

REVIEW

Listen to the public and fulfil their information interests – translating vaccine communication research findings into guidance for regulators

Correspondence Dr Priya Bahri, Principal Scientific Administrator, Surveillance & Epidemiology Service, Pharmacovigilance Department, European Medicines Agency, 30 Churchill Place, London, E14 5EU, UK. Tel.: +44 20 3660 8454; E-mail: priya.bahri@ema.europa.eu

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Priya Bahri  and Mireia Castillon Melero

Surveillance & Epidemiology Service, Pharmacovigilance Department, European Medicines Agency, London, UK

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Regulatory authorities have a crucial role in communicating about the vaccines they license. In terms of content and timing, their communication to the public is usually driven by data on quality, safety and efficacy. However, concerns over safety and vaccine hesitancy have emerged in some communities in various countries, and this demands a new approach to communication, starting with listening to the public debate. Reviewing communication research findings, coming in particular from the cognitive, decision-making and media sciences, constitutes one mechanism of listening and has led the European Union (EU) regulatory network to developing guidance about which common concerns and information needs of the public to address through pro-active and prepared communication. The guidance has been welcomed by EU and international fora. The current article summarizes the recommendations and shares the underlying research findings, as well as a proof of concept that communication research can be valuable for regulators. It is critical that regulators integrate the communication process with product risk assessment in the framework of pharmacovigilance, to ensure that public concerns are addressed in the assessments and that information about evidence and uncertainty relating to safety is provided to the public and vaccination policy makers in a specific, clear and accurate manner. Additionally, information from regulatory authorities should support healthcare professionals in their communication with patients. Meeting the information interests of the public is the principal prerequisite for informed decisions as well as safe and effective use of vaccines and medicines overall. This is also fundamental for trust in the authorities' commitment to patient and population health.

WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT

- Addressing safety concerns and tailoring messages to different audiences are important for communication with the public about vaccines.
- Best communication practice guidelines exist for immunization programmes and healthcare professionals.
- Regulatory authorities, which license vaccine products, play a role in communication too.

WHAT THIS STUDY ADDS

- It summarizes guidance issued by the European Union (EU) regulatory network for their communication about the safe use of vaccines with the public, which is proactive and well prepared in addressing the information interests of the public.
- It shares the evidence base for the guidance and frequent information interests of the public identified through a global literature review.
- It puts the guidance in a complementary context of recent further guidance applicable for regulators inside and outside the EU.
- It exemplifies that findings from cognitive, decision-making and media research can be helpful to regulators and advocates for communication research for further classes of medicinal products.

Introduction and objectives: relevance of communicating about vaccines for regulators

Communicating about vaccines is important for informed decisions as well as for the safe and effective use of these products, which are among the most successful tools of health protection to date [1, 2]. This is particularly important now, given that some communities or individuals in various countries are unsure about vaccines and refuse or delay vaccination, a phenomenon referred to as vaccine hesitancy [3]. While acceptance of vaccination is the norm in most populations globally [3], vaccine hesitancy can cost children's health and lives. This is demonstrated by the examples of recurrent measles outbreaks in low- and high-income countries, and the delay in the global eradication of polio [4]. However, it is neither true nor helpful to narrow the perception of the situation to a 'yes-no' confrontation between pro- and antivaccine parties. Causes of vaccine hesitancy in individuals are multiple and complex, and among them are concerns about vaccine safety and the benefit-risk balance [5]. Communicating about vaccines therefore requires conveying not only what is known about immunization benefits, but also about safety concerns.

Besides public health authorities, which are responsible for the national immunization policies and programmes, regulatory authorities have a crucial role in communicating about vaccines too: they license these products and provide information about quality, safety and efficacy (QSE) through the product information, public assessment reports and advice, as well as media statements. Communication from regulators is driven by the QSE evidence available at the time of product licensure or whenever it emerges thereafter. Valuable general guidance for regulatory authorities and the pharmaceutical industry on communication about the risks of medicines has now been available for more than a decade in various territories,

mainly on principles, processes and messaging tools [e.g. 6–9]. Given the experiences of the European Union (EU) regulatory network with challenging communication relating to vaccines [e.g. measles–mumps–rubella (MMR), human papillomavirus (HPV) and pandemic influenza vaccines], some EU regulators in 2010 discussed whether communication guidance could be strengthened specifically for vaccines.

