2014 but with the guidelines on pharmacovigilance practices on vaccines for prophylaxis against infectious diseases published by INFARMED in Portugal (National Authority of Medicines and Health Products).

Table 3: Guidance documents on communication about vaccination


	CZ	HU	IE	LV	LT	MT	NL	NO	PL	PT	SE
National Ministry/Department of Health, Public Health institutes	X				X		X	X		X	X
National Immunisation committees or institutes			X								
Other National Institutes	X										
EMA						X					
ECDC	X		X	X	X		X				X
UNICEF				X							
WHO			X	X	X			X			X
Other countries: Australia			X								
Other countries: Canada				X							

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Other countries: UK			X	X				X		
Other countries: US			X	X						
Experience with GVP PI			X			X			X	X

List of national documents cited

- Guidance from Australia
- Guidance from Canada
 - o British Columbia Centre for Disease Control (<http://www.bccdc.ca/health-professionals/clinical-resources/immunization>)
- Guidance from Czech Republic
 - o Ministry of Health
 - o The State Institute for Drug Control
 - o The National Institute of Public Health
- Guidance from Ireland
 - o “NIAC Immunisation Guidelines for Ireland”, National Immunisation Advisory Committee (<http://hse.ie/eng/health/immunisation/hcpinfo/guidelines/immunisationguidelines.html>)
 - o “Guidelines for Vaccinations in General Practice”, National Immunisation committee of the Health Service Executive (<https://www.hse.ie/eng/health/immunisation/infomaterials/pubs/guidelinesGP.pdf>)
 - o “HSE Guidelines for maintaining the vaccine cold-chain including maintenance of vaccine fridges and management of vaccines”, National Immunisation committee of the Health Service Executive (<http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/SOP2016.pdf>)
- Guidance from Malta
 - o Summary of product characteristics
- Guidance from the Netherlands
 - o RIVM guidelines (http://www.rivm.nl/Onderwerpen/L/LCI_Richtlijnen)
- Guidance from Norway
 - o Norwegian Institute of Public Health (<https://fhi.no/en/id/vaccines/>; <https://www.youtube.com/user/Folkehelseinst;> <https://www.facebook.com/folkehelseinstituttet.no>)
 - o NIPH Vaccine guidelines (<https://www.fhi.no/nettpub/vaksinasjonsveilederen/>)

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- o Annual report on Childhood Immunization Programme in Norway (<https://www.fhi.no/publ/2014/barnevaksinasjonsprogrammet-i-norge/>)
 - o Reports on recommendation of new vaccines in the National Childhood Immunization Programme, (<https://www.fhi.no/globalassets/migrering/dokumenter/pdf/anbefalinger-om-bruk-av-rotavirusvaksine-i-norge-rapport-201310-pdf.pdf>)
 - o The National Childhood Immunization Programme Brochure/Poster (<https://www.fhi.no/publ/2014/vaksinasjon-i-barne--og-ungdomsalde/>)
 - o The rotavirus vaccine in the National Vaccination Programme Brochure/Poster (<https://fhi.no/en/publ/2014/om-rotavirusvaksine-i-barnevaksinasjonsprogrammet/>)
 - o HPV vaccine in the National Childhood Immunization Programme Brochure (https://www.fhi.no/contentassets/906c1f335a044ea5b701d6d878471c93/hpv-foreldre-barnbrosjyre_web_rev6_alt5_060616.pdf)
 - o Vaccination of children against tuberculosis Brochure/Poster (<https://www.fhi.no/sv/smittsomme-sykdommer/tuberkulose/vaksine-mot-tuberkulose-bcg---publi/>)
 - o Information letter on meningococcal vaccine to youth (<https://www.fhi.no/nyheter/2015/ungdom-bor-vurdere-a-vaksinere-seg-/>)
 - o Influenza vaccination: Brochures/posters/information letters to healthcare professionals, risk groups, and pregnant women
 - o Maler for bivirkningssvar til helsesøster som melder bivirkning (Templates for response to Community Nurses who report AEFIs)
 - o RSOP-001: Vaksinasjonsboka som e-veileder: Logg av oppdateringer, informasjon om oppdateringer (Vaccination guidelines as e-guidelines: Logging of changes, updated information)
 - o RSOP-002: Vaksinasjonsboka som e-veileder: Faglige oppdateringer (Vaccination guidelines as e-guidelines: Medical updates)
 - o RSOP-003: Basisrutiner for vaksinasjonsrådgivningen (Basic routines for counselling on vaccination)
 - o RSOP-004: Vaksinedagene – prosedyrer for forberedelse og gjennomføring (Procedures for preparing and carrying through the annual national vaccine conference)
- Guidance from Portugal
- o Directorate General of health (<https://www.dgs.pt/pagina.aspx?f=1&lws=1&mcna=0&inc=&mid=5005&codigoms=0&codigono=683368347177AAAAAAAAAAAA>)

