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Assessment of risk perception of patients concerning adverse drug reactions

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ABSTRACT

Introduction. The use of medicines involves trade-offs between their therapeutic benefits and inherent risks. Several studies show that numerous adverse drug reactions (ADRs) could be avoided by increasing patients' awareness of medicine's risks. Even though drug labels enclose relevant information about risks and benefits, this information often requires patient education and overall health literacy to improve medication adherence, thereby preventing ADR frequency.

Aim. To describe patient awareness of ADR risks and the Portuguese Pharmacovigilance System.

Methods. A questionnaire comprising 27 questions was conducted at a health centre in Coimbra, Portugal. This study included ninety-one patients. Risk perception was scored as positive (≥2.5 points) or negative (<2.5 points). Results were analysed by SPSS v 27.0.

Results. This work highlights poor patient perceptions of risk with a rate of negative responses of 85,7%. Although some responders were aware of the possibility of reporting ADRs, only some participants were familiar with the Portuguese Pharmacovigilance System. Additionally, only five patients – out of the vast majority of those who had previously encountered ADRs – reported the event to INFARMED.

Conclusion. Patient low literacy regarding ADRs and the national reporting systems need to be urgently improved. Patient-centred communication strategies for recognising regulatory requirements and standards of product safety are important measures to achieve effective awareness through routine reporting within the Pharmacovigilance systems.

INTRODUCTION

According to Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010, an adverse drug reaction (ADR) is defined as a "noxious and unintended effect to a medical product" [1]. Such a directive was an outcome of the thalidomide tragedy in 1961, which accelerated the development of an international system aimed at improving drug safety while identifying ADRs previously unknown [2].

In July 2012, Directive 2010/84 was adopted in the several European countries that had committed to implementing an automatic reporting system where healthcare professionals and patients could share integrated notification channels towards active participation [3]. The Portuguese Pharmacovigilance System was earlier, and was put in place in 1992 under the regulatory frame of INFARMED. It was intended to accomplish three challenging goals: i) improve risk/benefit analysis, ii) provide early notice of ADRs' and iii) enable data analysis and accurate information divulgation [4]. Accordingly, every spontaneous report was to be analysed to identify and properly integrate public health concerns. Under the directive, healthcare professionals and patients are both encouraged to report to the Pharmacovigilance System [5-7]. Hospital reports are crucial because they often disclose risks in administration of new and innovative drugs, hence, allowing earlier detection of risk, and more accurate data analysis [8,9]. Still, ADRs elicited by over-the-counter drugs are equally relevant given their frequent misuse due to poor literacy.

Age, education, health status, information, media, culture and beliefs are among the factors that influence patient perception of risk. Individual vulnerability strongly

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impacts ADR risk and further contributes to data heterogeneity. Noticeably, an expressive number of mistaken beliefs subsist. For example, the false statement that the occurrence of an ADR in a given individual parallels its frequency in a population still prevails [10]. Moreover, perception exists that generic prescription drugs display far more risks than the corresponding brand-name products or that the more security-related information there is, the riskier a product remains [10]. The major factors that foster misleading perceptions have yet to be fully discussed. Yet, it is well-accepted that healthcare professionals need to become more familiar with the ADR report system [6,11]. Patients need to be properly informed about the possible side effects that can be experienced, and communication strategies conveyed by simple verbal and written information favour the bi-directional risk communication process [10,12-14]. However, evidence discloses patient poor literacy regarding medicine's benefit/risk assessment and adequate adherence. Therefore, the application of proper communication strategies is strongly recommended [13,15-19]. Collectively, there is consensus on the pertinence of complementary policies that raise awareness within the pharmacovigilance systems towards improved ADRs prevention and management [20-22].

Nowadays, ADRs are a substantial cause for concern worldwide, being responsible for extended admission times in healthcare units, permanent disability and/or increased morbidity and mortality [9,20,23,24]. There are still many obstacles to positive communication strategies between patients and healthcare professionals that jeopardize risk perception [5]. Healthcare professional risk perception and communication are core to improving notification and to empowering citizen health literacy [25]. This work aimed to characterize patient risk perception of medicines, and to reveal the awareness of their knowledge of ADRs and the national reporting system.

