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A Survey on Factors that Could Affect Adverse Drug Reaction Reporting According to Hospital Pharmacists in Great Britain

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Abstract

Introduction: Since April 1997, UK hospital pharmacists have been invited to submit reports of suspected adverse drug reactions (ADRs) to the Committee on Safety of Medicines (CSM) and Medicines Control Agency. Three studies have investigated the involvement of hospital pharmacists in ADR reporting; however, they did not investigate the possible factors that could affect ADR reporting.

Objectives: (i) To analyse the extent to which hospital pharmacists think that specified factors could affect reporting ADRs; (ii) to identify any additional factors that could hinder reporting; and (iii) to recommend possible methods to improve reporting.

Methods: Piloted questionnaires were sent to 548 hospital pharmacists in Great Britain randomly selected by the Royal Pharmaceutical Society of Great Britain (RPSGB) from their computer database. 346 questionnaires were returned and 280 were included in this study.

Results: 46% of the pharmacists had identified ADRs that were considered to be reportable according to the CSM criteria in the 6 months prior to the survey. 39% did not report these ADRs either to the CSM or the manufacturers. Only 8.2% reported that their hospitals had a written policy; conversely, 73.7% agreed that such a policy could enhance ADR reporting. Although not statistically significant, the result showed an increasing tendency to report ADRs by pharmacists who had received training. Furthermore, there was an increasing tendency to report ADRs with increasing seniority.

Discussion: The results show that hospital pharmacists say they are more likely to report serious and rare ADRs and ADRs associated with newly marketed drugs. Factors that could reduce ADR reporting included being busy at work, lack of confidence in recognising ADRs and the fear of breaching patient confidentiality. Most common suggestions on methods to improve ADR reporting were to provide ADR training and meetings (34%) and a hospital written policy (24%).

Recommendations: ADR training and meetings would be a useful step in improving hospital pharmacist ADR reporting. Therefore, we recommend that the CSM and the RPSGB liaise with regional drug information centres and schools of pharmacy to provide more study days and training programmes for hospital

pharmacists. Furthermore, the CSM should write to the 'Drugs and Therapeutics Committee' of each hospital and encourage them to develop a written local policy for pharmacist ADR reporting. Further studies should be conducted to test the recommendations noted here, assessing the response of the pharmacists in terms of absolute numbers of reports made. It would be particularly interesting to study the need for a written hospital policy and education.

Adverse drug reactions (ADRs) are a significant cause of morbidity and mortality,[1,2] which account for considerable utilisation of healthcare resources. Pharmacovigilance is the process of identifying and responding to risk-benefit issues arising with marketed medicines. The 'Yellow Card Scheme' in the UK is one of the leading pharmacovigilance systems in the world. It is jointly run by the Committee on Safety of Medicines (CSM) and the Medicines Control Agency (MCA). This system relies on the voluntary aid of health professionals to report adverse drug reactions on yellow cards supplied by the CSM. These reports are reviewed regularly by a group of medical and scientific staff. If the number of reports for a particular ADR are sufficient to generate a signal, appropriate regulatory action will be decided upon.[3] This system is especially useful for newly marketed ('Black Triangle') drugs that are under intense surveillance. However, there has been a gradual decline in the overall number of 'Yellow Cards' (i.e. ADR reports) received, from a peak of more than 20 000 in 1992 to just over 17 000 in 1996.[4] Changing patterns in healthcare management and an increased involvement in patient care by pharmacists[5] prompted the initiative to include hospital pharmacists in the 'Yellow Card' reporting scheme. A previous study, encompassing the north of England, concluded that direct reporting of suspected ADRs by hospital pharmacists would enhance the 'Yellow Card Scheme' and improve pharmacovigilance within the UK.[6] Consequently, the 'Yellow Card Scheme' was extended nationally in April 1997[7] to include hospital pharmacists as recognised reporters.

Three studies have recently been completed to assess the extent of hospital pharmacist ADRs reporting.[8-10] All 3 studies concluded that a large number of ADR reports are not forwarded to the CSM, possibly due to lack of information or uncertain causality. The first study,[8] performed in 1996, found that important features that would increase reporting included the presence of an ADR specialist pharmacist, provision of feedback and promotion. It concluded that there is a leading role for pharmacists in the detection, reporting and management of ADRs. One year later, another study[9] found that hospitals that provided a reporting procedure, promoted reporting, provided education and assigned a designated ADR person, had greater ADR reporting than hospitals that did not have these procedures. It was suggested that future work should include identification of factors that had a positive or negative influence on reporting. The third study[10] was conducted at the end of the first year of pharmacist reporting, analysing reports submitted from 1 April 1997 to 31 March 1998. It concluded that hospital pharmacists will require continuing stimulation and education about reporting in order to raise further the profile of their role in reporting of suspected ADRs.

