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Perspective in communication for pharmacovigilance

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ABSTRACT: Communication plays an important role in every aspect of life. It means to share something, to share our ideas, to share emotions etc. When communication comes with pharmacovigilance, that means it is the heart of successful pharmacovigilance. Interactions between healthcare professionals, patients, regulators, and pharmacovigilance experts are intended to manage medicine risks and prevent patient harm.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, in order to prevent adverse reactions, medication errors, and other medicine-related problems.

Key Words: Pharmacovigilance, Communication, Adverse drug reaction, Drug safety, Drug information, Health authority.

I. INTRODUCTION

Communication can be defined as either intentional or unintentional messages, such as unconscious body language or connotations. When a definition includes normative judgements (statements about what is and is not desirable or acceptable), only messages that achieve the intention are considered to be communication.

The best way to communicate information about the effective and safe use of medicines is currently being debated by patient organizations, healthcare professionals, the pharmaceutical industry, and regulators. This debate is important because

- there is significant medicine-induced patient harm that may be avoidable through communication;
- patients have a right to understand the benefits and risks of any treatment and to choose and act accordingly.[1]

W. McBride, an Australian doctor, officially introduced pharmacovigilance (PV) in December 1961.

Pharmacovigilance is the science of gathering, measuring, researching, and evaluating information from healthcare providers and patients on the adverse events of various medicines, vaccines, toxoids, blood products, medical devices, traditional herbal and synthetic drugs with the goal of gathering information about various threats associated with these molecules and preventing harm to patients.[2]

It is widely acknowledged that effective communication is at the heart of successful pharmacovigilance. Interactions between healthcare professionals, patients, regulators, and pharmacovigilance experts are intended to manage medicine risks and prevent patient harm. Although communication is not a new issue, there is an urgent need for new ideas to properly practise it and experiment with new methods.

What's the rush? Adverse drug reactions (ADR) can be fatal and are a leading cause of morbidity and mortality. The absence of information and communication has been discussed and identified as a challenge for pharmacovigilance professionals. In today's world, it is common for people to seek advice and remedies from websites and social media. Although most people have access to information, few truly comprehend what they read or obtain the knowledge they seek because not all content on the Internet is validated.

Patients are concerned about their lack of understanding and want their medical risks to be taken seriously, whereas healthcare professionals prefer the benefits of medications over the risks. Only two-way communication can and should eliminate perception differences. This necessitates extensive patient surveys and research. Furthermore, patients would benefit from longer and more detailed consultations; however, this would be more expensive and put additional strain on healthcare professionals.

Communication among healthcare professionals, regulators, and the general public is also difficult. The public frequently requests information and transparency, whereas decision-makers prioritise benefit-risk balance. Because

