Perception of Nigerian medical students on adverse drug reaction reporting

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INTRODUCTION

Pharmacovigilance (PV) is described by WHO as a process of detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem. The first endeavor made to resolve the problem of drug safety was announced in 1961 promptly after the disaster caused by thalidomide treatment in pregnant women. The spontaneous reporting system, on many occasions, was applied to facilitate early detection and prevention of new drugs tragedy also to expand quality assurance and safety in labeling of pharmaceutical products. However, apart from the advantages of spontaneous reporting (SPR) the major hitch is underreporting; in many hospitals only 10% of adverse drug reactions (ADRs) incidents were reported. The primary focus of SPR is to report all the prevalence of ADRs even if not much data is available and the causal relationship is yet to be established. Surveys carried out specified that SPR have continuously received reports from doctors, dentists, and pharmacists in all of the countries studied. Surprisingly, <25 reports obtained

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from countries such as Congo, Cyprus, and Uzbekistan. One of the advanced country on the African continent is South Africa, and the reported cases were only a few hundred; however, over 20,000 reports were generated from the USA annually.\textsuperscript{[7,8]} PV as the program requires a multidisciplinary approach and can only be accomplished if all health care teams are committed to organizing and implementing proper ADRs reporting system.\textsuperscript{[1,3,4,8‑10,12]} As such doctors, nurses, and pharmacists are the backbone of PV program and are solemnly responsible for detecting, recording, and reporting ADRs.\textsuperscript{[1,3,4,8‑10,12]} It is the responsibility of doctors, as well as a pharmacist, to counsel their patients on the likelihood of ADRs that may occur during the treatment.\textsuperscript{[1,3,4,9]}

The WHO center for ADRs monitoring is known as Uppsala Monitoring Centre.\textsuperscript{[4,7,13,14]} It is an International establishment with the responsibility of coordinating PV program based on an agreement made in 1978, and reconsolidated in December 2001, between the WHO and Swedish Government.\textsuperscript{[4,7,13,14]} The current survey will be carried out to assess the knowledge, attitude, and the practice of medical students in Nigeria.

**MATERIALS AND METHODS**

The appraisal was carried out among the population of medical students of Bayero University Kano (BUK), Nigeria, which is located in the Kano state of Nigeria, with a population of 9.4 million people.\textsuperscript{15} This research was designed as a cross-sectional questionnaire-based study to assess the medical students’ knowledge, attitude, and the practice on ADRs and PV. A universal sample of 146 medical students of year-IV and V from BUK, Nigeria were selected out of the total of 519 medical students in the department of medicine. Only students studying medicine that reached year-IV and V and who were willing to take part in the study were selected. All other year medical students were excluded. The survey tool was adopted, modified, and validated.\textsuperscript{[11,16]} It comprises of four parts: Section A is demographic information. Section B comprises of knowledge questions designed with yes/no options; a score of 1 was allocated to the yes answer and 0 to the no answer. Section C comprise of attitude questions framed into three points Likert’s scale (3 = strongly agree, 2 = neutral, 1 = strongly disagree). Finally, section D comprises of practice questions with yes/no options. A score of 1 was assigned to the yes answer and 0 to the no answer. It was first pilot-tested in 20 medical students who were not involved in the main survey. Their response was then tested for validity and reliability and the overall Cronbach’s alpha was calculated as 0.69.

The questionnaires were shared among 146 respondents to answer. One-hundred and eight medical students from year-IV and V completed and returned the questionnaires giving the response rate of 74%. Descriptive statistics were carried out to evaluate the knowledge, attitude, and practice score of the participants. Independent \textit{t}-test was performed to determine if there was the difference in mean knowledge score on ADRs and PV between year-IV and V; and between genders. The study was conducted from June 2014 to February 2015. This research was approved by the ethical committee of UniSZA; Memo No: UniSZA.N/1/628-1 (70), July 21, 2014.

**RESULTS**

One-hundred and eight medical students responded giving the response rate of 74%. The summary of the demographic information is shown in Table 1.

**Knowledge**

Of the 108 participants, 86 (80%) and 71 (66%) got the right definition of ADR and PV; 68 (63%) identified the correct functions of PV. Similarly, 77 (71%) knew the right people to report ADRs, 77 (71%) learned how to treat ADRs. Ninety-two (85%) heard about drugs banned due to ADRs; 101 (94%) said not all drugs on the market are safe. In addition, 92 (85%) felt that it is mandatory to have PV center in all medical schools. In contrast, only 11 (10%) located any PV center; and 42 (39%) recognized the method commonly applied in ADR reporting. The results are shown in Table 2.

