

Public Pharmacovigilance Communication

A Process Calling for Evidence-Based, Objective-Driven Strategies

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Abstract

As a contribution to the debate on how best to communicate information on the effective and safe use of medicines to patients, healthcare professionals and the general public, this article proposes to distinguish between communication and transparency purposes, and to test a strategic health communication approach. Any organization aiming to improve medicines use could adapt this approach to its remits and legal obligations.

The approach includes agreeing measurable communication objectives through shared problem ownership of all concerned parties, evidence-based design and a cyclic process for planning, implementation and evaluation of communication as a public health intervention.

The evidence base, which supplements risk assessment for product- and situation-specific communication on safety concerns, would be derived from research into drug utilization, medical decision making and risk perception, as well as from the participation of patients and healthcare professionals. It is crucial to address the practical questions and concerns of medicine users and to find out why unfavourable patterns of medicine use persist, in order to develop behaviour change models for overcoming these obstacles. For this purpose, appropriate models for facilitating the participation of medicine users in the risk management process will need to be explored. Such two-way communication would inform risk assessment as well as the analysis of risk minimization options, allow for agreement upon communication objectives and enable understandable, attractive communication materials to be designed. The communication programme should use mixed media and repetition of messages for long-term success. This would require cooperation within healthcare and medical information systems. An evaluation of the effectiveness of the communication should support the sustainability of the programme and provide lessons for the future.

Given its mission, the pharmacovigilance community has the standing and duty to expand its scale of action and take the initiative in advancing risk management through a scientific approach to improving public communication for the safety of patients.

How best to communicate information on the effective and safe use of medicines is currently a subject of debate between patient organizations, healthcare professionals, the pharmaceutical industry and regulators. This debate is important because:

- there is considerable medicine-induced patient harm that may be preventable through communication;
- patients have a right to understand the benefits and risks of any treatment and to choose and act accordingly.

Patient harm as a result of medication errors and adverse reactions to medicinal products has been recognized as a major concern in healthcare.^[1-7] Medication errors are preventable events that may be related to healthcare products, procedures or systems, including prescribing, dispensing, administration and patient education.^[8] Knowledge and performance deficits in healthcare professionals have been found to cause 44% of medication errors.^[9] An adverse reaction is a response to a medicinal product that is noxious and unintended,^[10] and sometimes these reactions are due to medication errors. About 30% of adverse reactions leading to hospital admissions are considered preventable,^[11] rising to as much as 88% in the elderly.^[1] A systematic review of studies found that a median proportion of 33% of such admissions were due to treatment adherence problems, 31% were due to prescribing problems and 22% were due to patient monitoring problems.^[12]

It is the mission of pharmacovigilance to prevent adverse effects and any other problems related to the use of medicines.^[13] Consequently, the latest developments in pharmacovigilance have focused on product-specific risk management.^[14-18] To be effective, risk minimization activities require communication with patients and healthcare professionals as well as between these two parties.

However, a consensus on how best to communicate has not yet been achieved, mainly because of the complexity of the matter and the different objectives legitimately pursued by the various parties: regulators have to communicate product-related decisions taken in the interest of public health, i.e. affecting all subgroups of a population, while healthcare professionals need information that enables them to individualize medications in order to improve the overall health of their patients in a given healthcare system. The pharmaceutical industry does not deal with just one country and one healthcare system; it has to take a global view and to consider business issues while focusing on product safety and liability. Patients with various degrees of ability and self-empowerment need information that can be easily obtained, understood and applied to their specific life situations. In addition, it is academia's role to

research and debate evidence and uncertainty, while the media have a dual role to disseminate new information of interest to their customers as well as to review critically how important processes are conducted by various parties within society. This dual role may lead to the combined dissemination of health news and critical reports.

