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Conference report

CIOMS Guide To Vaccine Safety Communication – Executive summary

Priya Bahri [a,*], Lembit Rägo [b], on behalf of the CIOMS Working Group on Vaccine Safety

[a] European Medicines Agency (EMA), Pharmacovigilance Department, Surveillance & Epidemiology Service, 30 Churchill Place, London E14 5EU, United Kingdom
[b] Council for International Organizations of Medical Sciences (CIOMS), 20 Avenue Appia, 1211 Geneva 27, Switzerland

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ABSTRACT

Background: In 2018, the Council for International Organizations of Medical Sciences (CIOMS) issued their Guide to Vaccine Safety Communication. This has been built upon existing guidance and a new review of research and compilation of latest experiences, in order to fill, for the first time at global level, a specific niche for regulatory authorities in the contexts of vaccine hesitancy and informed choice. The Guide was developed by the international multi-stakeholder CIOMS Working Group on Vaccine Safety, formed to assist the Global Vaccine Safety Initiative (GVSI) of the World Health Organization (WHO).
Summary: Besides the public health authorities responsible for immunization programmes, regulators have their own role in communicating about vaccine safety. As they are responsible for licensing vaccine products, they need to be transparent about their assessments of data on quality, safety and efficacy. Furthermore, they are responsible for continuous safety surveillance and keeping safe use advice to the public up-to-date. The Guide stresses the fundamental importance of regulatory bodies to have a system in place with defined functions and skilled persons who can efficiently run vaccine safety communication in collaboration with stakeholders. This system should take a strategic approach to communication, be integral to safety surveillance and risk assessment, and support vaccine safety communication plans (VacSCPs) adapted to vaccine types in local situations. The Guide provides recommendations and examples for the system components as well as a practical VacSCP template.
Conclusions: While the Guide should help strengthening regulatory bodies worldwide with regard to vaccine safety communication, it is meant to help regulators in resource-limited countries in particular. It can also be of interest to other stakeholders and be leveraged to other medicinal products.

1. Background

In January 2018, the Council for International Organizations of Medical Sciences (CIOMS) issued their Guide to Vaccine Safety Communication [1]. This discusses the relevance of communicating about vaccine safety in the contexts of vaccine-induced health gains, vaccine hesitancy and informed choice over immunization. The Guide has been developed to fill, for the first time at global level, a specific niche for regulatory authorities in low, middle and high-income countries. Among the many stakeholders and besides the public health authorities responsible for immunization programmes, regulators have their own role to play in communicating about vaccine safety. As they are responsible for licensing vaccine products, they need to be transparent about their assessments of the data on quality, safety and efficacy. Furthermore, they are responsible for continuous safety surveillance, or pharmacovigilance, and keeping safe use advice to the public up-to-date. While the Guide has been developed for strengthening regulatory systems, it may be of interest, and in many aspects transferrable, to other stakeholders.

With the objective of supporting the dissemination and raising interest in the Guide in wider communities of healthcare professionals, health policy makers and leaders in public bodies, this article summarises the recommendations. An overview of the

Abbreviations: ADVANCE, Accelerated Development of Vaccine Benefit-Risk Collaboration in Europe; AVSS, active vaccine safety surveillance; CDC, Centers for Disease Control and Prevention of the United States; CIOMS, Council for International Organizations of Medical Sciences; ECDC, European Centre for Disease Prevention and Control; EMA, European Medicines Agency; EPI, WHO Expanded Program of Immunization; EU, European Union; EVI, essential vaccine information; GACVS, Global Advisory Committee on Vaccine Safety; GVSI, Global Vaccine Safety Initiative; HPV, human papillomavirus; ICDRA, International Conference of Drug Regulatory Authorities; IMI, Innovative Medicines Initiative; MMR, measles-mumps-rubella; NESI, Network for Education and Support in Immunisation; SAGE, WHO Strategic Advisory Group of Experts; SEM, social-ecological model; TIP, WHO Tailoring Immunization Programmes method; UNESCO, United Nations Educational, Scientific and Cultural Organization; UMC, Uppsala Monitoring Centre; VacSCP, vaccine safety communication plan; VSN, Vaccine Safety Net; WHO, World Health Organization; WHO-EURO, WHO Regional Office for Europe.

