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FROM THE ISoP

Communicating for the Safe Use of Medicines: Progress and Directions for the 2020s Promoted by the Special Interest Group of the International Society of Pharmacovigilance

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1 The International Society of Pharmacovigilance Special Interest Group on Medicinal Product Risk Communication (ISoP CommSIG)

Pharmacovigilance has developed, and continues to develop, a wealth of surveillance methods, pharmacological knowledge, and measures for preventing patient harm. However, ensuring the safe use of medicines in daily healthcare remains a challenge and requires strong collaboration across medicines regulatory bodies, pharmaceutical companies, healthcare professionals, health policy makers, and patients. Many patients today expect a dialogue with their healthcare professionals and participation in decisions regarding their treatment. Communication may at times be challenging for pharmacovigilance specialists who are first of all dedicated to the collection and assessment of data on adverse events. Recognising the importance of communication, the International Society of Pharmacovigilance (ISoP) launched a Special Interest Group on Medicinal Product

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Risk Communication (CommSIG) in 2014 during the 14th Annual Meeting of ISoP in Tianjin, China, with a mandate to:

- Establish medicinal product risk communication as a discipline within pharmacovigilance, including integration of communication in all pharmacovigilance processes;
- Provide for multidisciplinary and global exchange, learning and development of communication practice;
- Promote research for planning and evaluating communication interventions [1].

The initiative to establish the CommSIG was built on the long-standing interests of ISoP members. Communication of risks and its relevance for pharmacovigilance have been discussed since the start of ISoP in 1993 and has always been part of ISoP's vision. ISoP was therefore among those at the forefront of developing the fundamental Erice statement on medicines communication and patient safety in 1997 and the follow-up statement in 2009 [2, 3]. ISoP dedicated a range of activities to communication about the risks and safe use of medicines in the decade before creating the CommSIG [4], including a pre-conference training course in Tianjin in 2014 [5].

Establishing the CommSIG also built on a forward-looking attitude to changes in medicine, communication technology, patient expectations, and societies overall. It was also recognised that the multidisciplinary approach to communication would support reaching out to patient groups, healthcare, medicine information and media professionals, and experts from the communication, social, healthcare and data sciences. The nine founding members of the CommSIG published its background and aspirations in ISoP's official journal, *Drug Safety* [4].

The initial challenges of having wide membership for global learning and creating opportunities for members to actively contribute have been addressed. Since its launch in 2014, the CommSIG has been steadily growing and currently has over 50 members with a wide geographic spread over Europe, Asia, the Americas, Africa and Oceania. During ISoP's annual meetings, the CommSIG members meet to reflect on the achievements and decide on next activities. These annual CommSIG members' meetings are open to all attendees of the ISoP annual meetings, to provide for an influx of new ideas in roundtable discussions and to welcome new CommSIG members. ISoP members can join the SIG at any time, and between meetings, its members stay in contact, exchange information and contribute to ISoP activities, mainly via group emails and, since 2021, through regular online meetings. Several work streams have been set up to ensure achievement of the annual goals and to offer opportunities to CommSIG members to contribute to or lead activities. The deliverables cover organising sessions at ISoP meetings and training courses, and disseminating key messages from the CommSIG to wider forums for creating synergies, as highlighted later in this article.

There are also cross-memberships and collaborations with the ISoP Special Interest Groups on Women's Medicines [6], Herbal and Traditional Medicines [7], Medication Errors [8], Vaccines [9], Risk Minimisation Methods for Asian Countries [10], and Patient Engagement [11], and with various regional ISoP Chapters.

A first update on the CommSIG activities was published in 2018 [12]. This article further updates what the CommSIG has achieved to date, gives a complete overview of the key messages arising from the sessions at ISoP meetings as a basis for continuing progress, and presents the CommSIG's directions for the 2020s in addressing current challenges.

2 Sharing Experience and Expertise Around the Globe

The ISoP annual meetings are the highlight of the Society's life every year, allowing its worldwide members and local pharmacovigilance specialists to come together. In 2015 and 2018, the CommSIG organised sessions involving specialists from outside pharmacovigilance, and in 2016 and 2019, sessions were organised based on accepted conference abstracts, particularly from Asia and the Americas, as the respective host regions. The 2017 meeting included a session on 'The Language of Pharmacovigilance' as the Bengt-Erik Wiholm Memorial Lecture. The sessions were interactive, with lively, moderated panel and audience discussions. In 2018, eight flash talks followed by ample discussion time offered the audience a new session format at an ISoP annual meeting for presenting a broader range of perspectives from pharmacovigilance, patient, and communication experts in different settings and regions. The key messages from these sessions are summarised in Appendix 1. In addition, knowledge was shared at the annual meetings during the poster sessions, and Appendix 2 presents a selection of references to posters that are relevant to medicinal product risk communication (while it is interesting to note that considerably more posters regarding a wide range of pharmacovigilance processes and product safety concerns have referred to the opportunities of communication in their conclusions). Furthermore, the CommSIG supported pre-conference training courses in 2015 and 2016 on risk management and communication.