A number of factors make communicating pharmacovigilance information complex. These include limitations of evidence on the safety concern, rapid advancement of science, variable perceptions, knowledge, literacy and numeracy levels in the population, as well as daily competition for headlines.^[19-22] Health risks are difficult to understand properly in quantitative terms, even for specialists.^[19,21] How the data are perceived by specialists and others depends, *inter alia*, on the respective values of the receivers,^[23] psychological factors^[24] and the trust the receiver has in the sender.^[25]

For the purpose of consensus building, the principles and practical guidance already made available by international pharmacovigilance experts in the Erice Report^[26,27] and in the more detailed publication "*Dialogue in Pharmacovigilance*"^[28] will be helpful. More recently, high-level recommendations on communication and patient safety have emerged from workshops with concerned parties.^[29,30] These principles and recommendations should be read together with latest research findings from sociology, psychology and neuroscience. Furthermore, there is valuable experience from public communication on environmental and food risks.^[31,32]

Beyond consensus building, the challenge lies in implementation. The drive to improve pharmacovigilance communication may benefit from a review of implementation frameworks that have proved successful in similarly complex risk areas, thus validating their practicability and effectiveness for supporting the effective and safe use of medicines.

As a contribution to the debate, this article proposes to apply the strategic approach used in other areas of health communication to public pharmacovigilance communication. In this context, public pharmacovigilance communication will refer to the communication of information

on the safety of medicines in the context of their benefits between any organization aiming to improve the use of medicines and the public or subgroups of the public such as groups of patients or healthcare professionals. The proposal will be based on a theoretical transfer of concept, discussed critically with a view to future testing.

1. Defining Communication and Transparency

Within the area of pharmacovigilance, the terms communication, information and transparency are often used and understood differently.

1.1 Communication

In communication science, various definitions of communication exist: communication may be characterized as having an intention or it may also refer to non-intentional messages, such as unconscious body language or connotations. When a definition includes normative judgements (i.e. a statement about what is and is not desirable or acceptable), only messages achieving the intention are regarded as communication. Other definitions of communication are not necessarily concerned with the communication outcome. Communication scientists recommend developing, for any given situation, a specific model that best describes the situation, and defining the term communication accordingly.^[33]

For pharmacovigilance, with its mission to prevent medicine-related problems, an intention-focused definition of communication seems appropriate. Furthermore, experience with vaccines has shown that a two-way model is more suitable than a one-way model in the risk management of medicines.^[34] In a two-way model or dialogue, the information flow goes from sender to receiver, as well as in the opposite direction where the original receiver becomes the sender of information. This model goes beyond the traditional one-way model for public communication, in which experts aim to educate the public.^[35] Hence, *communication* may be defined as a two-way process, involving a sender transmitting information to a receiver with a declared intention or expectation.

Specific communication models need to be developed to describe each product-specific situation of pharmacovigilance communication, with these models describing the complexity of each situation and all parties involved, including the media.

The term *information* refers to knowledge obtained or given,^[36,37] i.e. the contents of the communication process. In general, information is a meaningful set of signs.^[38] Communicated information may be called a *message*.^[38]

The intention of the sender may be termed the *communication objective*, referring to a specific action and aiming to change behaviour in the receiver, i.e. the target audience.

Bringing the terms communication and information together, communication can be viewed as an information-based, message-centred process.^[33]

1.2 Transparency

Transparency literally describes the quality of allowing light to pass through an object, so that objects behind it can be seen.^[36,37] In the figurative sense, as derived from a definition approved by the International Monetary Fund for monetary and financial policies,^[39] *transparency* may be defined as processes and features that create an environment in which information on policy and action objectives, decisions and their rationales, as well as terms of accountability (including their legal, institutional and economic frameworks), are provided to the public in an understandable, accessible and timely manner. This includes clarity on the absence of arbitrariness and conflicts of interests.^[40]

1.3 Relationship Between Communication and Transparency

While communication and transparency are two different concepts, they are nevertheless linked. Firstly, it has been shown that communication is more effective in reaching its objectives when the sender is trusted^[25] and that transparency creates trust in an organization.^[41] Secondly, transparency is a prerequisite for and a result of public participation, which is an element of strategic communication, as outlined in section 2. Thirdly,

both communication and transparency processes make information available, although for different purposes. While transparency serves democratic decision making, communication aims at behaviour change. These two different purposes require different content and differentiated presentation of information.

