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Factors that Influence Under-Reporting of Suspected Adverse Drug Reactions among Community Pharmacists in a Spanish Region

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Abstract

Background: The spontaneous reporting system is the most efficient warning system of adverse drug reactions (ADRs). Pharmacists can play an important role in the detection and reporting of ADRs. The factors that affect under-reporting among these professionals are unknown in Spain.

Objective: To identify the factors that influence community pharmacists' ADR under-reporting in Navarra, a Northern Spanish region.

Methods: A case-control study was conducted on a population of 802 community pharmacists working in Navarra. Cases were pharmacists who had reported at least two ADRs to the region's drug surveillance unit between 2003 and 2005 and who agreed to participate in the study (18/20; 90%). A random sample of 60 controls was selected from the 762 pharmacists who had not reported any ADR during the same period of time.

Results: Factors positively associated with ADR reporting were age, years of work experience as a pharmacist, participation in educational activities related to the detection and resolution of drug-related problems, the habit of detecting ADRs as part of pharmacists' duties, having the basic knowledge needed to report ADRs, and disagreement with the common belief among healthcare professionals that 'to report an ADR it is necessary to be sure that the reaction is related to the use of a particular drug'. The most frequently mentioned reasons for not reporting ADRs were the ADR is not serious, the ADR is already known, uncertainty concerning the causal relationship between the ADR and the drug, forgetting to report the ADR and a lack of time.

Conclusions: Pharmacists' knowledge, beliefs, behaviour and motivation play an important role in ADR reporting. Under-reporting might be improved through activities focused on modifying such factors.

Background

Adverse drug reactions (ADRs) represent an important clinical issue that accounts for considerable morbidity, mortality and extra costs for health services.[1,2] Once drugs are marketed and used by patients, continuous monitoring is needed to detect ADRs.[3] The spontaneous reporting of ADRs is the primary method in pharmacovigilance to generate signals on new or rare ADRs. However, under-reporting compromises the effectiveness of the system. It is estimated that reported ADRs rarely exceed 10% of all ADRs produced.[4,5]

Spain is a country that has been participating in the WHO Programme for International Drug Monitoring since 1984. In this country, community pharmacists, like all health professionals, must collaborate with the spontaneous reporting system for ADRs in accordance with Royal Decree 711/2002, which regulates pharmacovigilance of medicinal products for human use.[6] Spain is among the six countries with the highest percentages of pharmacist-reported ADRs received via the spontaneous reporting system.[7] However, the contribution from community pharmacists to the spontaneous reporting system in Spain is still considered low. In 2003, 16.4% (n = 1395) of the ADR reports in this country were submitted by community pharmacists; in Navarra (a Northern Spanish region), only around 9% of the reports received were sent by community pharmacists (data provided by the regional drug surveillance unit in Navarra).

Pharmacists play an important role in the scientific field, dealing with the safety of drugs (pharmacovigilance). Given the continuous relationship between drug consumers and community pharmacists, a pharmacy is an exceptional place to detect and report ADRs. Furthermore, in Spain and other countries, community pharmacists are the only professionals in contact with over-the-counter[8] and herbal[9] medicines.

There is ample evidence showing that the pharmacist is both willing and capable of reporting ADRs,[10-17] and that a greater participation by pharmacists in ADR reporting would substantially reduce the problem of under-reporting.[17,18] Factors that influence under-reporting have been largely studied among medical practitioners,[19-31] and include the professionals' attitude towards their perceived role in the reporting of ADRs, factors that encourage or discourage the actual submission of reports, and their behaviour in relation to ADRs. However, there are very few studies of under-reporting among pharmacists,[14-16,32-35] and only a handful among community pharmacists.[14,32-35] To our knowledge, there are no studies focusing on the factors that influence under-reporting among community pharmacists in Spain.

Thus, the aim of this study was to identify the factors (sociodemographic and professional factors, behaviour, attitudes and knowledge) that influence community pharmacists' ADR reporting in the Northern Spanish region of Navarra.

Methods

Population

The study was conducted on a population of 802 community pharmacists working in 546 pharmacies at the end of 2005 in Navarra, a region with around 600 000 residents.

