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FROM THE ISOP

The ISoP CommSIG for Improving Medicinal Product Risk Communication: A New Special Interest Group of the International Society of Pharmacovigilance

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1 Focus on Risk Communication

Communicating to patients and healthcare providers about the risks of harm with medicines and how to use medicines safely is vital to pharmacovigilance for fulfilling its objectives—there is no or little risk avoidance/mitigation or patient safety without risk communication. Communication about risk characteristics and factors should also enable patients and healthcare providers to make informed therapeutic choices. This requires discussing risks of medicines in the context of their benefits as well as the risks of deciding against medication. Usually medicines are meant to benefit the individuals taking them. In the area of infectious diseases, however, vaccines are aimed at protecting the vaccinee and also, through repressing or eradicating the disease, protecting vulnerable individuals who cannot be vaccinated.

For a considerable time, guidance documents on communications have been available from international pharmacovigilance specialists [1–4] and some regulatory authorities (e.g. [5–8]). However, application of these documents in everyday pharmacovigilance has been a challenge. An issue of *Drug Safety* not long ago, dedicated to the theme of risk communication, discussed barriers to implementation and proposals for improving communication practices from worldwide experience [9–17]. There is much more research on medical information, communications and risk perception available, but every time a major safety concern arises with a medicine, designing a communication strategy and materials for avoiding and mitigating risks is perceived as a complex new challenge by both industry and regulatory authorities, and either the available evidence from the communication sciences is not fully applied or specific research to guide them is lacking. With rapidly changing communication tools, landscape and behaviour, it is not easy for research to catch up.

However, communicating must be a paramount consideration whenever new safety information becomes available. Independently from which communication modalities are chosen, the content must be useful and understandable for those that should benefit from it (patients and healthcare providers), but also for other possible recipients like the general public and those in mediating roles such as drug information pharmacists and journalists. This

On behalf of the ISoP CommSIG.

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involves managing the differing communication needs of multiple stakeholders, including some very vulnerable patient groups.

So, with effective medicinal product risk communication being a vital necessity, how can communication practices be progressed, based on evidence from the communication sciences? Leaving communicators such as press officers and journalists, or each individual healthcare provider alone with this challenge seems neither effective nor fair. In most pharmaceutical companies, risk communication is dealt with by medical affairs or marketing departments. However, communicating about medicines is a joint task, and in whatever setting, those who investigate the risks and take decisions on the benefit–risk balances should shoulder their responsibility to develop messages to those using medicines. Moreover, they need to find ways to listen to patients and healthcare providers, to understand the characteristics, impact and meaning of the risks fully, and to see which risk mitigation measures and messages may work best in real life. In addition, they need to understand how to adequately support healthcare providers and those in mediating roles to inform patients and the general public. In fact, reviewing possible risk communication strategies should be intrinsic to any risk assessment concluding that action has to be taken to avoid harm and to enable informed choice.

The pivotal question is how to best communicate measures to avoid or mitigate risks in order to achieve safe behaviours around medicine use. Some of the associated challenges may actually be opportunities. In particular, developments in various media may help overcome the limitations of the printed word and offer opportunities for dialogue. With new media tools, one can learn by asking stakeholders whether information provided has been useful and evaluate the utility of communication efforts. Above all, this might bring pharmacovigilance into a real partnership with patients and healthcare providers. Perhaps, at last, this dialogue can move us away from underreporting of adverse effects and beyond the merits of controlled clinical trials and observational studies, shifting the gaze towards those particularly at risk because of reasons such as genetic factors, medical conditions or social situations. Obtaining their input might enable specific communication strategies to avoid or mitigate risks and optimise benefits in those individuals.

Another major strategic consideration relates to timing of communication. Should information be disseminated as soon as a safety concern has arisen, only after its full assessment, or at regular intervals during the assessment process? Increasing transparency and dialogue with patients and healthcare providers during assessments intensifies communication needs, also with a view to informing about uncertainty and preventing social risk amplification. Communication processes should also facilitate effective communication in situations where new information needs to be disseminated urgently or where there is a potential media crisis.

"Inadequate communication is a risk in itself, and hence communication expertise and functions within pharmacovigilance should be installed alongside all other crucial functions", the editorial of the *Drug Safety* theme issue concluded [9]. This means that pharmacovigilance specialists with risk communication expertise should reach out and build bridges for collaborations with patient representatives and healthcare providers during assessments. They should further collaborate with those specialists leading communication operations for development of communication strategies and messages, as well as promote and conduct relevant research for planning and evaluating communication. Pharmacovigilance systems and processes should provide for this, underpinned by quality management. Efforts should in particular be made to understand why so far implementation of already available communication evidence and guidance, including recommended listening mechanisms, has been slow and how practice uptake can be improved. Issues and opportunities regarding the latest media developments are also an important area to tackle.