2. Strategic Health Communication

In the area of health, one approach to communication is known as strategic health communication. This is established practice in the US for disease prevention, with proven positive effects.^[42] It has also been applied with some success for purposes as challenging as the prevention of birth-related deaths in developing countries^[43] and HIV transmission.^[44] Another example is the anti-smoking campaign in the UK in the 1990s.^[45]

The key features of this approach are the agreement upon the communication objective involving all concerned parties, strategic programme design and implementation according to a planning cycle. Communication is seen as a public health intervention with desired health outcomes.^[46]

Engaging all parties in the process reflects the latest thinking in risk communication, which aims to build up mutual trust by responding to public concerns, address questions relevant to the individuals concerned and enhance public understanding of risk assessment results, thereby enabling individuals to make an informed choice. This thinking is based on psychological risk perception and related cognitive behaviour research.^[47] The insights gained from involving all parties forms the evidence for designing situation-specific communication programmes.^[46]

In practice, the approach combines elements of project, quality and change management using social marketing and participation models. Social marketing is the use of marketing principles and techniques to persuade a target audience to voluntarily change behaviour for the benefit of individuals or groups.^[48]

The five procedural steps of strategic health communication^[46] are shown in figure 1.

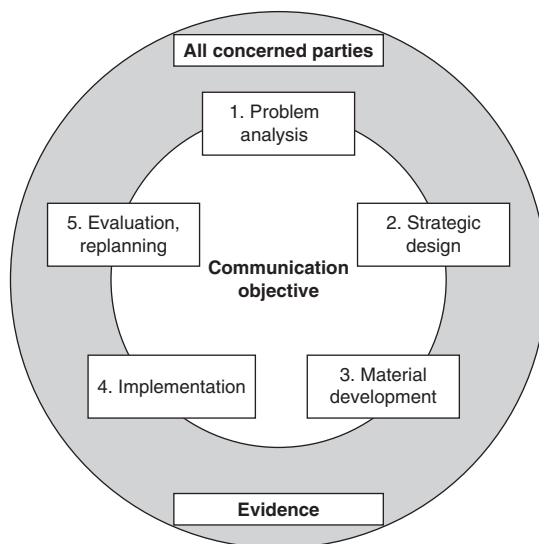


Fig. 1. Five-step process of strategic health communication.

2.1 'SMART' Objectives

Within this five-step process, agreeing upon the communication objective means deciding how to remedy a health problem by means of a communication programme. The strategic health communication approach uses an established management principle, according to which objectives should be 'SMART', i.e.:

- specific in terms of the behavioural action they call for;
- measurable for the purpose of programme evaluation;
- appropriate to remedy the problem;
- realistic, taking into account the present environment, cultures and systems with a view to potential for change;
- time-bound, i.e. having a realistically set point in time by which the programme should be successfully completed in accordance with public health needs.^[49]

2.2 Theories of Behaviour Change

Aiming at behaviour change involves selecting an appropriate behaviour change model, explaining why and how the communication programme is expected to change that behaviour, based on

informed choice. This requires determination of the necessary changes in attitudes, knowledge and skills for each audience segment, taking into account their emotions, social environments, values and goals.^[46] Stimuli that are involved in changing behaviour work in combination at the rational, emotional and social level. How these three levels relate to each other varies between individuals and groups, and this is reflected in various generic behaviour change models.^[50]

To give a classic example, the communication objective could be to cut the teenage smoking rate by 50% within 5 years. One audience segment may have started smoking as a result of social learning from their parents, bolstered by a desire to belong to an adult cohort. In another audience segment, a teenager raised in a health-conscious environment may have chosen to smoke in order to express independence from the family. The obstacles to behaviour change in these two segments are different, and a communication campaign would have to issue different communication messages: for example, one message raising confidence in being recognized as a member of a mature group, even when behaving differently from that group, and another appealing to independent-minded personalities who nevertheless relate to their group by indulging in contrary behaviour or following an external opinion leader. This shows that when developing communication messages, it is not enough to simply translate the communication objective into a message such as 'don't smoke'; the audiences must be approached in terms that reflect their motivations, using slogans such as 'my best friend doesn't smoke' and 'I'm going my own way; smoking isn't part of it'.

