

Do Health Professionals have Positive Perception Towards Consumer Reporting of Adverse Drug Reactions?

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ABSTRACT

Aim: The aim of this study was to evaluate the perceptions of general practitioners (GPs) and community pharmacists (CPs) in Penang, Malaysia, towards consumer reporting of Adverse Drug Reactions (ADRs).

Methodology: A cross-sectional mail survey was adopted for the performance of the study. Survey questionnaires were sent to 192 CPs and 400 GPs in the state of Penang, Malaysia. Reminders were sent to all the non-respondents after 3 weeks of the initial mailing. Data which were collected from the questionnaires were analyzed by using the Statistical Package for Social Science (SPSS), version 15. The Chi-square test was used to determine as to whether there was any significant difference between expected and observed frequencies at the alpha level of 0.05.

Results: Only 104 respondents (47 CPs and 57 GPs) returned the survey, with a response rate of 18.0% - a figure which could be considered to be low. This study indicated that GPs and CPs were aware about the importance and benefits of consumer reporting. A majority of them (88.0%) thought that consumer reporting would add more benefits to the existing pharmacovigilance program. Similarly, 97% of the respondents agreed that reporting of ADRs was necessary and 87.0% respondents had seen ADRs among their patients. However, 57 of them (6.0%), had not been aware

that the national program in Malaysia allowed consumers to report ADRs. A majority of them (97.0%) agreed that consumers needed more education regarding ADR reporting. Most of them (84.0%) thought that consumers could not write valid reports which were similar to reports which were made by healthcare professionals (HCPs). A majority of the respondents (68.0%) had not heard about the consumer reporting program in Malaysia and half of them did not believe that consumer reporting could overcome under-reporting, which was the main problem of the national pharmacovigilance program in Malaysia.

Conclusion: The GPs and CPs were aware about the importance and benefits of consumer reporting. Such reporting will add more benefits to the existing programmes in Malaysia, although the barrier that we are facing now is the doubt that they hold over patients' ability to write valid reports which are similar to reports which are made by healthcare professionals (HCPs). Therefore, the consumers need to be educated more about their medications, on how to validate any complaints that they had about the drug consumption and on how to file a proper report and channel it to the 'right' person or bodies. Equally importantly, the media and the non-governmental organizations (NGOs) should play an important role in determining the success of consumer reporting.

Key words: Adverse drug reaction, Community pharmacists, Consumer reporting, General practitioners, Malaysia

INTRODUCTION

Previous studies which were done in both developed and developing countries have shown poor knowledge of healthcare professionals on reporting of Adverse Drug Reactions (ADRs). This is due to the fact that drug safety is not being taken seriously and as it is not one of the top priorities in healthcare programs worldwide. There have been exceptions, of course; for instance, studies which were done in the U.S. and Sweden have shown that healthcare professionals (HCPs) had good knowledge on the rules for reporting ADRs. Nonetheless, in many parts of the world, there is not enough knowledge on ADRs and their reporting.

This study explored the knowledge, attitudes and practices of HCPs in Malaysia regarding consumer reporting of ADRs. Previous studies have shown that there was a lack of knowledge regarding ADRs and consumer reporting in Malaysia. This study hoped to explore this further. The perception of healthcare professionals (HCPs) towards consumer reporting will help in gaining more knowledge on consumer reporting of ADRs and on choosing the best methodology for adopting such programs in Malaysia.

METHODOLOGY

Study Design

Data were collected from all community pharmacists (CPs) (n=192)

and general practitioners (GPs) (n=400) in Penang Island by using a mail survey and a validated self-developed questionnaire on their perceptions towards consumer reporting of ADRs. The respondents were requested to mail the survey back after they had completed it. Each questionnaire included a letter of explanation and a self-addressed, stamped envelope for returning the questionnaire. Reminder letters were sent to all those who were involved, after 3 weeks of first sending the questionnaires.

Population and Sampling Method

The population which was chosen as the subjects for our research was all community pharmacists (n=192) and general practitioners (n=400) who lived in Penang island. Penang (which includes an island and a mainland) is a state which is located in the northwest part of the peninsula, Malaysia. Penang Island has a population of 0.75 million.

Development of Questionnaire

The questionnaire consisted of 6 demographic questions and 24 questions which were related to the perceptions of the HCPs towards consumer reporting of ADRs. In section A, the respondents were asked to provide relevant demographic details such as gender, year of graduation, country of graduation and length of experience and

whether they had reported any ADRs during the past 12 months. In Section B, respondents were asked to answer all the questions to evaluate their perceptions towards consumer reporting of ADRs.