* Corresponding author.
E-mail addresses: priya.bahri@ema.europa.eu (P. Bahri), ragol@cioms.ch (L. Rägo).

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presented examples (Table 1) and a visualisation of the Guide's approach to vaccine safety communication (Fig. 1) have been developed specifically for the purpose of this article.

1.1. CIOMS and its support to WHO's Global Vaccine Safety Initiative (GVSI)

CIOMS is an international non-governmental, non-profit organization, established by the World Health Organization (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1949. Since its inception, CIOMS gathered senior scientists from regulatory authorities, pharmaceutical industry and academia in working groups and other fora, to develop consensus guidelines within topics globally relevant to ethical research and safety of medicines. Over time, this has led to the publication of a range of guidelines, many of them for pharmacovigilance [2].

In 2013, CIOMS created the Working Group on Vaccine Safety to address unmet needs related to vaccine pharmacovigilance identified by WHO's Global Vaccine Safety Initiative (GVSI), taking into account the need of resource-limited countries in particular. CIOMS was asked to support the strategic objective 8 of the GVSI Blueprint, which is "to put in place systems for appropriate interaction between national governments, multilateral agencies and manufacturers at national, regional and international levels" [3]. The Working Group divided itself into three areas of importance when a newly-developed or new-to-the-country vaccine is introduced into a population: topic group 1 on safety data needed by regulatory authorities and immunization programmes; topic group 2 on active vaccine safety surveillance; and topic group 3 on vaccine safety communication.

Through the course of discussions, topic group 3 saw an opportunity in creating the CIOMS Guide to Vaccine Safety Communication, to complement existing helpful communication guidance from WHO and other organizations by addressing the specific needs of regulatory bodies. This Guide additionally supports the implementation of the strategic objective 3 of the GVSI Blueprint, which is "to develop vaccine safety communication plans at country level, to promote awareness of vaccine risks and benefits, understand the perception of the risk and prepare for managing any adverse events and concerns about vaccine safety promptly."

Apart from the final CIOMS Guide to Vaccine Safety Communication presented in this article, the Working Group delivered, in 2017, the CIOMS Guide to Active Vaccine Safety Surveillance (AVSS) with an appendix on Essential Vaccine Information (EVI) [4]. A summary of the AVSS Guide has been published already [5].

1.2. Structure of the CIOMS Guide to Vaccine Safety Communication

The CIOMS Guide to Vaccine Safety Communication consists of six chapters, presenting:

- underlying communication concepts (chapter 1);
- considerations for vaccine safety communication as relevant to regulators (chapter 2);
- vaccine safety communication as a pharmacovigilance task with a product-life cycle approach to the safety of vaccine products (chapter 3);
- an annotated template for vaccine safety communication plans (VacSCP) as a practical tool (chapter 4);
- components and functions of vaccine safety communication systems (chapter 5); and
- skill requirements and proposals for capacity-building of such systems (chapter 6).

The Guide includes 62 pages of condensed and referenced text, illustrating examples, bullet-pointed summaries, tables, checklists, the VacSCP template and figures, all colour-coded for the ease of reading and application. A reading list at the end provides selected references organised by topics for those who want to enlarge their knowledge and skills. A public consultation of the draft guide was held from 29 August to 11 October 2017. The now final Guide is available via the CIOMS website [2] as print and electronic versions, the latter offering additionally hyperlinks to references. The CIOMS VacSCP Template can be downloaded from the website free of charge [6].

1.3. Evidence base of the CIOMS Guide to Vaccine Safety Communication

The Guide has been based on more than 100 publications, either established guidance and practice documents or peer-reviewed conceptual or empirical research findings. This includes the wealth of communication experience of public health authorities and immunization programmes. While the communication of such programmes aims specifically at ensuring sufficient vaccination coverage for public health protection, a lot of their guidance is applicable to regulatory authorities with their own specific communication objectives. Further, 13 case examples, written up by those with the real life experience, were reviewed for learning from different countries. The recommendations are however not only based on established practices and research conclusions, as further value has been added by the regulatory expertise and the vision of topic group 3.