This example illustrates the theories of social learning and diffusion by opinion leaders. Other key theories of behaviour change are the theories of reasoned action and threat management. Behaviour change, according to the theory of reasoned action, is triggered by rational processing of information in which the information itself may or may not be evidence-based. The theory of threat management derives from the discipline of risk management and uses information about terrible potential outcomes to provoke emotions as triggers for risk minimization action.^[50]

3. Public Pharmacovigilance Communication

When applying the strategic health communication approach to pharmacovigilance, communication to patients and healthcare professionals is not seen as a mere risk minimization activity at the end of the risk management process, but rather as a two-way communication between those responsible for planning risk management and medicines users integrating with all stages of the risk management process.

The following five-step process (see figure 1 and sections 3.1–3.5) is proposed for communication on the safety of medicines in the context of their benefits between any organization aiming to improve the use of medicines and the public or subgroups such as groups of patients or healthcare professionals.

3.1 Analysis of the Safety Concern as a Communication Challenge

The first step aims to understand the communication challenge of the relevant safety concern and should deliver situation and audience analyses. This means reviewing the preliminary risk assessment as well as the scientific and mass media, and engaging in a direct dialogue with patients and healthcare professionals.

A review of the scientific media relates to research on drug utilization, healthcare, medical decision making, patient safety and risk perception, as well as cognitive, behaviour, communication and media science.

A situation analysis will help to understand the following:

- Who are the users of the medicine concerned in terms of patients and healthcare professionals?
- How is the medicine used within various healthcare systems and settings?
- Which social and medical aspects may be involved?
- How is the safety concern discussed in the scientific and the mass media?
- Which risk management options are feasible and how likely are they to be communicated effectively?
- Which populations and organizations should be part of the communication process?

The analysis should address prescribing, indications, contraindications, off-label use, dosage, length of treatment, typical concomitant medications, dispensing, administration, misuse and abuse, as well as medication errors or inconveniences that undermine the effective and safe use of the medicine. Examples of cultural aspects requiring consideration are the different attitudes various societies have towards pain management^[51,52] and differences of concerns patients from various religious backgrounds express over psychotropic medicines.^[53]

An audience analysis regarding the medicine's users should apply audience segmentation and focus on the following:

- What risk perceptions do the various medicine users have and how have these been formed?
- What information needs in terms of the benefits and risks of the medicine do the medicines users have?
- What information is already available to each audience segment?
- Which cultural aspects might apply to the various audience segments?
- What behaviour changes are needed to minimize risks and what might be the obstacles that deter the various medicine users from engaging in favourable behaviour change?
- Which media do the various medicine users prefer?

Information needs and risk perceptions are interrelated and differ amongst and between patients and healthcare professionals^[54,55] by, for example, culture, education/specialization, attitude, age, health status and rating of the expected treatment benefit.^[56] It is important not to offend the audience through inaccurate knowledge of their perceptions^[57] or lose the audience's attention through repeating widely known information instead of filling information gaps.^[58] Perceptions and underlying beliefs and values of non-experts and those bearing a risk are not irrational *per se* and often they are more complex than those of specialists.^[59]

Within two-way communication, the results of the situation and audience analyses will inform the benefit-risk assessment so that medicine use patterns, practical questions, as well as concerns

and risk perceptions of medicine users may be addressed in the assessment, and the conclusions may be used as a basis for communication.

The situation and audience analyses may further serve as an evidence base to analyse risk minimization action options and respective communication objectives in terms of their risk minimization potential. This potential will be enhanced by designing acceptable, feasible risk minimization activities that can be easily integrated into medical practice and patient routines.

3.2 Strategic Design of Public Pharmacovigilance Communication

The benefit-risk assessment and option analysis conclude with a recommended risk minimization action and communication objective. The risk minimization action may relate to, for example, a contraindication or a dosage restriction, and necessitate further advice on identifying risk factors, patient monitoring, dose tapering or switching to alternative medication. Taking into account the situation and audience analyses, a communication plan for how to achieve the objective should be available at the end of the second step of the communication process (figure 1). The plan should describe the communication model, the behaviour change model, the strategic design and the envisaged implementation. This includes allocated responsibilities, types of communication materials, channels and timelines for their dissemination, and the plan for monitoring the effectiveness of the programme.

