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Influence of Pharmacists' Attitudes on Adverse Drug Reaction Reporting

A Case-Control Study in Portugal

Maria T. Herdeiro,[1,2] *Adolfo Figueiras*,[1] *Jorge Polónia*[3] and *J J Gestal-Otero*[1,4]

1 Department of Preventive Medicine and Public Health, University of Santiago de Compostela, Santiago de Compostela, Spain
2 Northern Polytechnic Health Institute (Cooperativa de Ensino Superior Politécnico e Universitário [CESPU]), Gandra, Porto, Portugal
3 Northern Pharmacovigilance Unit, Faculty of Medicine, University of Porto, Porto, Portugal
4 Preventive Medicine Service, University Hospital of Santiago de Compostela, Santiago de Compostela, Spain

Abstract

Introduction: Pharmacists can play a fundamental role in adverse drug reaction (ADR) reporting, although the factors that affect underreporting among these professionals are unknown. The objectives of this study were to identify (i) professional or demographic characteristics; and (ii) attitudes associated with pharmacists' ADR reporting in northern Portugal.

Methods: We conducted a case-control study on a population of pharmacists employed in hospital and community pharmacies across Portugal's Northern Regional Health Authority catchment area in 2003. Cases (n = 34) comprised pharmacists who had reported at least one ADR to the northern region's drug surveillance unit, and controls (n = 280) were randomly sampled from pharmacists who had never reported an ADR. All were interviewed using a mail questionnaire. Most attitudes were based on Inman's 'seven deadly sins' and were measured using a continuous visual analogue scale. Answers were recorded in a range from 0 (total disagreement) to 10 (total agreement). Logistic regression was used to determine the ADR reporting adjusted odds ratio (OR) for a change in exposure corresponding to the interquartile range for each attitude.

Results: The response rate was 86.8%. Reporting probability proved higher among hospital versus community pharmacists (adjusted OR 20.0; 95 CI 3.3, 125.0; $p < 0.001$). Attitudes to ADRs were strongly associated with reporting probability. Hence, an interquartile decrease in any of the following attitudes increased the probability of reporting by (i) 223% (95% CI 51, 595; $p < 0.05$) for "Really serious ADRs are well documented by the time a drug is marketed"; (ii) 240% (95% CI 89, 508; $p = 0.002$) for "I would only report an ADR if I were sure that it was related to the use of a particular drug"; (iii) 316% (95% CI 44, 1104; p =

0.010) for "It is only necessary to report serious or unexpected ADRs"; and (iv) 171% (95% CI 13, 549; p = 0.020) for "I do not have time to think about the involvement of the drug or other causes in ADRs".

Conclusions: ADR under-reporting is strongly associated with certain attitudes, possibly indicating that under-reporting could be minimised through educational interventions targeted at changing such attitudes. Pharmacists' ADR education must be improved and educational programmes should be focused on altering attitudes identified by the study as being associated with under-reporting. Our data also indicate that community pharmacists must be a priority target for this intervention.

Introduction

Adverse drug reactions (ADRs) are an important cause of morbidity and mortality and their occurrence results in an increased use of health services in developed countries,[1,2] accounting for up to 6.5% of all hospital admissions.[3,4] Pharmacovigilance plays a crucial role in the study of safety and, by extension, in pharmacotherapeutic decision making. Voluntary ADR reporting is one of the most versatile pharmacovigilance systems because, among other advantages, it covers the entire population as well as all medical drugs throughout their commercial life. Nevertheless, the effectiveness of the system is seriously compromised by underreporting: it is estimated that reported ADRs rarely exceed 10% of the real total.[5-8] In Portugal, the pharmacovigilance system was first introduced in 1992, yet the country's ADR reporting figure of 134 per million population falls far short of the WHO target of 250 per million.[9]

