The Future of Safety Communication: How Digital Solutions Can Enhance Safety Practices

By **MAGALI PULLINO**, Senior Director, UK Direct Medical Engagement, Real World & Commercial Solutions, IQVIA

Medication safety has been recognised as a key global patient safety challenge by the World Health Organization[1]. Despite considerable efforts to ensure patient safety throughout the patient journey, medication errors remain a common source of harm. Approximately 1 in 30 patients are exposed to preventable medication harm, with more than a quarter of cases being severe or life-threatening[2].

Preventing and monitoring safety occurrences is a key responsibility for pharmaceutical companies. As part of their commitment to patient safety, they must ensure that patient risks are minimised and that all relevant safety information about a product is communicated to both healthcare professionals (HCPs) and patients in a timely and effective manner.

However, despite regulatory bodies and industry best efforts, recent systematic reviews have found mixed or insufficient evidence of the effectiveness of additional Risk Minimisation Measures (aRMMs)[3].

The traditional approach of paper-based educational materials, while foundational, has limitations in interactivity, distribution, updating processes and effectiveness assessment. This article aims to explore how digital technologies can offer a transformative potential to enhance the effectiveness of Safety Communications through improved design, delivery, and engagement[3].

Current challenges in safety communications

Both the European Medicines Agency (EMA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA) are recognising that safety communications present some challenges, and both regulators have launched initiatives to address some of these challenges:

- The EMA's *Good Pharmacovigilance Practices (GVP) Module XVI*[4] *and Addendum II*[5] have been updated to reflect the evolving landscape of Risk Minimisation Measures (RMMs). Although these updates do not consider how digital technologies will affect RMMs in terms of dissemination and effectiveness monitoring, a reflection paper on this topic is under development and a draft for public consultation is expected in 2025[6].
- Following an extensive consultation in 2023, the MHRA has launched its new 3-year Strategy for Improving Safety Communications[7] which aims to transform the way information is provided on the risks and safety of medicines and medical devices.

The lack of effectiveness of safety communications can stem from either a lack of adherence (from the HCP, patient, or both) or a lack of understanding of the importance and risks linked to the drugs, and how it can link to specific patients.

In order for safety communications to be most effective, industry and regulators need to focus on three key areas:

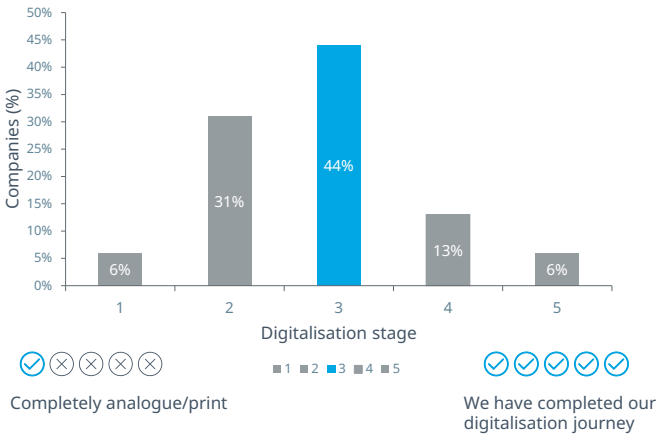
1. **Design**: how to ensure that safety communications are easy to understand
2. **Dissemination**: how to ensure that the communication reaches the right doctor, in a timely manner
3. **Impact**: how to ensure that recommendations are understood, acted upon and how to monitor and measure this

DESIGN	Content	Content needs to be engaging, interactive, and easily digestible. Paper-based educational aRMMs do not present information interactively, and their update and distribution can be costly and complex[8].
	Accessibility	Paper-based materials need to be physically filed and can be challenging to refer to when needed, and both healthcare professionals and patients are likely to benefit from information accessible online via an app or an online portal.
DISSEMINATION	Distribution channels	Postal mailing remains the most common channel for dissemination. It facilitates universal coverage, where a multi-channel approach can be challenging due to poor database cross-matching capabilities. Online resources, such as those provided by the MHRA, are underused due to limited functionalities[9]
	Targeting the right HCPs	There is a need for more targeted and relevant communications. A participant in the MHRA consultation stated, "If I work in a GP practice, I don't see why I should see info about meds that are only used in hospitals"[9]
	Speed and timeliness	Safety communications are time-critical and need to reach their intended audience quickly to ensure minimal delay in broadcasting any safety concerns or related guidance.
IMPACT	Tracking of usage	It is currently challenging to guarantee that safety messages have reached their intended audience. While postal mailing can be tracked, there are no insights into whether HCPs have opened, read, and understood the materials, and integrated the recommendations into their day-to-day practice.
	Tracking effectiveness	Effectiveness of aRMMs is typically measured using both quantitative and qualitative data, either via PASS studies or using real-world data. While these methods can be effective, there are challenges: data availability and quality, selection bias, timing of the research (e.g. if aRMM is implemented at launch, how can we truly measure effectiveness).[10]

The role of technology in facilitating Safety Communications

Pharmacovigilance and Safety departments in UK pharmaceutical companies are keen to adopt digital technology more widely, but a survey of 17 industry experts (Figure 1) shows that while most companies have started their digital journey, most still have a way to go[11].

