

Community pharmacists' views on adverse drug reactions reporting in Malaysia: a pilot study

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Abstract *Objectives* To investigate community pharmacists' knowledge, attitudes and views on adverse drug reaction (ADR) reporting. *Setting* Seven community pharmacies in Malaysia. *Method* Structured interviews with community pharmacists. Informed consent was obtained and interviews were audio-recorded and transcribed verbatim. *Main Outcome Measures* Content analysis of themes on awareness of ADR reporting, reporting activities, attitudes and views on patient reporting. *Results* All pharmacists claimed to have some knowledge of a reporting system but only one had submitted a report directly to the regulatory authority. Despite the low level of reporting activities, all participants agreed that it was part of their professional obligation to report an ADR. Most participants were not aware of the direct patient reporting scheme and were skeptical about its success. Lack of awareness and patients' limited knowledge about their medications were viewed as barriers to patient reporting. Local attitudinal issues including pharmacists' attitude towards ADR reporting were described as possible contributing factors. *Conclusion* Community pharmacists have an important role in reporting ADRs. Many Malaysian patients are still perceived to be ill-informed of their medications, an important determinant to the success of patient reporting. There is a need for further training about

ADRs and ADR reporting for health professionals and further education for patients.

Keywords ADR reporting · Adverse drug reactions · Community pharmacist · Community pharmacy · Malaysia · Patient reporting · Pharmacists · Pharmacists' views · Qualitative interview · Under-reporting

Impact of findings on practice

- Education is required to increase awareness of ADR reporting activities amongst pharmacy students, pharmacists and other health professionals.
- In order to improve active patient participation in ADR reporting health providers in Malaysia need to improve public education about medicines including educating GPs to use proper labelling on dispensed medicines.

Introduction

One of the cheapest and effective means of monitoring the safety profile of all drugs, supplements and cosmetic products post marketing is through the spontaneous reporting of ADRs utilized by many drug regulatory agencies worldwide. In Malaysia, all ADR reports are collected and reviewed by the Malaysian Adverse Drug Reaction Advisory Committee (MADRAC). Malaysia became a member of the World Health Organisation (WHO) Programme for International Drug Monitoring in 1990. Despite having a good reporting system in place, Malaysia suffers from a low level of reporting from health

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professionals [1, 2]. There are only very few studies in Malaysia that have investigated the low reporting rates of ADRs amongst the health professionals [2, 3]. It is reported that up to 40% of the physicians were unaware of the existence of the reporting system [2].

Patient reporting of ADRs was launched in Malaysia in 2007. Both positive and negative comments on patient reporting have been extensively debated [4, 5]. Only a small number of countries including the United Kingdom (UK), Sweden, the Netherlands and Australia, have incorporated patient reporting into their pharmacovigilance systems in recent years. There is huge support by the UK Consumers Association for patient reporting ADRs directly to the Medicines and Healthcare Products Regulatory Agency (MHRA) highlighting the view that doctors often failed to pass on such information to the authority [6]. Patient reporting scheme in the UK has been well received and in the 1st year of the scheme MHRA has received more than 2400 reports directly from patients [7]. There is no published data on patient reports in Malaysia to date, but information obtained from the National Centre indicated that the number is small.

Aim of the study

This exploratory study aimed to investigate community pharmacists' knowledge, attitudes and perceptions on ADR reporting in Malaysia. We hope to use the findings to develop an informed approach for the next phase of awareness programmes amongst pharmacy students, pharmacists and consumers.

Methods

For this pilot study convenience sampling was employed and we approached seven pharmacists from Selangor and Kuala Lumpur. An interview guide was developed from the European survey II questionnaire [8] where relevant questions on pharmacist reporting activities were used. We have included additional questions on patient reporting. Informed consent was obtained from each participant and all interviews were audio-recorded and transcribed verbatim. Discussion points were categorised into themes, coded and analysed by two independent researchers [9]. These themes included the awareness of ADR reporting, reporting activities, attitudes and views on patient reporting. Additional themes emerged were local issues, training and education. Some statements from the interviews were included to illustrate the points discussed (P1–P7 code for individual pharmacist).

Results and discussion

All seven pharmacists agreed to participate and they have an average of 10 years (range 7–14 years) working experience in the community pharmacy setting.

Awareness of ADR reporting system

Although all participants were aware of some forms of ADR reporting for health professionals in Malaysia only four implied or mentioned that they knew the existence of a national monitoring centre. The majority ($n = 5$) of the pharmacists were familiar with filling up a 'form' while only one mentioned online reporting.

Only two participants knew about patient reporting scheme in Malaysia. There were elements of surprise and scepticism in the other five participants' responses when they were asked about patient reporting of ADR.

"No. They (patients) always come to us" P4.

One genuine problem highlighted by all participants is the lack of awareness of the existence of patient ADR reporting system by both health professionals and patients.