2 Setting up the ISoP CommSIG

2.1 Call into Being and Mandate

It is for these reasons that in October 2013 the Executive Committee of ISoP, the International Society of Pharmacovigilance, agreed with the suggestion of the ISoP President Hervé Le Louet to establish a special interest group (SIG) on the topic of medicinal product risk communication, in short CommSIG. The Executive Committee also agreed the following mandate, the scope of which has never previously been attempted:

- Describe, develop and promote risk communication as a sub-discipline of pharmacovigilance;
- Provide a forum for global exchange on communication practices and experiences to maximise lessons learnt and drive progress;
- Connect with communications, social science and healthcare practice experts worldwide to improve risk communication, including collaboration to support communication operations;
- Reach out to others (e.g. patient groups, healthcare providers, drug information providers, patient safety experts, scientific journals, general media) to develop communication practices facilitating informed

therapeutic choice, safe use of medicines and credibility of the safety surveillance/regulatory system;
- Advocate for relevant research on risk communication;
- Provide training opportunities, ideally multi-disciplinary for mutual learning, e.g. with journalists.

A guideline on how SIGs should operate was adopted by the Executive Committee in April 2014. In line with this, at least five founding members were required to establish a SIG, and then colleagues who had been active in the area of communications at the annual meetings of ISoP or had contributed to the *Drug Safety* theme edition convened to establish the CommSIG.

2.2 Previous ISoP Activities as the Basis for the SIG

ISoP has not started this topic from scratch. There was a first pre-conference session discussing risk management and communication in 2006 at the ISoP Annual Meeting in Liège [18–20]; and in Bournemouth in 2007, editors from medical and pharmacovigilance specialist journals presented and discussed the roles of journals and in particular editors in this respect [21–23]. This was followed by a plenary lecture in Buenos Aires in 2008, where a strategic health communication approach was applied to pharmacovigilance [24]. In 2009, ISoP contributed to the second Erice report [2] and organised a session at the ISoP Annual Meeting in Reims with pharmacovigilance and media specialists [25–28] as well as a session on ethics where an anthropologist provided inspiring thoughts about the topic of healthcare communication [29]. Something different was organised in Accra in 2010 with an interactive debate consisting of vivid sharing of experiences and ideas of all presenters and more importantly all session attendees [30]. The ISoP Annual Meeting in Istanbul in 2011 took the topic to a new level: there was a specific call for research abstracts about risk perception and communication [31–33], and a lecture by an invited risk communication scientist [34] complemented the oral abstract presentations from the ISoP community [33, 35, 36]. It was this research-based event which led *Drug Safety* to pursuing their idea of the theme edition. ISoP continued its practice of having sessions dedicated to communication in pharmacovigilance at its Annual Meeting in Cancun in 2012, where theory and practice of risk communication was addressed with research and examples [37–40]. In Pisa in 2013, the focus of an invited speech was on the evolving media landscape and its meaning for pharmacovigilance [41], supplemented by reflections from a health journalist [42]. For many years, ISoP has also held training events on various aspects of risk communication.

The CommSIG will use the research, experiences and proposals discussed so far at ISoP meetings to inform their future activities, and will also build on the established contacts for expanding the expert network.

2.3 Interactions with the ISPE BRACE SIG

ISoP is not the only learned society that has recognised the importance of communication in relation to risks with medicines. ISPE, the International Society for Pharmacoepidemiology, established a SIG for BRACE in 2012. BRACE stands for benefit-risk assessment, communication and evaluation, and the purpose of the ISPE BRACE SIG is to promote knowledge sharing, education, best practices and new methods for BRACE activities, supported by multi-disciplinary input and collaboration [43]. The mandates of this and the ISoP CommSIG have some overlap, but more importantly they are complementary, and a fruitful exchange between the two SIGs is ensured through some common members. While the ISPE BRACE SIG looks more at methods to gather and analyse data for assessment, communication/risk mitigation interventions and their evaluation, the ISoP CommSIG aims more at applying such methods and developing best practices for everyday pharmacovigilance.

2.4 Announcements and SIG Membership

The Executive Committee's decision to set up a SIG on medicinal product risk communication was announced at the Annual Meeting of ISoP in 2013, and the newly established CommSIG was presented to the General Assembly at the Annual Meeting in Tianjin in October 2014 [44], where ISoP members with an interest in the area were invited to join. The first CommSIG meeting was held at the margins of this Annual Meeting in order to welcome new members, exchange what they would like to contribute, agree priorities and appoint a coordinator. The CommSIG currently counts 20 members (see Appendix 1).

In the meantime, a CommSIG webpage has been added to the ISoP website and will provide space for announcements, exchange and resources from other relevant initiatives [45].

3 Next Steps for the ISoP CommSIG

3.1 Connecting with Others for a Multi-Disciplinary Network

Most importantly, the CommSIG will actively connect with relevant experts outside traditional pharmacovigilance circles and invite them to contribute to progressing medicinal product risk communication, in order to address the scientific-medical, cultural, linguistic, social, political and media-technological complexity. Links are planned with experts from the social and communication sciences or those active in patient safety and human factors research and practice, as well as with representatives from patient, healthcare provider and media organisations. It is crucial to

listen to those who should benefit from pharmacovigilance and to set up opportunities for learning from other experts.