The CommSIG contributed to other meetings under the ISoP umbrella: in 2015, a presentation was invited by the African Society of Pharmacovigilance (ASoP) for the 2nd ASoP Conference held in Accra ('Transparency, Communication and Participation in Pharmacovigilance' by Priya

Bahri) [13]. CommSIG members also contributed to ISoP mid-year training courses in South America, one held jointly with the Uppsala Monitoring Centre (UMC) in São Paulo in 2015 ('Interaction with Media and Role Play' by Paula Alvarado, Alex Dodoo and Bruce Hugman) and one in Lima in 2016 ('Risk Communication' by Ulrich Hagemann and Paula Alvarado). In Berlin in 2016, a training course on 'Risk Assessment of Drug Use During Pregnancy and Lactation', organised by the European Network of Teratology Information Services (ENTIS), the Norwegian PhD School in Pharmacy NFIF and ISoP, included a session on communication [14]. Furthermore, the CommSIG supported work in Israel with advice on a campaign for the safe use of anticoagulants [15] and the 'International Multidisciplinary and Solution Oriented Symposium: Minimize Risks – Improve Communication' in 2019 [16].

In 2020, the flow of progress was abruptly halted by the global severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic. Recognising the crucial importance of pharmacovigilance communication during this crisis, the CommSIG has since then continued working in adapted ways through digital platforms.

In March 2020, ISoP started to develop two infographics for patients, one on the safe use of medicines during the pandemic, and a later on the safety of coronavirus disease 2019 (COVID-19) vaccines. The CommSIG contributed by developing the key messages and design of these first ISoP infographics, as well as the ISoP strapline '*Committed to safer medicines use worldwide*' for supporting ISoP outreach to medicines stakeholders. The infographics are now available in several languages for display free of charge in healthcare settings [17] (see Fig. 1).

The CommSIG also provided advice to the then new ISoP Communications Team, which developed and installed an outreach strategy for ISoP, using, in particular, social media channels such as Facebook/Meta, Twitter, Instagram, and YouTube, in addition to an existing LinkedIn page. The ISoP Communication Team includes a designer and community manager to support the activities with audience-tailored graphical elements and infographics [18].

On World Patient Safety Day on 17 September 2020, CommSIG member (and current ISoP President) Angela Caro-Rojas disseminated a talk '¿Y si hablamos? Comunicación para una medicación más Segura' [And if we talk? Communication for Safer Medication].

Later in 2020, other CommSIG members presented at a webinar series titled 'Tell Us a Safety Story' organised in Israel, with talks on 'Impact of the COVID-19 Infodemic on Drug-Utilization Behaviors' [19, 20] and 'The Public Hearing for Valproate at the European Medicines Agency (EMA): Stakeholder Input and Implications for Future Engagement' [21, 22]. Priya Bahri, in her CommSIG coordinator role, also represented the SIG as a panellist for the event on 10 February 2021 organised by the ISoP Latin American Chapter as part of their webinar series 'Vigilance of COVID-19 Vaccines' [23]. Other CommSIG members joined the discussions at these online events.

In November 2021, ISoP held its annual meeting in Muscat, Oman, in hybrid format, and the CommSIG sponsored a session on visual communication, which covered infographics, safe-use pictograms, and graphics for visualisation of risk estimates, and involved a digital communication and fact-checking specialist from Asia. Another relevant talk was part of the session on COVID-19 vaccine safety surveillance and provided a community perspective on safety information from public institutions and other stakeholders (see Appendix 1). The pre-conference training course 'Managing Safety Signals in Daily Practice' included a talk on 'Communication of Safety Signals: What, When and Where', with a subsequent workshop [24].