Useful best practice guides on communication had been available at the time for vaccination programmes, but did not provide details on specific content items of interest to the public. The latest of these guides, developed since 2012 for the EU [10–13] or global application [14], mentions safety concerns in general, or acknowledges a few specific concerns which can aggravate a public debate [15]. A communication guide developed by the European Centre for Disease Prevention and Control (ECDC) in 2016 addresses questions about a number of specific safety concerns, in order to support healthcare professionals in talking to parents [16]. However, there has been no guide specific to the role of regulatory authorities or pharmacovigilance in communicating about vaccines with the public. The public, in this context, comprises the individuals and groups in the territory of the authority's jurisdiction – e.g. individuals who consider vaccination for themselves or their children; healthcare professionals advising them; journalists raising a public debate; and individuals or communities expressing their views in the public domain, including public spaces of social media.

Therefore, guidance on developing message content on vaccine safety was issued by the European Medicines Agency (EMA) and the regulatory authorities of the EU member states in December 2013 as part of the EU good pharmacovigilance practices (EU-GVP) [17]. There was immediate interest in the guidance, not only within the EU, but also beyond, given the global need for capacity building in the area of regulatory vaccine risk communication. The guidance was welcomed at meetings of the World Health Organization (WHO), its collaborating centres and the WHO Global Vaccine Safety Initiative (GVSII) [18], as

well as at training events of the Global Research in Paediatrics Network of Excellence (GRiP) and learned societies, in particular the International Society of Pharmacovigilance (ISoP). At these events, interest in the triggers and evidence base for the recommendations was voiced by the participants and stakeholders. Further initiatives at EU and global level have involved regulators and resulted in the recent publication of additional guides based on the latest research findings and learning exercises [19, 20].

The objectives of the present article were therefore to respond to stakeholders and support awareness of the guidance in EU-GVP, its implementation and training activities through:

- Providing insights into the triggers and methods for developing the guidance;
- Sharing the evidence base for its recommendations; and
- Indicating how this guidance and recent other guides add value for regulators inside and outside the EU in a complementary manner.

Methods and results: guidance for developing content for vaccine safety communication based on communication research findings

Apart from the applicability of the guidance specifically to regulators, the other novelty was *how* the guidance was developed. It had been recognized that in order to overcome potential mismatches between the delivered information about medicinal products and public information interests, regulators should understand their audiences [21]. Listening mechanisms available to regulatory authorities include media monitoring and interacting directly with members of the public, and recently these mechanisms have increasingly been used in the EU. Another way of listening to the public – likewise, not yet applied by EU regulators at the time – is reviewing and using published communication research in relation to specific medicinal products. The idea emerged that an overview of concerns, knowledge, attitudes and medicinal product use behaviours of populations, as well as related media behaviours, media coverage and public debates, could be obtained from reviewing findings from the cognitive, decision-making and media sciences, and that these research findings could provide a useful basis for guidance. However, it was unclear whether such literature reviews could provide results that were truly useful, and worth the effort, for developing guidance for regulatory authorities. A pilot study was therefore set up at the EMA as a ‘proof of concept’, taking vaccines as an example and introducing a ‘historical simulation’ applied to the scientific literature for communication about (H1N1) pandemic influenza vaccines (see Box 1).

Box 1

Pilot study on the value of communication literature reviews for the development of communication guidance for regulatory authorities

Objective: To support answering the question of whether reviews of communication research published in the scientific literature have the potential to provide guidance for improving communication about medicinal products by regulatory authorities.

Methods: A ‘historical simulation’, comparing the findings from published vaccine communication research before the (H1N1) influenza pandemic of 2009/10 with the outcome of a lessons learnt exercise performed by the European Medicines Agency (EMA) after the pandemic [22] (the lessons learnt exercise included stakeholder feedback on the communication activities of the EMA). Literature search (see Appendix for search strategy) and extraction of those publications about influenza vaccines (seasonal or pandemic) with a cut-off date of 31 August 2009 [the time point when a literature review could have informed the EMA communication strategy for the (H1N1) pandemic influenza vaccines, given that the vaccines became available in Europe in autumn 2009 and the pandemic peak was expected there for autumn/winter 2009/10]. The hypothesis was such that if the research findings were found to be similar to the lessons learnt outcome, reviews of communication research would need to be considered as having the potential to improve communication planning (this pilot study was conducted by the authors of the present article, who had not been involved in the pandemic communication operations or in the lessons learnt exercise).