Cases and Controls

Cases were the totality of pharmacists who had reported at least two ADRs to the region's drug surveillance unit between 2003 and 2005 (n = 20), and controls were randomly sampled from pharmacists who had not reported any ADR during the same period of time. Three controls were selected per case (n = 60).

Those who reported only once between 2003 and 2005 were not included in the study as we considered that one report in 3 years was insufficient to admit those pharmacists in the group of 'reporters' or to include them in the group of 'non-reporters'.

Data Collection

Initially, pharmacists were sent a letter informing them of the existence of the study and its objectives, and stressing the importance of their collaboration. To ensure the participation of pharmacists from the group of cases, a follow-up telephone call was made to this group.

The letter was followed by a questionnaire survey (see also the supplementary material ['ArticlePlus'] at http://drugsafety.adisonline.com), which was administered in person (by the same interviewer) between January and February 2006 to the 78 community pharmacists who agreed to participate in the study (18 cases and 60 controls). Pharmacists were asked to answer the questions immediately without any intervention from the interviewer. Confidentiality was guaranteed to responders and all forms were coded to facilitate anonymity.

The questionnaire was two pages in length and contained 48 items grouped in the following areas: (i) personal and professional information (14 questions); (ii) attitudes and beliefs linked to spontaneous ADR reporting (5 questions); (iii) professional skills related with spontaneous ADR reporting (4 questions); (iv) reasons for not having reported an ADR (16 questions); (v) use of the yellow card system (3 questions); (vi) basic knowledge about the reporting of ADRs (4 questions); and (vii) suggestions to increase pharmacists' reporting (2 questions, one of them open-ended).

Items were formulated using a mixed theoretical model of the factors that condition the health professionals' attitudes in the reporting of ADRs[36] and published studies about health professionals and ADR reporting,[14-16,19-24,26-30,32,33,35] some of which have been validated.[24,30] The reasons for not having reported ADRs were based on Inman's 'seven deadly sins'.[37,38] Prior to the survey, the questionnaire was piloted with 15 pharmacists, which resulted in adaptation of the phrasing of several of the questions. Three of these 15 pharmacists participated in the main study in the group of cases.

To answer the questions regarding attitudes and beliefs linked to spontaneous ADR reporting, responders were asked to express their agreement using a 5-point Likert scale from 1 (total disagreement) to 5 (total agreement). The answers to other questions included in the questionnaire were either multiple choice or open-ended.

The study protocol was approved by the School of Pharmacy of the University of Navarra and by the Regional Pharmacovigilance Unit in Navarra. Completion of the self-administered questionnaire was considered to imply informed consent.

Variable Definition

Pharmacists' knowledge was a discrete quantitative variable, with a value between 0 and 4, which was calculated by adding up the score obtained in the four questions regarding basic knowledge to report ADRs.

The number of ADR reports was the number of yellow cards received by the Regional Pharmacovigilance Unit in Navarra between 2003 and 2005.

Statistical Analysis

Comparisons were made using the Chi-squared test and Fisher's Exact test for categorical variables and with the Mann-Whitney U test and Student's t-test for continuous variables.

Unconditional logistic regression analyses were conducted to assess the association between independent variables and the outcome of having reported at least two ADRs during 2003–5. In the multivariate analysis, we adjusted for the variables registered in the questionnaire that proved significant in the crude analysis. Results are expressed as odds ratios (ORs) with their corresponding 95% confidence intervals.

We used Spearman's rank correlation coefficient to evaluate the association between the pharmacists' knowledge, expressed as a continuous variable

Table I. Pharmacists' personal and professional characteristics and pharmacy characteristics