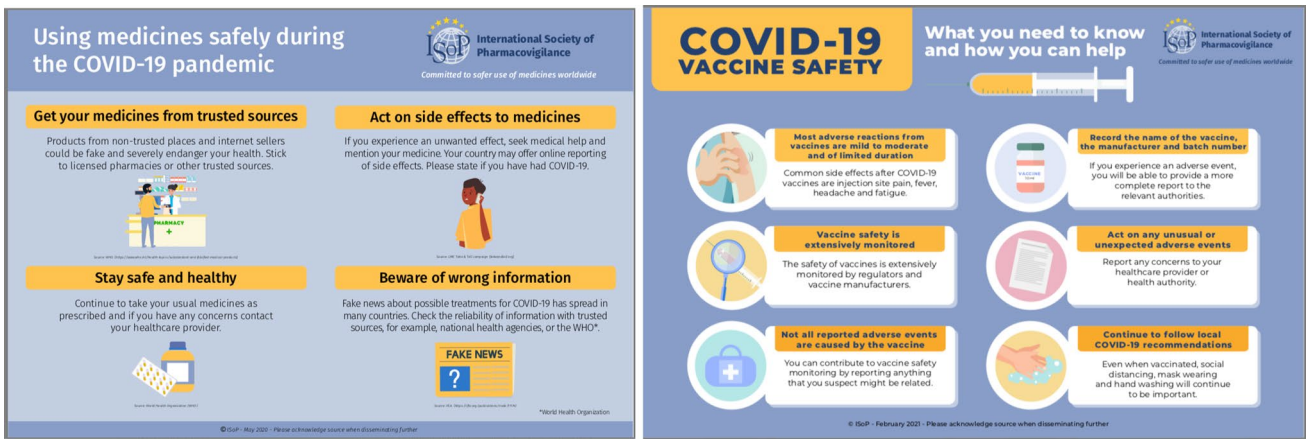

Fig. 1 Infographics developed by the ISoP [17].Abbreviations: *COVID-19* coronavirus disease 2019, *ISoP* International Society of Pharmacovigilance,*WHO* World Health Organization

3 Substantiating the Discipline of Medicinal Product Risk Communication

3.1 The Contribution from the CommSIG

Medicinal product risk communication has been defined as the structures, processes, and outcomes of information exchanges about risks and any concerns people may have with medicines, the measures to support safe use and minimise risks, and about risk governance in private, community, and society spheres [25]. Since the mid-1990s, an increasing range of parallel initiatives has established medicinal product risk communication as a self-standing discipline of pharmacovigilance, and the CommSIG has supported this. Thanks to ISoP's vision and the CommSIG's activities, medicinal product risk communication has become a permanent programme item in ISoP's annual meetings, reflecting the fact that communication is now a recognised, visible, and advancing discipline within pharmacovigilance. Some characteristics that are typical for a scientific discipline have been substantiated through the CommSIG-sponsored sessions at ISoP's annual meetings (see Appendix 1), as follows:

- ***A multidisciplinary approach:*** A notable exploit of the CommSIG is involvement of specialists from outside pharmacovigilance (2015, 2018 and 2021), covering communication psychology [26], healthcare services [27], patient advocacy [28], environmental crisis management with complex stakeholder interactions [29], and digital media [30]. This involvement took forward suggestions from experts in pharmacovigilance and other disciplines, collated in 2012 in a *Drug Safety* themed edition to lay the groundwork for multidisciplinary learning and practices for medicinal product risk communication [31–39]. Broad multidisciplinary collaborations are necessary for advancing medicinal product risk communication [40, 41] with in-depth understanding of the dissemination, perception, and adoption of information, and of the barriers and enablers of applying information for behavioural choices, both at individual and population levels in the different private, community, and society socioeconomic spheres [25].
- ***Global relevance:*** The CommSIG has provided a platform for exchange, visibility, and promotion of medicinal product risk communication in various pharmacovigilance settings worldwide. For local affiliates of pharmaceutical companies, the crucial importance of having risk surveillance and communication processes in place for effective interactions between local regulatory bodies and global company headquarters was highlighted (2019) [42]. A specific model for designing risk minimisation and pharmacovigilance activities in Asia was presented [43]. It was inspiring to learn how multilingual and multicultural challenges with medicines risk communication have been successfully overcome in Colombia (2018) [44], India (2016) [45], Mexico (2019) [46], and Thailand (2016) [47]. Other examples of enhanced communication practices and research were presented from Croatia (2015) [48], Israel (2018) [15], Italy (2016) [49], and Tunisia (2018) [50]. The DataLEADS initiative, originating from India and now active across Asia, was an example of how to use digital media for informing people and supporting them against misinformation (2021) [30]. Given that socioeconomic and health inequities of women are still prevalent in many countries, a special plea was made for listening and providing information to women regarding their health and suitable medicines (2018) [51].
- ***Innovative solutions:*** A scientific discipline must also be able to identify relevant problems and solutions. At the CommSIG, a start has been made in this respect by discussing fundamental concepts, such as verbal and numerical literacy (2015) [26, 27], risk proportionality of risk minimisation interventions (2016) [43], and implementation of interventions in the context of human factors (2018) [44, 53]. The study of human factors is a multidisciplinary science concerned with interactions of humans with system elements, applying anatomical, physiological, and psychological knowledge to design systems that complement human abilities and enhance safety [54–56]. Other innovative solutions were proposed from successful creative collaborations, such as role-play-based development of healthcare professionals' communication skills (2018) [44] and theatre performances for outreach to young people (2015) [48] or to indigenous communities (2019) [46]. The use of social media may also benefit pharmacovigilance, for example through well-designed tools for reporting suspected adverse reactions (2019) [57] and disseminating information in tailored ways to various audiences [30].
- ***Healthcare implementation:*** Solutions discussed increasingly focused on the role of communication in implementing risk minimisation measures in healthcare, underpinned by multidisciplinary concepts (2015 and 2018) [58–60]. Practical examples include a multilingual and visual guide for the safe use of medicines to support healthcare professionals in Thailand in their dialogues with patients (2016) [47], pharmacist-led interventions for the safe use of medicines in India (2016) [45], a campaign in Israeli community pharmacies to reduce risks with anticoagulants (2018) [15], and engagement of the Tunisian pharmacovigilance centre with healthcare professionals and patients for reporting suspected adverse reactions and risk minimisation advice (2018) [50]. A

European study explored communication preferences of healthcare professionals (2015) [61]; a study in the UK investigated how product information could best advise healthcare professionals in patient monitoring for avoiding haematological adverse reactions (2019) [62]; and a project in Colombia aimed at enhancing the risk communication skills of healthcare professionals (2018) [44].

- ***Research promotion:*** In relation to research for planning and evaluating communication interventions, the sessions promoted knowledge-sharing about local projects in various world regions. In 2016, a five-step strategic health communication approach with defined communication objectives [40, 52] was illustrated by the presented projects [60]. The model for developing risk minimisation measures [43] involved problem and situation analysis (step 1 of the strategic approach). Implementation of a multilingual and visual guide for the safe use of medicines [47] required strategic design (step 2), community engagement (step 3), and dissemination to healthcare settings (step 4). Evaluating the impact of communication events (step 5) can be achieved by various methods, such as an analysis of patient health records databases [49] or analyses of prescribing behaviours combined with healthcare professional knowledge-attitude-practice surveys, patient adherence surveys, and data on medicines-related problem and patient outcomes [45]. Such evaluations can provide evidence for re-planning interventions, feeding into a new strategic communication cycle.

To contextualise the establishment of the medicinal product risk communication discipline more broadly, other parallel initiatives need to be noted. Some of these have yielded synergies with the CommSIG, either actively created by its members or fostered by the openness of the SIG to mutual learning. The following are of particular importance:

3.2 Regulatory Bodies

Regulatory initiatives have had a crucial role in the development of communication as an important pharmacovigilance process, enabling risk management and underpinning transparency. Several guidance documents initiated by regulatory bodies have been of fundamental value, e.g. guidance for patient information or package leaflets, in Australia in 1997 [63] and in the European Union (EU) in 1998 (revised in 2009 to support compulsory readability testing [64]); expert reports on the leaflet in the UK in 2005 [65] and on a strategic risk communications framework in Canada in 2006 [66]; guidance on direct healthcare professional communications (DHPCs), with templates for DHPCs and communication plans, in the EU in 2006 [67] and later in Canada also [68]; and a communication guide in the USA in 2011 [41], a still valid and excellent resource today. A comparative overview of safety advisory policies of regulatory bodies in Australia, Canada, the EU, and the USA was published in 2020 [69]. In Japan, advanced communication policies have been issued by their Ministry of Health, Labour and Welfare (MHLW) [70–72], but publications in Japanese are unfortunately not easily accessible to an international audience to learn from. To generate evidence for progress, the European Commission launched major projects in the 2010s under their Innovative Medicines Initiative (IMI), which included research into risk communication for medicinal products [73, 74] and communication recommendations particularly for vaccines [75–77]. Similarly, a Joint Action project of EU Member States included a work package on safety communication for improvements [78, 79]. In the USA, a report relevant to regulators was issued in 2017, advocating for involvement of patients with diverse literacy, health literacy, language and cultural backgrounds in the testing of medicines information [80], and a model for multimodal analysis evaluating safety communication was developed by the USA Food and Drug Administration [81–85]. In the UK, the House of Commons initiated an examination of how the healthcare system responds to adverse reactions reports, which in 2020 recommended to the regulatory system incorporating behavioural science and best risk communication practice for patient autonomy [86]. Policy advances in other jurisdictions might have happened but be less well-featured in the scientific literature. Most recently, strengthening communication for stakeholder engagement for risk minimisation, as well as methods evaluating measures for risk minimisation that always involve communication, has been a major goal for EU regulators when revising guidance in 2021. This now incorporates approaches from the implementation, cognitive, and behavioural sciences [87]. ISoP participated in the public consultation of this guidance by submitting comments.