Results: Four influenza vaccine-specific publications were identified [23–26]. The comparison between these publications and the EMA lessons learnt outcome showed similarity in relation to needs for: (i) message tailoring for different groups with various levels of technical terms and content; (ii) providing information about the incidence and severity of the influenza disease; and (iii) addressing specific concerns and questions from the public regarding the vaccination of pregnant women and children (for examples, see the Discussion section).

Conclusion: It was concluded that the findings from the literature search, had it been carried out in summer 2009, could have provided an evidence base for matching messages from the EMA with the attitudes and specific information needs of various groups, and could have helped the EMA to fulfil these needs more proactively. The pilot project therefore suggested that reviewing communication research has the potential to improve the planning of communication interventions for medicines by regulatory authorities.

As the pilot study suggested that findings from communication research can be used by regulators for anticipating questions from the public and preparing communication messages addressing these questions, guidance for vaccine

safety communication was developed, based on a worldwide vaccine communication literature search and additional globally relevant key publications (see Appendix).

A summary of the guidance is provided in Table 1, together with its evidence base. The references to the evidence base do not necessarily indicate a one-to-one reflection of the research findings in the guidance. In some cases, detailed findings were translated into more suitable high-level recommendations; at other times, high-level research findings were made more specific, taking into account the communication experiences of the EU regulatory network. These included enquiries about the use of thiomersal as a vaccine preservative and other questions about vaccines frequently addressed to the EMA by members of the public. Expert

reflections contributed further, e.g. regarding how healthcare professionals might deal with vaccine anxiety in the context of HPV vaccination and whether they could be better supported with communication materials in the framework of regulatory risk management plans.

Discussion, outlook and conclusions: proactive and prepared communication about vaccine risks and safe use between regulators and the public

With this evidence-based policy making on vaccine safety communication, EU regulators pushed in a new direction.

Table 1

Summary of the guidance on vaccine safety communication in the EU good pharmacovigilance practices and its evidence base (see Appendix for search strategy and list of references)

Recommendations	References to the evidence base
Integrate a proactive communication process with risk assessment, and plan communication with public information needs and concerns in mind	[21, 89]
Arrange for fulfilling the communication objectives of: <ul style="list-style-type: none"> • Providing information for appropriate vaccine use and informed decision making in healthcare practice and immunization programmes; • Preventing anxiety-related reactions; • Avoiding vaccination errors; • Reiterating product information, in particular precautions for use and warnings 	For informed decision making: [22, 81]
Consider the multiple relevant parties for adapted communication exchange, e.g. vaccine-targeted/vaccinated persons, parents/carers, healthcare professionals, health/immunization policy makers and the general public	[9, 22, 24, 26, 28, 46, 47, 52, 57, 59, 67, 69, 70, 72, 74, 79, 81, 84, 86, 87]
Monitor the media regarding debates on vaccines and ensure appropriate, timely and meaningful communication with the media and the public	[21, 23, 26, 46, 51, 62, 67, 72, 74, 78, 79, 84]
Apply mechanisms of participation of the public in communication planning	[21, 49, 65, 74, 87, 88]
Include information on the benefits and risks of the vaccine, the target disease, risks of nonvaccination, key functions of vaccine pharmacovigilance systems with the roles or responsibilities of those involved, as well as on how a regulatory decision on vaccine safety has been reached (transparency), taking into account that risk perceptions may differ between stakeholders and culture, especially when there is uncertainty about a risk	[9, 22, 24, 26, 27, 46, 47, 50, 55, 57, 59, 61, 66, 71, 72, 74–77, 79–83, 85, 86]
Address frequent public information needs, including those relating to excipients, residues, special populations	[22, 24, 25, 27, 53, 67, 80]
Explain concepts such as coincidental event, temporal (but not necessarily causal) association between an adverse event and vaccination, a single case of an adverse event, mock-up vaccine and a safety monitoring need (which does not necessarily imply a confirmed risk)	[73] For term mock-up vaccine: [85]
Advise healthcare professionals on how to manage vaccination/needle anxiety and frequent concerns of vaccine-targeted/vaccinated persons and carers, such as in relation to pregnancy, puberty, immunosensitive conditions, general anxiety/mood disorders, epilepsy	[24, 46–48, 54, 56, 58, 60, 68, 75, 80, 81]
Prepare and test standard texts, in particular for frequently required explanations	[9, 24, 64]
Keep stratified exposure and background rates for causal and coincidental events up to date for contextualizing safety concerns	[22]
Foster a collaboration between regulatory authorities, stakeholders and international partners for consistency in messages	[24, 26, 82, 88]
Foster communication planning for pandemics and public health emergencies	[26, 63]
Monitor and evaluate the effectiveness and other impact of communication provision and interventions in line with the strategic health communication concept	[87]