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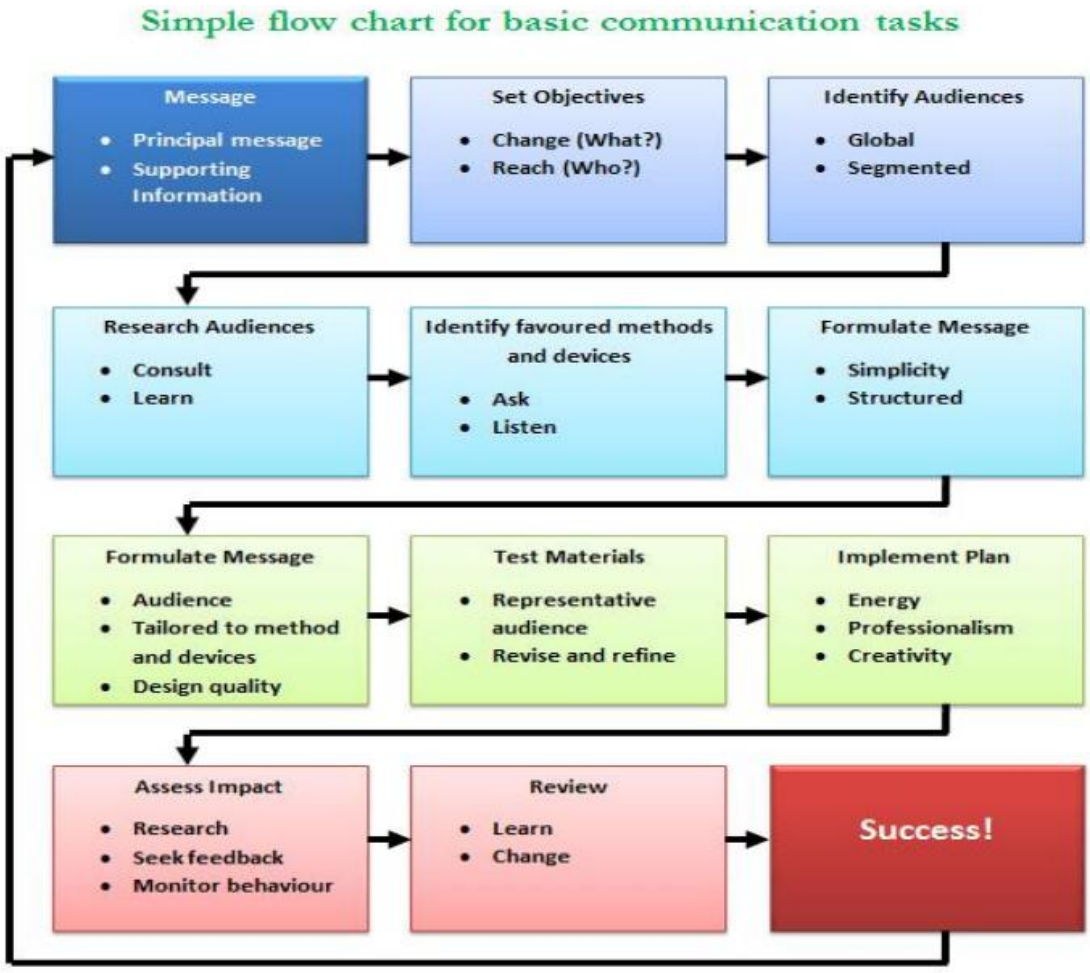
experts and regulators are afraid of causing a public drug scare or a failed vaccination programme, it is understandable that they are hesitant to explain to the public all of the risks and potential harms that medicines may cause.

Advocacy is achieved through effective communication. Failure can cause social problems and erode public trust in government, both of which are difficult to repair. For these reasons, communication in pharmacovigilance is a difficult task that health authorities should focus on and carefully practise.[3]

Every aspect of pharmacovigilance requires effective, skilled communication.

1) We cannot motivate health professionals to report suspected adverse reactions if there is no communication.
2) We are unable to collect the breadth and quality of data required to protect patients and save lives.
3) We cannot exert influence on health professionals and assist them in achieving safety.

When the vision of patient safety is buried in clerical routine, paper shuffling, and administrative preoccupation, pharmacovigilance risks becoming a sterile, bureaucratic system. PV should be a vibrant, dynamic, and ambitious enterprise with a focus on creative communication and a desire to make a real difference in the world's health and welfare.[4]



Source: https://whopvresources.org/images/flowchart.png

Communication in PV

- Promoting knowledge and best practises
- Educating professionals and the general public
- All parties must be engaged and motivated.
- Providing risk-related information
- Influencing prescriptions

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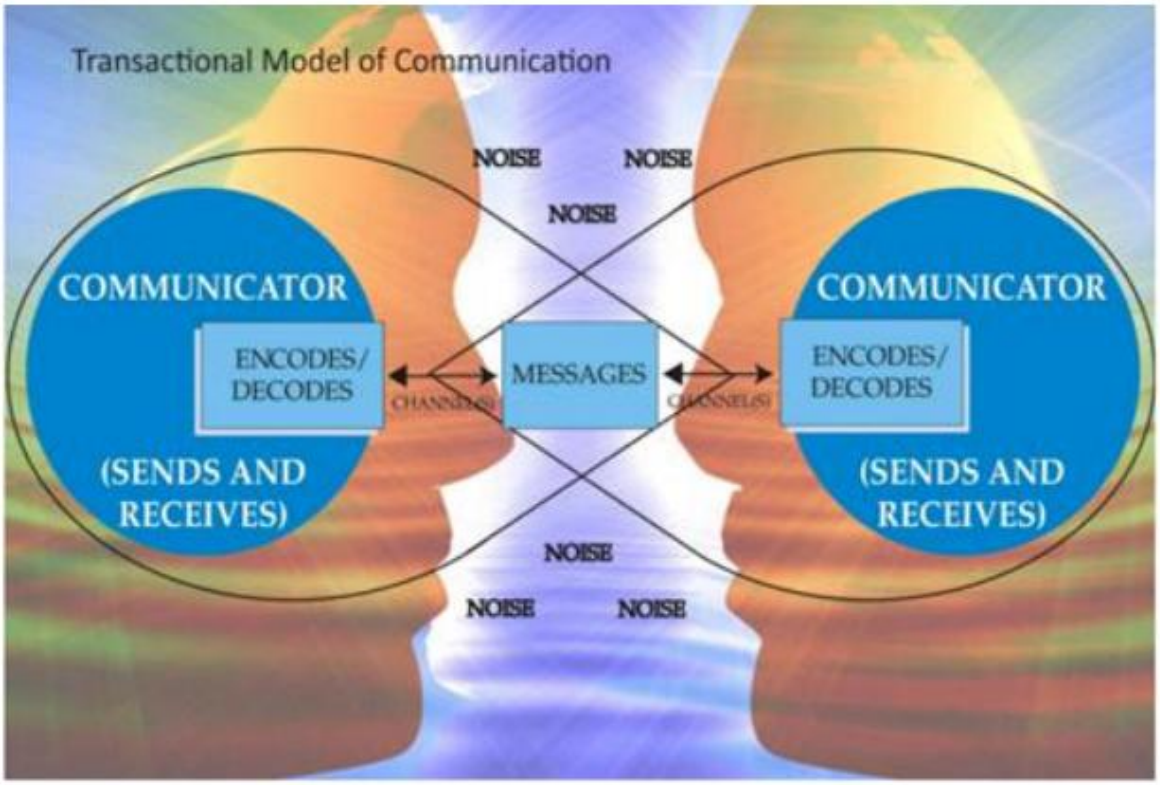
- Policy influencing
- Obtaining funding

