Knowledge and Practice of Reporting of Adverse Drug Reactions among Community Pharmacists in Ilorin, North-Central, Nigeria

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ABSTRACT

Background: Pharmacovigilance (PV) is the universal collation of adverse drug reactions (ADRs) intended to enhance the understanding of safety of medicines globally. Reporting of ADRs by healthcare professionals is vital for the success of PV.
Objectives: To examine knowledge and practice of reporting of ADRs among community pharmacists (CPs) in Ilorin.
Materials and Methods: A cross sectional survey was carried out using self-administered questionnaire developed for the purpose of the study among CPs present at their monthly meeting in March, 2016.
Results: Majority of the CPs were male (15 CPs; 78.95%), mean age of 46.06 years and duration of practice ranged from 2 to 30 years. Almost half of the CPs (47%) had no additional formal training and virtually all the CPs (84%) would like training on ADRs reporting. More than half of the CPs (58%) never reported ADRs identified from patients and one-fifth would only report when certain that the reaction was caused by the drug. CPs expressed concerns in reporting such as non-availability of ADR reporting yellow forms.
Conclusion: The study revealed moderate reporting of ADRs among CPs and suggests the need for appropriate and timely trainings of CPs on the reporting of ADRs and access to resources for proper reporting of ADRs. Larger studies are recommended to corroborate and further explore the findings of the study.

Key words: Adverse Drug Reactions; Pharmacovigilance; Spontaneous Reporting; Community Pharmacists; National Pharmacovigilance Centre; NAFDAC

INTRODUCTION

The World Health Organization (WHO) defines an adverse drug reaction (ADR) as an acute or delayed noxious and unintended response to a drug, (herb, traditional or complementary medicines, biologicals, vaccines, blood products, and medical devices) which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological functions[1-4]. Adverse drug reactions (ADRs) are common cause of morbidity[5], hospitalization[6-9], mortality[5,7] and economic burden[10-11] to the healthcare system globally[2,11]. ADRs were ranked among the top ten (10) leading causes of mortality [5,7,12,13] and identified as the 4th to 6th leading cause of mortality in a year [2,14]. A projected annual cost of ADRs was reported as £466m (706 Euro, $847m)[7] while an additional cost of hospitalization for 34 patients was reported as 1.83 million naira in Nigeria[11]. ADRs have also been identified as one of the factors that reduce patients' adherence to therapy[15].

Pharmacovigilance (PV) is described as the science and activities involving the detection, assessment, understanding and prevention of noxious effects or any other possible drug-associated problem[1-4,16-22]. PV as spear-headed by the WHO involves an international scheme of collection of ADRs into a central database for detecting previously unknown or poorly understood adverse effects of medicines[1-4, 18-22 .] A major aim of PV is to contribute to the work of national drug regulatory authorities in improving the safety profiles

of medicines, and preventing further disasters[2,20].

PV basically entails post-marketing surveillance of all medicines throughout their life span, thereby allowing detection of new or increase in frequency of known ADRs[-21]. The thalidomide crisis was an awakening call to the limitations of pre-marketing clinical trials in the fifties resulting in the emergence of PV[2,18-22]. Identification of a case report linked with thousands of congenital abnormality or birth defects of children born with phocomelia had led to the withdrawal of the drug in 1965[2].

Initially, the global progress had been slow and few countries were earlier involved in the international PV scheme, however the numbers have since grown especially in the last decade, though individual countries have their own framework[22,23]. Nigeria became the 74th Member of the WHO-PV program for international monitoring in September 2004, almost 50 years later [18,19, 23]. Most pre-market testing of drugs are not conducted within Nigeria and the PV system is not well developed, therefore all suspected ADRs are mandated to be reported in Nigeria[18,19,23]. A National Pharmacovigilance Centre is situated in the Federal Capital Territory (FCT), Abuja and being run by the National Agency for Food and Drug Administration and Control (NAFDAC)[18,19]. In addition, there are PV centers in each of the 36 States with zonal headquarters in each of the six geo-political zones[18,19].