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- Guidance from Sweden
 - o National Plan for Vaccine Communication Strategies, from the National Board of Health and Welfare
- Guidance from UK
 - o PHE (<https://www.gov.uk/government/collections/immunisation#immunisation-training-resources-for-healthcare-professionals>)
 - o NHS (<http://www.fitfortravel.nhs.uk/home.aspx>)
- Guidance from US
 - o CDC (<http://www.cdc.gov/vaccines/index.html>)
 - o American Academy of Paediatrics (AAP)

List of international documents cited

- Guidance from WHO
 - o Why Invest in communication for immunisation? Evidence and Lessons Learned (http://www.who.int/immunization/hpv/communicate/why_invest_in_communication_for_immunization_unicef_healthcommunicationspartnership_path_usaid.pdf)
 - o World Health Organization Outbreak Communication Planning Guide (<http://www.who.int/ihr/elibrary/WHOOutbreakCommsPlanngGuide.pdf>)
 - o Risk communication guidance page (<http://www.who.int/risk-communication/guidance/en/>)
 - o Immunization webpage (<http://www.who.int/topics/immunization/en/>)
 - o International travel & health webpage: (<http://www.who.int/ith/en/>)
- Guidance from ECDC
 - o Technical Document: Communication on immunisation – Building Trust (<http://ecdc.europa.eu/en/publications/Publications/TER-Immunisation-and-trust.pdf>)
 - o Let's talk about protection: Enhancing childhood vaccination uptake. Communication Action guide for healthcare providers (<http://ecdc.europa.eu/en/healthtopics/immunisation/comms-aid/Documents/Vaccine-comms-action-2013.pdf>)
 - o Communication tools webpage (<http://ecdc.europa.eu/en/press/communication-tools/Pages/communication-tools.aspx>)

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- o Technical Report: Measles and Rubella elimination: communicating the importance of vaccination (<http://ecdc.europa.eu/en/publications/Publications/Measles-rubella-elimination-communicating-importance-vaccination.pdf>)
- Guidance from EMA
 - o Assessment reports, Committee for Medicinal Products for Human Use
- Guidance from UNICEF
 - o Global Vaccine Action Plan (<http://www.unicef.org/immunization/files/GlobalVaccineActionPlan.pdf>)

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Annex D: Glossary of scientific terms explained for the general public

One of the ultimate results of any communication strategy in healthcare is the distribution of information. Such information should be developed to be a transparent, understandable, well-structured transfer of knowledge or experience to – in most cases – the general public. Hence, there is a great need for scientific information to be translated into lay language, particularly in case of benefit-risk studies of vaccines. Scientific information obtained within such studies is usually difficult, full of technical-medical terms that makes it impossible to assimilate by the general public. Moreover, the main language of science, scientific information and also of all European Union institutions is English. The linguistic diversity of the European Union causes additional problems in translation of scientific information into lay language which should then additionally be translated into local languages paying attention to characteristic idioms, grammatical constructions used in lay, communicable versions.