3.2.1 Product- and Situation-Specific Communication Models and Strategies

Unfortunately, no generic communication strategy is available; the same strategy, when applied to a different audience, healthcare system or culture, may produce different outcomes.^[60] Experience with terfenadine, cisapride, bromfenac, troglitazone and acitretin has shown that the strategy needs to be specific if risk communication is to be successful.^[61] The underlying communication model for a safety concern on, for example, a routine vaccination of children and teenagers will be different than for a vaccination

campaign during a severe pandemic; it will be different again for a pregnancy prevention programme for a medicine used in young women than for cancer treatment in older patients. In each situation, the target audiences, their healthcare environments and media preferences will be different, different public bodies will be involved, schools may or may not play a role, and the mass media will have a different focus.

3.2.2 Obstacles to Behaviour Change

The behaviour change model should describe how to overcome the obstacles to behaviour change in each audience segment. Obstacles exist even where there is high motivation for good quality healthcare. The obstacles may, for example, be amplified risk perceptions and un-addressed fears, as in the area of vaccination,^[62] or structural and social, as with obstacles to changing prescribing behaviour.

The following obstacles to changing prescribing behaviour have become evident through research into quality of healthcare:^[63]

- deficiencies in knowledge of up-to-date comparative benefit-risk profiles of medicines;
- lack of time to switch patients to a new treatment;
- perceived patient expectations to issue a prescription of a particular medicine as proof of being taken seriously and receiving appropriate treatment;
- fear of losing the trust of the patient if the currently prescribed medicine is abandoned;
- general difficulties in changing behaviour and maintaining it.

For healthcare professionals, reasoned action backed up by opinion leaders/idea champions is probably an effective behaviour change model, given that research has shown that local opinion leaders may successfully promote evidence-based practice.^[64] For communication with patients, it is likely that the appropriate behaviour change model will often be derived from the theories of reasoned action and social learning. Because prescribing behaviour may depend on perceived patient expectations, it is proposed that communication programmes should target healthcare professionals and patients in parallel.

3.2.3 Addressing the Concerns of the Public

Concerns that might lead to inappropriate behaviour can only be overcome if the audience is taken seriously and their knowledge and emotions are acknowledged.^[65] According to findings from neuroscience, humans only seem to make decisions and take action when motivated at the emotional level.^[66-68] An analysis of the public debate surrounding the hypothesized link between the measles-mumps-rubella vaccine and autism in the UK from 1998 to 2005 claims that if public fears had been addressed there might have been a smaller decrease in vaccination coverage and the measles outbreaks might have been prevented.^[69] In order to provide a response to such vaccination fears, clear statements acknowledging public concerns and providing case narratives from disease outbreak victims have been proposed.^[69] This corresponds to threat management as a behavioural change model.

3.2.4 Mixed Media Approach

Communication channels, material types and timelines for dissemination can be selected for a mixed media approach in order to reach all audience segments according to their media preferences, and may benefit from the synergistic and mutually reinforcing effects of the same message reaching the targeted individuals repeatedly and in various contexts.^[46]

Communication channels are not limited to mail, websites and so-called new media, but also encompass other ways of informing groups through, for example, conferences and educational events.

Communication materials may take the form of written text and pictures, or be of the audio-visual type. Thus far, summaries of product characteristics or similar product datasheets, package leaflets, direct healthcare professional communications (commonly known as 'Dear Doctor letters'), drug bulletins and, more recently, video clips have been used in the area of medicines safety. For children and teenagers, video games about chemotherapies, explaining the importance of treatment adherence and explaining adverse reactions, have been tested successfully.^[70] Communication materials may include announcements to the media (press releases) and materials that may be provided

to healthcare professionals to support interpersonal communication with patients or carers (tear-off sheets). For medicinal products with specific high risks, risk management plans may require, for the purpose of risk minimization, comprehensive sets of documents with training materials for healthcare professionals, as well as educational materials and treatment consent forms for patients.

There is currently little evidence regarding the types of communication interventions that are successful in improving healthcare practices and the circumstances under which they best operate.^[71,72] Studies aiming at best practices for knowledge translation in healthcare have shown that while no single method is capable of achieving more than moderate success, a combination of interventions, such as information dissemination supported by opinion leaders,^[64] continuing education events^[73] and educational outreach visits,^[74] followed up by reminders and participation options with self-directed behaviour change, are more likely to be successful on a broader scale.^[75,76]

Launching combined and repeated interventions will require cooperation with academia, organizations providing continuing education for healthcare professionals, healthcare quality managers, healthcare professional organizations, organizations responsible for health education of the general public and patient organizations.

