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

ARTICLE INFO
Received 05 March 2023
Accepted 20 March 2023

**Keywords:**
adverse drug reactions,
risk perception,
pharmacovigilance system,
ADR reporting.

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.

**Keywords:** adverse drug reactions, risk perception, pharmacovigilance system, ADR reporting.

DOI: 10.2478/cipms-2023-0018

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Assessment of risk perception of patients concerning adverse drug reactions

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

<table>
<thead>
<tr>
<th>Group Age</th>
<th>Percentage</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-30</td>
<td>10%</td>
<td>9</td>
</tr>
<tr>
<td>31-50</td>
<td>44.4%</td>
<td>40</td>
</tr>
<tr>
<td>51-65</td>
<td>23.3%</td>
<td>21</td>
</tr>
<tr>
<td>66-85</td>
<td>22.3%</td>
<td>20</td>
</tr>
<tr>
<td>Qualifications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None - Middle School</td>
<td>24.2%</td>
<td>22</td>
</tr>
<tr>
<td>Senior School</td>
<td>24.2%</td>
<td>22</td>
</tr>
<tr>
<td>Higher Education</td>
<td>51.6%</td>
<td>47</td>
</tr>
</tbody>
</table>

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).

### RESULTS

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 medical 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

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**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 medical 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
Assessment of risk perception of patients concerning adverse drug reactions

According to Huang et al., the occurrence of ADRs is significant and may be significant. Thus, a patient-centered communication is key 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 polypharmacy 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

acknowledgements

We are grateful to Aishwaryalakshmi K et al. and Alshakka MA et al. for providing the questionnaires adapted to the present study.

Funding

No funding was received for the publication of this article.

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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