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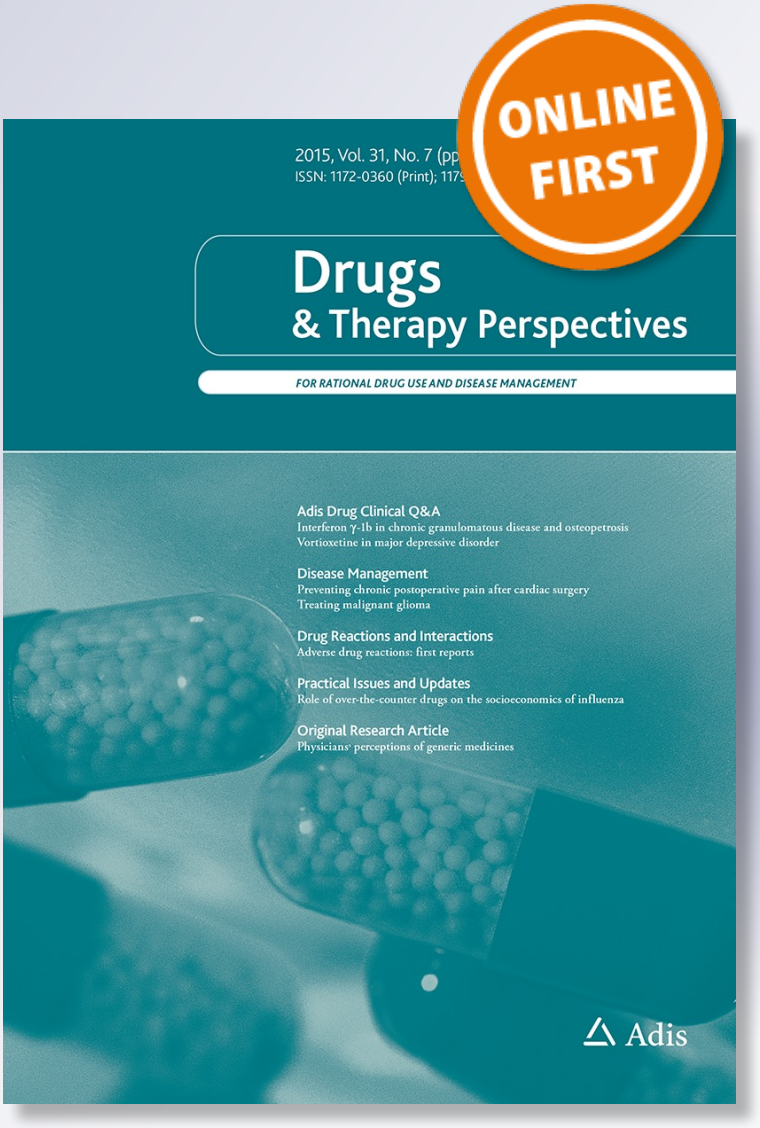

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ORIGINAL RESEARCH ARTICLE

Community pharmacists' attitudes towards adverse drug reaction reporting and their knowledge of the new pharmacovigilance legislation in the southern region of Portugal: a mixed methods study

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Abstract

Objective The study aimed to investigate the habits of spontaneous reporting of adverse drug reactions (ADRs) by community pharmacists employed in pharmacies across the southern region of Portugal, as well as their knowledge of the new pharmacovigilance legislation.

Methodology Two studies were conducted. An initial quantitative cross-sectional study used a questionnaire to survey a sample of pharmacies under the responsibility of the Portuguese South Pharmacovigilance Centre about their reporting of ADRs. This was followed by a qualitative study that interviewed a focus group of experts directly involved in the National Pharmacovigilance System, in order to explain the initial survey results.

Results One-quarter of 154 respondents were familiar with the new ADR definition and were aware that, since July 2012, patients in Portugal can report ADRs directly to the appropriate authority. Of the pharmacists interviewed, 38.3 % had previously reported an ADR. The main barrier to spontaneous reporting was uncertainty concerning the causal relationship between the ADR and the drug. Educational measures were considered the main facilitating factor. According to the focus group, reasons for underreporting were primarily related to pharmacists' attitudes.

Conclusions A higher reinforcement of this subject during education and training in pharmaceutical sciences, a greater awareness and use of the INFARMED website and its pharmacovigilance portal, and the reading of information specifically produced by the regulatory authority (e.g. the pharmacovigilance bulletin), are recommended, together with close collaboration between the regulatory authority, the Pharmaceutical Society, pharmacy associations and the pharmaceutical industry to promote and disseminate information about this topic among community pharmacists in Portugal.