3.3 Development of Pharmacovigilance Communication Material

During the third step (figure 1), the communication objective is translated into messages and the communication materials, in accordance with the communication plan, are developed by communication experts with user participation. Subsequent user testing and improvements should ensure the acceptability, understandability, attractiveness and effectiveness of all communication materials.^[46]

Through application of the 'SMART' criteria, the communication objective needs to clearly specify the action called for so that it may be translated into messages that patients and healthcare professionals can follow as easily as possible.

Ideally, this means, for example, providing laboratory value thresholds that require patients to be switched to alternative treatments or criteria for diagnosing adverse reactions with clear advice on how to manage them. It is important to avoid, whenever possible, unspecific or even message-diluting statements such as the following, found in recent communications to healthcare professionals: "monitor patients as clinically appropriate", "careful consideration to the risks of the medicine should be given when prescribing" and "monitor all patients, in particular those over 65 years of age." Such messages are open to the interpretation of the receiver and it is difficult to define parameters to measure whether they are followed.

3.4 Implementation of Public Pharmacovigilance Communication

During this fourth step (figure 1), implementation of the communication plan should be monitored and recorded to ensure that all interventions are taking place as planned and that unforeseen problems are promptly addressed, possibly by means of programme adjustments.^[46] All parties should stay in touch so that they may react appropriately to any event, such as emerging new safety data, a debate on the safety of the medicine in the media or uptake of the communication materials in a different way from that intended.

3.5 Evaluation of Public Pharmacovigilance Communication

Evaluation measures how well a programme achieves its communication objective and explains why it is effective or not. All parties should be made aware of the evaluation report so that programmes may be re-designed if necessary and maintenance programmes planned with a view to securing sustainable achievements. In order to maintain the desired behaviour, communication effectiveness must be monitored over time. The evaluation should also support future communication interventions.^[46] Hence, with this fifth step (figure 1), a new planning cycle may be entered.

The evaluation may take place on three levels, investigating whether:

1. implementation was in line with the communication plan;
2. the communication objectives were achieved in terms of behaviour change;
3. the communication programme improved health outcomes in accordance with the agreed objective.

At level 1 the effectiveness of the programme management is monitored, at level 2 one evaluates the effectiveness of the communication itself and at level 3 one validates the appropriateness of the regulatory action, including the related public pharmacovigilance communication.

The methods used for evaluating at level 2 are those used in drug utilization research and quality management of healthcare, in particular studies on prescribing practices using prescription databases. Also, medicine user surveys may document knowledge gains and the formation of new behavioural intentions. The methods for evaluating at level 3 are those developed by pharmaco-epidemiology for studying causal relationships of patient outcomes.

4. Discussion

There are a number of challenges in applying the strategic health communication approach to pharmacovigilance.

4.1 Applicability to Different Organizations

This article, which addresses the pharmacovigilance community as a whole, does not discuss the different roles and responsibilities or specific tasks of the various parties in relation to the proposed communication process. These will depend on local legislation, policies and practices. For example, pharmaceutical companies are legally obliged to submit risk reviews in various formats and proposals for risk minimization, but decisions on risk minimization actions lie with the regulatory authorities. Also, there may be legal restrictions on pharmaceutical companies regarding how they may approach medicine users. On a smaller scale, the proposed communication pro-

cess could be used by a hospital to promote the safer use of medicines. Consequently, any implementation must be adjusted to the respective organization.

4.2 Participation Models for Involving Users of Medicines

A direct dialogue with patients and healthcare professionals may be engaged by various means, such as surveys, meetings with representatives or internet-based calls to the public.^[47] Appropriate participation models must be explored and will also depend on the organization leading the communication process. A crucial criterion for appropriateness will be representativeness.

4.3 Situations Requiring Confidentiality

Specific participation models ensuring confidentiality will be necessary for emerging safety concerns that are not yet in the public domain and require well planned communication to prevent scares and detrimental behaviour in medicine users. This may be facilitated by involving a limited number of concerned party representatives. If, in such situations, any party breaches confidentiality during the communication planning stage, the strategic, proactive communication package must be replaced by reactive communication. Reactive communication is likely to be of lower quality and, in any case, will appear defensive, carrying with it a high probability of destroying public trust in those responsible for risk management; it should therefore be avoided whenever possible. Communication planning should not delay the availability of information to the public, but rather support timeliness.