Spontaneous (voluntary) reporting is a primary method used in PV [2,19]. A spontaneous report (SR) is an unsolicited communication by healthcare professionals or consumers describing one or more ADR occurring from one or more medicinal products[24,25]. However, under-reporting of ADRs remains a major challenge globally[26] despite the benefits of SR of suspected ADRs[27]. In a study, it was estimated that only 6 – 10% of all ADRs are reported[26]. The reason for under reporting of ADRs are multifaceted and therefore may vary in different countries[24,28,29].

The need for PV is more heightened in low economy countries and black ethnic population[22,30]. Evidence has shown that low-income countries have the lowest rate of ADR reporting (0 - 21 reports/million inhabitants/year) compared to high-income countries (3 - 613 reports/million inhabitants/year)[30]. The safety profile of medicines used in developing countries and blacks are less reassuring due to disproportionate representation in clinical trials[31]. Variation in disease, prescribing pattern, general healthcare practices, cultural belief, lifestyle, age and genetic predisposition can influence the outcomes of adverse effects of medicines[25,30,32,33]. Also, studies have demonstrated that patterns of ADRs are determined by race and economic situation of a population[13,30,34].

Pharmacists as healthcare professionals are crucial to the success of PV[35,36] through SR[27], however it is known that pharmacists' report of ADRs in some countries may not be accepted [26,28,29,37]. Fortunately, Nigeria is one of the many countries that require pharmacists to also participate in reporting of ADRs as a professional responsibility, albeit it is not mandatory[38-40]. The community pharmacy is often the first point of visit prior to contacting the physician[41] thereby making the community pharmacists (CPs) an indispensable link between physicians and patients[42]. It is easy for patients to visit community pharmacies because of their wide geographical distribution and accessibility without the need for an appointment[36]. The CPs have distinct roles of dispensing, counseling and monitoring of drug usage and abuse to a wide and diverse type of patients and the public[43,44].

Since CPs are the most accessible healthcare provider to the public[41,43] and serve patients with and without prescriptions, their knowledge and active participation in ADR monitoring and reporting is expected to improve the scope and quality of spontaneous ADR reporting. Meanwhile, previous studies have shown poor reporting of ADRs among healthcare professionals including CPs[10,12]. However, at the time of this study no published work was identified among CP within the North-Central region where a zonal PV is located. Therefore, the present study was carried out to examine knowledge and practice of reporting of ADRs among community pharmacists in Ilorin metropolis of Nigeria.

MATERIALS AND METHODS

Study design

A cross-sectional survey of community pharmacists (CPs) was employed in the study.

Population setting

Ilorin is the capital city of Kwara State. Meetings of all CPs are held in Ilorin once in a month. At the time there were about 100 community pharmacies in Kwara State.

Inclusion and Exclusion criteria

All fully registered pharmacists practicing in a community pharmacy either part time or full time present at the monthly meeting in March, 2016 during the period of the study were eligible to take part in study. Pharmacists who gave their consent were included in the study. Pharmacists who were not fully registered or not practicing in a community pharmacy and who did not agree to participate were excluded from the study.

Sampling

The study involved a convenience sample of registered CPs present at the general monthly meeting in March, 2016.

Approval and Informed consent

Permission was obtained from the head of the Association of CPs prior to the study. The CPs were further informed about the purpose of the study by the researcher during the meeting and signed consents were obtained from CPs who agreed to participate in the study.

Data collection

A short questionnaire developed for the purpose of the study was distributed to CPs and collected at the end of the meeting by the researcher [a]. The questionnaire included a short introduction on the purpose of the study and informing participants that the findings would be disseminated in published reports.

Study questionnaire

The questionnaire was brief due to the very tight schedule of the meeting and consisted of six short questions and an open-ended question for opportunity to provide further comments. In addition, the number of years of practice in community pharmacy and demographic information which included gender and age were collected. No financial incentives were exchanged for the study.

Data analysis

Data were analyzed using descriptive summary statistics by determining frequencies and percentages of responses of the participants. Content analysis was used to identify similar themes from the responses to the open-ended question. Microsoft excel was adopted for data analysis.

RESULTS

A total of 19 community pharmacists (CPs) completed the questionnaire out of 29 CPs at the time of data collection, giving a response rate of 66 % of CPs in the meeting and about 36 % of the

population of community pharmacies located in Ilorin.