2. Vaccine safety communication

The approach to vaccine safety communication for regulatory bodies has been developed with the vision to ensure that regulators can fulfil their legal mandate as well as address needs of stakeholders and expectations of the public in a collaborative and accountable manner. The following key messages and harmonized approaches are presented in the Guide:

2.1. Considerations and objectives of vaccine safety communication from a regulatory perspective

'Vaccine safety communication' is understood by the topic group as communication about potential risks, demonstrated safety and measures to minimize risks, and about programmes to support the safe and effective use of vaccines.

The communication discussed in the Guide happens between regulatory authorities and multiple stakeholders. These include national, regional and international public health bodies, ministries of health, immunization advisory committees and those in charge of implementing immunization programmes; manufacturers with their own responsibility for the safety of their vaccines; donors; non-governmental organizations; and the public. The public consists foremost of those vaccinated or for whom immunization is intended; parents, families and carers; teachers, religious leaders, communities and interest groups, like anti-vaccine groups, women's groups or citizen watchdog groups; healthcare professionals, whether modern, traditional or alternative; as well as journalists and others active in the news or social media. The media landscape has fundamentally changed since the wide introduction of the internet at the end of the 20th century. It is now comprised of the 'classic' press, television and radio; the 'traditional' media, such as story-telling and folk art-linked sharing of news and advice; and the 'new' fast evolving electronic and web-based media. Overall this means that vaccine safety communication today consists of complex interactions between many parties. The information interests of these parties will vary by time and place, and are heightened at the level of individuals or groups,

Table 1
Summaries of examples presented in the CIOMS Guide to Vaccine Safety Communication.

Involving local health workers and communication experts for setting up clinical trials adhering to good clinical practices and informed consent in Liberia, Sierra Leone and Guinea for Ebola virus vaccines with an understanding of traditions and concerns in the various communities with limited literacy and initial mistrust
Applying findings from global risk perception research to understand safety and other concerns of healthcare professionals and the public prior to vaccine licensure, here presented with the example of human papillomavirus (HPV) vaccines, in order to proactively design communication materials that address widespread concerns and support healthcare professionals in their dialogue with potential vaccinees and parents
Developing a package leaflet with clear safe use advice for the quadrivalent vaccine against diphtheria, tetanus, pertussis and hepatitis B to facilitate comprehensive immunization of children in line with recommendations of the WHO Expanded Program of Immunization (EPI)
Introducing the pentavalent vaccine against diphtheria, tetanus, pertussis, hepatitis B and Haemophilus influenzae type B in Kerala, India with support from a committee of local paediatricians and community doctors re-assessing the benefit-risk balance and underpinned by media monitoring and a comprehensive communication strategy of the state government with assistance of UNICEF as well as strong engagement with journalists and folk art communicators
Conducting a large-scale media campaign with monitoring of the social media during supplementary immunization activities against polio in Israel to understand public opinion and concerns and with engaging polio victims in informing the public about the severity of the disease [20]
Delivering at the time of vaccine launch information materials to healthcare professionals and parents in the United Kingdom about the need for prophylactic paracetamol when administering serogroup B meningococcal vaccines to prevent possible febrile seizures [21]
Managing a case of death that occurred in a girl in the United Kingdom after HPV immunization, where health officials avoided loss of public confidence in the immunization programme through immediate investigation of the case, sensitive collaboration across public institutions, adherence to an honest and strict media policy and building on existing media collaboration [22]
Applying findings from worldwide online news media monitoring with regard to human papillomavirus (HPV) vaccines for drafting public statements about an EU risk assessment, predicting questions from the public and hence being prepared for interactions with parliamentarians and journalists [23]
Reviewing effectiveness and stakeholder satisfaction with communicating in Sweden about the assessment outcome regarding cases of narcolepsy in children observed during the early post-licensure phase of an H1N1 pandemic influenza vaccine, resulting in recommendations for future communication about vaccine safety concerns [24]
Re-establishing trust in measles-mumps-rubella (MMR) vaccines and high vaccination rates in the United Kingdom through a communication strategy including fact sheets to be handed to parents by their healthcare professionals and appreciating investigational journalism which helped identifying fraudulent research and prevented further negative reporting about MMR vaccines by journalists
Overcoming hesitancy related to measles-mumps-rubella (MMR) vaccination in the anthroposophic and Somali communities in Sweden with the help of the WHO Tailoring Immunization Programmes (TIP) method and fulfilling the communities' expectations for complete and neutrally framed information and arranging for individualized and peer-supported dialogue between community members and healthcare professionals [25,26]
Developing a training programme on vaccine safety communication based on social psychology and communication science as well as lessons learned from country experiences for improved decision-making and responding to vaccine safety-related events with a focus on maintaining trust and confidence, issued by the WHO Regional Office for Europe (WHO-EURO) [27]
Preparing resources for communication training from experience in Kenya, South Africa, Tanzania, Zambia and Zimbabwe, and making them available for capacity-building for immunization programme managers, issued through a collaboration of Ministries of Health in Africa and the University of Antwerp in Belgium within the Network for Education and Support in Immunisation (NESI) [28]