The core elements of all communication

- Universal elements
- Sender
- Receiver
- Intention and reaction
- Message or signal
- Encoding and decoding
- Channel (voice, print, social media, etc)
- Noise: interference, disruption
- Response or effect. [5]



Good pharmacovigilance practises (GVP) are a set of measures designed to make pharmacovigilance more efficient in the European Union (EU). GVP apply to holders of marketing authorizations, the European Medicines Agency (EMA), and medicine regulatory authorities in EU Member States. They cover both medicines approved centrally by the Agency and medicines approved at the national level.

Guideline on GVP

The GVP guideline is divided into two sections:

- modules covering major pharmacovigilance processes
- product- or population-specific considerations.[6]

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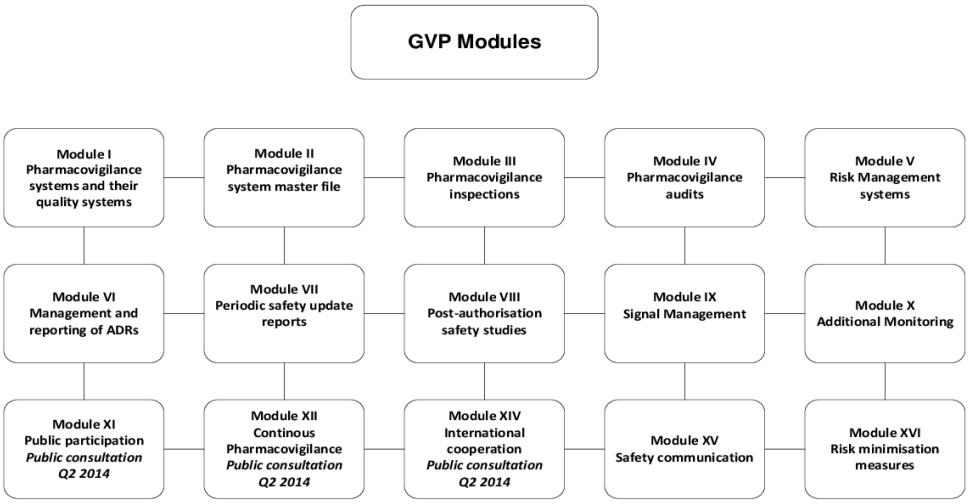

Fig. 1: GVP Modules [8]

Pharmacovigilance safety communication (GVP module XV)

- Guidance to marketing authorization holders, competent authorities in Member States, and the European Medicines Agency on how to communicate and coordinate safety information about medicinal products authorised in the EU.
- MAH, regulators, and HCPs are all responsible for public health safety communication.

What are safety communications:

Safety communication is a broad term that encompasses various types of information on medicines, such as statutory information contained in product information (such as the summary of product characteristics (SmPC), package leaflet (PL), and packaging labelling) and public assessment reports.

- The module XV focuses on communicating 'important new safety information,' which means new information about a previously known or unknown risk of a medicine that has or could have an impact on the risk-benefit balance and condition of use of the medicine.
- When new safety concerns arise, high levels of public interest are expected, and it is critical that clear and consistent messages are distributed across the EU in a timely manner.

