Barriers to reporting of adverse drugs reactions

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Original Research

Barriers to reporting of adverse drugs reactions: a cross sectional study among community pharmacists in United Kingdom

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Abstract

Background: Adverse Drug Reactions (ADRs) are a major public health problem. Prompt reporting of suspected ADRs is fundamental in the post-marketing surveillance of medicines and helps in ensuring medicine safety. However, fewer ADRs are reported in general and in particular by community pharmacists. There is limited knowledge about the factors which are preventing community pharmacists in the UK from reporting an ADR.

Objectives: To identify the barriers to ADR reporting among community pharmacists practicing in the UK.

Methods: A cross sectional study using a 25-items questionnaire (both online and paper based) including 10 barriers to ADR reporting was conducted from 1st April 2012 to September 2012. Community pharmacists practicing in the West Midlands, UK, were approached for the participation in this study. Chi-Square and regression were applied to identify covariates for the barriers to ADR reporting. A significant value of 0.05 was assigned for analysis.

Results: Of the 230 invited community pharmacists, 138 pharmacists responded (response rate 60%). The median age of respondents was 31 years. All pharmacists reported that they would report both serious and mild ADRs from drugs with black triangle among children as well as adults. About 95% (n=131) of the pharmacists were familiar with the paper based ADR reporting system. Store-based pharmacists were more likely to be more confident about which ADRs to report [0.680, 95% Confidence Interval 0.43-3.59]. Lack of time 46.4% (n=64), and pharmacists perception that ADR is not serious enough to report (65.2%; n=90) were identified as barriers to ADR reporting. Majority 63.0% (n=87) of the pharmacists identified training and information about what to report and access to Information Technology (IT) (For example access to internet connection) 61.6% (n=85) as facilitators to ADR reporting process.

Conclusion: Lack of time and ADRs considered not serious enough by pharmacists to report were barriers to ADR reporting. Further training and education about the types of ADRs to be reported can help to improve the reporting of ADRs.

Keywords

Adverse Drug Reaction Reporting Systems; Professional Practice; Attitude of Health Personnel; Pharmacies; Pharmacists; Surveys and Questionnaires; Regression Analysis; United Kingdom

INTRODUCTION

Adverse Drug Reactions (ADRs) are a major public health problem and are a known cause for prolonged hospital stay and increased cost of therapy.[1,2] Recent systematic reviews[3,4] and meta-analysis of observational studies[5] indicate that the rate of hospital admissions directly related to ADRs is between 3-5%. An ADR is defined by the Medicines and Healthcare Products Regulatory Agency (MHRA) as "an unwanted or harmful reaction experienced following the administration of a drug or a combination of drugs under normal conditions of use and which is expected to be related to the drug".[6]

Some ADRs are predictable when patients are prescribed the same medications to which they have previously experienced an ADR.[7] The spontaneous and prompt reporting of ADRs is one of the important activities of pharmacovigilance and is fundamental in the post-marketing surveillance of medicines that helps in ensuring medicine safety.[8] Spontaneous reporting system (SRS) is the most commonly used system worldwide to report ADRs by health care professionals as well as patients themselves to the national authorities regulating pharmacovigilance activities.[9] The United Kingdom (UK)'s Yellow Card Scheme, administered by the Medicines and Healthcare products Regulatory Agency (MHRA) was initially open for doctors and dentists only to report ADRs. In 1997, this scheme invited hospital pharmacists to report ADRs and two years later accepted community pharmacists as ADR reporters.[10] Community pharmacists in particular are well placed to identify and report ADRs, as they have direct interaction with the public[11] who visit community pharmacists to obtain Over The Counter (OTC) and herbal medicines as well vitamins and other supplements. However, despite of this frequent interaction with the public, fewer ADRs are reported by community pharmacists compared to hospital pharmacists.[11] This variation in ADR reporting could be explained by the fact that hospital pharmacists' clinical background, access to medical records together with their frequent interaction with the prescribers allows them to develop better understanding about suspected ADRs and the ADR reporting system.[12] However, community

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pharmacists considered as the most accessible healthcare professional can effectively utilize this opportunity by making important contributions to the ADR reporting through early identification and reporting of suspected ADRs.