Introduction

Pharmacovigilance relates to the detection, assessment, understanding and prevention of adverse drug reactions (ADRs) and other possible drug-related problems [1]. The primary method for collecting post-marketing information on the safety of drugs is through the use of spontaneous reporting systems (SRSs) [2]. Spontaneous reporting of ADRs remains one of the main tools of pharmacovigilance in the post-marketing phase, and has contributed significantly to the rapid detection of ADRs and signals [3–5], as well to the formulation of causality hypotheses, leading to further confirmatory investigations or, sometimes, regulatory warnings and changes in product information leaflets [6]. Also, withdrawals due to safety problems are often based on data from SRSs [7–9].

In Portugal, the National Pharmacovigilance System (NPS) was established by law in 1992, and is primarily based on the spontaneous reporting of ADRs [10]. Although the NPS was established in a centralized manner, it soon became apparent that geographic decentralization would be advantageous; as a result, four regional pharmacovigilance centres (North, Centre, Lisbon and South) currently cover the entire mainland. These centres are responsible for collecting, processing and evaluating spontaneous reports of ADRs from healthcare professionals

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(HCPs) and consumers, conducting pharmacoepidemiological studies in the area of drug safety, providing continuing disclosure of the activities of the NPS to HCPs, and promoting spontaneous ADR reporting [11, 12]. These units work in collaboration with INFARMED (the National Authority of Medicines and Health Products), which is responsible for supervising and coordinating the activities of these units, and validating the information in the safety database [12]. In summary, the NPS structure integrates the INFARMED department responsible for the surveillance of pharmacovigilance activities, the regional pharmacovigilance centres, HCPs, health services, marketing authorization holders (MAHs) and, since July 2012, patients [12].

Pharmacists in Portugal have been allowed to independently report ADRs since 1995 [10, 11], with such reporting being considered a technical and professional duty. As community pharmacists establish close connections with patients before, during and after treatment, they have a fundamental role in monitoring ADRs [12, 13].

Of the total number of ADR reports received by the NPS from HCPs and patients in 2012, 46 % were sent by pharmacists. Of these, 58 % were sent by community pharmacists, with the remaining 42 % sent by pharmacists working in other fields rather than community pharmacy [14].

Underreporting of ADRs is one of the main disadvantages of SRSs, and a greater knowledge of the purpose of pharmacovigilance is needed to improve both the quantity and quality of reports [15]. The attitudes and reasons for underreporting among HCPs have been investigated in several studies [7, 16–22], some of which have been conducted in pharmacists [23–32]. The main barriers to spontaneous ADR reporting have been described as drug-event causality uncertainty, lack of time and the fact that the ADR is already known [28]. In Portugal, the number of ADRs reported by HCPs has slowly increased, with 1411 reports in 2012, 1461 reports in 2012 and 1760 reports during the first 9 months of 2014 [33–37]. During 2009–2011, pharmacists in the southern region of Portugal accounted for a higher proportion of reports relative to the rest of the country, and the South Pharmacovigilance Centre had a 39.3 % increase in the number of reports received from HCPs [38].

The main objective of drug regulations is to protect public health. The aims of the new European pharmacovigilance legislation are to strengthen the timeliness, effectiveness and transparency of pharmacovigilance activities, thereby making the whole system more robust, and to increase the participation of HCPs [39]. The most meaningful regulatory changes are the inclusion of patients as ADR reporters, the new ADR definition (which now covers use outside the marketing authorization terms, medication errors, overdose, misuse, abuse, off-label use and occupational exposure), and the provision of risk management data (e.g. public summaries of the risk management plan and monitoring of effectiveness of risk minimization) [40, 41]. In Portugal, the new pharmacovigilance adaptation was implemented, together with recent European legislation (December 2010), at the start of the second half of 2012 [11].

This study aims to evaluate the habits of spontaneous reporting of ADRs by community pharmacists employed in pharmacies under the responsibility of the Portuguese South Pharmacovigilance Centre, as well as their knowledge of the new pharmacovigilance legislation, and to investigate the reasons behind potential issues.