for example when parents receive an invitation to bring their baby forward for vaccination; when a new vaccine becomes available, like it was the case in 2006 for the first human papillomavirus (HPV) vaccine or in 2015 for the first malaria vaccine; when a vaccine safety concern arises; or when infectious diseases develop into a major public health threat, as recently due to pandemic influenza, Ebola and Zika viruses.

Those engaged in safety and communication at regulatory authorities can of course not ignore the complexity, the current information interests and overall contexts in which they work. Vaccines have been one of the most successful health interventions in countries all over the world and are necessary for reaching sustainable development goals in low and middle-income countries. While vast population groups agree with immunization, at the same time vaccine benefits and risks are subject to public debates. Some groups and individuals are hesitant towards vaccines, and hence contemplate, delay or reject immunization [7–9]. The triggers for vaccine hesitancy are manifold, varying by time, place and vaccine type. Concerns about risks of vaccines are one major trigger [10,11] and specifically relevant to the role of regulators in communication. Their challenge lies in operating efficiently in a field of tension between public concerns, scientific evidence and uncertainty. They also need to pay careful attention to the relationship between communication, transparency and public trust. The Guide provides short, bullet-pointed recommendations on these aspects.

In line with the legal mandate of regulatory authorities to assess, licence and supervise medicinal products, the Guide recommends that regulators set their objectives of vaccine safety communication around:

- understanding stakeholders;
- providing accurate and complete information about risks and safe use;
- demonstrating trustworthiness of the safety surveillance system; and
- preventing crisis situations due to safety concerns.

Fulfilling these communication objectives should support the informed decision-making of individuals, healthcare professionals and public health bodies in relation to immunization policies, recommendations and appropriate vaccine use. Information should be provided in formats that can support healthcare professionals and vaccinators when communicating with individuals considering or receiving immunization, their carers and community leaders.

With a view to achieving these objectives, the recommendations in the Guide build on concepts that have proven successful in other areas. These include the strategic approach to health communication [12], the model of dialogue in healthcare [13] and the social-ecological model (SEM) [14]. The SEM looks at the multifaceted and interactive effects of personal and environmental factors that determine the behaviours of individuals and groups. Within a dialogue, listening and speaking alternates between individuals or groups, or audiences, who should not be viewed as opponents, but as partners in an exchange over a topic of major personal and public interest. Dialogue with audiences is a crucial prerequisite of health communication that is strategic about achieving communication objectives agreed by stakeholders. Listening to stakeholders allows for understanding their concerns and the information needs that regulators are expected to address through scientific assessment and with honesty.

To clarify the relationship between the regulatory authority and the public health authority in a country, the Guide explains that information from the regulatory authority should not opine on immunization policy, which falls under the responsibility of the public health authority, but should be useful to those making decisions on immunization programmes. There should also be inter-institutional collaboration, for example, to agree consistent safety