There is specific interest to ground the work in cognitive risk communication and decision science theories [7, 46–51]. Some CommSIG members have already started applying these [14, 17, 24], and a related lecture was invited at an ISoP Annual Meeting [34]. Also, the *Drug Safety* theme edition included an article on this subject [11].

In general, and for multi-disciplinary work in particular, the CommSIG finds it essential to compile existing definitions and to work further on defining terms and concepts in the context of medicinal product risk communication; for example, for communication, communications, information, dialogue and risk communication, to name the most obvious ones.

3.2 Working Arrangements

Several work streams have been set up under the lead of different CommSIG members, so work on various deliverables can go on in parallel. There will also be collaboration with the Uppsala Monitoring Centre (UMC) for synergies. The SIG works through telecommunications and personal meetings, including regular gatherings at the annual meetings and training sessions of ISoP.

Contributions of the CommSIG to ISoP training activities will follow chapter 14 of the recently published WHO-ISoP Curriculum [52] and be further informed by the teaching experience gained from ISoP events, the Eu2P Programme [53] and other training activities SIG members have been involved with.

3.3 Deliverables for 2015

The following are the concrete deliverables for 2015, which were proposed by the founding members and agreed with all CommSIG members:

- Organise a session for the 15th Annual Meeting of ISoP on a defined question and invite experts with the objective to learn about the challenges and explore solutions;
- Review the *Drug Safety* theme edition on risk communication to identify relevant questions for the next and future annual meetings;
- Finalise and publish a founding paper (i.e. this publication), which will also act as background material when reaching out to experts from other disciplines or to other organisations;
- Start an inventory of ongoing relevant publications and initiatives ISoP members are involved with or know about for the CommSIG webpage [45];
- Start developing a set of definitions for clear, meaningful exchange on the topic;
- Contribute to ISoP training activities.

The preparations for the Annual Meeting in Prague in 2015 have already begun and a major session with contributions from a healthcare researcher and a communication psychologist is under preparation [54].

4 Outlook

This paper presents the ISoP CommSIG, a new special interest group of the International Society of Pharmacovigilance (ISoP) on medicinal product risk communication, describing the way it has come into being, its mandate, plans, and above all its rationale, reflecting the intrinsic role of communication in pharmacovigilance. The key messages are summarised in Box 1. This is a call to interested ISoP members to join the CommSIG as well as a backgrounder for experts from other disciplines with whom the SIG wants to collaborate. It will be essential for the SIG to bring in worldwide expertise from the areas of communications and the social sciences. The SIG hopes to invite such experts to ISoP's annual meetings each year to review possible recommendations for another challenge in risk communication, so it can gradually progress.

The CommSIG will of course also connect with those practicing and researching healthcare and most importantly with patients in order to improve risk communication. It should provide a platform for a critical discussion on how new communication tools/channels, the social media, and new(er) concepts such as two-way risk communication can actually be applied effectively, and also how these can be incorporated effectively and efficiently into the patient–healthcare provider interaction. The global flow of local information and the need for local adaption of global information needs specific attention.

Overall, the CommSIG aims to develop concepts for communication at an expert-quality level and best practices which can be integrated into operational everyday pharmacovigilance, and hence contribute to enabling informed therapeutic choices and keeping patients safe.

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Appendix 1: Current members of the ISoP CommSIG

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Alexander N. Dodoo
Brian D. Edwards
I. Ralph Edwards
Irene Fermont
Kenneth Hartigan-Go
Ulrich Hagemann
Bruce Hugman
Agnes Kant
Viola Macolic
Tamas Megyaszai
Peter G. Mol
Kaori Nomura
Sylvie Tomczyk
Panos Tsintis
Banu Unal

Box 1: Key Messages

- ISoP, the International Society of Pharmacovigilance, has set up their Special Interest Group on Medicinal Product Risk Communication (ISoP CommSIG), which started its work in 2014.
- The CommSIG's mandate is to establish risk communication as a sub-discipline of safety surveillance and risk management of medicines, provide for multi-disciplinary exchange, learning and practice development and promote related research.
- This builds on ISoP members' long-standing interest in the topic, with sessions at the annual meetings of ISoP since 2006, training events and articles published in the scientific literature.
- Reaching out to others, such as patient groups, healthcare providers, drug information providers, the media, as well as connecting with experts from the fields of communications, social and healthcare sciences will be essential to the CommSIG.
- The overall goal is to support improving risk communication practices in the various pharmacovigilance settings worldwide with a view to facilitating informed therapeutic choice, safe use of medicines and credibility of the regulatory system.
- The objectives of pharmacovigilance, and the wider vision of patient safety, cannot be achieved without communication with patients, healthcare providers and other influential parties at expert quality level.

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