Variables	Cases (n = 18)	Controls (n = 60)	Crude p-value
Pharmacists' personal and professional characteristics			
Sex (%)			
male	16.7	15.0	1.000[a]
female	83.3	85.0	
Age (years) [median (IQR)]	43.43 (11.99)	37.56 (16.14)	0.019[b]
Work experience as pharmacist (years) [median (IQR)]	16.50 (14.25)	12.00 (14.00)	0.041[b]
Job function (%)			
senior pharmacist	94.4	74.6	0.098[a]
adjunct pharmacist	5.6	25.4	
University (%)			
University of Navarra	77.8	51.7	0.060[a]
Programme of detection and resolution of DRPs (%)	72.2	31.6	0.002[c]
Continuing education [in last 3 years] (%)	94.4	71.7	0.057[a]
pharmaceutical care	83.3	66.7	0.174[c]
detection and resolution of DRPs	94.4	38.3	<0.001[c]
pharmacovigilance	22.2	15.0	0.483[a]
Pharmacy characteristics			
Number of workers [median (IQR)]	3.00 (1.00)	2.00 (2.00)	0.075[b]
Area (%)			
urban	100.0	86.7	0.187[a]
Dominant population[d] (%)			
children and adolescents (0–18 years)	11.1	21.7	0.498[a]
young adults (19–35 years)	5.6	16.7	0.441[a]
adults (36–65 years)	77.8	60.0	0.168[c]
elderly (>65 years)	61.1	63.3	0.864[c]
Professional relationship with medical practitioners (%)			
no	16.7	15.0	1.000[a]
yes	83.3	85.0	

a Fisher's Exact test.
b Mann-Whitney U test.
c Chi-squared test.
d Not mutually exclusive categories.
DRPs = drug-related problems; **IQR** = interquartile range.

(points obtained in the questions regarding basic knowledge), and the number of ADR reports.

All p-values presented are two-tailed. p-Values < 0.05 were considered statistically significant. The analyses were performed using SPSS version 13.0 (SPSS Inc., Chicago, IL, USA).

Results

A total of 78 questionnaires were collected (18 from cases and 60 from controls). The response rate was 90% for cases and 100% for controls.

Table I shows the personal and professional characteristics of case and control pharmacists, as well as some relevant characteristics of the pharmacy where they work. Factors associated with ADR reporting, in a crude analysis, were older age, longer work experience as pharmacists, participation in a programme for the detection and resolution of drug-related problems (DRPs), and participation in a continuing education programme on detection and resolution of DRPs. However, none of these variables remained an independent predictor of ADR report-

ing when we adjusted for all significant variables found in the crude analysis (see table II).

Detection of Adverse Drug Reactions

All pharmacists had considered the possibility of finding an ADR at least once when attending a patient with symptoms. However, cases considered this possibility more often than controls (see table II). Similarly, almost every pharmacist had detected an ADR at least once in their professional life (cases: 100%; controls: 95%).

Reporting History

Pharmacists usually tell the patient to visit the doctor (cases: 83.3%; controls: 81.7%) when they detect a suspected ADR. A lower proportion of pharmacists directly contact the medical practitioner (cases: 55.6%; controls: 53.3%) and very few pharmacists communicate the occurrence of suspected ADRs to the drug industry (cases: 33.3%; controls: 8.3%). The yellow card system had been used by all the cases. In contrast, only 23.3% of the controls (n = 14) had ever used the system (reports submitted before 2003). A total of 66.7% of cases (n = 12) and 50% of controls (n = 7) that had used a yellow card indicated that they never found any difficulty using this reporting form.

Attitudes and Knowledge

Although 95% of pharmacists from the control group had ever detected an ADR, only 23.3% had ever used the yellow card to report an ADR. Figure 1 shows the five major reasons for not reporting ADRs for both groups. Only 'forgetting to report' was significantly associated with ADR reporting (see table II).

Attitudes and beliefs towards ADR reporting were explored by asking pharmacists' to express their grade of agreement with five statements; responses were collected using a 5-point scale, where a score of one indicated total disagreement and a score of five indicated total agreement (see table III). In general, the majority of pharmacists from both groups agreed with the statements about the importance of the spontaneous reporting system and their role as reporters, which indicates a positive

Table II. Characteristics associated with under-reporters in adverse drug reactions (ADRs)