Objectives of safety communications

Safety communication aims at:

- Providing timely, evidence-based information on the safe and effective use of medicines;
- Facilitating changes in healthcare practises (including self-medication practises) as needed
- Changing attitudes, decisions, and behaviours regarding the use of medications
- Supporting risk-aversion behaviour facilitating informed decisions on the rational use of medicines
- Restoring public trust in regulatory processes

Principles of safety communication

- The message- Safety communication should deliver relevant, clear, accurate, and consistent messages to the right audiences at the right time, allowing them to take appropriate action.
- Audience- Safety communication should be tailored to the appropriate audiences (e.g., patients and healthcare professionals) by using appropriate language and accounting for the various levels of knowledge and information needs while maintaining the accuracy and consistency of the information conveyed.
- Part of the PVG process- The need to communicate safety information should be considered throughout the pharmacovigilance and risk management process, and should be included in risk assessment and risk minimization measures.
- Coordination and cooperation- Adequate coordination and cooperation should exist between the various parties involved in the dissemination of safety communications (e.g. competent authorities, other public bodies and marketing authorisation holders).

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- Risk-Benefit context- Risk information should be presented in the context of the medicine's benefits, and should include all available and relevant information on the seriousness, severity, frequency, risk factors, time to onset, reversibility of potential adverse reactions, and expected time to recovery.
- Risk of doing nothing- Information on competing risks, such as the risk of not receiving treatment, should be included where appropriate.
- Use numbers whenever possible- When describing and comparing risks, the most appropriate quantitative measures should be used, such as using absolute risks rather than just relative risks; when comparing risks, denominators should be the same size. Other tools, such as graphical representations of the risk and/or the risk-benefit balance, may also be considered.
- Stakeholder involvement- Patients and healthcare professionals should be consulted and messages pre-tested early in the preparation of safety communication, especially for complex safety concerns.
- Follow-up - Where applicable, safety communication should be supplemented later with follow-up communication, such as on the resolution of a safety concern or updated recommendations.
- Efficacy- Where appropriate and feasible, the effectiveness of safety communication should be assessed.
- Concerns about confidentiality and data privacy- Safety communications must adhere to relevant data protection and privacy regulations.

Target audiences (the three M's)-

1) **Any Body who has Medicinal Product**- Patients, caregivers, and healthcare professionals should be the primary target audiences for safety communication issued by competent authorities and marketing authorization holders.
2) **Message Multipliers**- Patient, consumer, and healthcare professional organisations can act as message multipliers by disseminating critical safety information to target audiences. The trust factor, word of mouth effect, and social proof all contribute to a safety communication and central message sticking, resulting in real-life response and subsequent result, and thus not just spread, but effectiveness.
3) **The Media**- The media is another target audience for safety communication. The media's ability to reach out to patients, healthcare professionals, and the general public is critical for disseminating new and important information about medicines.

Content of safety communication:

- The information in the safety communication must be accurate and presented objectively.
- Important new information on any authorised medicinal product that has an impact on the risk-benefit balance of the medicine under any conditions of use.
- The purpose of launching safety communication is clearly explained to the intended audience.
- How to handle- any advice to healthcare professionals and patients on how to handle a safety concern.
- Statement on the agreement reached between the holder of the marketing authorization and the competent authority regarding the safety information provided Any proposed changes to the product information (for example, the summary of product characteristics (SmPC) or package leaflet (PL).
- Additional information about the medication's use or other data that may be useful in tailoring the message to the intended audience.
- A list of relevant literature references or a reference to where more detailed information can be found, as well as any other background information deemed relevant
- Call for action- Where applicable, a reminder to report suspected adverse reactions in accordance with national spontaneous reporting systems.

Means of safety communication

Communication tools and channels have grown in number and variety over time, providing the public with more information than was previously available. When issuing a safety communication, relevant communication tools and channels should be considered in order to reach the target audiences and meet their growing expectations.

Different communication tools and channels are :

- DHPC letter
- Website (regulatory)
- Press briefs and releases
- Communication material in lay language (e.g. using a questions & answers format)
- Social media and other online communications.