The simplest example of different meanings and different interpretations of translation are two extremely important medical terms: “side effects” and “adverse reactions”. Although in scientific English language both terms are of the same meaning, for the general public those terms are different because of the context: “adverse reactions” is the term used for regulatory and legal purposes and “side effects” is a more commonly used term describing unexpected, medical events after a medicine is taken by a patient. This situation become more complicated if translated into other, European languages. In German the term of “adverse reactions” or “side effects” is translated into “die Nebenwirkungen” or “die nachteilige Auswirkungen”, although the meanings of the first term is “adverse effects” (not reactions) and the second term is more connected to adverse, medical events including medical accidents. Similar semantic implications are present in Polish language. Moreover, a common, semantic difference between “side effects” and “adverse reactions” is already used in IMI-ADVANCE project web-site: “In fact, serious side effects are very rare. Nevertheless, as vaccines are given to healthy people, public acceptance of the risk of any adverse reaction is much lower than for medicines designed to treat sick people”¹. The “Side effects” term is presented in an acute, severe meaning, while “adverse reaction” is connected to public acceptance of the risk.

Every institution in charge of communicating with the public should have at hand a glossary of terms translated for communication with the general public and in local languages. This glossary should be developed by organisations that can easily share it to interested parties, but most important should be developed together with the general public. The glossary in this Annex is provides suggested translations of some key words (in English). However, these have not been tested and should only constitute a starting point for institutions that wish to develop and test their own glossaries. Institutions will also want to add other key words relevant to their own context. The glossary was elaborated by paying special attention to explanatory language, which would allow only one possible translation. The list of terms that

¹ <http://www.advance-vaccines.eu/?page=background>

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should have been translated into lay-language within explanatory definitions, used in vaccine benefit-risk studies and proposed English language lay-formulation is presented below:

TERM	EXPLANATORY DEFINITION
Adverse reaction	Unexpected reaction of a patient to a medicine after it is taken. In case of vaccines, adverse reaction occurs after vaccination and may be connected to observable symptoms such as fever, rash, or pain. Adverse reaction is the term used sometimes interchangeably with the term of side effects. Although side effects are usually described by vaccine manufacturer, some of them may occur as not-identified. Each adverse reaction shall be immediately reported to a doctor, nurse or pharmacist.
Benefit – risk assessment	The most important process allowing for authorisation or withdrawal of a medicine or vaccine. The process includes results of clinical trials before regulatory approval (medical tests of new medicines or vaccines on humans performed under controlled conditions) and/or post-authorisation studies on approved medicines or vaccines.
Benefit – risk evaluation	The process allowing for description of medicine or vaccine potential, basing on available clinical data, using statistical, mathematical methods.
Benefit – risk monitoring	Continuous process of a medicine or a vaccine effectiveness and safety.
Clinical efficacy	A measure describing how a medicine or a vaccine succeed in treatment of disease or (in case of vaccines) in disease prevention in a clinical setting.
Clinical efficiency	A measure allowing for describing how a medicine or a vaccine succeed in treatment or disease prevention in relation to costs (financial and non-financial, expenditures and efforts expended) in a clinical setting.
Code of conduct	A set of regulations and obligations describing mutual connections and relations between stakeholders involved in defined studies (e.g. in benefit-risk studies on vaccines). Defined code of conduct allows for preservation of transparency at each level and on each step of the studies and projects.
Epidemiology	The study and analysis of the patterns, causes, and effects of health and disease conditions in defined populations. It is the cornerstone of public health, and shapes policy decisions and evidence-based practice by identifying risk factors for disease and targets for preventive healthcare ¹ .
European Centre for Disease Prevention and Control (ECDC)	A European Union agency aimed at strengthening Europe's defences against infectious diseases. ²
European Medicines Agency (EMA)	A European Union agency for the evaluation of medicinal products, including vaccines. EMA recommends medicines or vaccines to be approved or withdrawn by European Commission from European market and public use, recommends additional studies, provides scientific advices and expertise, ensuring that all medicines available on the EU market are safe, effective and of high quality. ³


