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Original Research

The PharmWatch programme: challenges to engaging the community pharmacists in Jamaica

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ABSTRACT[*]

In February 2006, there was a renewed effort to encourage reporting of adverse drug reactions (ADRs) in Jamaica. It involved renaming the process the "PharmWatch" programme and revising the reporting form.

Objectives: The aims of this study were to assess the attitudes of community pharmacists to ADR reporting and to assess their utilization of the PharmWatch programme.

Methods: The survey was conducted in January 2007, involving 102 community pharmacists islandwide. A questionnaire was designed to assess their attitudes towards ADR reporting, their awareness of the PharmWatch programme and also to collate number of ADRs through recall. Pharmacists were then followed prospectively to collect ADRs occurring over the next three months using the PharmWatch form.

Results: Although most of the pharmacists involved in the survey had more than five years of experience, the majority (67%) were not aware of the PharmWatch programme; however, 86% of the responding pharmacists indicated that they accepted that ADR reporting was a professional responsibility. They identified "reaction already known", "more information needed about reporting ADRs" and "lack of time" as key factors that would cause non-reporting. One hundred and twenty eight retrospective ADRs were collected; none were reported to the Ministry of Health directly, while two were reported to the respective drug companies. A three month prospective follow-up with pharmacists yielded 45 reports. The most common ADR reports among both the retrospective and prospective data were associated with anti-infectives.

Conclusions: The results suggest that awareness of the PharmWatch programme is not adequate to facilitate active participation in ADR reporting. More proactive interventions, such as continuous training and encouragement in the use of ADR reporting should be considered.

Keywords: Adverse Drug Reaction Reporting Systems. Pharmacists. Jamaica.

PROGRAMA PHARMWATCH: EL RETO DE INVOLUCRAR A LOS FARMACÉUTICOS COMUNITARIOS EN JAMAICA

RESUMEN

En febrero de 2006 hubo un nuevo esfuerzo para animar a la comunicación de reacciones adversas (RAM) en Jamaica. Conllevó el cambio de nombre a "PharmWatch" y la revisión del formulario de comunicación.

Objetivos: Los objetivos de este estudio fueron evaluar las actitudes de los farmacéuticos comunitarios a la comunicación de RAM y evaluar su utilización del programa PharmWatch.

Métodos: La investigación corrió en enero de 2007, involucrando a 102 farmacéuticos comunitarios de toda la isla. Se diseñó un cuestionario para evaluar sus actitudes hacia la comunicación de RAM, su conocimiento del programa PharmWatch y parta recopilar algunas RAM por reclamo. Se siguió a los farmacéuticos prospectivamente para recoger las RAM que ocurrieron en los tres meses siguientes utilizando el formulario PharmWatch.

Resultados: Aunque muchos de los farmacéuticos involucrados en el estudio tenían más de 5 años de experiencia profesional, la mayoría (67%) no conocía el programa PharmWatch; sin embargo, el 86% de los respondentes indicaron que aceptaban que comunicar RAM era una responsabilidad profesional. Identificaron "reacción ya conocida", "necesidad de más información sobre comunicación de RAM" y "falta de tiempo" como los factores que podrían causar la no comunicación. Se recogieron 128 RAM retrospectivas; ninguna fue comunicada directamente al Ministerio de Salud, mientras que 2 fueron reportadas directamente a los laboratorios fabricantes. Un seguimiento prospectivo de 3 meses rindió 45 comunicaciones. Las RAM más comúnmente comunicadas, tanto en el retrospectivo como en el prospectivo, estaban asociadas a antiinfecciosos.

Conclusiones: Los resultados sugieren que el conocimiento del programa PharmWatch no es adecuado para facilitar la participación activa en la comunicación de RAM. Deberían considerarse intervenciones más proactivas, como la formación continua y el aliento de la comunicación de RAM.

Palabras clave: Sistemas de comunicación de reacciones adversas. Farmacéuticos. Jamaica.

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INTRODUCTION

While clinical trials involving drugs provide significant information on the efficacy of pharmaceuticals, they provide limited information on the safety of their use because of the controlled conditions under which pre-marketing clinical trials take place. These trials occur with small numbers, sometimes excluding the elderly, children, patients with co-morbidities or on multi-drug therapy and are also of limited duration.[1] Therefore there are inherent risks when drugs enter the general market and their usage essentially becomes a balancing act of benefits verses adverse drug reactions.