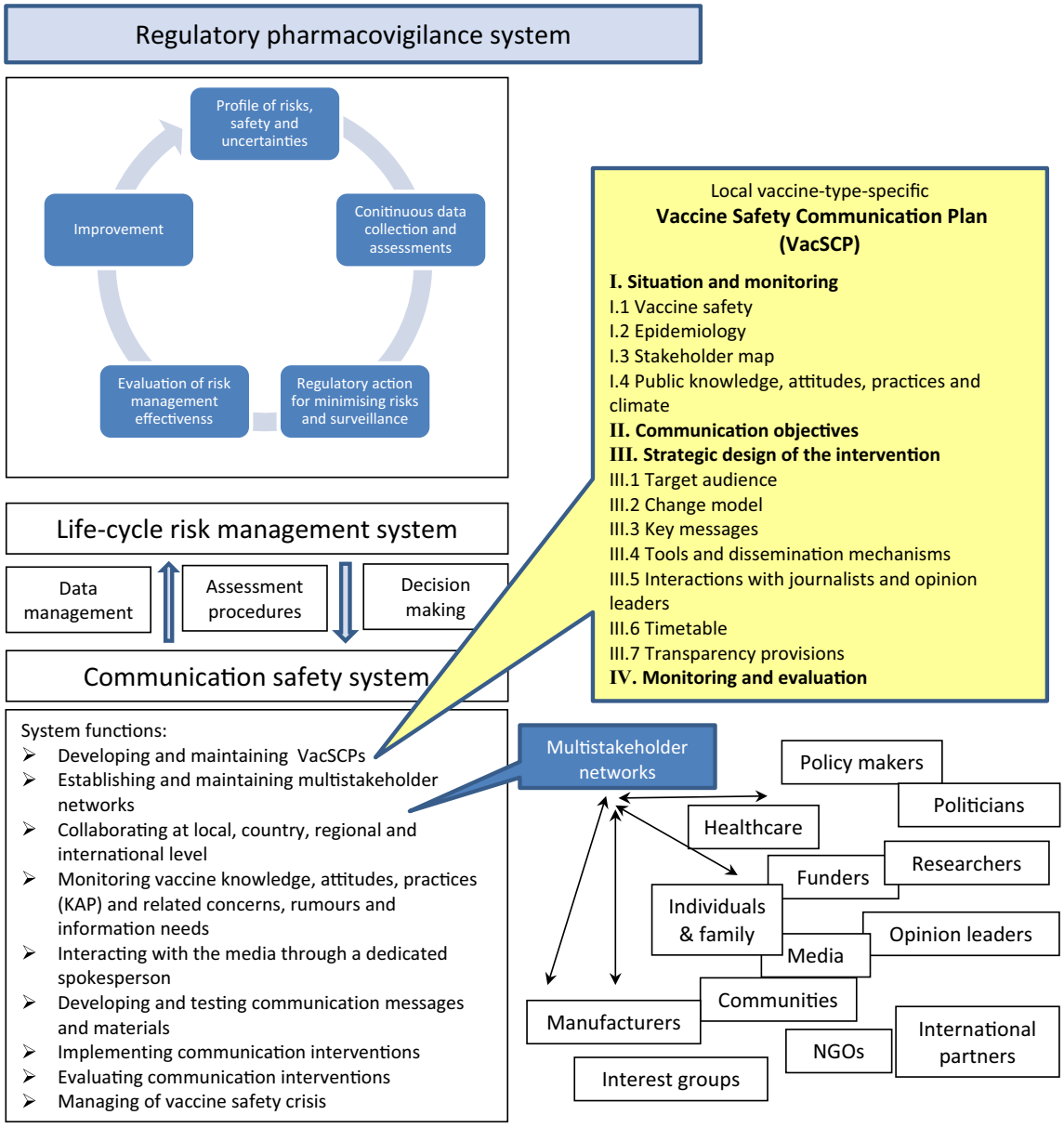

Fig. 1. Systems approach to vaccine safety communication and structure of vaccine safety communication plans.

messages from various organisations to the public, or to benefit from worksharing between organisations, such as in the area of vaccine sentiment monitoring.

2.2. Pharmacovigilance and safety communication plans

Vaccine pharmacovigilance has been defined, in an earlier CIOMS Report, as the science and activities relating to the detection, assessment, understanding and communication of adverse events following immunization and other vaccine- or immunization-related issues, and to the prevention of untoward effects of the vaccine or immunization [15]. Understanding the cognitive concept of risk perception and the need for managing concerns of the public with the same degree of importance as risks arising from scientific considerations is important for a new holistic model of risk assessment and communication [16].

Thus, vaccine safety communication is a recognized part of pharmacovigilance, and the Guide recommends integrating communication processes with the processes for monitoring and assessing the benefit-risk balance of vaccines, so that concerns and information needs of stakeholders get included in the assessments and can be addressed by regulators in their communications. For contextualizing a risk or a concern, several kinds of additional data, e.g. on disease epidemiology, vaccination rates and baseline rates of adverse events, need to be collected by the pharmacovigilance system, routinely and proactively. For trust-building, there needs to be transparency for the public in relation to the pharmacovigilance processes, available data, remaining uncertainties, the rationale for regulatory decisions and how bias has been prevented and scientific integrity been preserved.