¹ <https://en.wikipedia.org/wiki/Epidemiology>

² <https://ecdc.europa.eu/en/about-us>

³ http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000426.jsp&mid

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Governance models in PPC	Proposed structures of dependencies and relations between particular stakeholders involved in the studies founded in private-public collaboration. Clearly defined models of governance allow for maximum transparency provision in parallel to maximum efficiency of the projects' stakeholders.
Healthcare databases (referred to vaccines)	Electronic databases constructed, monitored and overseen by adequate national or international public health institutions. In relation to vaccines such databases include personal health records with information on vaccines already taken, expected to be taken, adverse reactions, etc. Leading and management of such databases is strictly regulated by national, European and international legal acts, with special emphasis put on privacy preservation.
Injection site reaction(s)	A specific reaction(s) that occur during or after the process of a medicine or a vaccine injection in the place of injection. Such reactions are usually defined as adverse reactions or side effects and their observable symptoms may include: reddening, oedema, swelling, pain, itching, or rush at the site of injection. The intensity of injection site reaction may be different and all such reactions shall be reported to a doctor, nurse or pharmacist.
Immune system	Defence system of a body (human or animal) that protects against diseases. For proper functioning, immune system must be able to recognize different agents (e.g. viruses, parasitic worms), distinguish them from health tissues and destroying them within the body. Due to its complexity and limited, natural ability of different agents' recognition and distinguishing, it is necessary to support natural immune system with specific "protectors" – e.g. vaccines.
Immunisation	The process by which an individual's (human or animal) immune system becomes resistant (immune) to different agents (e.g. viruses).
Marketing authorisation of a medicine or a vaccine	Regulatory process of a medicine or a vaccine approval for public use. In the European Union, the process of marketing authorisation is performed centrally by European Medicines Agency, however the Agency gathers necessary, scientific documentation and introduce it to European Commission with recommendation for granting (or not) marketing authorisation.
Marketing authorisation holder	Organisation, usually a company, that holds marketing authorisation after a medicine or a vaccine is approved for public use
Multiple-criteria decision analysis (MCDA) in vaccines studies	A statistical, analytical method for assessment of vaccine efficiency on the basis of conflicted factors in the process of decision making (approval of a vaccine) e.g. adverse reactions and efficacy in chosen population.
Monitoring	The observation of one or several parameters continuously over time to signal an alarm if there is indication of abnormality, in order to intervene to minimise the risks
Private-public collaboration (PPC)	A scheme of different project management, realisation and funding when public institutions and private companies are involved and united to reach specific outcomes, intend to serve for general public good.
Project consortium	The term describing all partners and their involvement in the project realisation. Projects consortium includes usually executive partners, associated partners, the scheme of project's governance, and its coordination. Although in general, the project consortium is responsible for adequate, timely and proper realisation of the project,

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	particular tasks and responsibilities are divided for specific groups (e.g. steering committee, advisory boards, working groups and working packages). The quantity of project consortium depends on the project range, objectives, aims and expected results.
Proof of concept study	Study that aims at conducting a benefit-risk evaluation from the start until the end
Side effect	Interchangeably (with adverse reaction) used term describing unexpected effects of a medicine or a vaccine. The term side effects is commonly used in leaflets of medicines and refers to the observable, undesired effects that occurred during clinical trials. All side effects shall be immediately reported to a doctor, nurse or pharmacist.
Stakeholder	An individual or organisation (institution, authority, foundation, research academy, company...) taking part in the project/initiative and having an interest in the project results ¹
Vaccine	A vaccine is a biological preparation that provides active acquired immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins. The agent stimulates the body's immune system to recognise the agent as a threat, destroy it, and recognise and destroy any of these microorganisms that it later encounters. Vaccines can be prophylactic (e.g. to prevent or improve the effects of a future infection by a natural or "wild" pathogen), or therapeutic (e.g. vaccines against cancer are being investigated). ²
Vaccine preventable disease(s)	An infectious disease, which can be avoided due to use of vaccine (vaccination). The World Health Organization lists 25 diseases for which vaccines are available: anthrax, measles, rubella, cholera, meningococcal disease, influenza, diphtheria, mumps, tetanus, hepatitis A, hepatitis B, hepatitis E, pertussis, tuberculosis, pneumococcal disease, typhoid fever, poliomyelitis, tick-borne encephalitis, haemophilus influenza type b, rabies, varicella and herpes zoster (shingles), human papilloma-virus, rotavirus gastroenteritis, yellow fever, Japanese encephalitis, malaria, dengue fever.
Vaccination programme(s)	A vaccination schedule is a series of vaccinations, including the timing of all doses, which may be either recommended or compulsory, depending on the country.
Virus	A virus is a small infectious agent that replicates only inside the living cells of other organisms. Viruses can infect all types of life forms, from animals and plants to microorganisms, including bacteria and archaea. Viruses are specific because of lack of cell structure. Usually they are built of genetic material (DNA or RNA) closed within protein shell. Such simple structure allows them to spread quickly and infect easily other, living cells. Treatment of infections caused by viruses is usually difficult, because viruses do not have their own metabolism, which can be blocked as it is in the case of bacteria. This is the reason why antibiotics are not effective in treatment of virus-caused infections. Currently, the main defence from viruses are vaccines.