Pharmacists are well positioned to provide valuable postmarketing information on drug products[10-13] because (i) they are a vital link with the patient before and during a course of drug therapy;[14,15] (ii) they can play an important role in monitoring adverse events in hospitals;[16,17] and (iii) they are the only professionals in contact with over-the-counter[18] and herbal[19] medicines. Indeed, the important role of the pharmacist in the detection, notification and handling of ADRs has been confirmed in many countries,[20-22] with pharmacists accounting for 88% of all notifications in Canada, 40% in The Netherlands and 18% in the US.[23] A study performed in the US[24] about the contribution of pharmacists to the serious reports received by the US FDA concluded that the quality of the reports by physicians and pharmacists were identical and 68% of notifications of all serious reports were originated from pharmacists. However, the number of reports submitted by pharmacists in many countries is lower than expected.

In contrast to the attention that has been given to the reasons for under-reporting among medical practitioners,[25-32] the reasons for under-reporting among pharmacists have not yet been studied. To our knowledge, there are no studies that have assessed the influence exerted by the various factors (knowledge, attitudes, professional and personal characteristics) on pharmacist-led reporting. We have only located three studies[10,22,33] that describe opinions and attitudes held by pharmacists regarding ADR reporting and in these studies no link was made between such opinions and attitudes and a higher or lower likelihood of reporting. Accordingly, this study sought to assess the influence of pharmacists' knowledge and attitudes on ADR reporting. Identification of the factors that influence under-reporting in Portugal will enable a specific intervention strategy to be designed to address this problem.

Methods

Settings

In Portugal, pharmacists were incorporated into pharmacovigilance in 1995 and reported in collaboration with physicians until 1997. From 1997 onwards, however, pharmacists have submitted their reports directly, without the involvement of medical practitioners. Community pharmacists in Portugal do not keep registers or patient medication records (a computerised registration system is currently being developed), so information is almost exclusively obtained from the patient. Hospital pharmacists can contact patients and access their clinical and treatment histories, and they have frequent contact with medical practitioners.

Cases and Controls

The study population was made up of pharmacists employed in hospital and community pharmacies across the designated catchment area of Portugal's Northern Regional Health Authority in 2003 (n ≈ 1300). All pharmacists working in other fields, such as teaching or corporate pharmaceutical production and distribution, were excluded.

Cases (n = 34) were defined as pharmacists who had reported at least one ADR to the regional drug surveillance unit between 2000 and their inclusion in the study, while controls (n = 280) were sampled randomly from those pharmacists who had not reported any ADRs. Stratified random sampling was carried out in five regions, with a simple random sample proportional to the number of non-reporting pharmacists being taken for each. Eight controls were selected per case (cases being few in number). One sub-region had no reported cases, so it was presumed to have had one case.

Data Collection

A self-administered questionnaire was mailed to the study population, together with a cover letter in which we outlined the objectives of the study, stressed the importance of participating and enclosed a pre-paid addressed envelope for returning the completed questionnaire. The first questionnaire was sent out in June 2003. This questionnaire was then re-sent up to four times to non-respondents.[27,34,35] Pharmacists were guaranteed confidentiality and all forms were coded to facilitate resending. In the first mailing, a report card was sent together with the questionnaire.

The questionnaire was two pages long, contained 26 items (25 questions and a suggestions box) and sought information in the following three areas: (i) personal and professional information, such as age, sex, place of work (hospital or community pharmacies), type of activity (private or public), job function and number of drugs dispensed; (ii) knowledge and attitudes linked to spontaneous ADR reporting (15 questions); and (iii) use of the voluntary reporting system over the 3 years during which regional drug surveillance had been in place in northern Portugal (three questions).[1]

The 15 questions regarding knowledge and attitudes linked to spontaneous ADR reporting were based on Inman's 'seven deadly sins'[36] and on previous studies[26,28,33,36] conducted on medical practitioners and suitably adapted to pharmacists. Agreement with the questions included in the questionnaire was measured using a horizontal, continuous visual analogue scale (VAS), 8cm long and unnumbered.[37] Recorded answers were read in a range from 0 (total disagreement) to 10 (total agreement), with a precision of 0.5.[27]