Although, a lot of work has been done to explore the knowledge, perception and barriers towards ADR reporting by community pharmacists worldwide[13-17], very little is known about the factors which are preventing community pharmacists in the UK from reporting an ADR.[18,19] Some of the reasons for not reporting ADRs reported in previous studies in the UK included lack of time, lack of information about suspected ADRs and ADRs not considered serious enough to report. However, it is noteworthy to mention here both studies referenced above were conducted prior to the permission granted to community pharmacists by MHRA to report ADRs in the UK. Given the limited and out dated evidence on ADR reporting by community pharmacists in UK, there was a need to update the current evidence base. The current study, therefore aims to identify the barriers to ADR reporting among community pharmacists practicing in the UK. This will assist the stakeholders to intervene and facilitate the reporting of ADRs by community pharmacists.

METHODS

A cross sectional study was conducted from 1st April 2012 to September 2012. Community pharmacists practising in the West Midlands, UK, were approached for participation in this study.

Study development

A questionnaire approach was used in this study. Both paper as well as online questionnaires were developed using the style and format of some of the questions (barriers to ADR reporting) used in a previous study.[20] Since the previous questionnaire was designed for medical practitioners, the authors expected the barriers reported by community pharmacists to be different from those reported by the medical practitioners. Therefore, the study questionnaire included specific questions to identify the barriers of ADR reporting in community pharmacy. For example, the questionnaire included barriers such as lack of access to internet in the pharmacy, lack of complete information about ADR and lack of awareness about what to report and how to report. The authors removed barriers such as ADR process being too bureaucratic and concern that report could be used in a legal case for damages by the patient from the previous questionnaire as these questions were not considered to be relevant for this study. The questionnaire was piloted among a small number (n=30) of community pharmacists. The reliability and internal consistency of the questionnaire was assessed using Cronbach's alpha. The alpha value for the study tool was found to be 0.78. In addition, factor analysis was performed using Bartlett's test of sphericity and Kaiser-Mayer-Olkin measure of sampling adequacy. The Bartlett's test of sphericity was found to be 0.0000 and Kaiser-Mayer-Olkin measure of sampling adequacy was found to be 0.840. According to Sheridan and Lyndall[21], a measure of more than 0.6 reflects the adequacy of the contents of the questionnaire.

Contents of study questionnaire

The study questionnaire was comprised of 25 Items. Section one had six items that explored the demographic information of respondents and the number of ADRs reported by them. Section two was comprised of two main items that gathered information about the types of ADRs that would be most likely reported by pharmacists among children and adults. In addition, this section also collected in depth information about the nature and severity of ADRs reported by pharmacists in the past three months.

Section three was aimed to assess the awareness and confidence of pharmacists to report an ADR. Four items were displayed in this section and a nominal scale (yes/no) was provided for the respondent's convenience to disclose their response. Section four of the questionnaire was aimed to identify the barriers to ADR reporting process. This section was comprised of ten items and a nominal scale (yes/no) was used to document pharmacist responses. Section five was the last section of the study and comprised of three items that aimed to identify the facilitators to ADR reporting process.

Inclusion and exclusion criteria

The study included community pharmacists male or female, newly qualified or experienced working in the community pharmacies including large multiples, small multiples and independent pharmacies. The study did not include pharmacists working in hospitals, pharmaceutical industries or academia.

Questionnaire distribution and data collection

Pharmacists were invited to participate in the study by extending invitations to them individually by post and email as well as by giving a ten minutes long presentation at two local pharmacy committees meetings in the West Midlands area. Furthermore, management of the national Pharmaceutical Services Negotiating Committee were approached to request the distribution of online questionnaire to the local pharmacy committees. As a result two local pharmacy committees each in Dudley and Northampton posted the questionnaires on their relevant websites. In our further efforts to achieve the required number of participants, the local management of a large high street pharmacy chain in the UK was also approached to request the distribution of questionnaires. As a result, the management of the company agreed to distribute paper and online copies of questionnaires among their pharmacists based in the West Midlands area.

