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EDITORIAL ARTICLE

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Risk Communication in Pharmacovigilance: Lookouts, Challenges, and Strategies

Sakshi Desai [a, *]

[a] Global IPV Strategy Realization Lead, Johnson & Johnson, India.

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ABSTRACT

Risk communication is a critical aspect of pharmacovigilance that must be considered by organizations during their Risk Management planning phase. The main challenges that hinder effective risk communication is its dependence on the perception of stakeholders, underpinned by their opinions, experiences and emotional responses to risk. The way to address these challenges is two-fold. One is dealing with it at a strategic level which involves collaborative problem-solving providing an understanding of strengths and limitations of risk analysis along with tools for internal and external communication to ensure consistent messaging. And the second is dealing at an interpersonal level, which involves utilizing empathetic listening to understand needs of the stakeholders and then sharing expert insights, translating technical information into understandable language to ensure effective delivery of messages. Ultimately, integrating expert communication with computational methods creates a strong foundation and increases success of risk communication.

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Risk communication, in particular in the pharmaceutical world, is a highly underappreciated, yet critical aspect that must be considered by organizations and institutes during their Risk Management planning phase.

Some of the considerations to make are not only on what is communicated, the time of communication, who makes the communication, and to whom is it communicated, but also to make a judgment of how it will be received and the degree to which it may result in changes in behavioral outcomes.

The main challenges often seen hindering effective risk Communication is its dependence on the perception of stakeholders (consumers, patients, health care professionals, etc.) which are underpinned by their opinions, experiences, emotional responses to risk, and the vast amount of information load on the internet that may lead to misinformation. Therefore as stated by Melissa in her report, trust in institutions and organizations, risk-related emotions, public proximity to risk, the severity of risk faced, overall tolerance of risk, and past public experiences with similar risks, should each be considered in developing effective risk communication messages (Janoske et al., 2012).

To address these challenges, Risk communication therefore should be at 2 levels, one at a strategic level and one at an interpersonal level. At the strategic level, risk communication should include long-term phased-out planning and strategic partnerships with groups such as the legal, communications team, Pharmacovigilance team, and

* Corresponding Author
Sakshi Desai
E-mail: sakshi.pihu@gmail.com
Contact: +919820255412

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the regulatory team as necessary, and have the endorsement and sponsorship of senior management (Nuclear regulatory commission, 2017). It must include collaborative problem solving that provides an understanding of the strengths and limitations of risk analysis and it must provide appropriate tools for both internal and external communication to ensure consistent messaging. While, at the interpersonal level, risk communication should utilize empathetic listening, building trust and credibility, sharing expertise and insights, translating technical information into understandable language, managing conflict, and effective delivery of messages (Nuclear regulatory commission, 2017).

So how can regulators strategize on their communication objectives? Fischhoff in his article proposes a framework that integrates expert judgment and computation to evaluate risk and decide on the best mode of communication (Fischhoff B, 2012). As Fischhoff points out, a decision/process has the greatest chances of success, if they are based on the theory of science and are then evaluated statistically with computational methods to prove it, giving the process a sound foundation. A second framework, developed by Sandman, expands the definition of risk primarily from a mathematically calculable event (Hazard), to include the psychosocial context (Outrage) of the event, which is experienced by the public. How the Risk = Hazard + Outrage model could enhance risk communication in pharmacovigilance is an area of future research and worth considering (Sandman P, 2017).

Ultimately, the purpose of risk communication is that anyone who is at risk can take informed decisions to reduce the effects of the risk, such as a disease outbreak, and take the required protective and preventive measures. Therefore, as evident, ineffective communication is a risk in itself, and hence organizations and specifically pharmacovigilance functions must start giving this the attention it deserves to enable keeping patient safety at the heart of everything they do!

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