Characteristics	Cases	Controls	Crude analysis		Adjusted analysis[a]	
	(n = 18)	(n = 60)	OR (95% CI)	p-value	OR (95% CI)	p-value
Age (years) [median (IQR)]	43.43 (11.99)	37.56 (16.14)	1.06 (1.01, 1.11)	0.031	1.13 (0.93,1.37)	0.209
Working experience as pharmacist (years) [median (IQR)]	16.50 (14.25)	12.00 (14.00)	1.06 (1.00, 1.12)	0.035	0.93 (0.76, 1.13)	0.462
Participation in a programme for detection and resolution of DRPs (%)	72.2	31.6	5.63 (1.74, 18.20)	0.004	2.04 (0.17, 25.03)	0.576
Received continuing education on detection and resolution of DRPs (%)	94.4	38.3	27.35 (3.41, 219.53)	0.002	9.40 (0.23, 389.25)	0.238
Frequently considering the possibility of finding an ADR when attending to a patient with symptoms (%)[b]	66.7	35.0	3.71 (1.22, 11.32)	0.021	1.54 (0.26, 8.97)	0.631
Forgetting to report an ADR (%)	33.3	5.0	9.50 (2.08, 43.41)	0.004	5.58 (0.68, 45.89)	0.110
Disagreement with: "to report an ADR, it is necessary to be sure that the reaction is causally related to the use of a particular drug" (%)	44.4	8.3	8.80 (2.39, 32.45)	0.001	18.91 (1.92, 186.34)	0.012
Scores on questions about basic knowledge for ADRs reporting [median (IQR)]	3.25 (0.25)	2.75 (1.25)	9.29 (2.12, 40.71)	0.003	12.98 (1.04, 162.50)	0.047

a Multivariate analysis adjusting for all variables of the table.

b Frequently is defined as when they answered "very often" or "always" to the question: "When attending a patient with symptoms, do you consider the possibility of finding any ADRs?".

DRPs = drug-related problems; **IQR** = interquartile range; **OR** = odds ratio.

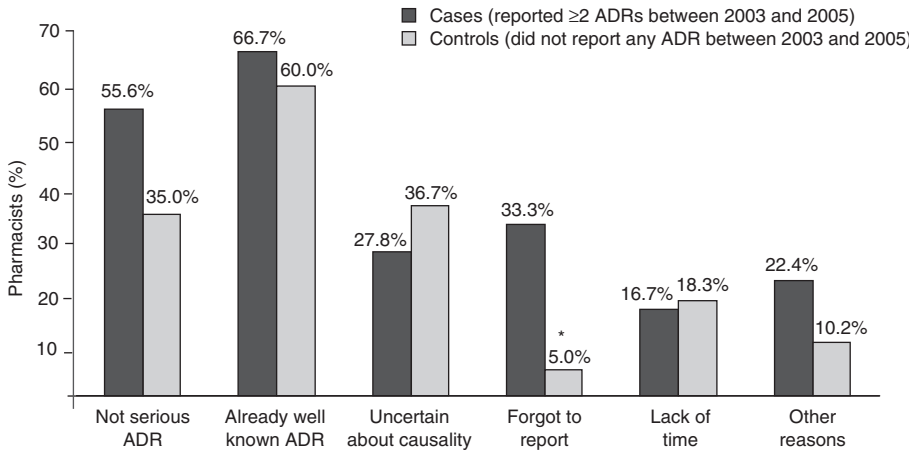

Fig. 1. Reasons for not reporting an adverse drug reaction (ADR) using the yellow card system. * $p < 0.01$.

attitude towards ADRs reporting. Furthermore, most pharmacists disagreed with the statement 'all serious ADRs are well documented by the time a drug is marketed' (76.3% of controls and 83.3% of cases). However, a small number of responders disagreed with the statement 'to report an ADR, it is necessary to be sure that the reaction is causally related to the use of a particular drug' (see table II).

Basic knowledge needed to report an ADR (who, what, how and where) was common among both groups of pharmacists. On a scale of 0–4 points, cases scored higher than controls (cases median: 3.25; controls median: 2.75; $p = 0.004$) and a positive correlation was found between the score and the number of ADRs reported (coefficient correlation = 0.387; $p = 0.001$). Most pharmacists (75.6%) were not aware of the possibility of reporting an ADR by electronic yellow card, phone or e-mail, in addition to the traditional paper yellow card. Furthermore, 100% of cases were aware of the fact that yellow cards have to be sent to the region's drug surveillance unit, whereas 31.7% of controls were not.

Factors that remained independent predictors of ADR reporting in the multivariate model were disagreement with the statement 'to report an ADR, it is necessary to be sure that the reaction is causally related to the use of a particular drug', and higher scores for questions on basic knowledge about ADR reporting (see table II).

Suggestions from the Pharmacists

Although both groups of pharmacists demanded education on detection and reporting of ADRs, pharmacists from the control group were more interested in education (91.7%) than pharmacists from the case group (83.3%).