Ethical issues

Ethical approval was obtained from the central research and development office of the participating pharmacy chain. Furthermore, individual verbal consent was also obtained from the participants. The research protocol was in compliance with the University of Warwick research code of practice. The survey was completely anonymous as the researchers did not request any personal data from participants which could identify the participants. All information collected from this study was kept strictly

Table 1. Respondents and frequency of ADRs reported (N=138)

Demographics	N (%)
Gender	
Male	61(44.2%)
Female	77(55.8%)
Age years) Mean SD	34 (10.57)
Median [Range]	31 [23 – 65]
23- 30 years	57 (41.30%)
31- 40 years	32 (23.19%)
41-50 years	20 (14.49%)
51 and over	14 (10.14%)
Position	
Pharmacy Manager	31(22.5%)
Store Based Pharmacist	59 (42.8%)
Relief Pharmacist	46 (33.3%)
Not Disclosed	2 (1.4%)
Job Experience	
<1 year	11 (8.0%)
1-5 year	56 (40.6%)
6-10 year	17 (12.3%)
11-20 year	19 (13.8%)
>20 years	33 (23.9%)
Not disclosed	2(1.4%)
Have you reported an ADR in the last 3 months	
Yes	62(44.9%)
No	55(39.9%)
Not Disclosed	22 (15.9%)
Number of ADRs reported in last 3 months	
1 ADR reported	28 (20.3%)
2-5 ADR reported	26 (18.8%)
6-10 ADR reported	3 (2.2%)
>10 ADR reported	5 (3.6%)

There were some missing values therefore the sum of responses will not be 100%

confidential. The procedures for handling, processing, storage and destruction of the data complied with the Data Protection Act 1998. Only members of the research team had access to the completed questionnaires.

Statistical analysis

A sample size of 145 was required based at the 5% level, 95% Confidence Interval and keeping response distribution as 50%. This required us to recruit 230 pharmacists to compensate for any incomplete responses.

For data analysis, Statistical Package for Social Sciences (SPSS) version 20 was used. The data was found to be not normally distributed due to the diversity in the professional experience, age of the participants and their position. Therefore, non-parametric tests were applied to estimate the association among the responses and demographic variables. Chi-Square test was applied to test the association between the demographics and barriers to ADRs reporting. However, in the case when cell count was less than 5 among less than 25% cell, fisher exact test was preferred. Furthermore, Binary regression was applied to identify the covariates for the barrier to ADRs reporting. All the binary responses were kept as dependent variables. Position, gender, age and no. of years qualified as a pharmacist (Job experience) were independent variables. Exp(B) at confidence interval of 95% was used to interpret the regression analysis. Overall, a significant value 0.05 was assigned for analysis.

RESULTS

Demographics of respondents

Of the 230 invited community pharmacists, 138 pharmacists responded (response rate 60%). Although, both paper and online copies of the questionnaire were distributed to the participants, all 138 participants who participated in the study completed paper based questionnaire. No online responses were received. The median age of respondents was 31 years. Most of the respondents were female 56% (n=77). Majority 43% (n=59) were store based pharmacists, followed 33.3% (n=46) relief pharmacists. Based on experience, 41% (n=56) of the pharmacists reported to have a 1-5 years of experience. Around 45% (n=62) of the pharmacists reported that had reported an ADR in the last three months. Details about the respondent's demographics and number of ADRs reported are presented in Table 1.