Methodology

Study design and population

The study comprised two parts:

- *A cross-sectional study* Conducted in a sample of 154 pharmacies in Southern Portugal between April and June 2013. The study population consisted of all community pharmacists working in the area covered by the South Pharmacovigilance Centre, namely Faro, Beja, Portalegre, Évora, Alcácer do Sal, Grândola, Santiago do Cacém and Sines. A questionnaire (open-ended questions) was used to survey pharmacists by telephone (complemented by e-mail when participation via telephone was difficult).
- *A qualitative study using a focus group (FG)* Conducted after the survey, with members invited using a purposive sampling method. Nine pharmacists were invited to participate (two each from community pharmacies, the regulatory authority and the pharmaceutical industry, and three from regional pharmacovigilance centres). Seven pharmacists agreed to participate, with the remaining two pharmacists (one each from the pharmaceutical industry and a regional pharmacovigilance centre) unable to participate due to scheduling conflicts. Members of the FG were required to have a degree in pharmaceutical sciences, and be employed either in a community pharmacy in the area covered by the South Pharmacovigilance Centre or in pharmacovigilance.

Research tools development and survey administration

The survey questionnaire was tested in ten pharmacies in Lisbon and Barreiro, under the same conditions in which

the final questionnaire would be used. Small changes to the questionnaire were made with regard to the order of items and phrasing of text.

Of the 301 eligible community pharmacies in the southern region, 271 pharmacies were successfully contacted. These were invited to participate in the survey with the options of (i) responding at a time convenient to them; (ii) scheduling the best time for a second contact; or (iii) receiving the survey via e-mail. The questionnaire could be answered by any pharmacist at the participating pharmacy, with the decision of which pharmacist completed the questionnaire being determined by the individual pharmacy (the investigators only asked for the participation of 'a pharmacist'). Pharmacies that asked for a later contact or did not answer were contacted via telephone at different hours and days up to three more times. A reminder was e-mailed from the South Pharmacovigilance Centre to those pharmacies who had requested the questionnaire be sent by e-mail, but who had not responded within 2 weeks. The objectives of the interview were clarified and assurance of the ethical principles of inquiry was given, guaranteeing participants' anonymity and data confidentiality. This research was ethically approved by the coordinating council of the South Pharmacovigilance Centre. All data were treated with respect for the principle of good faith; as stated in the current Portuguese law of personal data protection.

The questionnaire evaluated demographic data, habits and factors associated with spontaneous ADR reporting, and knowledge of the new pharmacovigilance legislation (Table 1).

The FG session lasted around 1.5 h and consisted of a short introduction on the interview objectives, a first engagement question, followed by a few exploratory questions and an exit question (Table 2). FG members were provided with the main survey results before the session, and the moderator supervised individuals' participation, ensuring a balanced response from all FG members.

Data analysis

The quantitative data was processed and analyzed using the IBM Statistical Package for Social Sciences (SPSS) v20 software. A descriptive analysis of all variables was conducted. The absolute and relative frequencies of qualitative variables were calculated. An analysis of associations between variables using the χ^2 test was carried out.

The FG session was audiotaped with permission and anonymized at an individual and institutional level [42]. FG transcripts underwent a reflexive qualitative coding process according to a three-dimensional attitude theory (QSR NVivo® v10) [43].

Results

Community pharmacy survey

Of the 271 pharmacies invited to participate in the cross-sectional survey, 154 agreed to participate (response rate 57 %). Of the 154 pharmacists who completed the questionnaire, 116 (75.3 %) were female and 38 (24.7 %) were male. The mean pharmacist age was 37 years (range 22–69 years), and their mean duration of work experience in community pharmacy was 11 years (range 2 months to 37 years).

Each pharmacist was asked if he or she had ever reported an ADR. Of the 154 respondents, 59 (38.3 %) had reported a suspected ADR and the remaining 95 (61.7 %)

Table 1 Key domains of the community pharmacist survey

Demographics	Age
	Gender
	Years of practice
	Region
Adverse drug reaction reporting experience	Have you ever reported an adverse reaction?
	To whom did you send your spontaneous report?
	Have you felt difficulties during the process? Please, explain
Barriers for spontaneous reporting and factors believed to increase spontaneous reporting	What is in your opinion the most discouraging factor for reporting?
	Which of the measures presented would you think to improve spontaneous reporting?
	Do you receive the pharmacovigilance bulletin? Do you read the bulletin?
	Do you frequently search for information through the INFARMED and/or European Medicines Agency websites?
New pharmacovigilance legislation	Do you know that patients can report directly their adverse drug reaction?
	Are you familiar with the new definition of an adverse drug reaction?