An adverse drug reaction (ADR), as defined by the World Health Organization[2], is 'the response to a drug which is noxious and unintended and which occurs at doses normally used for the prophylaxis, diagnosis or therapy of a disease, or for the modification of physiological functions. These ADRs may be previously described or appear with use of the drug in the general market. To ensure that an ADR is not missed, it is estimated that at least 30,000 persons need to be treated with a drug to produce an incidence of 1 in 10,000 exposed persons.[3] Therefore, adequate assessment of the safety profile of a drug requires active pharmacovigilance.

Pharmacovigilance, as defined by the World Health Organisation, is the pharmacological science and activities relating to the detection, assessment, understanding and prevention of adverse effects, particularly short- term and long -term side effects of medicines, or any other drug related problems.[4] Therefore pharmacovigilance will effectively encourage safe, rational and more effective use of drugs. It has been estimated that through pharmacovigilance, 1 in every 5 drugs on the market has been discovered to have a serious ADRs (e.g. requiring hospitalization or causing death) resulting in changes made to drug monographs or withdrawal from the market.[5] It was through pharmacovigilance that incidence of cardiovascular complications occurring with Cisapride, Terfenadine, Tegaserod and Rofecoxib warranted their removal from the market.[6-8]

In Jamaica, through the Pharmaceutical and Regulatory Unit of the Ministry of Health, all healthcare professionals are encourage to report ADRs using the spontaneous ADR monitoring form. This unit collects these reports, undertakes further investigations and takes appropriate actions. Oral communication with the Ministry of Health indicated that there is very little use of the spontaneous ADR form by health professionals. In 2006, through a collaborative effort involving the Ministry of Health and the Pharmacology Section of the University of the West Indies, there was a renewed effort to encourage utilization of spontaneous ADR reporting with the design of the PharmWatch programme. The original ADR reporting form was revised in February 2006 to produce a "PharmWatch" form to report ADRs. This form is currently available to all healthcare professionals and patients from the Ministry of Health and Pharmacology section of UWI.

The form was also placed on the website of the Jamaica Pharmaceutical Society in an effort to encourage pharmacists to become actively involved in the reporting process. Many countries have the active participation of pharmacists, especially community pharmacists in ADR reporting and have indicated that pharmacists' involvement in this process can make significant contributions to the benefit verse risk analysis among populations.[9-12] Therefore it is important to engage the Jamaican pharmacists in this process.

In January 2007, an islandwide survey of practicing community pharmacists was done. The aims of the survey were to assess the attitudes of community pharmacists to ADR reporting and their awareness of the PharmWatch programme.

METHODS

The study design employed a retrospective opinion survey of community pharmacists in Jamaica. The list of registered pharmacies as of August 2006 was obtained from the Pharmacy Council of Jamaica. One hundred and two pharmacies were randomly selected from the three counties of Jamaica (Cornwall, Middlesex and Surrey) to conduct the survey. The survey required one pharmacist from each pharmacy to complete a short questionnaire that was designed by nine pharmacists, each with over five years of community pharmacy practice experience. It was then validated by pharmacists in the pharmacy training programme at the University of Technology, Jamaica (UTech). The final questionnaire was drafted, taking reviewers comments into consideration. The questionnaire included demographic information, as well as their opinions on the importance of ADR reporting and whether they were aware of the PharmWatch programme. They were also asked to indicate the factors that affect their reporting of ADRs and to record all the ADRs they could recall occurring in the last twelve months. They were then provided with copies of the PharmWatch form, which they were required to use to record all ADRs occurring in the next three months (prospectively). Pharmacists were called on a weekly basis as a way to encourage the participation.

The information on the questionnaires was treated with the SPSS version 12 for frequency analysis.

RESULTS

Pharmacists (one per pharmacy) from 102 community pharmacies islandwide (Cornwall = 36, Middlesex = 36 and Surrey =30) participated in the survey; this represents 28.8% (total number of registered pharmacists = 354) of the pharmacies registered with Ministry of Health, as of August 2006. The majority, 75%, of the pharmacists had more than five years of professional experience in pharmacy practice.