Overall, the guidance draws from the concept for strategic health communication, which provides for objective-focused planning of communication interventions and impact evaluation. This approach advocates for listening and understanding patients, healthcare professionals and others concerned, and then using this understanding for scoping medicinal product-specific risk assessments and analysing communication options [21]. This requires studying the real-world use of medicines and its drivers, as well as the concerns and questions of those using medicines. This should allow for formulating and contextualizing risk messages, so that they address information needs, appeal to motivations and are specific about feasible safe use behaviours. For this purpose, the guidance encourages collecting frequently asked questions from the public, media monitoring of the public debate and concerns expressed by subgroups of the public, and implementing public participation in communication planning. As the guidance details frequent communication interests of the public identified through communication research, e.g. relating to excipients, pregnancy or epilepsy (see Table 1), the guidance itself can be considered as based on listening. The awareness of information interests should enable regulators to fulfil them proactively through communication to the public, or to be prepared to respond immediately. In this context, proactivity refers to providing information before someone specifically asks for it, and preparedness refers to having responses readily available if someone does ask.

Discussion

During the development of the guidance, questions were raised within the EU regulatory network as to whether naming, in a regulatory guidance document, specific concerns voiced in the public domain may be perceived by the public as an official risk confirmation. Therefore, the guidance describes these concerns clearly as the information needs of the public. Providing, in the present article, the evidence base for these information needs should support familiarization with communication research and motivate the application of the derived guidance in practice. A second question during the development phase referred to the guidance on addressing concerns raised by members of the public in regulatory communications. It was discussed whether addressing such concerns when they are unsubstantiated could either divert public attention from other statements in regulatory communications on the evidence for safe use, or contribute to an undue amplification of public risk perception. The guidance therefore advises a focus on the most frequent public information needs and insists on transparency of evidence-based regulatory decision making. A third question was how best to organize the recommended integration of risk assessment and communication planning within a regulatory authority. This will depend on how the authority is organized overall. It remains crucial, however, that listening and messaging are operated competently and linked in a way that ensures that concerns voiced by the public are addressed in assessments. Responses can then be based on these assessment outcomes. In addition, processes for immediate information

exchange between the pharmacovigilance and the product quality departments need to be in place for emerging safety concerns. Their rapid coordination should include decisions about communication to the public.

What may appear quite abstract in a regulatory guidance document becomes lively and convincing when reading the actual research – e.g. about influenza vaccines, as reviewed for the pilot project (see Box 1). For example, a focus group study identified as the primary barrier to vaccination the mothers' lack of information about whether the protection would cover current virus strains, and to what degree (see Table 1, reference 27). Other research describes the frustrations of healthcare professionals concerning simple messages used by the authorities in influenza vaccination campaigns, when they really wanted scientific information targeted specifically at them (see Table 1, reference 28). The need for information regarding special populations can be derived from the divergent views of healthcare professionals about whether to vaccinate healthy children against seasonal influenza, while advice to vaccinate at-risk (i.e. not fully healthy) children has often been ignored (see Table 1, reference 23). In addition, confusion about seasonal influenza vaccination of at-risk children with asthma or other cardiopulmonary diseases has been observed in some speciality healthcare settings (see Table 1, reference 25).