Table 2 Key domains of the focus group interview	
Opening (engagement) question	Could you please introduce yourself (i.e. describe to the other participants the main tasks you have regarding the pharmacovigilance system)?
Spontaneous reporting system improvement	In your opinion, how do you assess the reported pharmacovigilance activity?
	What needs to be done to improve the participation of community pharmacies in the spontaneous reporting system, if any?
Educational measures	In the study we conducted, pharmacists who responded opted for educational measures as a way to increase the number of ADR reports. What do you think of this option?
Closing (exit) question	Imagine that you have the opportunity to introduce one change to improve the National Pharmacovigilance System. What would it be?

had never done so. In order to identify possible differences between these groups, responders were stratified into reporters and non-reporters. There were no significant differences in age, region and years of practice between these groups. No statistically significant difference in the ADR reporting rate was found between reporters and non-reporters with regard to training in pharmacovigilance ($p = 0.062$, $\chi^2 = 3.461$), but there was a trend for reporters to be trained in pharmacovigilance and also to be receiving the pharmacovigilance bulletin ($p = 0.055$, $\chi^2 = 3.675$).

Of the pharmacists who had reported an ADR, 52.5 % sent the report to INFARMED, 32.2 % sent it to the South Pharmacovigilance Centre, and 10.2 % sent it directly to the MAH. Most (78 %) respondents who had reported an ADR said that they did not experience difficulties during the procedure. The difficulty identified most often by the respondents was the extensive ADR form, which requires the reporting of a great deal of information, followed by a lack of ADR forms in the pharmacy and malfunctioning of reporting websites.

Most (66.9 %) respondents thought that ADR reporting was very important. The most common primary factors that discouraged ADR reporting among the 154 participants were the uncertainty concerning the causal relationship between ADR and the drug (31.2 % of respondents), followed by lack of time (22.1 %), and the fact that the ADR was already known (18.2 %). Other factors identified by respondents included the very bureaucratic process (12.3 %), unknown reporting procedures (9.1 %), lack of feedback from the authority (4.5 %), insufficient clinical knowledge (1.9 %) and fear of unreliability (0.6 %).

The most frequently mentioned measure to increase the number of spontaneous ADR reports was the inclusion of a mandatory pharmacovigilance course as part of the pharmaceutical sciences degree (27.3 % of respondents), followed by the dissemination of pharmacovigilance information at scientific conferences accredited by the Pharmaceutical Society (24.7 %). Other actions identified by the respondents included improving the authority system to provide feedback to ADR reporters, periodic transmission of information and brochures from the Southern Pharmacovigilance Centre to pharmacies, making reporting forms mandatory in community pharmacies, and being able to directly notify the Southern Pharmacovigilance Centre of ADRs through the pharmacies' computer systems.

Regarding the knowledge of the new pharmacovigilance legislation, 69.5 % of respondents knew that patients can report their ADRs directly since July 2012, while 30.5 % did not know. Most (71.4 %) respondents had no knowledge of the new definition of an ADR, and more than one-third (37.7 %) did not have the habit of accessing the INFARMED website.

Focus group

Of the seven FG participants, all had a degree in pharmaceutical sciences, six were female, two worked in community pharmacies in Southern Portugal, one worked in a medical department of the pharmaceutical industry, two worked in the pharmacovigilance department of the regulatory authority and two worked in different regional pharmacovigilance centres.

According to the participants of the FG, the main reasons for underreporting ADRs were primarily related to

- *Pharmacists' attitudes* "Pharmacovigilance, in the end, is made by motivation or consideration" (quotation 1); "I have many colleagues working in community pharmacies who do not report and they say that this is not for lack of time, but for lack of will" (quotation 2); "Not so much to the younger generations or to those who left in the last 5, 6 years, but for those who came before us is a very underestimated problem" (quotation 3).
- *Pharmacists' lack of knowledge* "Often pharmacists finish college without even knowing that they can report, that they should report and the reason for reporting" (quotation 4); "The lack of training in specific areas, particularly in clinical pharmacology and therapeutics, determines the individual's approach to the case and the attribution of causality, the moment

when people decide if they report it or not" (quotation 5).