4.4 Timing in Situations of Urgency

When a safety concern warrants urgent communication for health protection, it could be argued that the participation of medicine users and performing situation, option and audience analyses delay the release of important information. However, if participation and collection of the relevant data could become a continuum in pharmacovigilance, and the analysis of the collated

information a routine in risk assessment, delays might not occur or may be justified by the increased quality of risk management. Risk assessment and agreement upon risk minimization activities are often subject to urgency, but urgent messages are also important messages and, if communicated poorly, are public health risks in themselves. This was sadly demonstrated by the 'pill scare' of 1995, resulting in increased rates of unwanted pregnancies and abortions in the UK.^[77] Therefore, thought should be given within the pharmacovigilance community to building an infrastructure for urgent situations. For example, participation of medicine users could possibly be limited to a task force, involving only very few but competent representatives who are trusted by the population they represent.

4.5 Situations of Uncertainty

An important point in the debate about best communication practices for patient safety relates to whether public communication should take place at a time of uncertainty over a new concern or whether evidence should be awaited.^[30] Where there is clear evidence of a risk and effective risk minimization action can be taken, communication objectives fulfilling the 'SMART' criteria are obviously required. The most prominent example here is the teratogenic risk of thalidomide, necessitating pregnancy prevention.

Specific, measurable communication objectives are less obvious in situations of uncertainty when evidence is limited – a common situation in pharmacovigilance. In such situations, it may be decided to continue data collection, restrict use of the product or withdraw it on precautionary grounds, or raise risk awareness in healthcare professionals and patients without providing detailed guidance for risk minimization. In the latter case, the strategic communication approach cannot be exploited to the full given the absence of a call to medicine users to engage in specific action. Consequently, the pharmacovigilance community should discuss whether and how to provide as much detailed guidance as possible to medicine users in situations of uncertainty. Public participation is particularly required in situations

of uncertainty because, in these situations, perceptions, values and trust are crucial.^[78,79]

4.6 Development of Behaviour Change Models

The development of behaviour change models for improving medicines use will be a new topic within pharmacovigilance and will necessitate cooperation with social and healthcare scientists, as well as psychologists, in order to learn about decision making on therapeutic choices and obstacles to behaviour change.

4.6.1 An Example Relating to Prescribers

Although the risk posed by benzodiazepines in terms of increased accident rates is well established,^[80] it is still unclear why, despite the lack of any benefit, widespread over-prescribing for prolonged use continues.^[81,82] One reason could be that prescribers perceive the risk as low. Social care workers are aware of cases where prescribers of medication for mental health problems do not seem to have considered the increased risk of patient falls in the home and where improved inter-professional coordination between health and social care is required for risk minimizing actions.^[83] If that proved to be a common omission on the part of prescribers, a communication programme targeting prescribers with a slogan such as 'Benzodiazepines? How many stairs are there in my patient's house?' could be worthwhile.

Another possible reason may be that physicians feel under pressure from patients to continue prescribing. A recent study in the Netherlands found that general practitioners felt more inclined to educate patients about the lack of efficacy and risks of long-term benzodiazepine use when they also saw benzodiazepine use as disadvantageous, expected their patient education to have a positive impact, perceived more social pressure to educate and felt they were more capable of educating patients.^[81] The study indicates that a communication programme is more likely to be effective if it increases risk awareness in prescribers, builds up a professional norm and strengthens prescribers' confidence in their own ability to educate patients.

4.6.2 An Example Relating to Pharmacists

A Dutch study on the effectiveness of the risk management plan for isotretinoin showed that <10% of pharmacists complied with their obligations regarding pregnancy prevention, although 64% agreed with their role in the risk management plan.^[84] One reason for this could be that they simply forgot their obligations, in which case computer-based risk management systems should be helpful. It is, however, also important to find out whether there are other reasons. Our own experience shows that pharmacists do not always feel comfortable raising personal questions of a young female or may be afraid of embarrassing her in front of other customers when asking her into the confidential counselling space. An appeal to the professionalism and interpersonal skills of the pharmacist could build self-confidence and help overcome these social obstacles, with reminders such as 'Isotretinoin requires pregnancy prevention. Talk to her, care for her.'