Figure 1: Pharmaceutical companies' readiness towards aRMMs digitilisation[11]
Where do you think your company is currently positioned on the journey towards aRMMs digitalisation?



- Conversations are happening, but it is challenging to find the budget to move forward
- Most RMMs are accessible online, but evidence shows that doctors rarely access them - although it is unclear why
- Digital is still considered less "safe" than paper as it is challenging to track

It is important to align on what digital means in the context of aRMMs distribution. There is no such thing as a single type of digital communication, and the term digital encompasses a variety of channels and formats.

- Digital Channels can be emails, websites, social media, or apps.
- Digital Formats can be anything from a simple PDF file to complex interactive online content.

The choice of both channel and format should be driven by the objectives and the type of audience: what are the preferred channels (through detailed audience targeting and segmentation) and what is the most effective tool in the specific context of each aRMM?

Figure 2: Strengths and challenges of digital channels

DIGITAL CHANNELS

Emails

- ✓ Direct engagement with the HCP
- ✓ Email is already the messaging system that HCPs interact with the most time in a day[9]
- ✗ May require recipient consent
- ✗ May be blocked by firewalls or redirected to spams
- ✗ Recipients may ignore due to high volume of emails

Institutional websites

- ✓ Allow more engaging and interactive content
- ✓ Easy to update with the latest information
- ✗ Require active visit from the HCP — and may require log-in
- ✗ Multiple websites to get information on multiple drugs

Mobile apps

- ✓ Make information easily and quickly available
- ✓ Can include an element of gamification, increasing engagement and effectiveness
- ✗ Require to download the app
- ✗ Risk of app overload
- ✗ Format needs to be adapted

Overall, digital technologies can bring many improvements to the design, dissemination and effectiveness of safety communications:

Enhanced flexibility and engagement

Digital technology provides a dynamic platform for presenting RMM information. Unlike static paper materials, digital tools can incorporate interactive elements such as videos, graphics, and knowledge checks, which can significantly increase user engagement and comprehension. *"Risk minimisation programme developers should seek to take fuller advantage of digital technology by incorporating website design features that promote and sustain engagement and motivate users to adopt safe use behaviours."*[12]

Rapid and cost-effective updates

The ability to quickly update information is crucial for the accuracy of RMMs. Digital platforms allow for the rapid dissemination of up-to-date information once approved, ensuring that healthcare professionals and patients have access to the latest safety guidelines. This is a significant improvement over paper-based materials, which are costly and complex to update and distribute.

Measurable impact and user insights

Digital methods enable the tracking of distribution, receipt, and user engagement with RMM content. This data can be invaluable in assessing the effectiveness of RMMs and tailoring them to user needs and preferences.

Reducing environmental impact

Limiting paper-based documents will de-facto reduce the carbon footprint of safety communications.

Conclusion and recommendations

With that in mind, we propose six recommendations to improve the design, dissemination and impact of safety communications:

1. **Centralised repository/online portal:** Leveraging digital tools can enhance the reach and effectiveness of RMMs. This includes having a centralised online repository or portal for all safety information, with an intuitive search function, and potentially a print-on-demand service if/when HCPs require a physical version of the documentation.
2. **Digital integration:** Integrating safety communications into prescribing and pharmacy dispensation software to ensure that the risks are flagged at the point of patient interactions.
3. **Consistent safety flagging**: Implementing a consistent "Safety Flag" system on all safety communications to help standardise safety communications and ensure they are easily recognisable by HCPs.
4. **Interactive educational tools**: Developing interactive formats such as videos and podcasts to make safety information more accessible and engaging for both HCPs and patients. These tools can also be linked to accreditation points for HCPs, incentivising engagement.
5. **Enhanced data collection and analysis**: Robust data integration from various sources, including wearables, healthcare records, and spontaneous adverse event reports, for continuous monitoring and adaptation of RMMs. This will ensure that RMMs are responsive to real-world data and evolving risks.
6. **Regulatory support and collaborations**: The pharmaceutical industry and the MHRA need to collaborate to align on the use of digital options for safety communications and what this should look like. Collaboration with professional bodies and patient advocacy groups can also enhance the development and dissemination of RMMs.

In conclusion, integrating digital solutions into the framework of aRMMs presents a significant opportunity to enhance patient safety and the effectiveness of pharmacovigilance practices. By addressing the current challenges and leveraging technological advancements, we can create a more responsive and efficient system for risk minimisation. This paper calls for a collaborative effort between regulators, healthcare providers, and the pharmaceutical industry to embrace these changes and work towards a safer healthcare environment.

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CONTACT US

X: @IQVIA_UK | **LinkedIn**: IQVIA UK & Ireland

ASKIQVIA@iqvia.com

iqvia.com