MATERIAL AND METHODS

Ninety-one participants were enrolled in this observational cross-sectional study conducted at a health centre in Coimbra, Portugal. For it, a questionnaire was adopted from two previous studies to assess and describe risk perception by patients [11,21]. The result was the Electronic Supplementary Material Portuguese Version of Questionnaire. Accordingly, twenty-seven questions comprising i) sociocultural factors, ii) participants' attitudes towards medicines and iii) the knowledge and awareness of the ADR reporting system were applied. Each participant was informed about the study's main objective and their rights to confidentiality prior to signing the informed consent. Patients under 18-years-old were excluded from this study, as well as those displaying impediments that could affect their ability to participate and/or that could add bias to the study results, such as cognitive or physical disabilities, mental health conditions, chronic medical conditions, substance abuse or dependence, language barriers and prior participation in a similar study. In this study, data were analyzed using the Statistical Package for the Social Sciences (SPSS) software, version 27.0. This allowed efficient computation of descriptive statistics to provide an accurate summary and understanding of the collected information. Age and qualifications were stratified in four and three groups, respectively. To assess risk perception and knowledge of the ADRs reporting system, five questions were scored (0; 0,5; 1 value) and classified as positive (≥2.5) or negative (<2.5) perception.

RESULTS

Ninety-one respondents were included in this study, ranging from 18- to 85-years-old (Table 1). Most respondents were women (67%; n=61), whereas 33% (n=30) were men.

Table 1. Age and qualification distribution

Group Age	Percentage	Frequency
18-30	10%	9
31-50	44.4%	40
51-65	23.3%	21
66-85	22.3%	20
Qualifications		
None - Middle School	24.2%	22
Senior School	24.2%	22
Higher Education	51.6%	47

When asked whether they were currently taking any medicines, 74,7% (n=68) responded affirmatively, 54,4% (n=37) of whom claimed to be knowledgeable of their side effects. Moreover, 60,4% (n=55) preferred to use a medication they are familiar with, when needed due to common health-related issues (e.g. headache, flu or cough), instead of requesting the corresponding advice from a healthcare professional. In contrast, it was clear that most respondents accepted healthcare recommendations, as evidenced in their answers to several questions were intended to evaluate participants' perceptions and knowledge of the ADR reporting system (Figure 1 and Figure 3). Overall, it is possible to conclude that individual's perception is negative with only 13 positive responses (Figure 2).

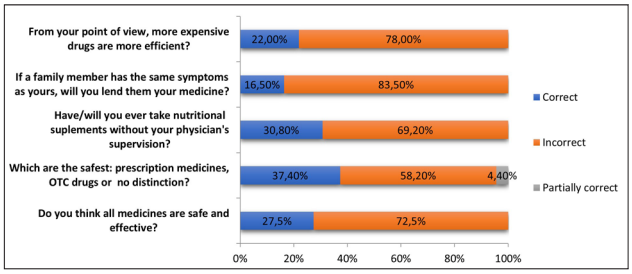

Figure 1. Questions applied to evaluate participant perception about medicines

When knowledge about medicines was assessed, it was possible to identify a low perception level that is strongly related with safety issues. Results all scored below 50% of correct answers which represents a challenge to medicinal communication. Among the results, what stands out are difficulties to properly correlate the efficiency of medicines to their costs (78%; n=71), also the fact that the medicines that are at home are correctly used by family members with

similar symptoms (83,5%; n=76) and, lastly, the wrong perception that all medicines are effective and safe (72,5%; n=66). Figure 1 and Figure 2 show a positive symmetric distribution and unveil low literacy about medicines.

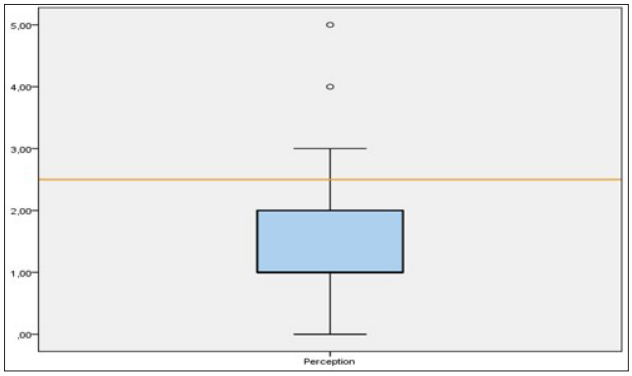

Figure 2. Individual risk perceptions

A second endpoint was related to the assessment of held knowledge on the current reporting system in Portugal. Figure 4 clearly shows a global lack of information among respondents (Figure 4). Only 17,6% (n=16) recognized the Portuguese Pharmacovigilance System, despite the evident aim to learn more about the reporting procedure (93,4%; n=85). Additionally, 39,6% (n=36) of the respondents stated that they had experienced a side effect, yet only 13,9% (n=5) reported this to INFARMED. Alternatively, they preferred to report the event to their physician (61,1%; n=22), pharmacist/ pharmacy technician (5,6%; n=2), or not to inform any professional at all (33,3%; n=12).