However, these studies targeted hospital pharmacy departments in general and not individual hospital pharmacists or used reports submitted to the CSM/MCA. Thus, the previous studies were unable to obtain a more personalised view from individual pharmacists and identify the specific factors that could affect ADR reporting.

Aims and Objectives

This study aimed to explore the pharmacists' agreement with attitudinal statements on ADR reporting. Background and demographic details were also compared in order to determine how these factors enhanced or hindered reporting. An additional aim was to obtain suggestions from the pharmacists

for methods to improve hospital ADR reporting in their particular situation.

Methods

A questionnaire was developed covering 3 main areas. Pilot questionnaires were distributed to 50 hospital pharmacists in the Yorkshire area. The first section of the questionnaire focused on the number of reportable ADRs (according to CSM criteria) that pharmacists had seen and reported personally in the past 12 months, and whether these ADRs were reported by pharmacists, Drug Information Centres, or clinicians to the CSM or manufacturers. Most pharmacists expressed difficulty in answering this question because they were unable to remember the information or incident and did not keep records of these events. Consequently, this section was replaced by more generalised questions regarding the number of ADRs seen and reported personally by the pharmacists in the past 6 months.

In the second section of the questionnaire, the pharmacists were asked to indicate their level of agreement with statements regarding aspects of ADR reporting behaviour, and identify any additional factors that may have not been considered. This section was designed based on a similar attitudinal survey involving medical practitioners in 1992.[11] Some of these statements were aimed directly at Inman's 'seven deadly sins'[12] to determine if they inhibited reporting. The remainder of these statements targeted other factors that might deter reporting, such as seriousness or rarity of the reaction, 'Black Triangle' drugs, the degree of confidence of the pharmacists and fear of legal liability. They were asked to specify any factors that may influence their decision to report an ADR. This was done to reveal any additional factors that might not have been covered.

The final part of the questionnaire dealt with personal information such as age, gender, further training and career details. The pharmacists were asked to specify the number of hours per week spent in various departments. It also prompted any suggestions to improve their reporting of ADRs.

The modified questionnaire was sent to 548 hospital pharmacists in Great Britain (13% of the total hospital pharmacist population in Great Britain) along with a freepost envelope and a cover letter explaining the background of ADR under-reporting and the aims of this study. The sample was randomly selected by the Royal Pharmaceutical Society of Great Britain (RPSGB) from their computer database. The questionnaires were distributed in July 1998 and reminder letters with another copy of the questionnaires were sent to nonresponding pharmacists 1 month later. The anonymised data were entered into Statistical Package for the Social Sciences for Windows volume 7.3 (SSPSS Inc, Chicago Illinois, 1996). The Chi-square test was used for comparison between groups. P values of 0.05 or less were taken to be significant. The answers to the open-ended questions were classified into different groups by the investigator. All the responses for job title were classified into 3 main grades: basic, senior and management. Also, the different types of hospitals were classified into district general, teaching, specialist, community and other.

Results

Of the 548 questionnaires that were sent out, 346 (63%) were returned. Of these, 136 responded after

Table I. Demographic details of the 280 hospital pharmacists whose responses to the study questionnaire were included in the study analysis

Gender	Grade	Hospital type	Work load[a]
55 male	17 basic	138 district general	52 0-5h
225 female	196 senior	68 teaching	86 6-10h
1 not reported	67 management	21 specialist	63 11-20h
		16 community	21 21-30h
		37 other	23 >30h
			35 not reported

a Hours on ward per week.