Awareness of PharmWatch programme and challenges

The majority of the pharmacists involved in the survey, 67%, were not aware of the PharmWatch programme. However, 86 % of the responding pharmacists indicated that they accepted that ADR reporting was a professional responsibility and only 5% thought ADR reporting was a low priority task.

When pharmacists were asked what would contribute to them not reporting problems to the Ministry of Health, the top three reasons given were, "reaction already known", "more information needed about ADR reporting" and "lack of time" (Table 1). However fifty percent of them indicated that reporting ADRs would increase if an incentive for reporting was granted.

Table 1. Reasons given by pharmacists for not reporting ADRs*

Reason affecting reporting of ADRs	% of pharmacists
Reaction already known	50
Limited time to spend with patient	38
More information about ADR reporting needed	35
lack of time/too busy	32
Lack of motivation	23
lack of confidence in making the report	18
Patient confidentiality	12
* Pharmacists were able to tick more than one reason.	

Retrospective and prospective ADR reports

The questionnaire asked pharmacists to list any ADRs they could recall in the past twelve months. Over the three counties, 128 ADRs reports were collected of which none were reported to the Ministry of Health; but, two were reported to the respective pharmaceutical companies.

Once pharmacists agreed to participate in the survey and made aware of the PharmWatch programme, they were then asked to participate in a monthly follow-up for three months. During this time they were expected to record any ADRs occurring using the PharmWatch form. For this time period, 45 forms were collected, but in most cases only the name of the drug, the reaction that occurred and the action taken were noted. For both the retrospective and prospective ADRs, anti-infective drugs dominated the reports (39.1% and 37.8% of the reports respectively).

DISCUSSION

Pharmacovigilance on a national level is important for assessing the occurrence of differences that can result from factors related to diet, genetics, herbal product use or cultural practices.[3] In this survey, we found that while community pharmacists were aware that they have a critical role in ADR reporting, most were not aware of the PharmWatch programme. Pharmacists involved in the survey were able to list 128 ADRs that occurred in the twelve months prior to participating in the survey; of which none were ever reported to the Ministry of Health. Reporting of ADRs plays a significant role in ensuring the safe use of drugs[6]; therefore the unavailability of reports to the Ministry of Health will affect the success of the PharmWatch programme. For example, the most common ADRs reported in this survey were associated with anti-infective drugs; while this is an expected trend[13,14], their benefits are significantly influence by resistance development and therefore evaluation of these ADRs may be critical for resistance detection.

Another factor that requires community pharmacists' active involvement in ADR reporting is the need to facilitate confidence in the efficacy of drugs. In the United States, through active surveillance of ADRs, it was determined that "failure of therapy" rated as the top ADR outcome during the period 1969 to 2002.[6] Promoting ADR reporting to ensure efficacy is of particular importance in the Jamaican setting, where pharmacists are mandated to offer patients generic alternatives to the more expensive innovator brands. Most pharmacists (and physicians) have expressed lack of confidence in many generics[15,16]; however, with non-reporting of ADRs, the Ministry of Health would be unable to adequately address this issue.

Community pharmacists in this survey indicated reaction already known, lack of information about ADR reporting and confidence in making reports, as reasons for not reporting ADRs. Therefore, insufficient knowledge is a major challenge to community pharmacists' participation in ADR reporting. Lack of time and motivation were also given as predominant reasons for non-reporting. These major challenges of Jamaican community pharmacists are consistent with those identified by pharmacists in other countries[1,9,17,18], and suggests that pharmacists' awareness of the PharmWatch programme is inadequate to promote the current pharmacovigilance system. This fact was very clear from quality of the prospective ADR reports collected; while this part of the survey netted 45 reports, in most cases, only the name of the drug, the reaction that occurred and the action taken were noted. Continuous training and encouragement in the use of the PharmWatch programme should therefore be considered; as such interventions can improve pharmacists' participation in ADR reporting.[19-21]

CONCLUSIONS

Spontaneous ADR monitoring is a standard process proven to be an important part of evaluating the safety of drugs in the general market. This is the first report that assesses the attitudes of community pharmacists in Jamaica towards pharmacovigilance and specifically their willingness to participate in ADR reporting. While it is encouraging that most of the pharmacists were aware that they have a significant role in ADR reporting, much needs to be done to engage their participation including providing training opportunities.

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CONFLICT OF INTEREST

The authors declare that they have no competing interests.

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