Types of ADRs likely to be reported by pharmacists

Overall, it was reported that both serious and mild reactions from drugs with black triangle and ADRs associated with herbal drugs were the types of ADRs that would be most likely reported among children and adults (Table 2). Some of the ADRs reported by pharmacists included swelling of tongue suspected with gabapentin, severe cramps with rivaroxaban, severe myalgia with

Table 2: Types of ADRs likely to be reported among children and adults (N=138)

Population	Yes	chi-square	p –values
Children			
Serious reaction from a POM	128(92.8%)	2.561	0.110
Serious reaction from a herbal drug	111(80.4%)	3.823	0.148
Serious reaction from an OTC medicine	120 (87.0%)	4.977	0.083
Serious reaction from a drug with black triangle	132 (95.7%)	1.117	0.572
Mild reaction from a drug with black triangle	105 (76.1)	8.049	0.018*
Mild reaction from an existing drug	14 (10.1%)	1.804	0.406
Other	2 (1.4%)	0.823	0.663
Adults			
Serious reaction from a POM	132 (95.7%)	0.085	0.770
Serious reaction from a herbal drug	114 (82.6%)	0.076	0.783
Serious reaction from an OTC medicine	126 (91.3%)	0.179	0.672
Serious reaction from a drug with black triangle	136 (98.6%)	1.608	0.205
Mild reaction from a drug with black triangle	112 (81.2%)	3.878	0.038
Mild reaction from an existing drug	53 (38.4%)	1.585	0.208
Other	3 (2.2%)	0.147	0.702

Association of age and position was non-significant; *significant; ì= gender; Fischer exact test was applied. There were some missing values therefore the sum of responses will not be 100%

Table 3. Awareness about ADR reporting methods and confidence to report an ADR (N=138)

Items. N (%)	Yes	No
Familiar with paper based ADR reporting	131 (94.9%)	3 (2.1%)
Familiar with online ADR reporting	86 (62.3%)	52 (37.7%)
Confident how to report and ADR	100 (72.5%)	32 (23.2%)
Confident which ADR to report	86 (62.3%)	47 (34.1%)

There were some missing values therefore the sum of responses will not be 100%

simvastatin, breathlessness with finasteride, fainting with ramipril, pruritus with dipyrimadole, severe allergy with tiotropium, severe urticaria with metformin and blotching with amlodipine. A severe ADR suspected from St. Johns Wart resulted in patient hospitalisation.

Awareness about ADR reporting methods and confidence to report an ADR

Overall, 94.9% (n=131) of the pharmacists were familiar with the paper based ADR reporting system. In addition, 62.3% (n=86) of the pharmacists reported that they were familiar with the online reporting system. 72.5% (n=100) of the pharmacists were confident about how to report an ADR and of these, 62.3% (n=86) pharmacists were confident about which ADR to report (Table 3). Further analysis has reported that pharmacists from the age group of 51 and over [0.800, CI 0.190 – 3.370] are more likely to report an ADR in comparison to those from the age group ≤ 50years. It was also reported that store based pharmacies were likely to be more confident about which ADR to report [0.680, 0.434 – 3.599]. In addition, age and experience of pharmacists were the other two factors that were reported to be associated with ADR reporting (Table 4).

Barriers to ADR reporting

Lack of time 46.4% (n=64), and pharmacists perception that ADR is not serious enough to report (65.2%; n=90) were identified as barriers to ADR reporting. Reactions too well known to be reported 37.0% (n=51) was identified as another barrier to ADR reporting process (Table 5)

Facilitators to ADR reporting

Training and information about what to report 63.0% (n=87) and access to information technology to report 61.6% (n=85) were identified as the two main facilitators to improve reporting of ADRs (Table 6). Further analysis reported that female pharmacists with less job experience strongly emphasised on the need for provision of 1) access to IT 0.859 [0.394 -1.872] and 2) information about how to report an ADR 0.845 [0.385 -1.855] to improve the reporting of ADRs (Table 7).

DISCUSSION

This study aimed to assess the understanding of community pharmacists about ADRs, their level of reporting and challenges to spontaneous reporting of ADRs. Majority of the pharmacists were reported to be more familiar with the paper based method than the online method of ADR reporting. About 72.5% of the pharmacists were confident to report an ADR.