1 The full questionnaire is available on the *Drug Safety* website (http://www.adisonline.com/drs).

Questionnaire Validation and Pilot Study

The questionnaire and letters of invitation (a different letter per mailing) were evaluated in linguistic and interpretative terms by experts in the matter, resulting in small changes in the order and phrasing of the text. The questionnaire was then validated by experts in pharmacology and pharmacovigilance. To assess reproducibility, a pilot test was performed at a Regional Health Authority centre on a sample of 20 pharmacists (five hospital and 15 community pharmacists). The questionnaire was sent out twice, with an interval of 4 weeks between each mailing.

Statistical Analyses

The questionnaire's reproducibility was evaluated using the intraclass correlation coefficient, based on the results obtained for the first and second answers, for each pharmacist.

Logistic regression analysis was used to model the associations between independent variables and the outcome of having reported an ADR. Two sets of statistical models were created: in the first, we evaluated all the personal and professional variables using crude and adjusted analyses, and in the second, we evaluated the influence of ADR-reporting attitudes, such as those quantified in the questionnaire, adjusting for personal and professional variables that proved significant in the first model. Results were expressed as odds ratios (ORs) with their 95% confidence intervals, which indicated the increase/decrease in the probability of being a responder for an increase of 1 unit on the continuous VAS (score range 0–10). To take into account the distribution of independent variables among the study subjects, we calculated the interquartile OR (IqOR), which is based on an incremental exposure corresponding to the interquartile range (IQR) of these attitude measures. Since most ORs assume values lower than unity, we calculated the inverse of the IqOR (1/IqOR), which can be interpreted as the increase in the probability of being a responder when exposure decreases from the 75th to the 25th percentile of the distribution.

Results

In the pilot study, the correlation coefficients yielded by assessment of the questionnaire's reproducibility exceeded 0.75 for all 15 attitudes and opinions, except for the attitudes "I should be financially reimbursed for providing the ADR service" and "I do not have time to think about the involvement of the drug or others causes in ADRs", in which the coefficients were 0.71 and 0.74, respectively ($p < 0.005$).

Of a total of 314 questionnaires mailed, 19 (16 from controls and three from cases) were returned by the postal service because of errors in their postal addresses. Of the remaining 295 eligible pharmacists, 256 returned a completed questionnaire (86.8%); of these, 31 were returned by cases (100%) and 225 by controls (85.2%).

Table I sets out the responding pharmacists' personal and professional characteristics for both cases and controls. Also shown in table I is the influence exerted by personal and professional characteristics on voluntary ADR reporting. As can be seen, after adjusting for the remaining independent variables, only workplace was associated with reporting, with hospital pharmacists being 20 times more likely to report an ADR than community pharmacists (1/OR = 1/0.05 = 20.0; 95% CI 3.3, 125.0; $p < 0.001$). The variables of sex, age and job function failed to display any influence on ADR reporting.

Table II shows the degree of agreement between the study subjects and each of the attitudes studied (in terms of percentiles) and the related influence on reporting (in terms of the OR and IqOR). In general, pharmacists tended to agree with the attitude statements "I would only report an ADR if I were sure that it was related to the use of a particular drug" (median 8.5) and "I have a professional obligation to

Table I. Influence of personal and professional characteristics on voluntary adverse drug reaction (ADR) reporting

Characteristic	Ever reported an ADR (n)[a]		Crude analysis		Adjusted analysis[b]		
	yes	no	OR	95% CI	OR	95% CI	p-Value
Sex							
Male	3	49	1.00		1.00		
Female	27	172	2.56	0.75, 8.80	2.08	0.57, 7.58	0.266
Age[c] (y)							
<29	7	63	1.00		1.00		
29–39	18	83	1.95	0.77, 4.96	1.39	0.49, 3.89	0.534
>39	4	73	0.49	0.14, 1.76	0.36	0.09, 1.50	0.161
Job function							
Registered pharmacist	10	98	1.00		1.00		
Assistant pharmacist	9	80	1.10	0.43, 2.84	0.81	0.28, 2.28	0.685
Other	11	43	2.51	0.99, 6.34	0.39	0.07, 2.11	0.275
Workplace							
Hospital	8	9	1.00		1.00		
Community pharmacy	21	213	0.09	0.03, 0.25	0.05	0.01, 0.30	<0.001

a Continuous variables categorised in tertiles for all participants.