When pharmacists were asked about how their participation in ADR reporting could be improved, through an open-ended question included in the questionnaire, a wide variety of responses were received. Suggestions were addressed to pharmacists, doctors, patients and the reporting system. In general, the most common suggestions were education on ADR reporting for pharmacists and making pharmacists, doctors and patients aware of the importance of the reporting system.

Discussion

This is the first study identifying the factors that influence ADR reporting by community pharmacists in Spain. The response rate of 97.5% (90% in cases and 100% in controls) was higher than in other similar studies,[15,16,20-24,27-30,32-35] which is probably due to the personal administration of questionnaires. The results of our survey are consistent with the data available in the literature on community pharmacists, hospital pharmacists and medical practitioners.

This study indicates that pharmacists' knowledge is an important factor in ADR reporting. Therefore, the development of education strategies, focused on altering wrong beliefs and some attitudes, communicating basic knowledge on ADR reporting and spreading a 'reporting culture' among these professionals, could reduce under-reporting.

Age and length of work experience as a community pharmacist have an influence on ADR reporting; the probability of reporting rises with increasing seniority and years of practice. This tendency has also been detected in two other studies.[15,32]

Having received education and training in DRPs (an ADR is considered a safety-DRP) was associated with ADR reporting among community pharmacists. The positive influence of education and training on ADR reporting has been found in three other similar studies focused on pharmacists, two on hospital pharmacists[15,16] and one on community pharmacists.[39]

In countries where pharmacists are highly motivated to report ADRs, as in The Netherlands, it has been found that these professionals consider ADR reporting to be an integral part of their duties.[33] According to our study, pharmacists from the group of controls, who are less motivated than cases to report ADRs, do not assume this activity to be an integral part of their professional duties. This behaviour is a point that could be modified by providing special practical training in this area.

Almost every pharmacist interviewed had already detected an ADR once in their professional life, which indicates that pharmacists are capable of identifying ADRs in their work setting. However, they are not in the habit of reporting the ADRs they detect via the spontaneous reporting system. On the other hand, it has been seen that our pharmacists tend to refer their patients to medical attention when they detect a suspected ADR, delegating ADR reporting to the medical practitioner. We found only one other study involving community pharmacists that observed this tendency; the study found that younger pharmacists were more likely to delegate ADR reporting.[32] This behaviour is identified as another point that should be changed by an intervention in order to increase ADR reporting.

Contrary to what would be expected, taking into account the relatively low reporting rate from community pharmacies in Navarra, pharmacists working in this region have, in general, a positive attitude towards ADR reporting. In fact, the prevalence of ADR reports from pharmacists in Navarra are among the highest in Spain. This situation has also been found among health professionals in previous studies.[14,27,33,39]

The 'seven deadly sins' described by Inman[37] in 1976 as reasons for under-reporting of ADRs by health professionals, to which Inman added another sin some years later,[38] are not very common among pharmacists participating in this study. According to our study, which is in line with a study on pharmacists in Portugal,[34] neither the reasons connected with their professional activity nor the reasons related to the use of the yellow card system are consid-

Table III. Attitudes and beliefs related to adverse drug reaction (ADR) reporting using a 5-point scale (Likert-scale)

Statements	Cases (n = 18) [mean (SD)]	Controls (n = 60) [mean (SD)]	OR (95% CI)	p-Value
To report an ADR, it is necessary to be sure that the reaction is causally related to the use of a particular drug	3.28 (1.708)	4.02 (1.017)	0.64 (0.43, 0.96)	0.032
All serious ADRs are well documented by the time a drug is marketed	2.11 (1.132)	1.97 (0.890)	1.17 (0.68, 2.02)	0.568
ADR reporting is an important contribution to drugs' safety knowledge	4.72 (0.575)	4.53 (0.873)	1.45 (0.62, 3.39)	0.396
Community pharmacist is an important agent in the detection of ADRs	4.67 (0.485)	4.23 (0.963)	2.39 (0.92, 6.25)	0.074
Detecting and reporting ADRs is an important role of the community pharmacist	4.50 (0.618)	4.30 (0.908)	1.39 (0.66, 2.90)	0.384

OR = odds ratio; **SD** = standard deviation.