Data Collection

The data was collected by sending the questionnaires by post to the respondents. After 3 weeks, reminders were sent to all who had not responded.

Data Analysis

The data which was collected through the filled questionnaires was analyzed by using the Statistical Package for Social Sciences (SPSS®), version 15.0. Frequency counts were checked for all the variables. Descriptive statistics such as frequencies (percentages) and means (sd) were used in the analysis of the data. The Chi-square test was used to determine the significant difference between the expected frequencies and the observed frequencies in one or more categories. The statistical significance was determined by using p values of less than 0.05.

RESULTS

A total of 104 respondents (47 CPs and 57 GPs) returned the survey, with a response rate of 18%. Further demographic information on the respondents can be observed in [Table/Fig-1 and 2] below.

Perception of General Practitioners Towards Consumer Reporting of ADRs

Most of the respondents agreed that reporting adverse drug reactions was necessary (n=55;96.5%). A significant difference was noted between job tenure and category of general practitioner ($\chi^2=8.668$; $p<0.05$) in the response to this question. It was observed that 68.4 % respondents (n=39) had not agreed that adverse drug reactions were considered to be serious in Malaysia. A high percentage (87.7%) of respondents had seen patients experiencing adverse drug reactions. Most of the respondents had informed their patients about adverse drug effects of their medicines (n=56; 98.2%). Respondents were asked about adverse drug reactions which could occur during the treatment. A majority of the respondents (n=52; 91.2%) had asked patients to inform them about adverse drug reactions which could occur during the treatment.

It was noted that more than three-quarters (n=43; 75.4%) of the total respondents had thought that consumers are not aware enough of adverse reactions of their medicines. Only 3.5 % respondents (n=2) had asked the patients to report directly to the national centre about adverse drug reactions of their medicines. As per the study finding, most of the respondents (n=?; 86%) thought that consumers could report ADRs through their healthcare providers. A majority of the respondents (n=39; 68.4%) had not heard that the national ADR monitoring program in Malaysia allowed consumers to report on ADRs. Almost all the respondents were pessimistic (n=37; 64.9%) about the success of consumer reporting of ADRs in Malaysia. Ninety-three percent of total respondents (n=22) believed that the involvement of patients was as important as that of healthcare professionals in reporting ADRs.

Respondents were asked regarding their agreement with respect to under-reporting of ADRs. Almost half the total respondents (n=33; 57.9%) agreed that the main problem of national program could be solved only through consumer reports. Interestingly, 86 % respondents (n=49) thought that consumer reporting would increase the knowledge on ADRs . As per the study findings, a majority of respondents (n=49; 86%) agreed that consumer reporting would improve the existing monitoring program in Malaysia.

With respect to agreement with the statement on consumer reporting and promoting consumer rights in Malaysia, results indicated that 86% of respondents (n=49) had agreed with this statement.

Item	Frequency	Percent
Gender		
Male	43	75.4
Female	14	24.6
Year of Medical Graduation		
1961–1970	6	10.5
1971–1980	19	33.3
1981–2000	31	54.4
> 2000	1	1.8
Post Graduate Qualification	14	24.56
Country of Graduation		
Malaysia	22	38.6
Other	35	61.4
Overseas graduation (country)		
Australia	2	3.5
Barbados	1	1.8
India	22	38.6
Indonesia	1	1.8
Singapore	3	5.3
Taiwan	2	3.5
UK	4	7.0
How long have you been as General Practitioners		
1–10 Years	25	43.9
11–20 Years	8	14.0
21–30 Years	13	22.8
> 30 Years	11	19.3

[Table/Fig-1]: Profile of general practitioners

Item	Frequency	Percentage
Gender		
Male	19	32.76
Female	28	48.28
Year of Pharmacy Graduation		
1971–1980	5	8.62
1981–2000	32	55.17
> 2000	10	17.24
Post Graduate Qualification		
None	46	97.8
M.Pharma	1	1.72
Country of Graduation		
Malaysia	36	62.07
Other	12	20.69
Overseas graduation (country)		
Australia	4	6.90
Scotland	2	3.45
Singapore	1	1.72
UK	3	5.17
USA	2	3.45
How long have you been a Community Pharmacists?		
1–10 years	20	34.48
11–20 years	22	37.93
21–30 years	5	8.62

[Table/Fig-2]: Demographic profile of community pharmacists

With respect to the statement on whether consumer reporting would ensure the safe use of medicines in Malaysia, 71.9% of respondents (n=41) indicated their agreement on this matter.