**Attitude**

Eighty-nine (82%) strongly agreed that ADR reporting is health care workers responsibility; 88 (82%) said PV should be taught in detail. Similarly, 103 (95%) strongly agreed that ADRs monitoring will help patients. In addition, 56 (52%) worried about a legal aspect of PV. In contrast, 91 (84%) strongly agreed that ADR reporting is a waste of time; 80 (74%) strongly disagreed that they were adequately trained on PV; also, 52 (48%) stated that all serious ADRs were recognized before the drugs are marketed. The results are shown in Table 3.

**Practice**

Of the total respondents, 107 (99%) have noticed patient experiencing ADRs; 72 (67%) said mild ADRs such as a headache, fever, and vomiting should be reported. Similarly, 90 (83%) acknowledged that patient can report his symptoms to nearby PV center; 105 (97%) expected feedback from PV center. In contrast, only 4 (4%) have ever reported ADRs; only 9 (8%) had access to the ADRs reporting form. Furthermore, only 15 (14%) had training on PV; only 20 (19%) read any article on ADRs monitoring. The results are shown in Table 4.

**Level of study**

Independent \textit{t}-test conducted showed that there was no statistically significance difference in the mean knowledge score on ADRs and PV between year-IV and V medical
students at $P = 0.956$, upper and lower confidence interval (CI) $(-0.0654$ and $0.0619)$.

**Gender**

Independent $t$-test performed indicated that there was no statistically significance difference in the mean knowledge score on ADRs and PV between male and female medical students at $P = 0.080$, upper and lower CI $(-0.1266$ and $0.0072)$.

**DISCUSSION**

**Knowledge**

According to our findings, 80% and 66% of the participants got the definition of ADRs and PV correctly. These findings are similar to the outcome of another survey among pharmacy students$^{[14,18,19]}$ but higher than the previous researches conducted.$^{[14,18,19]}$ Meanwhile, 63% knew the functions of PV, which is similar to the outcome of another study among pharmacy students.$^{[16]}$ In addition, 71% knew the people responsible for ADRs reporting which is higher than the result of another survey among medical and dental students.$^{[16]}$ In contrast, only 10% located any PV center which coincides with the outcome of another study among pharmacy students$^{[20]}$ and among medicine students.$^{[19,17]}$ Finally, 39% recognized the method commonly applied in ADR reporting. This finding is comparable to the result of a survey conducted among pharmacy and medicine students.$^{[17,21]}$

**Table 1: Demographic information of study respondents ($n=108$)**

| Category          | Frequency (%) |
|-------------------|---------------|
| Gender            |               |
| Male              | 77 (71)       |
| Female            | 31 (29)       |
| Age (years)       |               |
| 20-25             | 89 (82)       |
| 26 above          | 19 (18)       |
| Marital status    |               |
| Single            | 102 (94)      |
| Married           | 6 (6)         |
| Level of study    |               |
| Year-IV           | 68 (63)       |
| Year-V            | 40 (37)       |

**Table 2: Medical students’ knowledge on ADRs and PV ($n=108$)**

| Question                                      | Frequency (%) |
|-----------------------------------------------|---------------|
| ADR can be described as                       | Yes answer    | No answer |
| PV studies can best be defined as             | 86 (80)       | 22 (20)   |
| Functions of PV include the following         | Yes answer    | No answer |
| The health care professional responsible for  | 68 (63)       | 40 (37)   |
| reporting ADRs in a hospital is/are           |               |           |
| ADRs which are independent can be treated by  | 77 (71)       | 31 (29)   |
| Are you aware of any drug that has been       | Yes answer    | No answer |
| banned due to ADRs                            | 92 (85)       | 16 (15)   |
| Are all the drugs available in the market     | Yes answer    | No answer |
| safe                                          | 101 (93)      | 7 (7)     |
| The method commonly used in ADR reporting is  | Yes answer    | No answer |
| Are you aware of any nearby PV center         | Yes answer    | No answer |
| Is it mandatory to have PV unit in each        | Yes answer    | No answer |
| every medical college                         | 92 (85)       | 16 (15)   |