ered as reasons for not reporting ADRs. Of the seven deadly sins, only diffidence ('I was not sure that the reaction was caused by the use of a particular drug') and lethargy ('forgetting to report the ADR' and 'lack of time') were identified as common reasons for not reporting ADRs. In addition, 'nonserious ADR' or 'well known ADR' were identified as important factors; however, the background causes of these beliefs are unknown. These findings are close to the results of similar studies on physicians and pharmacists in other countries.[14,22,24,28,30,31,33]

'Forgetting to report an ADR' is associated with ADR reporting as shown in table II. Results may indicate that cases, who are generally more aware of how to detect and report ADRs than controls, may detect an ADR and intend to report it but simply forget to do so; controls do not forget to report ADRs because they may be less conscious of their role in reporting ADRs than cases.

The reason identified as diffidence was due to an incorrect belief associated with under-reporting that was detected among our pharmacists ('to report, it is necessary to be sure that the reaction is causally related to the use of a particular drug'), showing that ignorance is a background reason for not reporting ADRs. This attitude of 'reporting ADRs only if they are sure that it is caused by a drug' is very common among both pharmacists[16,32-34] and physicians.[20,22,24,28-31]

Ignorance is again detected as a factor involved in decreasing ADR reporting; a correlation has been found between the score obtained on basic knowledge and the number of reports submitted by pharmacists. Even though pharmacists know that the yellow card is the ADR reporting form, they do not know about the existence of other ways of reporting; this has been observed previously.[30] Furthermore, lack of knowledge about where the yellow card should be sent, an issue that has been also detected among our pharmacists, may not be a reason for not sending a yellow card because the address is already written on the form. However, this ignorance about the system and its activity could have some influence on ADR reporting. Providing information about the activity of the reporting system, which in turn makes pharmacists aware of the importance of their reports, could be another point of improvement.

To increase the participation of the pharmacists in the ADR reporting system, they declare that more education and training and increased awareness are required. This suggests that the current level of educational may not be satisfactory or that other kinds of strategies should be developed to increase their knowledge and motivation.

In line with the 'Knowledge-Attitude-Practice (KAP) model'[36] and previous studies,[15,16,20,24,28,29,34,39,40] we suggest that the modification of some attitudes and knowledge, and of the relationship with their work environment, should improve the participation of pharmacists in the spontaneous reporting system.[40]

Limitations

The main limitation of this study is the small sample size for both groups, which is determined by the small number of cases in the region. This fact could be a possible reason for null findings in some studied factors due to a lack of statistical power to detect associations. However, the response rate obtained was very high, decreasing the likelihood of selection bias. Another limitation is that the questionnaire was not previously validated. However, a pilot study was conducted to adapt it to pharmacists' comprehension, and we based it on previously published questionnaires that have been used for the same purpose and have achieved satisfactory results. In addition, the use of a 5-point Likert scale instead of a visual analogue scale to assess some attitudes could be a reason for not detecting small differences in pharmacists' attitudes; a finding in contrast with other studies.[29,34]

The multivariate analysis included variables that were highly correlated with one another (e.g. age and work experience). In addition to this, the condition index for multicollinearity exceeded 30. However, after running another multivariate logistic regression and maintaining those variables that, being correlated, had the highest determination coefficient in the crude analysis (age and getting higher scores

on questions) and those not correlated, the results obtained showed a similar effect magnitude but with statistically significant associations. Overall, due to a multicollinearity problem, we can not ensure the independent association of variables included in the model.

Conclusions

This study identified several factors that influence ADR reporting among community pharmacists in Navarra. The most important determinant of pharmacists' ADR reporting behaviour is knowledge. An appropriate knowledge of ADR reporting would increase pharmacists' awareness and improve their behaviour related to ADR reporting and so reduce under-reporting of ADRs.

Knowledge can be acquired either through pharmacists' own professional experiences or through activities that provide an appropriate education and training in this area. Therefore, future strategies targeted at increasing ADR reporting among these professionals should be focused on providing appropriate education and training related to ADR reporting.

Nevertheless, further studies with larger populations are needed to better understand why the use of the yellow card system is relatively low among Spanish pharmacists and to evaluate the impact of strategies used to improve adherence to the ADR reporting system.

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