A majority of the respondents (n=55; 96.5%) agreed that consumers needed more education regarding reporting of adverse drug reactions of their medicines. In response to the agreement of respondents about media playing a role in the success of consumer reporting in Malaysia, 93 % of respondents indicated their agreement. Most of the respondents (n=45; 78.9%) thought that non-governmental organizations (NGOs) in Malaysia could help in playing an important role in the success of consumer reporting.

Perception of Community Pharmacists' Towards Consumer Reporting of ADRs

Over two-thirds of respondents (n=32; 68.8%) agreed that the adverse drug reaction problem was not considered to be serious in Malaysia. 85.4% (n=40) respondents had seen patients experiencing adverse drug reactions. Year of medical graduation had a significant difference with this statement, with p values of less than 0.05 ($\chi^2=6.173$, $p>0.05$). It was noted that CPs had informed the patients about adverse drug effects of their medicines (n=40; 85.4%).

When the respondents were asked about patients' behaviours in informing them about adverse drug reactions which had occurred during their treatment, most of the CPs agreed that patients had informed them (n=39; 83.3%). A majority of respondents (n=32; 68.8%) agreed that consumers were not aware enough of adverse reactions of their medicines. The question was tested on respondents' characteristics. It was noted that CPs did not ask patients to report directly to the national centre about adverse drug reactions of their medicines (n=43; 91.7%). This finding suggested that respondents believed that consumers could report about their ADRs through their healthcare providers (n=41; 87.5%). A significant difference was observed between the aforementioned statement and gender of respondents ($\chi^2=6.008$, $p<0.05$).

Slightly more than half of respondents (n=26; 56.2%) had heard that the national ADR monitoring program in Malaysia allowed consumers to report ADRs.

Nearly half (n=24; 52.1%) of respondents were pessimistic about success of consumer reporting of ADRs in Malaysia. A majority of respondents (n=44; 93.8%) believed that the involvement of patients was important as well as that of healthcare professionals in reporting of ADRs. Respondents also agreed that reports which were given by patients could be a good source of information on ADRs (n=38; 81.2%). Similarly, a majority of respondents (n=41; 87.5%) agreed that there was an urgent need of consumer reports on adverse drug effects of their medicines. More than half of the respondents (n=27; 58.3%) did not agree that the main problem of national program could be solved by consumer reports. Almost all the respondents (n=42; 89.6%) believed that consumer reporting could increase the knowledge on ADRs. Similarly, most of the respondents (n=43; 91.7%) thought that consumer reporting could improve the existing monitoring program in Malaysia.

It was observed that 83.3% (n=39) of respondents thought that consumer reporting could promote consumer rights in Malaysia. A majority of respondents (n=35; 75.0%) agreed that consumer reporting could ensure the safe use of medicines in Malaysia. According to CPs (n=40; 85.4%), consumers could not write valid ADR reports like healthcare professionals. Respondents thought that the quality of consumer reports would not be similar to healthcare professionals' reports (n=45; 95.8%).

Respondents agreed (n=42; 89.6%) that media could play a role in the success of consumer reporting in Malaysia. When the respondents were asked about whether the role of nongovernmental organizations (NGOs) in Malaysia could help in the success of the consumer reporting program, a majority of respondents agreed to it (n=39; 83.3%).

Comparison of the Perceptions of Community Pharmacists versus General Practitioners Towards Consumer Reporting of ADRs

The Chi-square test was employed to assess the different means between GPs and CPs in answer to survey questions. The respondents are given two options (yes/no) to respond to each question [Table/Fig-3].

DISCUSSION

Previous studies which were done on ADR reporting have shown that in many countries, there was a lack of knowledge regarding consumer reporting. However, this was not a global phenomenon and Green et al., [1] confirmed this by studying the attitudes of the US hospital pharmacists and their understanding of ADR reporting [2]. Authors concluded that this type of professionals had reasonable knowledge and that they supported the Yellow Card spontaneous ADR reporting scheme. They also saw education and training as two aspects that should not be abandoned, in order to keep maintaining and increasing the number of ADR reports which came from the pharmacists. Similarly, Backstrom et al., investigated attitudes of general practitioners and hospital physicians in Sweden towards spontaneous reporting of ADRs. The hospital physicians under study had good knowledge on the existing rules for reporting ADRs in the country [3]. However, a certain amount of under-reporting may be taking place because of matters which relate mainly to the medical impact of the reaction and of reporting it, and also the scientific 'myth' of not reporting only based on suspicions and due to the lack of time in the healthcare setting.