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- Bulletins and newsletters. [7]

1) Direct healthcare professional communication (DHPC)- A direct healthcare professional communication (DHPC) is a communication intervention in which important safety information is delivered directly to individual healthcare professionals by a marketing authorization holder or a competent authority to inform them of the need to take certain actions or adapt their practises in relation to a medicinal product. DHPCs are not responses to healthcare professionals' inquiries.
2) Website- A website is a valuable resource for members of the public (including patients and healthcare professionals) who are actively searching the internet for specific information on pharmaceutical products. Competent authorities, as well as holders of marketing authorizations, should ensure that critical safety information published on websites under their control is easily accessible and understandable to the general public. Website information should be kept up to date, with any out-of-date information labelled as such or removed.
3) Press communication- Press communication includes press releases and press briefings, which are primarily aimed at journalists. In addition to publishing press releases on their websites, competent authorities may send press releases directly to journalists. This ensures that journalists receive information that is consistent with the authority's scientific assessment, in addition to information obtained from other sources. Interaction with the media is an important means of reaching a larger audience and fostering trust in the regulatory system. Marketing authorization holders may also prepare and distribute press releases. Their press releases should mention the regulatory action taken by the appropriate authority. The marketing authorization holder should mention relevant ongoing reviews in any communication. Although aimed at journalists, press releases will also be read by healthcare professionals, patients, and the general public.
4) Communication material in lay language to patients and the general public-Communication material in lay language (e.g., in the form of questions and answers) assists patients and the general public in understanding scientific evidence and regulatory actions related to a safety concern. It can also be used by healthcare professionals as an additional tool in their communication with patients. Lay language documents should include the competent authority's recommendations and advice for risk reduction for patients, as well as relevant background information. Members of the general public who are interested in the subject but lack a scientific or regulatory background should find lay language documents useful. Other communication materials on the topic should be mentioned to direct readers to where they can find more information.
5) Social media and other online communication- Online safety advice can also be communicated through social media and other online methods. When employing newer, faster communication routes, extra care should be taken to ensure that the veracity of the data supplied is not jeopardised. Emerging digital communication tools used by distinct target audiences should be considered in communication techniques.
6) Bulletins and newsletters- Bulletins and newsletters provide information about drugs, their safety and effectiveness, at regular intervals. These techniques could be used to remind people about prior communications. Using web-based and other available ways, competent authorities can reach a large audience using these technologies.[8]

Effectiveness of safety communication:

- When the intended message is heard and understood by the target audience, and appropriate action is done by the target audience, safety communication is deemed effective.
- Mechanisms for determining efficacy
- In most cases, a research-based method will suffice to determine if safety messages have satisfied the criterion.
- This method can be used to assess a variety of outcomes, including behaviour, attitudes, and knowledge.
- When assessing the success of safety communication, the scope of the assessment could be expanded to include elements other than the performance of the individual tools employed in the communication.

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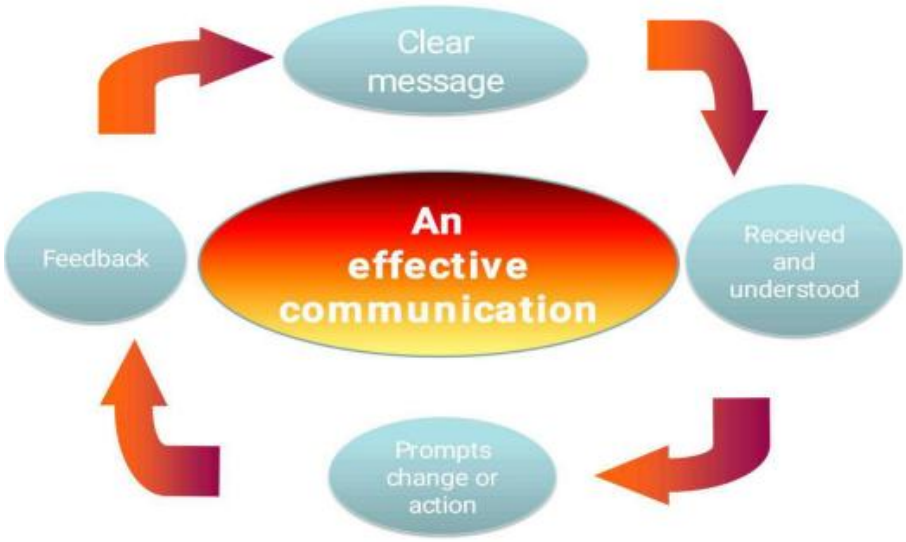

Source :https://www.slideserve.com/oshin/effective-communications-and-pharmacovigilance

Coordination of safety announcements in the EU:

- Patients and healthcare professionals in the EU are increasingly looking to competent authorities as sources of critical information on drugs.
- Adequate coordination and cooperation within the EU regulatory network are necessary for effective safety communication.
- Not all safety information made public by a Member State or the Agency will be subject to systematic coordination for practical reasons.