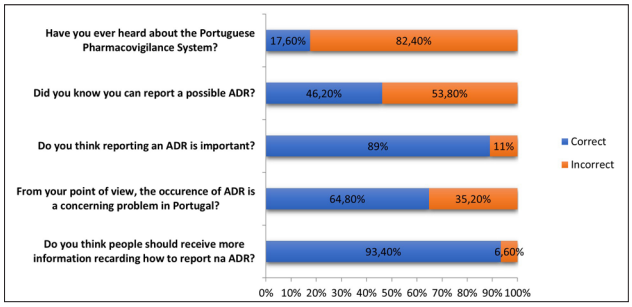

Figure 3. Questions applied to assess the level of held knowledge regarding the Portuguese Pharmacovigilance System

Considering the relevance of a robust system of pharmacovigilance, it is important to understand the level of held knowledge of patients, as they are important players in reporting suspected ADRs. When asked about the system, 82,4% (n=75) of all respondents were unaware of the national System of Pharmacovigilance. Nevertheless, an impressive 89% (n=81) held high perceptions of the importance of reporting problems related with medicines. Another issue that should be highlighted and maybe considered by the National Authority, is the fact that 93,4% (n=85) of all respondents considered it important to have more information on how to report (Figure 3). In Figure 4, it is possible to find symmetric distribution and information that points to a slightly satisfactory level of knowledge.

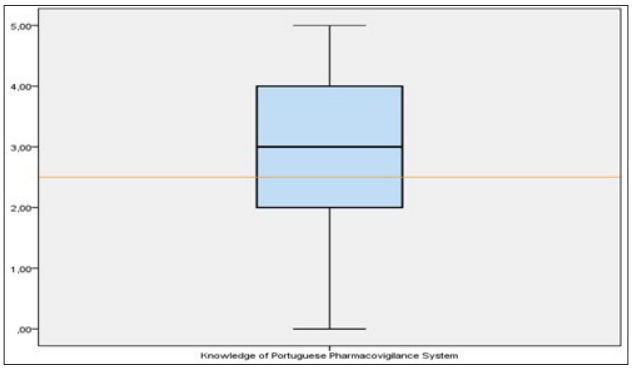

Figure 4. Level of knowledge regarding the Portuguese Pharmacovigilance System

Lastly, a third set of questions aimed to examine participant use of their medicine, as well as their communication flows with their physicians (Figure 5). It was interesting being able to verify that patients thought that they received enough information from their physicians.

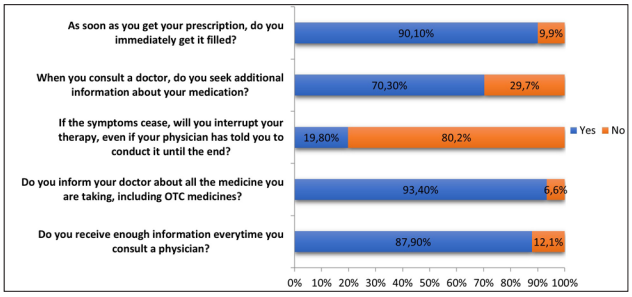

Figure 5. Questions applied to assess participant use of medicines and the communication between them and their doctors

It is important to highlight that the results of this study show a fairly good quality of understanding of the medications used, as well as of the information received by patients through their doctors. Yet, it is important to point out that 19.8% (n=18) of all respondents ceased their pharmacological treatments once their symptoms disappeared, which indicates a low perception of the importance of medicines adherence (Figure 5).

DISCUSSION

ADRs are a major concern for patients and healthcare systems. Any unpleasant and unintended reaction to a medication, including therapeutic and non-therapeutic effects, is referred to as an ADR. All medicated patients can experience an ADR, but patient own perceptions about the risk can vary significantly [10,26,27].