The knowledge and attitudes of community pharmacists towards pharmacovigilance and adverse drug reactions in Kadikoy district of Istanbul, Turkey, were scrutinized by Toklu and Uysal [4]. The results demonstrated Turkish pharmacists had poor knowledge on pharmacovigilance, and they stressed on an urgent need for educational programs for training professionals about pharmacovigilance and ADR reporting [4]. This was supported by Vessel et al., [5], Palaian et al., [6], and Subish et al., [7], who investigated the knowledge, attitudes and perceptions (KAPs) of some Iranian pharmacists and Nepalese healthcare professionals in the hospitals, respectively. These professionals were found to lack the necessary knowledge on the need for a spontaneous reporting and on how useful this reporting was to the regulatory authorities and public.

In a local context, Aziz et al., [8] conducted a study in Malaysia, to evaluate the causes of under-reporting of ADRs and it revealed that 81.4% of doctors, at some point, had suspected ADRs but had not reported them, while 40% of the respondents had not been aware that there was a system for monitoring the detrimental effects of drugs, and they lacked the awareness and understanding of the functions and the purpose of this national program [8].

This study hoped to enhance the research which was done by Aziz et al., and to further add to the knowledge on ADR reporting in Malaysia. This study indicated that 87% of the GPs and 73% of CPs had not reported any ADRs which were observed among their patients during the past 12 months, although a majority of respondents thought that ADR reporting was necessary and that they had seen patients with ADRs in their clinics and pharmacies. This highlights the fact that under-reporting of ADRs still persists as the main problem of the pharmacovigilance program in Malaysia. (Aziz et al., 2007). This present study indicated that the perception of GPs and CPs about the importance and benefits of consumer reporting was quite high. This was in contrast with the results of a small qualitative study which was done by Ting et al., [9], that showed low awareness among community pharmacists in Malaysia and with those of a study which had similar conclusions on the views of community pharmacists in the UK (Krska) [10]. Most of the GPs and CPs thought that consumer reporting would add more benefits, such as increasing the knowledge of and the information on ADRs, ascertaining safe use of medicines in Malaysia and promoting consumers' rights. Most of the GPs and CPs thought that patients should report ADRs through their healthcare providers, because they were not really aware of and knowledgeable about their medicines and their hazards.

Results of this study indicated the level of awareness among GPs and CPs and their perceptions about consumer awareness on ADR

No	Items and Response	GPs	CPs	p value
1	Do you think reporting adverse drug reaction is necessary? Yes No	55 2	47 1	0.57
2	In your perception, is the problem of adverse drug reaction considered serious in Malaysia today? Yes No	18 39	15 33	0.57
3	Have you ever seen any patient experiencing an adverse drug reaction? Yes No	50 7	41 7	0.48
4	Do you inform your patients about adverse drug effects of their medicines? Yes No	56 1	41 6	0.03
5	Do you ask your patients to inform you about adverse drug reactions which can occur during the treatment? Yes No	52 4	40 8	0.11
6	Do you think that consumers are not aware enough of adverse reactions of their medicines? Yes No	43 13	33 15	0.24
7	Do you ask your patients to report directly to the national centre about adverse drug reactions of their medicines? Yes No	2 53	3 44	0.43
8	Do you think that consumer can report through their healthcare providers? Yes No	49 7	42 4	0.39
9	Have you heard that the national ADR monitoring program in Malaysia allows consumer to report ADR? Yes No	17 39	27 21	0.01
12	Is the report given by patient can be a good source of information of ADR? Yes No	45 10	39 8	0.54
13	Do you agree that there is an urgent need for consumer reports about adverse drug effects of their medicines? Yes No	46 10	42 6	0.32
14	Do you agree that under reporting, the main problem of national program can be solved by consumer reports? Yes No	33 23	19 28	0.05
15	Do you think that consumer reporting will increase the knowledge about ADR information? Yes No	49 7	43 5	0.49
16	Do you agree that consumer reporting will improve the existing monitoring program in Malaysia? Yes No	49 8	44 4	0.27