The most important remaining question, however, is whether filling information gaps will make a change. For example, a study testing different formats of correcting information regarding MMR vaccines in the US showed only limited success in changing perceptions, and no increase in parental intent to vaccinate through information provision [29]. However, this study was an experimental testing of different message formats, without their delivery within a trusted personal interaction [30]. A number of studies have concluded that the content of communication is only accepted by others as true when the data source and information provider is trusted, in terms of the provider's motivation and integrity [31]. When investigating which type of information content can lead to change in favour of vaccination, an example from France on (H1N1) influenza vaccines showed that only purely scientific information addressing specific concerns of members of the public increased vaccine acceptance [32]. This finding stems from an interactive round-table setting, and others have expressed doubts as to whether specific concerns can be addressed effectively in non-interactive dissemination of information [33]. The latter is the usual mode of communication by regulatory authorities through websites and product information they authorize. However, this question about communication impact has to be considered in the context of the communication intent. Those in public health authorities responsible for the implementation of immunization programmes will measure the effect of their communication activities in terms of vaccination coverage. Regulatory authorities have a different legal remit: they authorize and supervise medicinal products, with product information being intrinsic to the authorization. Further, regulatory authorities may demand additional measures for managing risks that have to be communicated too, mainly through written materials. For the EU regulatory network, the legally underpinned quality objectives of pharmacovigilance include preventing harm and

promoting the safe and effective use of medicinal products [34]. Safety communication objectives have been set accordingly for providing accurate and timely information about the safety of medicinal products to patients, healthcare professionals and the public for facilitating informed decisions (in the sense of true choice) and safe use behaviours [17, 89]. Overcoming vaccine hesitancy would therefore not be a primary communication objective of regulators. However, the fact that safety concerns are among the main drivers of vaccine hesitancy in the EU [35] makes meeting the information interests of the public important to regulators, as a principal prerequisite for informed decisions as well as safe and effective vaccine use, and for trust in the authorities' commitment to patient and population health. Their information on QSE assessments and responses to concerns and questions raised by members of the public should enable taking vaccination decisions at policy and individual level on a fully informed basis. This is in line with how the ECDC also sees the relevance of knowledge-forming communication, in particular for those audiences that have questions about vaccine products, rather than rejecting them completely [12]. 'Information vacuums' should be avoided because such a lack of public information can lead to rumours, public outrage and health or trust crises [36, 37]. The provision of information to the public is also part of a regulatory authority's accountability as a public body. As demonstrated by the literature search, safety concerns should be put in the context of what is known about the benefit in various possible epidemiological scenarios and as a function of different vaccination rates. As simply filling information gaps based on what has been called the 'deficit model' is not sufficient for achieving the communication objectives of science in general [38], and of the EMA in particular [39], the guidance goes beyond merely advising on information provision. It not only explicitly encourages the monitoring of the public debate, but also the application of public participation mechanisms and collaboration with public health authorities, other local stakeholders and international partners. Further, the guidance stresses the need to provide information that supports healthcare professionals in their interactions with patients (see Table 1).

Outlook

With regard to the implementation of the guidance by the regulatory authorities in the EU, a survey in 2015 revealed that it had not yet been widely applied, as in a number of member states communication on vaccines is mainly enacted by the public health authorities [40]. Since then, however, the guidance has been followed increasingly. Most prominently, a recent study on listening to the public debate about HPV vaccines demonstrated the feasibility and utility of online news media monitoring for regulators in the situation of a real life risk assessment. The utility consisted of anticipating information needs relating to the safety data, procedures, methods and assumptions for their assessment and policies safeguarding integrity. This facilitated proactivity in fulfilling the information needs through public website statements, as well as preparations for immediate

responses to questions from journalists and giving statements in parliamentary hearings [41]. Continuous listening to the public has been confirmed as important because public concerns about vaccines are vaccine type-, country- and population-specific, and are subject to change over time [35]. With these latest research findings, the guidance has been included in this year's review and learning activities of the EU regulatory network.

The relevance of the guidance for capacity building for regulators outside the EU has been noted at meetings of the WHO and international societies (see the introduction). As the literature review for the guidance was performed on the worldwide literature and complemented by key publications of global relevance, the resulting guidance is, in principle, applicable in any country of the world. In particular, the role of the local and global news, as well as the social media, is becoming increasingly important, not only for disseminating messages, but also as a tool for real-time listening to the worldwide debate. From a global perspective, the value of vaccines can hardly be overestimated, as the outbreaks of the Ebola and Zika viruses have reminded us.