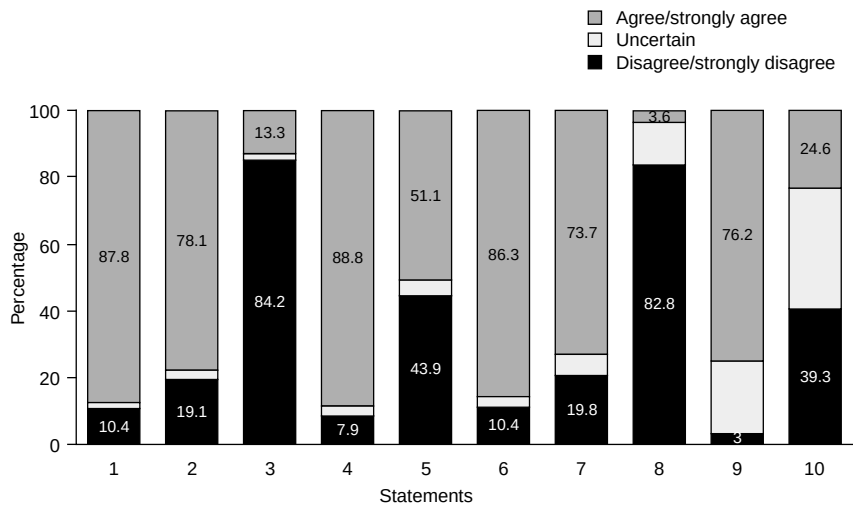

Fig. 1. Pharmacists' level of agreement with the following statements on aspects of adverse drug reaction (ADR) reporting behaviour. **1** = I am more likely to report a serious ADR, than a trivial one; **2** = I am more likely to report a rarely occurring ADR, rather than a common one; **3** = I am more likely to report an ADR to an established drug than a newly marketed ('Black Triangle') drug; **4** = The more confident I am in recognising an ADR, the more likely I am to report it; **5** = If I am busy at work, I am less likely to report an ADR; **6** = The active support of the medical/pharmacy staff would encourage me to report an ADR; **7** = A written hospital policy for pharmacist ADR reporting would encourage me to report an ADR; **8** = I am fearful that the clinicians and pharmacists involved may be exposed to legal liability if I report the ADR; **9** = In spite of possible legal liability, I will continue to report any ADR; **10** = I will not report an ADR if I fear it will breach patient confidentiality.

the reminder letter was sent off. 66 questionnaires were excluded for various reasons: 29 respondents were no longer hospital pharmacists; 12 had changed addresses; 9 had no clinical duty in their job description; the remainder were retired, were not currently working, or were working overseas, etc. Therefore, 280 responses were included in the analysis (approximately 7% of the total hospital pharmacist population in Great Britain). The demographic details of the respondents are shown in table I. The 50 pharmacists from the pilot study were not included in this study.

In response to the first section of the survey, 129 of the 280 pharmacists (46%) claimed to have identified reportable ADRs within the last 6 months, 49 of these 129 pharmacists (39%) did not report the ADR to either the CSM or the manufacturers. When asked about a hospital policy, only 23 of the 280 pharmacists (8.2%) reported that their hospital had a written policy.

The results of the next section are summarised in figure 1. In an attempt to simplify the results, the answers to 'agree' and 'strongly agree' were grouped together, as were the answers for 'disagree' and 'strongly disagree'. This did not alter the conclusions drawn since the objective of this section was simply to describe the general attitudes of the pharmacists. The data from this section were not used in any statistical analysis.

88% of the respondents agreed that they were more likely to report the ADR if they were confident of recognising it. When asked for suggestions on ways to improve ADR reporting in their individual situations, the most common suggestions were to provide ADR training and meetings (34%) and a hospital written policy (24%).

Finally, the demographic details of the pharmacists were taken into consideration to investigate if they had any effect on reporting. No difference was seen between the 2 genders in reporting ADRs (p

= 0.675). There was also no significant difference seen in tendency to report within the different age groups (p = 0.610). When the different types of hospitals were compared, there were no significant differences in tendency to report (p = 0.829). Although the results were not statistically significant (p = 0.084), they showed an increasing tendency to report ADRs by pharmacists who had received training (fig. 2). Furthermore, there was an increasing tendency to report ADRs with increasing seniority (p = 0.008) [fig. 3]. Although the results are not statistically significant (p = 0.084), figure 4 shows that pharmacists who spent 21 to 30 hours per week on wards reported the most ADRs.

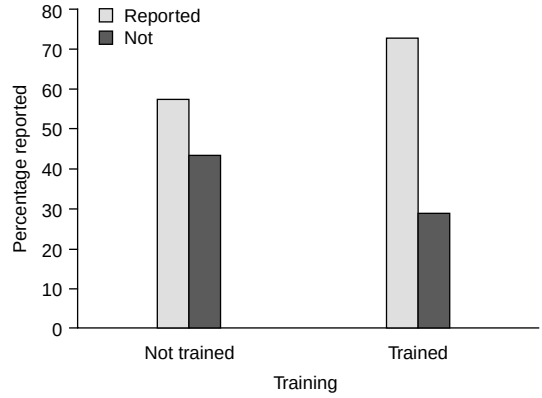

Fig. 2. Impact of level of training on reporting. Results from the 129 pharmacists who had seen an adverse drug reaction.

Discussion

Under-Reporting of Adverse Drug Reactions (ADR) by Hospital Pharmacists

One of the main features that distinguish this study from any previous studies is that it is the first questionnaire study conducted amongst individual pharmacists. Thus, a more personalised view on reporting from specific individuals responsible for this task have been obtained. During the pilot study, it was noted that many hospital pharmacists did not keep the record of the 'Yellow Cards' that had been sent and the outcomes of the ADRs were not known.