17	Do you think that consumer reporting will promote consumer rights in Malaysia? Yes No	49 8	40 7	0.56
18	Is the consumer reporting will ensure the safe use of medicines in Malaysia? Yes No	41 15	36 12	0.51
19	Can consumers write valid ADR reports like healthcare professionals? Yes No	8 48	6 41	0.53
20	Do you think that the quality of consumer reports will be similar to healthcare Professionals' reports? Yes No	6 50	2 46	0.19
21	Do consumers need more education regarding reporting of adverse drug reactions of their medicines? Yes No	55 2	47 1	0.57
22	Do you agree that media may play a role in the success of consumer reporting in Malaysia? Yes No	53 4	43 5	0.39
23	Do you think that nongovernmental organizations (NGOs) in Malaysia can help and play important role in the success of consumer reporting program? Yes No	45 12	40 8	0.38

[Table/Fig-3]: Comparison of the perceptions of community pharmacists versus general practitioners towards consumer reporting of ADRs

reporting. It was found that 97.14% of the respondents agreed that reporting adverse drug reactions was necessary and 86.67% of them admitted that they indeed noticed patients experiencing adverse drug reactions. More than half of them (57.69%) were not aware that the ADR monitoring program in Malaysia allowed consumers to report ADRs, but a vast majority of them (88.46%) agreed that consumer reporting would definitely increase their knowledge on ADRs .

From our results, we can conclude that patients should be involved in the process of drug safety monitoring in Malaysia. It was found that more than 85% of the respondents answered 'Yes' for each question regarding this matter. When they were asked on whether or not they informed their patients about adverse drug effects of the medicines that they gave, 93.27% answered 'Yes'. A total of 88.46% or 92 respondents admitted that they did ask their patients to inform them about adverse drug reactions which had occurred during their treatment. All 94.23% of the respondents believed that the involvement of patients, in addition to that of healthcare professionals, was important in reporting adverse drug reactions (ADR).

Another aspect was the necessity of improving the pharmacovigilance programme in Malaysia. Most of the respondents agreed that consumer reporting would improve the existing monitoring programme in Malaysia (88.57%), thus promoting consumer rights in Malaysia (85.58%). 82.5% of the respondents were of the opinion that the reports which were given by the patients could be a good source of information on ADRs, while 84.62% supported an urgent need of consumer reports on adverse drug effects of

the medicines that they prescribed or dispensed. However, when they were asked as to whether or not they agreed that the main problem of the national program of underreporting could be solved by consumer reports, the response was weaker. The response from the participants regarding this matter only differed by 0.97%, with 50.49% of them agreeing with the statement.

We can conclude that there is a need to educate consumers and healthcare professionals regarding reporting of ADRs. Our results reflect this especially, as 97.14% of the respondents agreed that consumers needed more education regarding reporting of adverse drug reactions of their medicines. This finding was backed by their responses, which revealed that irregularities existed in ADR reports which were filed by consumers. This was due to the fact that they were not well informed about the formats and contents of good ADR reports as healthcare professionals. In a study which was done on British community pharmacists' views on patient reporting [10], the overall results suggested that British community pharmacists lacked interest in and that they did not promote direct patient reporting. Increased awareness on the benefits and mechanisms of patient reporting may be required, to ensure that pharmacists can provide the necessary support to facilitate patient reporting.

A majority of respondents thought that ADR reporting was a very serious problem in Malaysia, due to the lack of a professional education on healthcare and pharmacovigilance. As they were not aware about the purpose and function of the pharmacovigilance programmes in Malaysia, they did not agree that the quality of the patients' reports was similar to that of the HCP reports and they thought that patients could not write valid ADR reports because of their lack of education on ADRs and the purpose and function of consumer report programmes in Malaysia. Also, a majority of the respondents had not heard about the consumers' programmes in Malaysia, due to the weakness of communications between GPs and CPs and the national pharmacovigilance centre. A large number of respondents were pessimistic about the success of consumer reporting in Malaysia. Previous studies which were done in Malaysia on views of CPs towards ADRs and patient reporting, showed that most of the CPs were skeptical about the success of direct reporting of present problems. Such views on the patients' limited knowledge on their medications should be extensively discussed [9].

CONCLUSION

The GPs and CPs were aware about the importance and benefits of consumer reporting. Such reporting will add more benefits to the existing programmes in Malaysia, although the barrier was the perception that respondents doubted whether the patients could write valid reports which were similar to HCP reports. Therefore, the consumers need more education on their medications, on how to validate any complaints that they had about the drug consumption and on how to file a proper report and channel it to the 'right' person or bodies, and for the media and NGOs to play an important role on determining the success of consumer reporting.

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