Since the issuing of the guidance, the EMA has participated in two projects, resulting in further guidance documents based on new research, experience and expert advice:

- (1) In October 2017, the Innovative Medicines Initiative (IMI) project on Accelerated Development of Vaccine benefit–risk Collaboration in Europe (ADVANCE) published the document 'Developing Communication Strategies on Vaccine Benefits and Risks'. This aims to support institutions in public–private collaborations with a framework for disseminating evidence from monitoring the benefits and risks of vaccines. Following a four-step process, the document provides advice on defining the goals and objectives of a communication strategy; mapping and engaging various stakeholders; selecting audiences, channels and messages; and developing an implementation and monitoring plan [19].
- (2) In January 2018, the Council for International Organizations of Medical Sciences (CIOMS) published the 'CIOMS Guide to Vaccine Safety Communication'. This discusses the complexity faced by regulators and others involved in vaccine safety, and takes a systems approach with defined functions and capacities integrating communication, pharmacovigilance and risk management. It also includes a template for vaccine safety communication plans (VacSCPs), which allow for communication specific to a vaccine product and the local situation. A number of positive examples from different countries, including low-resource settings, illustrate the implementation of the various components [20].

These two new documents and the EU-GVP guidance discussed in the present article are complementary. While the EU-GVP presumes that a communication system is in place, provides high-level recommendations on listening and public participation processes, and specifies frequent information needs, the ADVANCE guidance details a strategic process and the CIOMS guide focuses on the system requirements.

Conclusions

The work of regulatory authorities in assessing and supervising medicinal products throughout their life cycle becomes visible to the public only through communication. This justifies the efforts of regulators to understand, communicate and engage with patients, healthcare professionals and wider communities. It is critical that regulators: (i) explore how to listen efficiently to the public on a continuous basis; (ii) integrate this process with benefit–risk assessment; and (iii) address public concerns and questions effectively through proactive and prepared communication messages about QSE data and uncertainties in a specific, clear and accurate manner. Therefore, guidance on developing message content on vaccine safety was issued by the EMA and the regulatory authorities of the EU member states, and the present article provides a summary of the recommendations and their evidence base. The guidance has been welcomed by EU and international fora, and complements other guides for regulators that have become available more recently. Meeting the information interests of the public is a prerequisite for making informed decisions about using medicinal products, as well as for their safe and effective use, and trust in the regulatory authorities' commitment to patient and public health.

Research findings from the cognitive, decision-making and media sciences have shown value for regulators. Therefore, regulatory authorities should consider using published communication research for medicines of public health importance in the future. Given that most available medicinal product risk communication research focuses on vaccines, and a few other medicine classes [42–45], the present article should motivate researchers to engage in wider and deeper research. Regulators should consider, in their communications, not only the data on QSE, but also an outside perspective – namely, that of those they serve – and respond to what they need and want to know.

Competing Interests

The views expressed in this article are the personal views of the authors and may not be understood or quoted as being made on behalf of, or reflect, the position of the European Medicines Agency or one of its committees or working parties. The authors have no competing interests to declare.

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Appendix

Search strategy

The review of the worldwide scientific literature was performed on 22 October 2010 through a free text search in PubMed (<http://www.ncbi.nlm.nih.gov/pubmed>) ['vaccine*' and ('communication' or 'perception')]. A total of 1,647 articles were displayed and selected, with the following inclusion criteria. The article:

- investigates risk perceptions, concerns, information needs or communication effectiveness in vaccine target populations, parents, healthcare professionals or the public regarding vaccines in general or in immunization campaigns; or
- involves a major regional/global public health organization; or
- concerns (seasonal or pandemic) influenza, human papilloma virus (HPV) or measles–mumps–rubella (MMR) vaccines (combination or single virus type products) (given major communication challenges with these vaccines in the EU).

The following exclusion criteria were applied. The article:

- was published before 1990; or
- concerns vaccines other than those against influenza, HPV or MMR, or than those used in immunization campaigns; or
- concerns communication not involving vaccine target populations, parents, healthcare professionals or the public; or
- concerns data collection schemes rather than provision of information; or
- is published in a language other than English, French, Spanish or German (unless an English abstract was available).

The article information was reviewed online and 192 titles were selected, together with their abstracts, if available (32 on influenza vaccines; 33 on HPV vaccines; 23 on MMR vaccines; 104 on vaccine or immunization communication in general). Forty-five articles (full text or abstracts, as indicated in the references) were considered relevant for the recommendations [23–28, 46–84]. Additionally, EU reviews of the communication about 2009/10 (H1N1) pandemic influenza vaccines [22, 85] and key publications on medicines/vaccines communication were extracted [9, 21, 86–89].

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