Only safety alerts relating to the following and involving active chemicals in medical products approved in more than one Member State are subject to EU regulatory coordination.

1) The suspension, cancellation, or withdrawal of a marketing authorization due to a change in the risk-benefit balance.
2) The commencement or completion of an EU referral procedure for reasons of safety;
3) Indication or treatment population restrictions, or the addition of a new contraindication
4) A DHPC's dissemination
5) Other emerging safety concerns that a national competent authority or the Agency believes are likely to pique public or media interest in more than one Member State (e.g., publication of important safety findings in a (scientific) journal, safety-related regulatory action taken in a Member State or in a country outside the EU).

Language of safety communication:

- English is the language of centrally approved products.
- Translation into the local languages of the member states that apply
- For the sake of cooperation, the Agency (the EMA) will communicate any safety announcements to the EU regulatory network in English.
- When contacting the Agency, Member States' competent authorities are encouraged to offer English translations of their safety alerts in order to begin the network's coordination process.
- If a full text translation is not available, an English summary should be provided.

The role of patients in safety communication

At various stages of the development, assessment, licencing, and monitoring of medications, it is critical to incorporate patient experience and expertise. Patients should be active in detecting and reporting therapy side effects and problems.

In the EMA, patients are now involved in these activities. In terms of safety messaging, for example,

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- The Pharmacovigilance Risk Assessment Committee (PRAC) now includes a patient representative as a full member.
- The European Medicines Agency (EMA) has initiated a pilot project to involve patients in deliberations in the Committee for Medicinal Products for Human Use (CHMP).
- Patients are increasingly consulted on concerns including disease management, quality of life, and risk management programme feasibility.

One of the most important responsibilities is to report bad incidents. Information on adverse occurrences can be collected, reviewed, and analysed in the following ways:

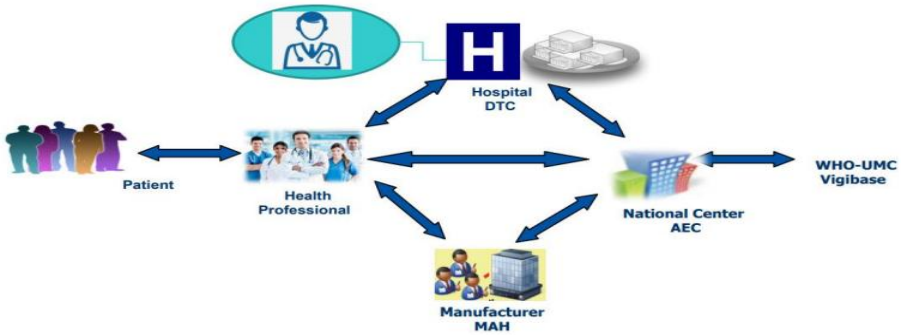
- As a result, product information and a medicine's benefit-risk profile may alter.
- Assist in the detection of dangers.
- Provide information on areas of the healthcare system that may be dangerous.

Patients can participate in the reporting of adverse events, for example, using the Yellow Card System or by downloading the WEB-RADR app. Although there is some overlap, patient focus in reports of suspected ADRs differs from that of healthcare professionals, and can produce new possible safety signals and describe suspected ADRs in enough depth to provide helpful information on likely aetiology and the impact on patients' lives.[9]

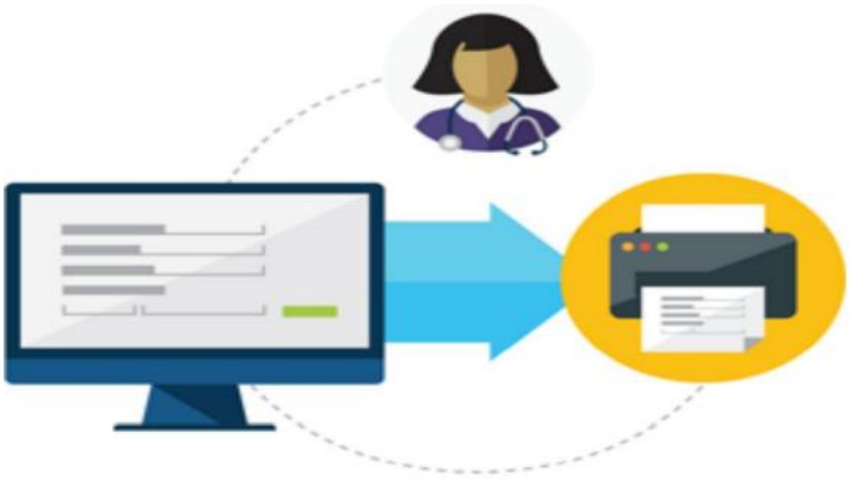
Improvement of the communication in Pharmacovigilance