3.3 Erice Statements

The local regulatory initiatives described above have also been informed by an important global initiative. ISoP, the World Health Organization (WHO), and the UMC were together involved in organising and contributing to meetings, resulting in the Erice statements. Some of the CommSIG's founding members had already participated in defining principles in the 1997 Erice Declaration on Communicating Drug Safety Information [2]. This was the first significant statement about the central role that ethical and transparent communication must play in the effective pursuit of patient safety. Even after more than 20 years, this declaration is still influential and often referenced as a seminal document. It was developed by a multidisciplinary international group, many of whom continued participating in further work, including that carried out by ISoP and the 2009 Erice follow-up statement on patient safety within evolving healthcare,

societal and digitalised environments [3]. In 2016, a new group of pharmacovigilance experts updated the original proposals, again under the lead of the late Giampaolo Velo, a previous ISoP President, for strengthening dialogue with patients for informed and shared therapeutic decision making as well as multi-stakeholder collaboration and integration of pharmacovigilance with healthcare [88]. The Erice Call for Change 2020 reinforced advocacy for an active role of patients in their own healthcare to improve quality and safety [89].

3.4 Council for International Organizations of Medical Sciences

The Council for International Organizations of Medical Sciences (CIOMS) is an international, non-governmental organisation that convenes expert working groups to develop guidance for medical research ethics and pharmacovigilance [90]. As a member, ISoP participates in selecting guidance topics. The CIOMS Guide on Vaccine Safety Communication of 2017 includes practical recommendations for strategic planning as well as roles and skills for people responsible for communication within an organisation, based on a systems and capacity-building approach with examples from around the globe on successful outreach to various communities. While it was developed for vaccines, it is, in principle, applicable to all medicinal products [91, 92]. With its report from the Working Group XI on Patient Involvement in Development and Safe Use of Medicines, CIOMS continues to address processes that require patient-centred communication between stakeholders [93].

3.5 WHO Programme for International Drug Monitoring

ISoP traditionally maintains a strong link with WHO's Programme for International Drug Monitoring (PIDM) [94], which started to include the topic of medicinal product risk communication in their annual meetings about two decades ago [95]. Major modules of WHO's 'Pharmacovigilance Resources' for practicing pharmacovigilance deal with regular and crisis communication [96], and some of the CommSIG's founding members had contributed to the underlying minimum standards and original toolkit. Among the WHO Collaborating Centres of the PIDM, the UMC has continually presented at ISoP's annual meetings new creative communication tools for multiple dissemination channels, taking into account people's evolving media preferences. These tools include the 'Take & Tell' campaign for direct patient reporting of suspected adverse reactions, with a website, printable materials, an application (app), a song, a YouTube video, and social media outreach. Furthermore, the entertaining 'Annie & Mac's Adventures' comics have been developed by the UMC to educate young people about medicines. The UMC also offers the podcasts on 'Drug Safety Matters', bringing stories and in-depth expert interviews to cover new research and pressing safety issues [57, 97].