b Adjusted for the effects of the other variables included in the table.

c Categorised in tertiles for the total sample.

OR = odds ratio.

report ADRs" (median 10), whereas they tended to disagree with the statements "I do not have time to complete the report card" (median 1.5), "Reporting ADRs puts my career at risk" (median 1.5) and "I should be financially reimbursed for providing the ADR service" (median 0.5). However, in the case of other attitudes wide discrepancies were in evidence, such as with the statements "Really serious ADRs are well documented by the time a drug is marketed" (IQR 55% of the VAS) and "The one case an individual pharmacist might see cannot contribute to pharmaceutical knowledge" (IQR 90% of the VAS).

Also shown in table II is the relationship between attitudes and opinions statistically associated with a lower likelihood of reporting ADRs. A 1-unit decrease on the VAS (score range 0 = total disagreement to 10 = total agreement) increased the probability of reporting by 19% (1/OR = 1/0.84 = 1.19; p = 0.01) in the case of 1-*complacency*, "Really serious ADRs are well documented by the time a drug is marketed"; 20% i.e. (1/OR = 1/0.83 = 1.20; p = 0.01) in the case of 2-*ignorance*, "It is only necessary to report serious and not expected ADRs"; and 37% i.e. (1/OR = 1/0.73 = 1.37; $p < 0.01$) in the case of 3-*diffidence*, "I would only report an ADR if I were sure that it was related to the use of a particular drug". The odds ratio for a change in exposure corresponding to the interquartile range of these measures (see table II) indicates that a change from the 75th to the 25th percentile in assessments of the following attitudes or opinions would lead to reporting probability rising by 223% (95% CI 51, 595; $p < 0.05$) for *complacency*, 316% (95% CI 44, 1104; p = 0.010) for *ignorance* and 240% (95% CI 89, 508; p = 0.002) for *diffidence* (see table II).

Other attitudes and opinions that showed an association with under-reporting were linked to (i) lack of time, i.e. "I do not have time to think about the involvement of the drug or other causes in ADRs" (171%; 95% CI 13, 549; p = 0.020); and (ii) method

Table II. Influence of surveyed attitudes and opinions on voluntary adverse drug reaction (ADR) reporting