Furthermore, it also casts doubt on Ferguson and Dhillon's study,[13] where they had suggested that hospitals with designated ADR pharmacists reported significantly more 'Yellow Cards' than the hospitals without. These results could be interpreted that hospitals with designated ADR pharmacists might have a better record keeping system rather than more ADR reporting. If individual pharmacists do not maintain records (as shown in our study), then it would be impossible for pharmacy departments to provide accurate data on the number of reports.

As this is the first study of this kind, we were unable to calculate the required sample size prior to the study. However, the final results covered 7% of the total hospital pharmacist population, which should be sufficient enough to provide representative results. Furthermore, when compared with a similar study on medical practitioners,[11] (sample size = 1.5%), this study covered a much higher percentage of the targeted population.

49 of the 129 pharmacists (39%) who had identified ADRs did not report them. In concordance with previous studies,[8-10] this study also suggests that hospital pharmacists may be under-reporting ADRs.

Attitudinal Statements

The results (fig. 1) show that hospital pharmacists said they were more likely to report serious, rare or 'Black Triangle' drug–associated ADRs.

88% of the respondents agreed that they were more likely to report the ADR if they were confident of recognising it (fig. 1). However, the CSM/MCA strongly urge pharmacists not to be deterred by any uncertainty regarding the cause and effect of an ADR.[14] One of the main purposes of the 'Yellow Card Scheme' is to identify unrecognised reactions; therefore, it is particularly important to report reactions that have not been recognised previously but are clinically plausible. The CSM/MCA stresses that 'conclusive evidence that a drug was responsible for an adverse reaction was not required before submitting a report'.[14] Such misconceptions could be improved by more training in pharmacovigilance, which may enhance the confi-

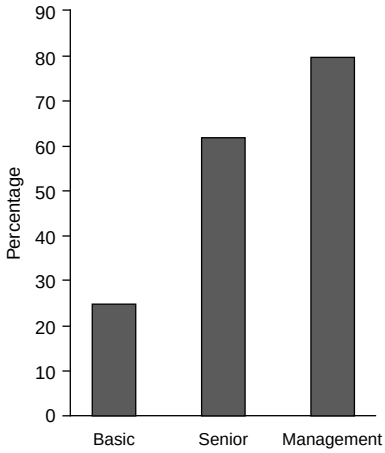

Fig. 3. Impact of seniority on reporting. Results from the 129 pharmacists who had seen an adverse drug reaction.

dence of pharmacists in recognising ADRs, as well as to decide which ADR should be reported.

51% of pharmacists revealed that they are less likely to report an ADR if they are too busy (fig. 1). Although this is actually only the pharmacists' perception and they may act differently in a case of an actual ADR, this could be ground for a major barrier to ADR reporting. In contrast, in a previous study, only 21% of medical practitioners reported that being too busy would discourage them from reporting ADRs.[11] The reason for such differences is not clear, but one speculation is that clinicians may consider reporting ADRs as part of their 'normal' duty. On the other hand, pharmacists may regard reporting ADRs as an 'additional' duty. In view of the current climate in the UK National Health Service and chronic shortage of hospital pharmacists in the UK, it is unlikely that hospitals can increase pharmacy staffing levels. However, support from hospitals or managers may provide the necessary incentive for hospital pharmacists to take time out of their busy schedule in order to report ADRs. In fact, 86% of pharmacists agreed that active support from the medical/ pharmacy staff would encourage them to report ADRs (fig. 1).

There was some controversy when addressing the issue of patient confidentiality. A quarter of the respondents agreed that they feared that it would breach patient confidentiality if they reported an ADR. However the CSM/MCA emphasise that 'information on the identities of patients and reporters sent to the CSM/MCA and the Regional Monitoring Centres is confidential and is not released without the permission of the reporter'.[14] Therefore, pharmacists have no reason to be concerned about this issue.

Suggestions from Respondents that Could Improve ADR Reporting

The most common suggestion to improve ADR reporting was to provide ADR training and meetings for pharmacists (table II). Only 45 of 79 of those who had not received any formal training (57%) had reported an ADR, whereas 34 of 47 of the pharmacists who had received training (72%) had reported the ADRs that they had identified (fig. 2). Although the results were not statistically significant ($p = 0.084$), they showed an increasing tendency to report ADRs by pharmacists who had received training.