Pharmacists' reporting activity and attitudes to reporting

Five pharmacists claimed to have sent an ADR report but only one had submitted it directly to MADRAC while the rest sent them to drug companies. It appears that the majority of the participants preferred to report directly to the drug company as it was viewed as a more convenient option: *"...what I did is, I call up the company so they will assign a person I will hand the form to"* P2. In contrast, a frustrated pharmacist accounted his experience when he tried to contact MADRAC.

Many years back I have tried to report at the time but I think the process is not very good, so when I tried to call, it would go into a voice message that would pass you around and at the end, nobody picked up the phone so I just gave up. I am not sure how you would do it now P3.

More than half ($n = 4$) of the participants revealed that they had come across more ADR cases but did not report them. The most frequent reason cited was that the reaction was common and mild. This reason has been identified as the strongest determinant for not reporting ADR [2]. Other reasons quoted included *"the procedure is a bit tedious"* P2; *"time constraints"* P5 and *"...the reporting system process itself is quite complicated"* P3. Such factors have been reported in other studies [2, 8].

Despite their low level of reporting activities, all participants agreed that ADR reporting is part of their professional roles as a community pharmacist. One clearly identified the importance of post marketing surveillance of newly registered drug through the ADR reporting system “...the bit after the actual launching of the drug is when some serious side effects can be detected and most of the pharmacists will be the first person the patient will contact...” P5.

Perceptions on patient reporting and local issues

Most ($n = 6$) were sceptical about the success of the direct patient reporting in Malaysia at present. Problems such as lack of awareness and the perceived patients’ limited knowledge on their medicines were extensively discussed.

Malaysians at large are, they are not very well informed about their medication because even now, the GP’s and all the clinics, they don’t even write down what are the medication they are taking which is quite bad, because imagine, patients don’t even know what they are consuming P6.

The problem of patients not knowing which drug he/she has been treated is a great concern. Practices of dispensing without proper labelling are common amongst the General Practitioners in Malaysia. Community Pharmacists do not have exclusive dispensing rights in Malaysia. In such a situation the active participation of patients will be difficult to achieve within the next few years [5]. However, this barrier has not stopped MADRAC’s initiative to accept patient reports. It was probably viewed that the scheme would benefit patients from the more educated classes.

A number of the interviewed pharmacists ($n = 3$) believed it would be more effective if patients could report any ADR through their health providers as they felt that this formed an essential filtering system with regards to the judgement of the seriousness of an ADR.

Depending on the education level of the patient, they may give a lot of irrelevant information and may skip out a lot of relevant information; so it is better to have healthcare personnel to help them report, to get the relevant information... P7.

It has been highlighted that not all ADRs experienced by patients are discussed with their health professional and that when they are, some had the view that the health professionals are not sending patients’ complaints to the relevant authorities [5, 6, 10]. A general consensus was that reporting through a health professional was essential in a country where patients are ill-informed of their medication [5]. This is an important factor to consider for Malaysia at present.

Only one participant was optimistic about the scheme but elaborated on the lack of awareness “*I don’t think our government have really advertised on paper and not many consumers are aware.But, I must say the awareness is not there despite the fact that it is very easy to log on online and send it off...*” P5.

Media advertisements, posters and distribution of leaflets were common suggestions to improve awareness and patient reporting. Communications through local consumer associations was also proposed. Interestingly, local attitudinal issues including pharmacists’ attitude towards ADR reporting were described as possible contributing factors to the perceived lack of patient participation.

I think most of our patients reluctant to do that even though they experience that side effect, they wouldn’t like to do that P2.

We can actually promote it to the consumers and patients but we have to start it with ourselves first.... P6.

Training and education

Participants in the study repeatedly mentioned the importance of education. Training and education have been identified as important features to improve awareness and reporting activities [2, 5]. It is imperative that such activities should be targeted at patients, the media, consumer organisations and health providers [5]. Feedback from the authority was also deemed to be a determinant to improve reporting [5].

..well maybe they have to re-educate the community pharmacists to tell them now they can report it there.....at least they could give us the feedback when they see the report.... P3.

...have a scheme but we don’t educate the public. I don’t think they would like it but even for pharmacists, if there isn’t any proper guideline for it, it won’t work P6.

The first thing is to improve the awareness and the service but education is still the most important... P7.

Limitations and conclusion

The small convenience sample is the main limitation of the study. As it is an exploratory study, the findings may not represent the views of the majority of community pharmacists in Malaysia. It is however, reassuring that many issues identified in our study have been previously discussed [2, 4, 5, 8]. Community pharmacists have an important role in reporting ADRs as they serve on the

frontline of healthcare. Local attitudinal issues towards ADR reporting are interesting variables that should be further investigated. Many Malaysian patients are perceived to be ill-informed about their medications and this is viewed as a barrier to active patient participation. The two main concerns highlighted are lack of awareness and the need to look into the training and education aspects of ADRs and ADR reporting for all parties involved.

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