- All health facilities must have a local contact person for pharmacovigilance. Establishment of electronic prescribing and electronic health recording system (medical information database).
- ADR online reporting system.
- SMS reporting system for pharmacy.
- Improvement of the online website and publication of the newsletter by the National PV.
- Development of a specific mobile application for the patient for access to medicine information also reporting of ADR.

1.Local contact person for pharmacovigilance in health facilities



2. Electronic prescribing and electronic health recording system



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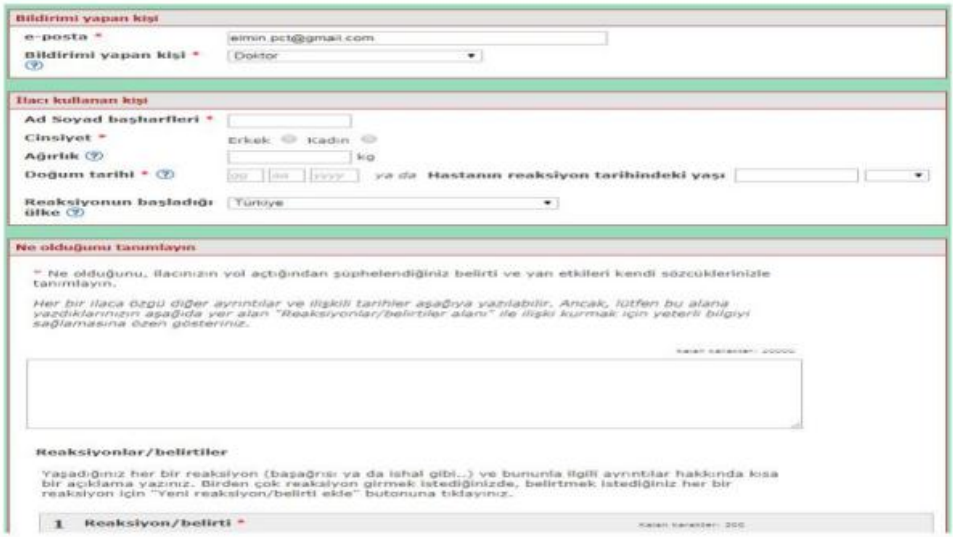
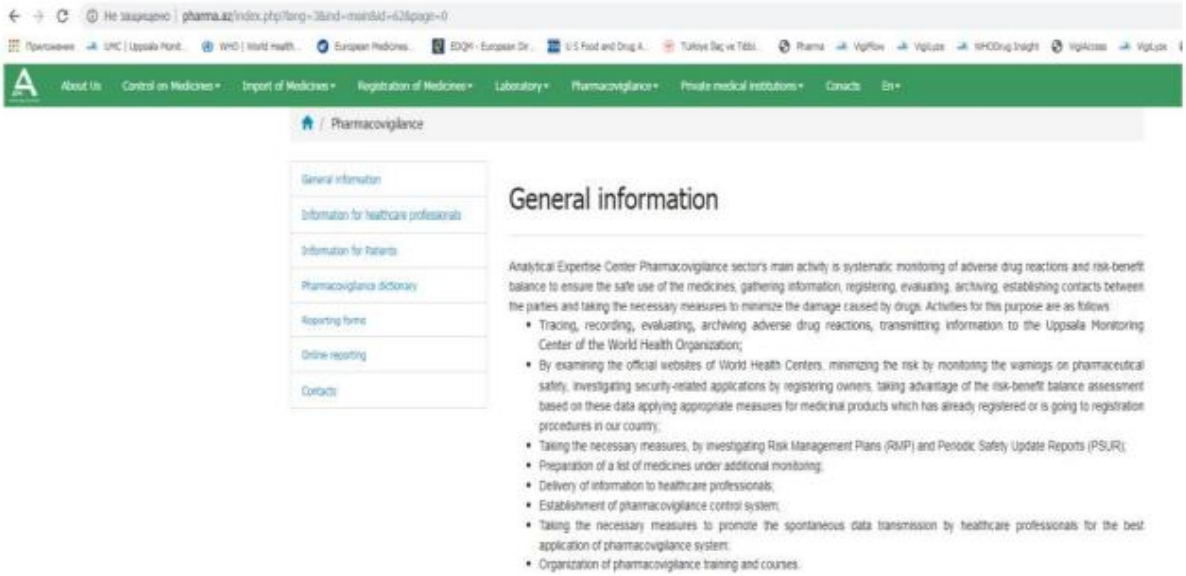
3. ADR online reporting system