24% of the respondents suggested that a hospital written policy would improve ADR reporting in their individual situations (table II). In spite of this, only 23 of the 280 pharmacists (8%) in the survey had

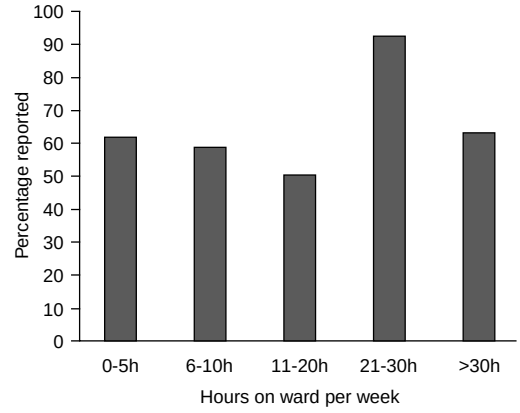

Fig. 4. Impact of hours worked on ward on reporting. Results from the 129 pharmacists who had seen an adverse drug reaction.

a written policy at work and all 23 of them agreed that a written policy had encouraged them to report ADRs. A comparison was made to investigate whether a policy could improve pharmacists recognising ADRs. Only 113 of the 247 without a policy (46%) claimed to have seen a reportable ADR in the past 6 months, whereas 15 of the 23 who had a policy (64%) saw a reportable ADR during this time. Furthermore, 68 of the 247 pharmacists who did not have a policy (28%) reported an ADR, whereas 10 of the 23 working in a hospital with a policy (45%) reported at least 1 ADR. However, the results were not statistically significant ($\chi^2 = 3.20$; $p = 0.071$).

Figure 3 shows that there was an increasing tendency to report ADRs with increasing seniority ($p = 0.008$). Because of the wide variety of job titles, it was necessary to classify the pharmacists as 'basic', 'senior' or 'management'. This may be due to the fact that as the pharmacists progress, they may have greater confidence allowing them to report ADRs more readily. It is important to note that the pharmacists who had not seen an ADR were not taken into consideration. Therefore, the issue is not the ability to recognise the ADR, but the confidence to report it after being recognised.

Table II. Suggestions for improvement of adverse drug reaction (ADR) reporting

	Total no. of questionnaires	Total out of 280 questionnaires (%)
Training and ADR meetings	94	34
Written hospital policy	68	24
Allocation of time for ADR monitoring	67	24
Publicity and promotion by hospital and the CSM	41	15
Better cooperation with clinicians	39	14
Support and encouragement by the pharmacy department	33	12
More ward rounds and direct patient contact	28	10
Simplify reporting system	12	4
ADR reporting team	11	4
Feedback from the CSM	9	3
Other	3	1

CSM = Committee on Safety of Medicines.

Recommendations to Improve Reporting

In the opinions of this sample of hospital pharmacists, ADR training and meetings would be a significant step in improving hospital pharmacist ADR reporting. In this aspect, we recommend that the CSM and the RPSGB liaise with regional drug information centres and schools of pharmacy to provide more study days and training programmes for hospital pharmacists. In representation of this, the RPSGB organised a national conference on ADR reporting in the UK on 11 February 2000.[15]

Despite of the presence of a national policy regarding pharmacist ADR reporting, local policies may have a greater impact on hospital pharmacists to report ADRs, indicating the best method for reporting in their particular hospital. Moreover, they may serve the purpose of publicising and encouraging pharmacists to report ADRs. The inhouse reporting scheme in Liverpool has already shown encouraging results.[16]

Both medical and pharmaceutical staff should agree upon the local policy, especially if there are disagreements between what action should be taken. Often, important aspects could be included such as whether the drug information department should also keep a copy of the 'Yellow Card' for future reference, and whether the pharmacist should contact the company for further information.

Clinical governance requires hospitals to develop a procedure to assess and reduce medical risk. The development of a local written policy is certainly a positive step to assess the risk of ADRs and indeed before the pharmacist can report an ADR, they must be able to detect it. This means that pharmacist must be more vigilant and may reduce patient exposure to further ADRs.

A study was conducted to analyse the effect of training on hospital pharmacists.[15] The results showed that problem-based learning (costing £57 per pharmacist in 1999) lead to an increase in 'Yellow Card' reporting. However, after the 4 teaching sessions, the pharmacists themselves began to have

meetings at no extra cost and 6 months later the reporting was still higher than the baseline. This type of teaching could be easily incorporated in future postregistration training such as a postgraduate diploma or MSc in clinical pharmacy course with little extra cost to the healthcare provider.

It would be important for further studies to be carried out to test the recommendations noted here, assessing the response of the pharmacists in terms of absolute numbers of Yellow Cards reported. It would be particularly consequential to study the need for a written hospital policy and education.

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