The study reported that just less than half of the pharmacists (45%) had reported one or more than one ADR. These results suggests a massive improvement in ADR reporting by the pharmacists in UK compared to the findings of two previous studies that reported 4%[18] and 21%[19] respectively. Although this study reported an improvement in ADR reporting among community pharmacists, the average reporting by community pharmacists in the UK in general remains low and static. Approximately 370 ADR reports are submitted annually by community pharmacists that accounts for 3 to 4% of all direct health professional yellow card reporting in the UK.[22] ADRs should not be hard to find in the community where around 2% of GP consultations are due to ADRs.[23] Other evidence suggests that up to 40% of patients in the primary care experience ADRs.[24] Community pharmacists are in regular contact with patients and should therefore make full use of their unique position to contribute to the spontaneous reporting of ADRs.

Table 4. Factors associated with the pharmacist s confidence about which ADR to report (N=138)

Covariates	df	Exp(B)	95% CI	
			Lower	Upper
Position				
Pharmacy Manager(r)	1	1.000	-	-
Store Based Pharmacist		0.680	0.434	3.599
Relief Pharmacist		0.581	0.540	3.001
Gender	1	2.08	0.939	4.60
Age				
23- 30 years	4	0.333	0.62	1.797
31- 40 years		0.666	0.195	2.269
41-50 years		0.486	0.123	1.919
51 and over		0.800	0.190	3.370
No. of year qualified as a pharmacist (Job experience)				
<1 year	4	0.342	0.063	1.841
1-5 year		0.769	0.313	1.890
6-10 year		0.839	0.249	2.829
11-20 year		1.231	0.385	3.937
>20 years (r)		1.335	0.441	4.120

Binary logistic regression was applied, - cannot be estimated Dependant variable was Factors associated with the pharmacist confidence which ADR to report and independent variables were position, gender, age and No. of year qualified as a pharmacist (Job experience)

Table 5. Barriers to ADR reporting (N=138)				
Barriers to ADR reporting N (%)	**Yes**	**No**	***Chi-square***	**Age (p-value)**
Not clear what ADR is	10 (7.2%)	128 (92.8%)	4.061	0.398
Not clear how to report it	17 (12.3%)	121 (87.7%)	2.894	0.576
Did not consider duty to report it	-	136 (98.6%)	-	-
Lack of time	64 (46.4%)	74 (53.6%)	3.644	0.456
Lack of access to internet	23 (16.7%)	115 (83.3%)	12.192	0.016*
Considered reaction to be too well known	51 (37.0%)	87 (63.0%)	15.466	0.004*
Did not consider reaction serious enough to report	90 (65.2%)	48 (34.8%)	6.281	0.188
Not sure which drugs were responsible	33 (23.9%)	105 (76.1%)	3.562	0.469
Did not have complete information for making the report	37 (26.8%)	101 (73.2%)	1.507	0.825
Other	11 (8.0%)	127 (92.0%)	0.317	0.989
Gender and position have no significant association with the barriers to ADR reporting;				

All pharmacists in this study reported that would report both serious and mild ADRs from drugs with black triangle among children as well as adults. Furthermore, more than 90% would report serious reactions from POM. 87% of the community pharmacists would report ADRs suspected from OTC medicines and 82% of pharmacists would report ADRs suspected with herbal medicines. The study suggested that ADR reporting process is more likely to be influenced by the community pharmacists' confidence to report an ADR. It was reported that pharmacists from the age group of 51 and over are more likely to report an ADR in comparison to those less than 50 years. Moreover, greater job experience and type of practice were identified as the other two factors that were reported to be associated with ADR reporting.

The study reported that community pharmacists' consideration that ADR is not serious enough to report, followed by well-known ADRs and lack of time were the three main barriers to ADR reporting process. Such barriers or deterrents to reporting have not only been reported by community pharmacists in studies conducted in the UK[18,19], but also in studies conducted outside the UK.[25] The barriers identified in this study suggest the need to plan for further intervention based studies that aim to address some of these barriers and it also forms the basis of our future work. Our future work would aim to assess the impact of pharmacovigilance-based specific education on ADR reporting by community pharmacists by conducting a randomised controlled trial.