Like pharmacovigilance overall, vaccine safety communication is necessary continuously during the entire life-cycle of a vaccine product, to keep information for stakeholders up-to-date with evidence about vaccine safety and effectiveness accumulating over time, and to be responsive to concerns and questions from stakeholders. As data that will give reassurance about safety or new concerns may arise, the messages will evolve. As pharmacovigilance nowadays applies a proactive risk management approach, for which planning should already start before a product obtains a license, the Guide provides recommendations on the risk

management model as well as on measures for safe use and risk minimization required by the license. Such measures may be included as advice in the product information approved by regulators or be applied by additional means.

Combining the models of strategic health communication and proactive risk management, the Guide proposes to understand the "vaccine safety communication plans at country level", referred to in the GVSI Blueprint, as vaccine safety communication plans that are specific to a vaccine-type and the local situation (VacSCP). Immediately tangible, the Guide provides the annotated CIOMS VacSCP Template [6], supporting the planning, monitoring and adapting of communication strategies and messages that can proactively fill information needs of stakeholders as well as respond to their questions about specific vaccines. A step-wise process [17] underpins developing VacSCPs. As 'living documents', they need to be kept up-to-date in accordance with changing evidence on the vaccine, emerging public health needs and the evolving debates at policy level and in the public domain. Individual VacSCPs may have generic elements in common or even be part of a single communication planning framework at country level, or there may be local priorities determining which vaccines need a VacSCP. The Guide includes a checklist to assist the management of a regulatory authority in their considerations relating to VacSCPs.

When implementing a VacSCP, evaluating whether the agreed communication objectives are being achieved or the plans need adapting is recognised as a crucial step, but in reality is often neglected. Therefore, the Guide recommends that regulators - as they continuously monitor the benefit-risk balance of vaccines - also monitor in real time the debate, sentiments and rumours about vaccines in the media and communities, both for planning and evaluation purposes. Feasible proposals for such monitoring are provided too.

2.3. Communication systems and capacity-building

The Guide takes the view that for high quality of vaccine safety communication, a system is needed at regulatory bodies to develop VacSCPs and run communication accordingly. The system consists of dedicated people and resources with defined objectives, functions and expertise, so they can operate continuously and efficiently in collaboration with stakeholders.

The Guide provides a checklist of skills requirements and a curriculum, which has been tailored for vaccines based on the "WHO-ISoP Core Elements of a Comprehensive Modular Curriculum for Teaching Pharmacovigilance" [18]. This has been supplemented by links to online training resources developed for global health initiatives in the area of vaccines and immunization. Taken together this can inform designing training and capacity-building for regulators at national and international level. Important to underline is the mix of capacities needed: technical, managerial and leadership capacities are essential but not sufficient. An alert, far-seeing and contextualising intellect is needed too, paired with empathy and emotional intelligence, to be able to understand different perspectives and bring science and society together.

The 'systems approach' is considered a major added value of the Guide, as this integrates safety communication with the pharmacovigilance system, and demands professionalism of communication. In this respect, it is stressed that communication cannot and is not meant to disguise any lack of evidence, uncertainty or flaws in the processes of safety surveillance, risk management or regulatory decision-making. The Guide provides the components of a vaccine safety communication system with a view to building them within a national authority gradually over time, taking into account local resources, opportunities and priorities.

The establishment and maintenance of local and global stakeholder networks lie at the core of the system and need to be underpinned by policies that prevent undue influences and bias. The Guide provides tables, a further checklist and a figure elaborating on this core component. Any stakeholder group or individual may take particular roles in shaping public and personal sentiments and impact on knowledge, attitude and behaviour of individuals. As the relationships between stakeholders will be different in each country and sometimes even for each vaccine type, regulators have to map their interactions as well as the given media landscape locally. Overall, collaboration with the network should make use of communication for increasing common understanding, disseminating the evidence about vaccines, solving issues and reaching agreements. Designing VacSCPs and testing tailored messages with stakeholders may seem challenging to implement, but establishing collaborations over time and pre-testing may allow for quick outreach to stakeholders and agreements even in situations of urgency.