**Table 3: Medical students’ attitude on ADRs and PV ($n=108$)**

| Question                                      | Frequency (%) |
|-----------------------------------------------|---------------|
| Do you think ADRs reporting is professional   | SA (82)       | N (13)    | SD (6) |
| obligation                                     |               |           |        |
| Do you think PV should be taught in detail    | 88 (82)       | 10 (9)    | 10 (9) |
| to health care professionals                   |               |           |        |
| Do you feel that you are adequately trained   | 16 (15)       | 12 (11)   | 80 (74)|
| on how to report ADRs                          |               |           |        |
| Do you think ADR monitoring and reporting     | 103 (95)      | 3 (3)     | 2 (2)  |
| will benefit patients                          |               |           |        |
| Do you feel that ADRs reporting is time       | 91 (84)       | 8 (7)     | 9 (9)  |
| consuming with no outcome                     |               |           |        |
| Do you think legal problem hinder the         | 56 (52)       | 32 (30)   | 20 (18)|
| reporting of ADRs                             |               |           |        |
| Do you feel that all serious ADRs are known   | 52 (48)       | 22 (20)   | 34 (32)|
| before drug is marketed                        |               |           |        |

**Table 4: Medical students’ practice on ADRs and PV ($n=108$)**

| Question                                      | Frequency (%) |
|-----------------------------------------------|---------------|
| Have you ever come across patient             | Yes answer    | No answer |
| experiencing ADR                              | 107 (99)      | 1 (1)     |
| Have you ever report an ADR                   | Yes answer    | No answer |
|                                              | 4 (4)         | 104 (96)  |
| Have you ever been trained on how to          | Yes answer    | No answer |
| report an ADR                                 | 15 (14)       | 93 (86)   |
| Have you ever read an article on how to       | Yes answer    | No answer |
| report ADRs                                   | 20 (19)       | 88 (81)   |
| The commonly seen ADRs like a headache,       | Yes answer    | No answer |
| fever, and vomiting should not be reported    | 72 (67)       | 36 (33)   |
| Do you have free access to ADR reporting forms| Yes answer    | No answer |
|                                              | 9 (8)         | 99 (92)   |
| Nonmedical person cannot report an ADR to a   | Yes answer    | No answer |
| nearby health care professional                | 90 (83)       | 18 (17)   |
| Do you expect feedback from ADRs monitoring   | Yes answer    | No answer |
| center                                        | 105 (97)      | 3 (3)     |

ADR: Adverse drug reactions, PV: Pharmacovigilance

SA: Strongly agree, N: Neutral, SD: Strongly disagree, ADRs: Adverse drug reactions, PV: Pharmacovigilance
Attitude
Eighty-two percent strongly agreed that ADR reporting is health care workers responsibility, which is much higher than the outcome of other surveys among pharmacy students and among medical and dental students. Similarly, 82% said PV should be taught in detail, which is similar to the result of another appraisal among pharmacy students. Similarly, 95% strongly agreed that ADRs monitoring will help patients, which is much higher than the outcome of a study carried out among pharmacy students. In contrast, only 15% strongly agreed that they were adequately trained on PV which similar to the findings of another study but lower than the outcome of a study carried out among medical students.

Practice
Of the total respondents, 99% have noticed patient experiencing ADRs, which is higher than the outcome of another appraisal conducted among medical and dental students and among pharmacy students. About 67% said mild ADRs such as a headache, fever, and vomiting should be reported; similar result was obtained in another research involving medicine and pharmacy student. Similarly, 83% acknowledged that patient can report his symptoms to nearby PV center; this is higher than what was obtained in another study involving pharmacy students. In contrast, only 4% have ever reported ADRs which is comparable to another survey among pharmacy students. Furthermore, only 8% had access to ADRs reporting form; the similar outcome was obtained in another study.

CONCLUSION
The outcome of this study showed good knowledge and attitude with respect to ADRs and PV among the medical students studied. Unfortunately, the practice of medical students was found to be unsatisfactory. ADR monitoring should be included in detail in medical students’ curriculum. Furthermore, to implement the use of information and communication technology in prescription, dispensing, and drug administration, as well as the use of the automated system, in ADRs monitoring.

Limitation of the study
The outcome of this survey cannot be generalized to all Nigerian medical schools; more schools need to be studied to enable generalization of these findings.

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Conflicts of interest
There are no conflicts of interest.

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