¹ D1.10 Final conceptual model for public-private interaction (“Good Practice Guidance Module 2: Governance models.”). IMI-ADVANCE.

² <https://en.wikipedia.org/wiki/Vaccine>


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REFERENCES

1. The Health Communication Capacity Collaborative. The P-Process: five steps to strategic communication. Baltimore: Johns Hopkins Bloomberg School of Public Health Center for Communication Programs, 2013.
2. World Health Organization. The importance of pharmacovigilance: safety monitoring of medicinal products. Geneva: WHO, 2002.
3. European Medicines Agency, Heads of Medicines Agencies. Good pharmacovigilance practices for the European Union (EU-GVP). London: EMA, 2012-2016.
4. Uppsala Monitoring Centre. Effective communication in pharmacovigilance: the Erice Report (report on the International Conference on Developing Effective Communications in Pharmacovigilance held in Erice, 24-27 September 1997, organised by the UMC, the World Health Organization, the University of Verona, the International School of Pharmacology, the Ettore Majorana Centre for Scientific Culture and supported by EQUUS Communications). Uppsala: UMC, 1997.
5. Uppsala Monitoring Centre. Dialogue in pharmacovigilance. Uppsala: UMC, 2002.
6. Erice Statement 2009. Communication, medicines and patient safety. Br J Clin Pharmacol. 2010;69:207-8.
7. Edwards IR. A New Erice Report Considering the Safety of Medicines in the 21st Century. Drug Saf. 2017.
8. Bahri P. Public pharmacovigilance communication: a process calling for evidence-based, objective-driven strategies. Drug Saf. 2010;33:1065-79.
9. Andre FE, Booy R, Bock HL, Clemens J, Datta SK, John TJ, et al. Vaccination greatly reduces disease, disability, death and inequity worldwide. Bull World Health Organ. 2008;86(2):140-6.
10. Shimp L. Strengthening immunization programs: the communication component. Arlington, VA: Basic Support for Institutionalizing Child Survival Project (BASICS II) for the United States Agency for International Development, 2004.
11. S Waisbord, H Larson. Why invest in communication for immunization: evidence and lessons learned. Baltimore, MD, New York, NY: Health Communication Partnership based at Johns Hopkins Bloomberg School of Public Health / Center for Communication Programs, United Nations Children's Fund, 2005.
12. Cairns G, MacDonald L, Angus K, Walker L, Cairns-Haylor T, Bowdler T. Systematic literature review of the evidence for effective national immunisation schedule promotional communications. Stockholm: ECDC, 2012.
13. European Centre for Disease Prevention and Control. Measles and rubella elimination: communicating the importance of vaccination. Stockholm: ECDC, 2014.
14. A Edwards, G Elwyn. Shared decision-making in health care: achieving evidence-based patient choice. Oxford: Oxford University Press; 2009.
15. World Health Organization. Strategies for addressing vaccine hesitancy: a systematic review (WHO-SAGE report). Geneva: WHO, 2014.
16. European Centre for Disease Prevention and Control. Rapid literature review on motivating hesitant population groups in Europe to vaccinate. Stockholm: ECDC, 2015.
17. Larson H, Brocard Paterson P, Erond N. The globalization of risk and risk perception: why we need a new model of risk communication for vaccines. Drug Saf. 2012;35(11):1053-9.
18. Innovative Medicines Initiative. Accelerated Development of Vaccine Benefit-Risk Collaboration in Europe (ADVANCE) Project Brussels: IMI; 2013. Available from: <http://www.imi.europa.eu/content/advance>.
19. YouGov. British attitudes to the pharmaceutical industry. YouGov, 2013.
20. Edelman Trust Barometer. Global healthcare sector trends. 2016.
21. Calnan MW, Sanford E. Public trust in health care: the system or the doctor? Qual Saf Health Care. 2004;13(2):92-7.
22. Kessel M. Restoring the pharmaceutical industry's reputation. Nat Biotech. 2014;32(10):983-90.
23. European Centre for Disease Prevention and Control. Communication on immunisation - building trust. Stockholm: ECDC, 2012.