4.7 Communication of Meaningful Information for Therapeutic Decision Making

Some healthcare professionals may reject the idea of being targeted for behaviour change as they may see this as an attempt to interfere with their responsibilities in therapeutic decision making. However, this is not the intention of strategic communication. Rather, it aims to disseminate meaningful information that makes informed therapeutic choice and individualization of therapy possible. The very consideration of this information already constitutes behavioural change, and it is up to the individual healthcare professional to judge whether and how the information applies to individual benefit-risk balances and to discuss this with their patients.

4.8 Cooperation with the Patient Safety Community

Close cooperation with the patient safety community is required, given the overlap in scope with pharmacovigilance. Patient safety as an action area is *inter alia* concerned with medical error analysis and prevention, and its scope includes medication errors regardless of whether

they cause patient harm or not.^[85] Interaction between these two communities may even manifest itself as integration with patient safety initiatives, pursuing reduction and mitigation of unsafe acts within the healthcare system, as well as best practices that have been shown to lead to optimal patient outcomes.^[86]

4.9 Impact of Scientific and Mass Media

The public debate surrounding the hypothesized link between the measles-mumps-rubella vaccine and autism in the UK, which resulted in severely decreased vaccination coverage and measles outbreaks, illustrates the impact of the media on health behaviour in the population.^[87] However, little research has been done on the type of information the public expects from the media or what might lead to a positive impact.^[88] In any case, health journalists normally have no interest in disseminating false information as this damages their reputation,^[89] although they may experience difficulties in the competition for headlines when presenting information in a well balanced manner.^[90] A lack of training opportunities has been identified as one of the barriers to high-quality health information in the media.^[91] The pharmacovigilance community might therefore consider providing training and engaging in relevant research, but it should also acknowledge that a key objective of the media is to provide a critical review of societal processes.

5. Conclusions

In order to prevent adverse reactions, medication errors and other medicine-related problems, this article proposes learning from health communication and transferring strategic concepts to the communication of pharmacovigilance information to the public or subgroups, such as groups of patients and healthcare professionals. Any organization aiming to secure the effective and safe use of medicines could adapt these concepts to its remits and legal obligations.

The strategic approach includes agreeing communication objectives through shared problem ownership of all concerned parties, evidence-based

design and a cyclic process for planning, implementation and evaluation. Strategic communication is seen as a public health intervention aiming at informed choice and behaviour change in order to produce desired health outcomes.

Shared ownership of a medicine-related problem and its solution can be achieved through participation of medicine users in all steps of risk management. Such two-way communication would inform risk assessment and risk minimization action options analysis with the concerns and information needs of patients and healthcare professionals, engage their respective organizations in the implementation of risk minimization activities, overcome paternalism and create trust between all parties. Appropriate participation models will need to be explored.

Further evidence for developing product- and situation-specific communication programmes would be derived from research into drug utilization, medical decision making and risk perception.

The desired behaviour change in medicine users would be defined as a measurable communication objective. The article posits that evidence on how to overcome obstacles to behaviour change and successfully implement safe prescribing and medicine use by patients would support decision making on risk minimizing action and designing of communication programmes.

With reference to behaviour change models and social marketing, mixed and repeated communication interventions should be promoted to secure the long-term sustainability of behaviour change. This change would then be a result of the participatory process rather than the transmission of a single communication document.

An evaluation of the effectiveness of the communication should support the sustainability of the programme and provide lessons for the future.

Because of the considerable patient harm due to avoidable medication errors and adverse reactions, it seems worthwhile testing whether public pharmacovigilance communication might benefit from this proposed scientific approach. Feasibility testing, adaptation and implementation will require multidisciplinary research and cooperation within healthcare and medical information systems. This cooperation should build on the

motivation of healthcare professionals to provide good-quality care and patients' increasing engagement in medical decision making.

Given its mission, the pharmacovigilance community has the standing and duty to expand its scale of action and take the initiative in seeking solutions to medicine-related problems, and in advancing risk management through improved public communication for the safety of patients.

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