Among the stakeholders, journalists have a special role, as they disseminate news or initiate discussions as the so-called forth power of democracy. Interactions of regulatory authorities with journalists should thus provide them with accurate information without trying to influence them in a way that would, truly or be perceived as trying to, jeopardize the independence and freedom of the media. Despite close collaboration, regulatory authorities must keep their independence too. Some of the examples in the Guide describe positive interactions with journalists to learn from.

The systems approach is also considered the best way to manage communication in the event of a public health emergency, such as a pandemic, and to prevent or manage situations of crisis, which can be triggered by a public reaction to a safety concern. Further reading regarding crisis management [19] is recommended in the Guide.

Fig. 1 visualises the systems approach, detailing its components and integration within pharmacovigilance, and provides the VacSCP structure too. Table 1 provides an overview of the examples detailed in the Guide to illustrate how the system components can be implemented successfully, taking into account feasibility and opportunities in various settings.

3. Conclusions

3.1. The CIOMS Guide in the context of other guidance documents

At its starting point, topic group 3 reviewed existing guidance documents, mainly from major organizations, i.e. WHO, UNICEF and national and regional public health agencies, such as the Centers for Disease Control and Prevention (CDC) in the United States and the European Centre for Disease Prevention and Control (ECDC) in the European Union (EU). These were often field-oriented and provided primarily for those in charge of immunization programmes about how to be prepared and manage communication when an adverse event occurs. Some also included guidance for healthcare professionals. Only little guidance on vaccine communication had so far been issued by regulatory authorities themselves, as existing regulatory guidance for communication usually focuses on tools and processes at the level of regulatory authorities and manufacturers in general.

However, the EU regulatory network, for example, had issued guidance specifically on vaccine safety communication, emphasising the importance of listening to the public and addressing their information interests. Derived from a scientific literature review, it encourages stakeholder dialogue and moreover details frequent information interests of the public in relation to the safety profile and benefit-risk balance of vaccines [29].

While the work for this Guide was ongoing, another project involving regulators in the EU run in parallel, i.e. the project of the Innovative Medicines Initiative (IMI) on Accelerated Development of Vaccine Benefit-Risk Collaboration in Europe (ADVANCE). Their document "Developing Communication Strategies on Vaccine Benefits and Risks" was published in October 2017 with the aim to support institutions in public-private collaborations for monitoring benefits and risks of vaccines and disseminating the evidence obtained. This includes advice on defining objectives of a communication strategy, mapping and engaging various stakeholders, selecting audiences, channels and messages, and developing an implementation and monitoring plan [17]. The CIOMS Guide considered this 4-step process also valuable for creating VacSCPs. In return, the ADVANCE document refers to the recommendations of the CIOMS Guide with regard to the communication system requirements and the VacSCP template.

Through the development of these three documents, synergies have been created, and they can now be viewed as a complementary set of guidance for regulators [30].

3.2. Outlook

The CIOMS Guide to Vaccine Safety Communication provides recommendations for regulatory authorities and has created a common ground at global level that has not been achieved otherwise. The principle recommendations are:

- Regulatory bodies licensinig vaccines need to have sound systems in place with defined functions and skilled persons who can efficiently run vaccine safety communication for keeping safe use advice up-to-date and continuous information exchange with the public in regular and and crisis situations; and
- Vaccine safety communications from regulatory bodies will be more effective if they are responsive to public interests and use a strategic approach with vaccine safety communication plans (VacSCPs) adapted to vaccine types in local situations and include evaluating and improving impact of communication interventions.

As with any global recommendations for complex interventions, the situations of their application will be highly variable and continuously changing. Hence, recommendations cannot be specific but can offer a framework for local adaptation and implementation. The Guide suggests building vaccine safety communication systems gradually over time, taking into account local resources, opportunities and priorities of the given regulatory body, as well as options for work-sharing between organisations and networking at regional and international levels. The required resources for building such systems are justified by both need and evidence, even where resources are limited. The examples in the Guide (Table 1) present how communicating about vaccine safety in low, middle and high-income countries has already successfully supported immunization. More broadly for global health and development, it has been demonstrated in many projects over the last decades that communication can improve health behaviours and outcomes [31], and communication has been called vital for Africa's development [32]. Communication and transparency of public bodies, like regulatory authorities, are fundamental for trust in medicinal products and governments in general. This is specifically important in countries where governments and regulatory authorities that are accountable to the public are still under development.