Demographic and years of practice of community pharmacists

Majority of the CPs were male (15 CPs), the mean age was 46.06 (range: 28 to 64 years), while 3 CPs did not provide their age, Table 1 below. The mean years of experience of practicing as CPs was 11.5 years (range: 2 to 30 years) and more than half (10 CPs) had practiced for at least ten years in community pharmacy practice.

Table 1: Demography of community pharmacists and Years of practice in community pharmacy

Demography	Frequency (percentage)
Gender	
Female	4 (21.05)
Male	15 (78.95)
Age in years	
Less than 30	2 (10.53)
31 - 45	3 (15.77)
46 - 60	10 (53.63)
above 60	1 (5.26)
No response	3 (15.79)
Range	28 - 64
Mean	46.06
Years of practice in community pharmacy	
0 - 1	0 (0)
above 1 - 5	6 (31.57)
6 - 10	5 (26.32)
11 - 15	2 (10.53)
16 - 20	2 (10.53)
21 - 30	4 (21.05)
above 30 years	0 (0)
Range	2 - 30
Mean	11.5

Knowledge and Practice of reporting of Adverse drug reactions

Tables 2 to 4 below shows the findings of the responses to questions used to elicit knowledge and practice of reporting of adverse drug reactions (ADRs) reporting among CPs in the study. Table 1 shows the meaning of the acronym ADR by almost half (42 %) of the CPs and details of definition of ADR among 9 CPs (47 %) presented in Table 2. A considerable proportion (47 %) of the CPs had no formal training on ADR reporting. Amongst those who had formal training (10 CPs) almost a quarter (4 CPs) revealed they had their training 2 to 15 years ago. Four CPs stated they had their training through a regulatory body (NAFDAC) while 1 CP mentioned that his training was through a pharmaceutical care training program. On the other hand, almost all the CPs (84 %) would like to have additional training. The results also showed 58 % of the CPs had reported ADR, albeit majority (64 %) had identified cases of ADRs in the pharmacy. Meanwhile, about 20 % of the CPs felt that reporting of ADR should be done only when it is established that an actual ADR experienced was being caused by the drug. Table 3 shows a variety of concerns were further elicited from the open-ended comments are presented.

Table 2: Knowledge and Practice of Reporting of Adverse Drug Reactions among Community pharmacists

Study questions	Responses (Frequency of Community Pharmacists (CP): Percentage)
1. What is ADR?	Adverse drug reaction (8 CPs: 42%); Detailed definition (9 CPs: 47% and Table 3); No response (2 CP: 11%)
2. Have you ever had any formal training on ADR reporting?	Yes (10 CPs: 53%); No (9 CPs: 47%)
3. Would you like to have more training on ADR reporting?	Yes (16 CPs: 84%, and Table 3); No (2 CP: 11%); No response (1 CPs: 5%)
4. Have you had to report ADRs to NAFDAC?	Yes (8 CP: 42%); No (11 CP; 58%)
5. How often do you get cases of ADR in your pharmacy?	Weekly (1 CP: 5%); Monthly (5 CP: 26%); Occasionally (12: 64%); Never (1CP: 5%)
6. What report of ADR should you be reporting to NAFDAC?	Any suspected ADR (12 CP: 63%); When certain patient experienced ADR (5 CP: 26%); Both (2 CP: 11%)

Table 3: Definitions of ADRs reported among community pharmacists

"when a patient cannot tolerate the side-effects of a drug due to body composition"
"an undesirable / harmful effect from the use of drug"
"untoward reactions after administration of drugs"
"unintended effects of a drug"
"a reaction to drug outside the normal action of the drug for which it is prescribed or produced"
"side-effects seen on any medications taking. OR other medical effect seen apart from main indications"
"a reaction that occurs in a patient even at normal therapeutic doses of drugs"
"unintended effects produced by a drug as against its intended purpose"
"any untoward effect of a drug, that occurs at normal therapeutic dose"

Table 4: Community Pharmacists' concerns towards ADRs reporting from the open-ended question for the opportunity to provide further comments

Perceptions of regulatory body:
Sceptical of Performance
No practical evidence to the public
Decentralization of activities
Feedback on outcomes of ADR
Perception of Pharmacists' involvement:
Insufficient
Encouragement/ Monetary motivation
Legal concern: limiting factor (lack of clarity), not a limiting factor
Availability of Resources:
ADR reporting forms
Personnel
Perception on research on ADR reporting:
Useful
Sceptical

DISCUSSION

As anticipated, the community pharmacists (CPs) in the study had an understanding of the acronym ADRs as elicited in the findings. However, the optimism for formal training on ADR reporting among CPs was laudable and needs to be acknowledged. This recommendation is similar to that of Najmeh *et al*., 2014[16,45].