3.6 International Society for Pharmacoepidemiology

In 2012, the International Society for Pharmacoepidemiology (ISPE), which some refer to as a sister learned society of ISoP, established its SIG on Benefit-Risk Assessment, Communication and Evaluation (BRACE) with the mandate to promote the intersection of pharmacoepidemiology and BRACE activities through methods development and training offers [98]. The ISPE BRACE SIG has called for multidisciplinary collaborations of pharmacoepidemiologists, patients, and healthcare professionals, and use of real-world data for evidence generation and decision making on risk minimisation [99, 100]. Furthermore, some of its members developed the RIMES Statement to improve the reporting quality of studies evaluating risk minimisation and communication interventions [101]. ISPE's annual conference in 2020 featured 'The Science Communication of Pharmacoepidemiology' in its final plenary session [102], followed in 2021 by the plenary session on 'Communicating COVID-19 Pharmacoepidemiological Research to Patients; [103]. The ISPE BRACE SIG and the ISoP CommSIG have some common members, who keep both SIG communities mutually aware of their work of complementary scopes: the ISPE BRACE SIG mainly looks at appropriate data sources and research methods for BRACE activities, while the ISoP CommSIG is more concerned with integrating communication and outreach in pharmacovigilance practice.

3.7 Textbooks

ISoP has also brought together experts for the purpose of issuing major textbooks. In 2015, previous ISoP President and CommSIG member Mira Harrison-Woolrych published 'Medicines for Women' [104], which includes two chapters about communication from Bruce Hugman, one of the CommSIG's founding members [105, 106]. In 2017, 'Pharmacovigilance: Critique and Way Forward', edited by previous ISoP President Ralph Edwards, also a CommSIG founding member, and previous ISoP Vice-President Marie Lindquist, emerged from a series of discussions at ISoP [107], and likewise contains a chapter from Bruce Hugman with suggestions for a culture change and innovative technologies for communication [108]. A book fully dedicated to 'Communicating about Risks and Safe Use of Medicines: Real Life and Applied Research' was published in 2020, edited by Priya Bahri [109]. Although this book was not an ISoP initiative, the invitation by the publishing house

in 2014 followed the visibility and relevance of the topic at ISoP level. Chapter authors were invited from inside and outside the pharmacovigilance community to bring together methods from other sciences and establish a platform for multidisciplinary and participatory research. In particular, approaches from the cognitive, behavioural, social, rhetoric, media, design, implementation, and epidemiological sciences, as well as ethical and legal frameworks, have been consolidated to advance planning and evaluate medicinal product risk communication with relevance to all settings globally [110–121]. Overall, the book aims at preparing the ground for research that provides evidence on the causal relationships between structures, processes, and outcomes of communication and factors affecting communication about medicines in its multiple layers, with many senders and receivers in the various locations, media, and socioeconomic spheres over time. With this research framework, a self-standing inclusive discipline of humanities and epidemiology of medicinal product risk communication has been suggested [25].

4 Directions for the ISoP CommSIG in the 2020s

Directions for moving forward in the 2020s were initially explored at the annual ISoP CommSIG Members' Meeting in Bogotá in November 2019, and further discussed at the CommSIG online meeting in June 2021, held to replace the annual in-person CommSIG meeting. In addition to the experiences shared by the CommSIG since 2015 as well as the parallel initiatives described above, the discussions considered the following:

4.1 Society

Societies in general and their expectations of healthcare are changing profoundly. The complete realisation of patient-centred, collaborative care is still in its infancy [122, 123]. Participatory governance in pharmacovigilance requires new practical frameworks and discourse skills [112, 115, 124, 125]. Trust in science, technologies, pharmaceutical companies, and governments is at stake, requiring public dialogue and engagement with society [126–129]. Research advances in the cognitive and behavioural sciences—partly also due to big data sources such as social media—help to understand the technical and social evolution of communication and expectations.

4.2 Media

The digitalisation and technical advances of the media support societal changes and lead to new media landscapes with fast and wide dissemination of information and expanded options for interactions between individuals and groups, and supplementary big data sources and methods for both safety and communication surveillance [110]. The usefulness of different communication tools for optimising use of medicines requires research [130], and various possible formats for conveying complex information [131–134] should be studied further, including visual formats for effective risk communication as discussed at the 2021 ISoP Annual Meeting [135].

4.3 Infodemics

With the SARS-CoV-2 pandemic, health as well as societal problems have been exacerbated [136, 137] and an infodemic has emerged, a phenomenon seemingly first mentioned in 2003 in connection with the SARS-CoV-1 outbreak [138]. This describes a situation that accompanies a pandemic with an overabundance of information, both correct and incorrect information, disseminated with various intentions. Crises, controversies, and rapid, uncontrollable multimedia dissemination of information intensifying public speculation or anxiety are specific features of infodemics [139, 140]. The content of the current infodemic has included sensational and distorted information about COVID-19 vaccines [141] and medicines used off-label to prevent or treat COVID-19 [20], fuelled by social media [142, 143]. It seems likely that the SARS-CoV-2 infodemic will make communication about other medicinal products and maintaining public trust in science and governments generally more demanding and challenging. Rumour monitoring and counteracting false information and epistemic trespassing (judging matters outside one's field of expertise) [144] are expected to become crucial activities in this respect.