4. SMS reporting system for pharmacy

5. Online website



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6. Publication of the newsletter

7. Specific mobile application for the patient for access to medicineinformation also reporting of ADR[5]

II. RESULT

Only when the prescriber has sufficient current information of the drug's possible hazards and expected benefits can it be done safely and effectively. When a new drug is first released, information concerning its adverse effects profile is restricted to what has been learnt from a small number of people (who may not be representative of the general population) in preclinical and clinical trials over a short period of time. Rare but major side effects may appear only after a medicine has been approved for sale, sometimes years later. As a result, it's critical to continue monitoring drug safety after they've been released, and to ensure that healthcare practitioners have access to timely information about any safety problems. Pharmacovigilance is the practise of monitoring the safety of medications in clinical use and taking appropriate measures to reduce risk. It is governed by a number of complicated UK and European legislation. It's not always easy to find background information on drug safety issues and pharmacovigilance choices. The pharmacovigilance process is described here, as well as how new information on side effects is shared to healthcare professionals.[12]

In order to address the issue of patient safety, we must examine the nature of the systems that make up healthcare and work to improve their coherence and concentration. 'Communication is a cornerstone of patient safety,' says one expert, and it's true in practically every element of healthcare, at almost any time of day. Without efficient communication, medical and technical knowledge

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will not serve the best interests of patients and, in fact, may end up harming them.[13]

III. DISCUSSION

This review article demonstrates how communication is crucial in many parts of life. However, when it comes to pharmacovigilance, communication is crucial.

In many respects, communicating with patients varies from communicating with healthcare professionals.

Communication is important in the control of a better health-care management system.

Effective communication in pharmacovigilance refers to a sort of information that is delivered along with evidence that it has been received and processed and can start an appropriate response.

Effective communication is required to report ADRs by outlining the drug's benefits–risk profile.

Finally, safe prescribing can only occur when the prescriber possesses appropriate information and when communication is precise and effective.

IV. CONCLUSION

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, in order to prevent adverse reactions, medication errors, and other medicine-related problems. These notions could be adapted to the remits and legal requirements of anybody trying to ensure the effective and safe use of medicines. The strategic method comprises establishing communication goals through shared problem ownership by all stakeholders involved, evidence-based design, and a cyclic planning, implementation, and assessment process.

Strategic communication is viewed as a public health intervention aimed at empowering people to make better decisions and changing their behaviours in order to achieve targeted health outcomes. Participation of medicine users in all stages of risk management might result in shared ownership of a medicine-related problem and its solution. With the concerns and information needs of patients and healthcare professionals, such two-way communication would inform risk assessment and risk minimization action options analysis, engage their respective organisations in the implementation of risk minimization activities, overcome paternalism, and build trust between all parties.

Appropriate involvement models must be investigated. Drug utilisation, medical decision making, and risk perception studies would provide more evidence for building product- and situation-specific communication programmes. A measurable communication target would be described as the desired behaviour change in pharmaceutical users. Evidence on how to overcome barriers to behaviour change and successfully implement safe prescribing and medicine use by patients, according to the paper, would aid decision-making on risk-reducing actions and communication programme design.

To ensure the long-term sustainability of behaviour change, mixed and recurrent communication interventions should be supported, with reference to behaviour change models and social marketing. Rather than the transmission of a single communication document, this transformation would be the result of the participatory process.

An assessment of the communication's efficacy should help to ensure the program's long-term viability and provide lessons for the future. Because of the significant patient suffering caused by avoidable prescription errors and adverse reactions, it seems worthwhile to examine if this proposed scientific approach will help with public pharmacovigilance communication. Multidisciplinary research and collaboration within healthcare and medical information systems will be required for feasibility testing, adaption, and deployment.

This collaboration should be based on healthcare professionals' motivation to offer high-quality treatment and patients' growing involvement in medical decision-making. Given its mandate, the pharmacovigilance community has the authority and responsibility to broaden its scope of action and take the lead in identifying and resolving medicine-related issues, as well as promoting risk management through increased public communication for patient safety.[1]

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