Attitude or opinion	Percentile			OR (95% CI)	1/IqOR (95%CI)	p-Value
	25	50	75			
"Really serious ADRs are well documented by the time a drug is marketed"	3.0	6.0	8.5	0.84 (0.73, 0.96)	3.23 (1.51, 6.95)	0.011
"It is nearly impossible to determine if a drug is responsible for a particular adverse reaction"	2.5	4.5	7.5	0.98 (0.85, 1.13)	1.20 (0.59, 2.45)	0.814
"I would only report an ADR if I were sure that it was related to the use of a particular drug"	5.0	8.5	10.0	0.83 (0.74, 0.93)	3.40 (1.89, 6.08)	0.002
"The one case an individual pharmacist might see cannot contribute to pharmaceutical knowledge"	1.0	4.0	8.0	0.93 (0.82, 1.06)	1.74 (0.74, 4.08)	0.264
"When I read pharmaceutical literature I am interested in articles about ADRs"	7.5	9.0	10.0	0.97 (0.79, 1.17)	1.14 (0.72, 1.78)	0.724
"I would be more likely to report ADRs if there were an easier method"	1.5	5.0	8.0	0.86 (0.75, 0.98)	4.20 (1.68, 10.45)	0.024
I think that the most correct way to report ADRs is in pharmaceutical literature"	1.5	4.0	6.5	0.99 (0.86, 1.15)	1.58 (0.77, 3.25)	0.896
"I should be financially reimbursed for providing the ADR service"	0.5	0.5	1.5	1.01 (0.83, 1.22)	1.02 (0.85, 1.24)	0.898
"I have a professional obligation to report ADRs"	9.0	10.0	10.0	1.45 (0.81, 2.61)	0.66 (0.37, 1.18)	0.217
"Reporting ADRs puts my career at risk"	0.5	1.5	5.0	0.85 (0.69, 1.04)	2.23 (0.90, 5.49)	0.110
"It is only necessary to report serious or unexpected ADRs"	0.5	2.0	5.5	0.73 (0.58, 0.93)	4.16 (1.44, 12.04)	0.010
"I do not have time to complete the report card"	0.5	1.5	5.5	0.86 (0.72, 1.01)	2.43 (1.05, 5.66)	0.072
"I do not have time to think about the involvement of the drug or other causes in ADRs"	1.0	2.5	6.0	0.81 (0.68, 0.97)	2.71 (1.13, 6.49)	0.020
"I do not know how the information reported in the report card is used"	1.0	3.5	8.0	1.00 (0.89, 1.12)	1.62 (0.71, 3.72)	0.998
"I talk to pharmaceutical companies about possible ADRs with their drugs"	3.0	5.5	8.5	0.96 (0.84, 1.09)	0.92 (0.45,1.87)	0.492

1/IqOR = inverse interquartile OR; **OR** = odds ratio.

of reporting, i.e. "I would be more likely to report ADRs if there were an easier method" ($p = 0.024$).

Discussion

The results of this study indicate that pharmacists' knowledge and attitudes exert a strong influence on ADR reporting. In addition, our data indicate that, while age, sex and job function appear to have no influence on reporting, pharmacists working in a hospital setting have a higher likelihood of reporting than their counterparts in community pharmacies. This study analyses the relationship between pharmacists' attitudes and reporting, inasmuch as studies conducted to date have confined themselves to describing pharmacists' opinions about ADRs.[10,22,33] Attitudes are potentially modifiable variables. Hence, this study supports the development of education strategies targeted at modifying pharmacist reporting-related attitudes and reducing under-reporting.

Although the pharmacist's role in ADR reporting tends to vary from country to country, pharmacists are authorised to report in most countries that participate in the WHO Programme for International Drug Monitoring.[23] This has brought about an improvement in the detection of ADRs, since their reports are complementary to those of staff physicians.[38] Nevertheless, under-reporting continues to be one of this system's principal limitations,[39] and this is equally applicable to pharmacists. Such under-reporting is more evident still in Portuguese community pharmacists, among whom the number of annual notifications per pharmacist does not reach 1% versus, for example, 43% in the case of the Dutch.[20] Among Portuguese pharmacists, however, reporting is 20-fold higher in a hospital than a community setting, a finding in line with other studies.[40] Setting-related differences in reporting, albeit of a diametrically opposed nature, have also been observed among medical practitioners, both in Portugal[32] and elsewhere.[27,31,34] Such workplace-related differences in pharmacist ADR reporting might be due to several factors: hospital pharmacists typically are better informed regarding pharmacovigilance and clinical pharmacy subjects;[41] have constant contact with patients experiencing serious ADRs;[10] and have close relationships with physicians,[10] who sometimes delegate ADR notification to hospital pharmacists.