The findings of this study underscore the importance of providing explicit education and training to improve the understanding and awareness of ADRs among community pharmacists. Previous studies aimed at investigating the extent of pharmacovigilance education provided to pharmacy students suggested an increased devotion to such education.[26] A study in Denmark demonstrated the capabilities and competencies of trained pharmacy students in the identification and reporting of ADRs.[27] However, it will not be wise to generalise the findings of this particular study[27] to practicing community pharmacists without extension of specific training and education to them.

Table 6. Support required improving the ADR reporting (N=138)	
Item	**N (%)**
Information about what to report	87 (63.00%
Information about how to report	64 (46.40%
IT access to report and ADR	85 (61.60%

There is a need to nurture the culture of reporting along with the strengthening and re-enforcement of the pharmacovigilance education to community pharmacists. The general attitude towards reporting of adverse events is variable among various healthcare professionals.[28-32] As far as community pharmacists are concerned, a previous study in UK reported that community pharmacists are unlikely to report an adverse event in the community pharmacy.[32] This culture of reporting needs to change and will only be possible if all stakeholders including pharmacy professional bodies and pharmacy schools play a proactive role in promoting and fostering the culture of spontaneous reporting.

This study has some key limitations. Although the barriers reported in this study are consistent with the barriers reported in previous studies, the study was conducted few years ago and therefore, some of the barriers reported in this study may not remain valid. The findings of this should therefore, be presented with caution. This study used an adopted questionnaire from an old study that was aimed to identify the barriers of medical practitioners towards ADR reporting. Since the study[20] was designed for medical practitioners, the authors expected the barriers reported by community pharmacists to be different from the medical practitioners. Therefore, the study questionnaire included specific questions to identify the barriers of ADR reporting in community pharmacy. This adaptation was necessary to ensure the inclusion of questions that were suitable to address the research outcomes. The questionnaire relied on self-reported responses from the participants, therefore the actual number of pharmacists not reporting an ADR could be higher or vice versa.

However, despite of the above mentioned limitations, this study has several strengths. The study achieved a response rate of 60% which was higher than the required sample size. Exclusion and inclusion criteria were rigorously applied to ensure that the study population was representative of the target population. The study achieved its objectives by identifying the barriers towards ADR reporting. Furthermore, the findings of this study have important implications for practice. Community pharmacists not only require encouragement to report ADRs but also need continuous professional educational programs with the aim of improving their knowledge and awareness about ADRs and its reporting. Furthermore, provision of access to patient medical records would allow community pharmacists to collect more information about the suspected drugs and would therefore help them in establishing the ADR causality.

Table 7. Predictors of facilitators identified for improving reporting for ADRs (N=138)

Statement. Exp.(B) CI95%	Position	Job experience	Gender	Age
Information about what to report	1.0052 [0.616 - 1.799]	0.419 [0.219 - 0.803]*	1.331 [0.592 - 2.990]	Y [1.015 - 1.203]*
Information about how to report	0.694 [0.409 - 1.177]	0.441[0.244 - 0.797]*	0.845 [0.385 - 1.855]	1.079 [1.003 - 1.161]*
IT access to report and ADR	1.191 [0.713 - 1.990]	0.735 [0.433 - 1.248]	0.859 [0.394 - 1.872]	1.032 [0.965 - 1.103]

* Significant, binary logistic regression was applied Independent variables were position, gender, age and No. of year qualified as a pharmacist (job experience).

CONCLUSIONS

The current study reported an increasing trend of ADR reporting among community pharmacists practicing in the UK. Lack of time, reactions too well to be reported and ADRs considered not serious enough to report were identified as barriers to ADR reporting. Further training and education about the types of ADRs to be reported coupled with access to IT to the ADR reporting system will help to improve the reporting of ADRs.

CONFLICT OF INTEREST

All authors declare no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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