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24. Karafillakis E, Larson HJ, consortium A. The benefit of the doubt or doubts over benefits? A systematic literature review of perceived risks of vaccines in European populations. *Vaccine*. 2017.
25. Connors MH, Halligan PW. A cognitive account of belief: a tentative road map. *Front Psychol*. 2014;5:1588.
26. Fischhoff B, Brewer N, Downs J. Communicating risks and benefits: An evidence based user's guide. Food and Drug Administration, US Department of Health and Human Services, 2011.
27. World Health Organization. Vaccine Safety Events: managing the communications response. A guide for Ministry of Health EPI Managers and Health Promotion Units. . Geneva: WHO, 2013.
28. Sense about Science. Standing up for Science: A guide to the media for early career scientists.
29. Science Media Centre. Top tips for media work: a guide for scientists.
30. Imperial College London. Do's and Don't's of talking about science to the media.
31. Kennon N, Howden P, Hartley M. Who really matters? A stakeholder analysis tool. *Extension Farming Systems Journal* 2009;5(2).
32. World Health Organization. World Health Organization Outbreak Communication Planning Guide. Geneva: WHO, 2008.
33. European Centre for Disease Prevention and Control. Let's talk about protection. Enhancing childhood vaccination uptake. Communication Action guide for healthcare providers. Stockholm: ECDC, 2013.
34. European Centre for Disease Prevention and Control. Let's talk about hesitancy. Enhancing confidence in vaccination and uptake. Practical guide for public health programme managers and communicators. Stockholm: ECDC, 2016.
35. US Institute of Medicine. Characterizing and communicating uncertainty in the assessment of benefits and risks of pharmaceutical products – workshop summary. Washington, DC: The National Academies Press, 2014.
36. Ropper AH. The Guillain-Barre syndrome. *N Engl J Med*. 1992;326(17):1130-6.
37. Juurlink DN, Stukel TA, Kwong J, Kopp A, McGeer A, Upshur RE, et al. Guillain-Barre syndrome after influenza vaccination in adults: a population-based study. *Arch Intern Med*. 2006;166(20):2217-21.
38. US Centers for Disease Control and Prevention. Update: Recommendations of the Advisory Committee on Immunization Practices (ACIP) regarding use of CSL seasonal influenza vaccine (Afluria) in the United States during 2010-11. *MMWR Morb Mortal Wkly Rep*. 2010;59(31):989-92.
39. Plotkin SA, Orenstein WA, Offit PA, Edwards KM. *Vaccine*, 7th edition: Elsevier; 2017.
40. World Health Organization. Global Vaccine Safety - Topics. Available from: http://www.who.int/vaccine_safety/committee/topics/en/.
41. Woloshin S, Schwartz LM, Welch HG. Know Your Chances: Understanding Health Statistics. . Berkeley (CA): University of California Press; 2008.
42. Lipkus IM. Numeric, verbal, and visual formats of conveying health risks: suggested best practices and future recommendations. *Med Decis Making*. 2007;27(5):696-713.
43. Lipkus IM, Hollands JG. The visual communication of risk. *J Natl Cancer Inst Monogr*. 1999(25):149-63.
44. Politi MC, Han PK, Col NF. Communicating the uncertainty of harms and benefits of medical interventions. *Med Decis Making*. 2007;27(5):681-95.
45. Visschers VH, Meertens RM, Passchier WW, de Vries NN. Probability information in risk communication: a review of the research literature. *Risk Anal*. 2009;29(2):267-87.
46. Woloshin S, Schwartz LM. Communicating data about the benefits and harms of treatment: a randomized trial. *Ann Intern Med*. 2011;155(2):87-96.
47. Peters E, Hart PS, Fraenkel L. Informing patients: the influence of numeracy, framing, and format of side effect information on risk perceptions. *Med Decis Making*. 2011;31(3):432-6.
48. Brown SM, Culver JO, Osann KE, MacDonald DJ, Sand S, Thornton AA, et al. Health literacy, numeracy, and interpretation of graphical breast cancer risk estimates. *Patient Educ Couns*. 2011;83(1):92-8.
49. Nayak JG, Hartzler AL, Macleod LC, Izard JP, Dalkin BM, Gore JL. Relevance of graph literacy in the development of patient-centered communication tools. *Patient Educ Couns*. 2016;99(3):448-54.