4.4 Health Literacy

Because withstanding infodemics requires specific health literacy, an urgent call for epidemiological literacy of both the general public and policy makers has been made [145], which should build on verbal, numerical, and statistical literacy for clinical decision making by healthcare professionals and patients [146, 147]. Likewise, understanding established concepts of risk assessment, such as 'uncertainty' [148] or 'absence of evidence of harm' versus 'evidence of absence of harm' [149], should be part of epidemiological literacy.

4.5 Risk Perception

Perception of risk, i.e. each individual's cognitive process of integrating new information into one's own knowledge and beliefs [150], is influenced by health literacy, the new information to which one is exposed, and how, and by personal

as well as social factors and expectations. Emotions and motivations are necessary for knowledge and beliefs to lead to behavioural choices and to result in actions [151]. There is evidence of a nocebo effect of information on risks with medicines, which increases the likelihood that an individual will experience an adverse reaction, and may lead patients to reject treatment [152, 153]. A considerable proportion of reported adverse events after COVID-19 vaccines has been estimated to be due to the nocebo effect [154], and concern about safety is a known driver of vaccine hesitancy [155]. Studying relationships between information and emotions is therefore essential formative research for communication interventions that avoid undue emotional impact and can support therapeutic decisions by patients and healthcare professionals.

4.6 Healthcare

Overall, fulfilling pharmacovigilance objectives for patient and public health depends on the effective and efficient integration of risk assessment and regulatory risk minimisation measures in healthcare processes, which is a major task ahead for communication. A number of points about why it remains difficult to connect pharmacovigilance and healthcare were raised at the audience discussion during the 2015 ISoP Annual Meeting [58]. This discussion highlighted the need to create comprehensible communication between healthcare professionals and patients about the benefits and harms of medicines, and for more research to better understand the obstacles in connecting pharmacovigilance and healthcare and in communicating effectively. At the CommSIG online meeting in June 2021, it was further emphasised that communication about harms and risk minimisation with healthcare professionals is not satisfactory, that both innovative and traditionally effective outreach tools are important, and that mutual engagement of regulatory bodies and stakeholders, and a stronger integration of pharmacovigilance and healthcare with collaboration across institutions and training on communicating with patients are needed. For this, guidance on language understandable to patients and the general public is required. Communication regarding vaccines was identified as being of particular relevance and inappropriate adverting of medicines as an area of concern. Only in the last 10 years has patient reporting of adverse events taken off widely, with countries providing means for patients and carers to submit electronic reports directly to their national pharmacovigilance centres [156]. People have specifically engaged in directly reporting suspected adverse reactions with COVID-19 vaccines [157]. Mobile information technology for direct reporting as well as for medicines supply management and therapeutic guideline dissemination offer great opportunities for health globally, as they are also feasible in low resource settings [158–160]. Independently from technology, psychology has shown that human understanding and beneficial behaviours rely on the match between risk perception and the actual impact of harms, and on effective mental shortcuts for daily decision making [161, 162]. Decisions regarding use of medicines are determined by personal as well social judgements about the acceptance of risk [163]. The CommSIG considers that strategies for connecting pharmacovigilance and healthcare should be based on the premise that people's awareness and skills should be boosted and empowered, rather than patronised [164].

4.7 The CommSIG's Agreed Focus Areas:

Taking into account the considerations above, the CommSIG agreed that, building on its mandate and achievements to date, it should continue to progress medicinal product risk communication in the 2020s in the following areas of focus:

1. ***Medicinal product risk communication practice and research capacity:*** To understand and apply to pharmacovigilance cognitive and communication concepts and research, digital technologies, including electronic prescribing/dispensing, and traditional and new dissemination modes that make use of local opportunities to involve relevant stakeholders and reach different audiences, including those who are at specific risks, are difficult to reach, or are disadvantaged by society.
2. ***Health literacy for pharmacovigilance:*** To support the development and use of clear technical as well as generally understandable languages for 'speaking pharmacovigilance' in healthcare and public domains, to enable informed therapeutic choices and safe use of medicines for everyone, to support reporting of suspected adverse reactions, and to contribute to counteracting infodemics, in particular regarding vaccines.
3. ***Integration of pharmacovigilance and healthcare for patient safety:*** To promote integration of pharmacovigilance and healthcare by means of communication, engagement of patients, healthcare professionals and other stakeholders, and implementation science with evaluation of impacts, barriers, and enablers of risk minimisation for sustainable patient safety.