In line with the specific legal mandate of regulatory authorities to assess, licence and supervise medicinal products, the central objective of their vaccine safety communication systems is to provide accurate and complete information about risks and safe use of vaccines. 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 [10,11] makes communicating risk assessment outcomes and answering questions from the public highly important to regulators. Their communication is thus a prerequisite allowing policy makers, healthcare professionals and individuals to make informed choices and use vaccines effectively and safely. Knowledge-forming communication is particularly relevant for those audiences that truly have questions [33]. "Information vacuums" should be avoided, because such lack of information in the public domain can lead to rumours, public outrage and crises. However, filling the vacuums with information will not be sufficient, and engagement and trust-building with stakeholders is necessary in addition [34]. This underlines why the stakeholder network and the dialogue model are at the core of the systems approach presented in the CIOMS Guide. Further, familiarisation with the multiple aspects of communication in healthcare has been recommended [35], as well as supporting healthcare professionals in communicating one-to-one with those considering or receiving immunization. The new CIOMS Working Group, launched in April 2018, on the topic of patient involvement in the development of medicinal products and pharmacovigilance is expected to provide more recommendations for stakeholder collaborations that puts patients and other individuals using medicinal products as those to care for first [36].

As immunization is a matter of global health, regional and international collaboration is vital for effective vaccine safety communication in all countries. A number of stakeholders are specifically important for low and middle-income countries, as their outputs can be a resource to rely on: The Global Advisory Committee on Vaccine Safety (GACVS) provides independent, authoritative scientific advice to WHO on global or regional vaccine safety concerns. Its assessments and statements on urgent issues are publicly available [37]. Informed by GACVS assessments, the WHO Strategic Advisory Group of Experts (SAGE) on Immunization advises WHO on global policies and strategies, ranging from technology, research and development of vaccines to delivery of immunization [38]. Particularly for supporting communication at country level, WHO has created the Vaccine Safety Net (VSN) of more than forty reputable governmental, professional associations' and academic websites that provide information in many languages. Each website has been evaluated by WHO against criteria for good information practices [39]. The Uppsala Monitoring Centre (UMC) maintains, for the WHO Programme for International Drug Monitoring, VigiBase as a global database of individual case safety reports, which can be accessed by member countries [40].

Since its release, the Guide has been publicized and disseminated to the GVSI and all major regulatory agencies and regional networks. The GVSI has welcomed the Guide, and the Meeting of the Vaccine Safety Net (VSN) in June 2018 and the International Conference of Drug Regulatory Authorities (ICDRA) in September 2018 were important occasions to raise awareness of the Guide with a broader international multi-stakeholder audience. CIOMS looks now forward to feedback from countries. For example, the EU regulatory network has made the Guide a source for their ongoing review and learning activities, and the Food and Drugs Authority Ghana is currently considering implementing recommendations from the Guide [41].

While developing the CIOMS Guide, the reviewed documents included some not specific to vaccines, but more broadly relevant to medicinal products [42–47]. It was noted that the implementation of established best practices for communication about risks and safe use for medicinal products had been slow and incomplete worldwide [48,49]. Therefore, the Guide makes regulatory bodies aware that its recommendations for vaccine safety communication

could be leveraged for communication systems and processes for medicinal products other than vaccines. The same systems approach could be tailored to other medicine classes, as each presents specific communication challenges and might involve different stakeholders. CIOMS sees the establishment of such communication systems at regulatory bodies as a major building block of regulatory system strengthening overall, with goals of improving patient and public health.

Authors' contributions

PB was chair of topic group 3 of the CIOMS Working Group on Vaccine Safety and lead author of the CIOMS Guide Vaccine Safety Communication as well as of this article. LR contributed to this article through reviewing, commenting and drafting suggestions. Both authors PB and LR read and approved the final manuscript.

Conflict of interests

The authors declare that they have no conflict of interests.

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Authors' information

For PB, the views expressed in this article are her personal views 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.

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