Most pharmacists covered by the study agree that they would only report ADRs if they were sure that they were associated with a medical drug and that really serious ADRs are already well documented before a drug is put on the market. It was observed that these attitudes, in addition to being in line with other studies,[10,33] were also associated with under-reporting, which means that they could constitute target attitudes and knowledge when it comes to designing what ought to be the subject of an intervention study. Furthermore, most Portuguese pharmacists feel that they have a professional obligation to report ADRs and that they therefore need no financial incentive to do so. Likewise, they do not regard ADR reporting to pose any legal problems. Unlike other studies, in which lack of time was an important reason for failure to report,[21,22] the Portuguese pharmacists in this study did not see it in this light, whether in terms of identifying ADRs or in terms of completing the report card. However, 50% of the Portuguese pharmacists nevertheless admitted experiencing difficulties in ascertaining whether or not a specific drug is responsible for a given ADR.

In 1976, Inman[36] proposed the 'seven deadly sins' as reasons for under-reporting, although in so doing he had medical practitioners in mind. It is conceivable, however, that many of the reasons could be common to medical practitioners[42] and pharmacists alike. Insofar as Portuguese pharmacists are concerned, we observed that none of Inman's reasons connected with professional activity (such as fear of possible involvement in litigation, economic incentive and ambition to collect and pub-

lish [we found no papers on PubMed on ADRs in Portugal that were published by pharmacists]) were shown to have any influence on ADR reporting. However, of the five remaining factors connected with ADR attitudes – *complacency*, *ignorance*, *diffidence*, *indifference* and *insecurity* (which Inman subsequently added as the eighth sin[43]) – the first three seem to be associated with a lower reporting probability among pharmacists.

Comparing these results with those of other studies is difficult because we only found articles about this topic relating to medical practitioners, and the comparison with these is rendered less easy still by the fact that most studies apply categorical scales having two, three or four categories, whereas we used the VAS. This scale can detect small, albeit relevant, differences in pharmacists' attitudes that would not be detectable using a categorical-type scale. The results of the present study show close agreement with two previous studies we conducted on the attitudes of medical practitioners in Spain[27] and Portugal.[32] Moreover, the scale may well be responsible for finding magnitudes as high as those indicated by our results (e.g. for *complacency*, *diffidence* and *ignorance*, changes in the degree of agreement with equivalent statements in the IQR increase the ADR reporting probability by over 220%).

This strong association between knowledge/attitudes and under-reporting may well indicate that educational interventions that are purpose designed to change such knowledge/attitudes could bring about important improvements in reporting (the Knowledge-Attitude-Practice, or KAP, model).[42] In order for this to occur, however, it is also important that these educational strategies enhance the degree of balance between pharmacist practitioners, their environment (patients, colleagues, health system administration and pharmaceutical industry)[42] and their ADR-related motivation. Not only must such education[44,45] be undertaken by institutions involved in this field, such as universities, pharmacovigilance units and other health system institutions, but it must be furnished to all heath system professionals, who have a duty to ensure that it becomes an activity that forms an integral part of their daily routines.

One of the main limitations of studies based on mail questionnaires is the non-response factor.[46] However, we obtained a percentage participation in excess of 85% (100% in cases and 85.2% in controls), a figure that can be regarded as extremely high, especially when it is compared with other studies conducted on the same topic, whether among pharmacists[10,11,33] or medical practitioners.[26,31] The higher response rate registered by Portuguese pharmacists answering this questionnaire not only enhances our study's internal validity but might also indicate a keen interest by pharmacists to participate actively in the National Pharmacovigilance System.

Conclusion

Pharmacists can play an important role in pharmacovigilance, both in community practice and in a hospital setting. In both settings, cooperation among pharmacists and medical practitioners is important. The results of our study may well constitute an important contribution, since they indicate which ADR attitudes are strongly associated with reporting. It therefore follows that modifying such attitudes among pharmacists could greatly reduce ADR under-reporting. We feel that this study could provide a good basis for designing intervention studies aimed at decreasing under-reporting and creating a 'reporting culture' among pharmacists.

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Correspondence and offprints: Professor *Adolfo Figueiras*, Dto. de Medicina Preventiva y Salud Pública, Facultad de Medicina, c/ San Francisco s/n, Santiago de Compostela (A Coruña), 15705, Spain.
E-mail: adolfo.figueiras@usc.es