It was also discovered that reporting of ADRs was not being incorporated as part of routine practice among CPs similar to findings among other healthcare professionals and pharmacists[14,15,37,39,40]. However, the findings suggest reporting among CPs was comparatively higher than reporting among other healthcare professionals. On the other hand, reporting could be lower among CPs than hospital pharmacists[40] consistent with recent study of CP in another region within Nigeria[37]. Thus, suggesting that CPs may be different from pharmacists in the hospital setting who may be more aware of the ADR reporting, because of the presence of Zonal PC in the hospital pharmacy[40].

The findings indicated that a considerable proportion of CPs were not reporting all suspected ADRs contrary to the framework of the NPC[18,19]. The goal is that in many cases it is impossible for an individual health worker to prove that the reaction was actually caused by a drug. In addition, lack of awareness about the outcomes of ADRs reported to the National agency expressed in the study may suggest an important gap in communication process and may be another reason for poor reporting of ADRs among CPs. Among its obligations, NAFDAC through the NPC is required to communicate, make recommendations and directives to appropriate organizations and/or individuals[18,19]. Such feedback is important as this is useful to support healthcare professionals in their decision and reaffirm the relevance of reporting of ADRs. For example, from September 2004 to June 2010 were received over 4,500 ADR reports and alerts were sent to healthcare professionals across the country for awareness of the public[18].

A challenge of access to ADRs reporting yellow forms revealed in the study was also consistent with findings of similar studies[26,28,37]. This could be concurrent with the fundamental problems unique to low economy countries as a result of the

challenges of power supply and access to the internet. Ideally, yellow forms are issued by the National Pharmacovigilance Center (NPC) and copies of the forms can also be obtained online or directly from any health institutions[18,19]. Hence, perhaps the supply of hardcopies to community pharmacies could be one measure of improving access to ADRs reporting forms and should be further investigated.

Pharmacists as custodians of medicines are in a unique position to contribute immensely to the success of pharmacovigilance (PV), yet as demonstrated in this study, they are not fully involved in reporting of ADRs. The global burden of adverse drug reactions (ADRs) would likely escalate as use of medicines would generally be expected to increase with the global population, changing lifestyle and growing complexity of novel medicines developed to manage old and new emerging diseases. While it is imperative to acknowledge the huge cost of running PV, however the dire consequences of ADRs are greatly burdensome and overemphasized in low economy countries.

A limitation of the study is that the sample size may not be an adequate representative of the entire population of CPs in Ilorin or North-Central, Nigeria. However, collection of data immediately from CPs during the study at the meeting ensures the credibility of the data. In addition, this may have contributed to the response rate of participants in the study. For instance, in a study, Ogundele et al., 2012 had demonstrated low response rate as a result of losing questionnaires that were not collected immediately from healthcare professionals.

CONCLUSION

The findings have given insights of modest reporting of ADRs among CPs in Ilorin, North-central, Nigeria, and larger studies would be necessary to validate the findings of the study. Notwithstanding, it is recommended that adequate and timely training, resources and new initiatives are provided by the appropriate authorities to address concerns and encourage positive perceptions and practice of ADRs reporting among CPs. This is pertinent to widely capture and contribute broadly to understanding of safe use of medicines globally.

In this respect, a report of the findings of the study had been disseminated to a larger audience of pharmacists and CPs who had participated in the region. In addition, published abstracts had been presented at the National Conference of the Pharmaceutical Society of Nigeria (PSN), Umuahia, and West African Society of Pharmacology (WASP), Cotonou, 2017 respectively [46,47].

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CONFLICT OF INTEREST

The authors declare no conflict of interest. However, it is requisite as pharmacists to be a member of the Pharmaceutical Society of Nigeria.

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