The most important actions pointed out by the FG to increase the number of spontaneous reports were divided into the following themes:

- *Education and awareness* "I think that education is one of most important issues, namely pre- and post-graduate training" (quotation 6).
- *The reporting process* "Spontaneous reporting by telephone, with no need of an ADR form to be completed by the reporter" (quotation 7).
- *Feedback* "If the change that we made has had an impact, we have started sending a feedback letter to the reporter" (quotation 8).
- *Pharmacovigilance system divulgation* "In my opinion, what is now missing is an intervention among the key partners, in particular regarding the disclosure of the pharmacovigilance system in the media and, in this case, the responsibility is on the regulator, not the pharmaceutical industry associations, which are several, and on the corporations of health professionals" (quotation 9).
- *Pharmacovigilance representatives* "A concrete proposal: the pharmacovigilance centre having pharmacovigilance representatives. I think this is a measure of proximity to the reporter, in my opinion, the only way to improve" (quotation 10).

Discussion

The aim of this study was to characterize the degree of knowledge of community pharmacists regarding the new pharmacovigilance legislation, as well as the ADR reporting habits in southern Portugal, and to find underlying reasons that can explain these results.

Social desirability bias and non-respondent bias may be considered as potential limitations of the research. The possible Hawthorne effect may be pointed out as a limitation for the focus group.

The results of the study indicate that age and gender apparently do not influence spontaneous reporting in this population. Similar results were found by the study of pharmacists carried out by the Portuguese's North Pharmacovigilance Centre [26]. The main reasons that could explain underreporting were similar to those in other previous studies [28, 31]. Although ADR reporting should be part of the pharmacists' regular routine, the lack of time for performing functions other than medicine dispensing in daily practice was one of the main reasons for not reporting ADRs in our study. Conversely, a recent study found that lack of time was not a primary barrier to spontaneous ADR reporting [44].

Considering there are variations in work-time perception from pharmacists [44, 45] and that ADR underreporting in this study was consistently associated with professional attitudes and behaviours, educational interventions could help decrease the level of ADR underreporting [26]. Indeed, the study pharmacists saw education as being important; however, the FG suggested that, although important, educational measures may have a limited effect over time. Similar views were observed in other studies [3, 15, 24, 25, 46–48]. New educational approaches are needed, such as hands-on involvement with real cases, to place ADR reporting closer to the day-to-day reality of work in community pharmacies. The mentioned lack of training can be confirmed by pharmaceutical syllabus analysis: there are no specific courses on patient safety, while the number of hours dedicated to pharmacovigilance training is below a full compulsory or elective course. Thus, final-year pharmacy students may have insufficient knowledge about pharmacovigilance [49, 50]. More time for teaching pharmacovigilance as a part of pharmacy undergraduate courses is needed [50]. In Portugal, pharmacovigilance is only an optional unit in one of the five public schools of pharmacy. In the remaining universities, pharmacovigilance is not part of the curriculum, even as an optional course.

The participants in the FG also suggested the following strategies to increase the reporting of ADRs: improved awareness; simplification of the reporting procedure, in particular with communication via phone or with a direct line free phone; improving the channel of communication with pharmacies and feedback to the reporter; and disclosure of the system in the media, which may be conducted by opinion leaders or top officials. Some of the suggested measures are consistent with the evidence published in several studies [47, 51, 52]. Perhaps it is necessary to improve access to the ways that pharmacists can communicate information about ADRs.

For community pharmacists who have completed their studies before 2011, the knowledge of the new pharmacovigilance legislation is probably related to the individual demand to stay updated on the subject, through post-graduate training, access to institutional websites from the regulatory authority and/or regional pharmacovigilance centres, and reading the pharmacovigilance bulletin and scientific journals in this subject.

Conclusion

The participation of community pharmacists from the southern region of Portugal in the ADR SRS is still small, below what can be considered optimal. It seems that

improved participation in the NPS requires an attitudinal change of all stakeholders, as well as improved communication between HCPs. To promote and disseminate information about this topic among community pharmacists, an increased focus on these topics during the undergraduate training in pharmaceutical sciences, a greater awareness and use of the INFARMED website and its pharmacovigilance portal, and reading the pharmacovigilance bulletin are suggested, together with close collaboration between the regulatory authority, the Pharmaceutical Society, pharmacy associations and the pharmaceutical industry. In the pharmacist population we studied, the explanations found for underreporting ADRs were comparable to those found in other pharmacist populations, reinforcing the need for national strategies for increased ADR reporting.

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