	Deliverable 1.12: Developing communication strategies on vaccine benefits and risks: Guidance for public-private collaborations		
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50. McCaffery KJ, Dixon A, Hayen A, Jansen J, Smith S, Simpson JM. The influence of graphic display format on the interpretations of quantitative risk information among adults with lower education and literacy: a randomized experimental study. *Med Decis Making.* 2012;32(4):532-44.
51. Hawley ST, Zikmund-Fisher B, Ubel P, Jancovic A, Lucas T, Fagerlin A. The impact of the format of graphical presentation on health-related knowledge and treatment choices. *Patient Educ Couns.* 2008;73(3):448-55.
52. Price M, Cameron R, Butow P. Communicating risk information: the influence of graphical display format on quantitative information perception-Accuracy, comprehension and preferences. *Patient Educ Couns.* 2007;69(1-3):121-8.
53. European Medicines Agency. Benefit-risk methodology project. Update on work package 5: Effects Table pilot (Phase I). London: EMA, 2014.
54. The Health Compass. How to develop a communication strategy. Health compass, 2016.
55. O'Sullivan GA, Yonkler JA, Morgan W, Merritt AP. *A Field Guide to Designing a Health Communication Strategy.* Baltimore, MD: Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs, 2003.
56. European Centre for Disease Prevention and Control. Conducting health communication activities on MMR vaccination. Stockholm: ECDC, 2010.
57. Health communication capacity collaborative. *Designing a social and Behaviour Change communication strategy.* Johns Hopkins, 2016.
58. Bingham A, Brawley M, Gopinath CY. *Designing communication strategies that work: Implementing the SIM process.* . Nairobi, Kenya: PATH, 2009.
59. Hyunyi Cho, Torsten Reimer, Katherine McComas. *The SAGE handbook of risk communication.* : SAGE publications; 2014.
60. US Centers for Disease Control and Prevention. *Crisis and emergency risk communication (CERC), 2014 edition.* US: CDC, 2014.
61. Infanti J, Sixsmith J, Barry MM, Núñez-Córdoba J, Orovioigoicoechea-Ortega C, Guillén-Grima F. *A literature review on effective risk communication for the prevention and control of communicable diseases in Europe.* Stockholm: ECDC, 2013.
62. Public Health Agency of Canada. *Canadian Immunisation Guide: Part 1: Key Immunisation Information 2016: Communicating effectively about Immunization 2016.*
63. British Columbia Centre for Disease Control. *Immunization: British Columbia: Provincial Health Services Authority.*
64. World Health Organization. *World Health Organization Vaccine Safety Supporting Document.* Geneva: WHO, 2017.
65. World Health Organization. *How to respond to vocal vaccine deniers in public.* Geneva: WHO, 2016.
66. Council for International Organizations of Medical Sciences. *CIOMS Guide to Vaccine Safety Communication [draft for public consultation].* Geneva: CIOMS, 2017.
67. Bahri P, Fogd J, Morales D, Kurz X, consortium A. Application of real-time global media monitoring and 'derived questions' for enhancing communication by regulatory bodies: the case of human papillomavirus vaccines. *BMC Med.* 2017;15(1):91.