For further progress, sharing examples from around the globe and sharing discussions will continue at ISoP sessions, and training webinars could conveniently supplement in-person pre-conference courses of ISoP's annual meetings. Synergies within and beyond ISoP will be nurtured for cross-fertilisation of ideas and generating evidence for novel and effective communication strategies. Possibilities for collaboration with other forums will be explored. Among future activities, a workshop with ISoP members experienced in

media interactions, as well as professional media trainers and journalists, on pharmacovigilance and safety communication is under consideration, as well as a similarly multidisciplinary workshop to address vaccine safety communication and strategies for counteracting misinformation during infodemics. The 2022 ISoP Annual Meeting in Verona therefore included a session on communication during health crises, with two examples on vaccines [165–167].

5 Conclusions

Since its launch in 2014, the ISoP CommSIG has successfully fulfilled its mandate to support the establishment of risk communication as a discipline within pharmacovigilance; to encourage multidisciplinary exchange, learning, and practice development; and to start promoting research for planning and evaluating communication interventions. This article consolidates the knowledge shared and progress achieved by the CommSIG to date and explains the CommSIG's directions for the 2020s, which are meant to contribute to ISoP's overall strategic goals.

The first years of the CommSIG have been devoted to setting up and enlarging a group that now includes members from different pharmacovigilance settings worldwide. While pharmacovigilance communication had been part of ISoP's initial vision and was addressed at some of its annual meetings before 2014, the CommSIG has drawn together the knowledge and expert networks of its members. It has provided dedicated sessions and/or contributed to training courses at all ISoP annual meetings, and has created synergies within and beyond ISoP. The CommSIG intends to continue strengthening risk communication in pharmacovigilance worldwide, so that medicines can be used in an informed manner, safely, and with trust in pharmacovigilance systems.

The CommSIG recognises that both communication and pharmacovigilance are evolving topics in the context of broader changes in society, media, and healthcare. Communicators, such as journalists, press officers, and providers of medicines information, patient organisations, and individual healthcare professionals need support in communicating with the public and patients, to improve understanding and dialogue, considerations of potential benefits and harms with medicines, and informed therapeutic choices. They need to be supported by basic knowledge of pharmacovigilance and risk communication skills. Pharmacovigilance specialists, whether in regulatory bodies, pharmaceutical companies, or healthcare settings, should therefore collaborate with communicators. Moreover, listening to and engaging with patients and healthcare professionals needs to become a stronger part of the pharmacovigilance communication process in order to understand fully the impact and perceptions of the risks in clinical contexts, and to identify which safety, risk, and risk minimisation messages may work best. This engagement should also create public understanding and trust in regulatory decisions and actions. The immediate future of safe use of medicines, with emerging pharmaceutical technologies, poses different demands in relation to the variety of medicinal products.

For the 2020s, the CommSIG has therefore set itself three focus areas: medicinal product risk communication practice and research capacity; health literacy for pharmacovigilance; and integration of pharmacovigilance and healthcare for patient safety. The CommSIG exists in a world of diversity and inequity, where messages need to be tailored for diverse populations with the aim of reducing health inequities. The CommSIG will continue to connect within the ISoP community, access expertise from beyond pharmacovigilance, and create synergies for global progress, inspiring solutions that can be adapted to different settings and parts of the world. The ISoP CommSIG looks forward to continuing to contribute to safer medicines use worldwide.

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Priya Bahri, Geoffrey Bowring, Brian D. Edwards, Angela Caro-Rojas, Bruce P.J. Hugman, Peter G. Mol, Katarina Ilic, Riadh Daghfous, Irene Fermont, Wolfgang Gaissmaier, Mohammad Ishaq Geer, François Houÿez, Hansjörg Neth, Gediminas Norgela, Yaowares Oppamayun, Mehdi Bouhlel, Federica Santoro and Janet Sultana have no conflicts of interests to declare. Christopher Anton receives an annual grant from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and owns shares in AstraZeneca, GlaxoSmithKline, BioNTech, Smith and Nephew, and Advanced Oncotherapy. Jeffrey K. Aronson has written articles and edited textbooks and has given medicolegal advice about adverse drug reactions. Giovanni Furlan is an employee

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