The present study reveals that risk perception is openly negative among patients. Most people still believe that medicines, given their long and rigorous process of research and development, are necessarily safe and efficient, and their hazards in intake are not even questioned. In addition, they falsely consider prescription drugs to be less harmful when physician instruction is given. What is also concerning is the misconception that generic prescription drugs are less efficacious than the corresponding brand-name ones. Indeed, while those with higher qualifications tend to find no distinction between prescription and OTC drugs, they are likewise

convinced that generic prescription drugs are not as efficient as the brand medicaments available in the market.

Moroever, although the participants' knowledge of the Portuguese Pharmacovigilance System was found satisfactory, yet, when asked about the methodology applied to report, the literacy levels fall, preventing patients from actively reporting ADRs. Albeit they are not entirely aware of the reporting system, 46,2% did reveal prior knowledge of the possibility of using an integrated reporting system for ADR identification and management. Younger and older ages represent the age groups with less levels of information regarding the Portuguese Pharmacovigilance System. Moreover, those with higher qualifications were found to be irrefutably more acquainted with the occurrence of ADR and the significant need to report them.

The perception of risk can have a significant impact on patient behaviour [28], as patients who perceive a high risk of ADRs may choose not to take their medications or may hesitate to start new medications. This can have a negative impact on their health and may result in the use of alternative therapies that are not evidence-based. Looking for the factors that can influence the risk perception of patients, it is possible to highlight the age, previous experiences, culture and beliefs and fear and anxiety [28].

Consumer experience is absolutely crucial, as it adds significance and value to ADR reports while enabling the identification of possible new reactions. Therefore, healthcare providers need to be gradually more empowered to identify new potential ADRs and to report them, as well as to thoroughly educate patients about drug side-effects and the Portuguese Pharmacovigilance System [5,29]. The behavioral influence of the health professionals on patients can be significant. Thus, a patient-centered communication is a key-issue for enabling patients to play active roles in the decision-making process of healthcare systems [18,19,30]. Among several hot-topics to fulfill, issues comprising the recognition of the regulatory requirements and education on applicable standards and responsibilities regarding product safety are widely encouraged [30,31]. Communication channels need to be improved in order to translate patient concerns about ADRs into effective awareness by routine reporting within pharmacovigilance systems [32].

Furthermore, an accurate understanding of risk perception is crucial for healthcare professionals when considering the de-prescribing of medicines, as it helps identify patients who might benefit from a reduction or discontinuation of certain medications. By employing de-prescribing tools, clinicians can systematically evaluate medications and minimize the potential for ADRs, thus improving patient safety and overall health outcomes [33].

Collectively, this work emphasizes patient low literacy regarding ADRs and national reporting systems. Future initiatives to improve public communication for the safety of patients through engaging the pharmacovigilance systems, are strongly advised.

Strengths and limitations

This preliminary study was conducted in Portugal and brings new data to properly characterize patient perception on ADR risks, which can highlight future research on the topic. However, the lack of knowledge of the topic limits a proper expression of perception. Moreover, more patients should be included to reflect the characteristics of the Portuguese population and to build a more assertive and effective communication.

Further studies

It is important to conduct more research in this area to improve our understanding of risk communication and patient reporting procedures, increase public awareness of medication-related risks, and inspire and encourage the reporting of suspected ADRs. In order to emphasize their characteristics, it is also important to study special patient populations, such as the elderly and polimedicated populations.

CONCLUSIONS

To effectively communicate risks to patients, healthcare professionals must be fully trained, use appropriate communication styles, and take into consideration the patient's gender, age and cultural background. It is also necessary to apply new tactics to educate people about reporting processes and their importance. However, such conversation must be carried out with caution, on a limited scale, and ideally one-on-one rather than globally, otherwise it may result in disorder and disarray among patients, as well as the interruption of therapies due to misunderstanding among numerous ethnically and socially diverse individuals. Of note, older populations are more apt to have more difficulties adhering to the reporting method of ADRs due to their unique characteristics. Over all, it would be beneficial to increase awareness of the national pharmacovigilance system, in particular, the method for reporting suspected reactions.

DECLARATIONS

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

ETHICS APPROVAL

The study was conducted in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

CONSENT TO PARTICIPATE

Informed consent was obtained from all individual participants included in the study.

CONSENT FOR PUBLICATION

Participants consented to submission of the manuscript to the journal.

AVAILABILITY OF DATA AND MATERIAL

The datasets presented in this study are available on request from the corresponding author upon reasonable request.

CODE AVAILABILITY

Not applicable.

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