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Knowledge and attitudes of physicians relating to reporting of adverse drug reactions in Sokoto, north-western Nigeria

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Abstract

Background/Objectives: Adverse drug reactions (ADRs) are important causes of morbidities. Voluntary reporting of ADR is important in safety surveillance of medicines already in the market. This study was, therefore, conducted to appraise the current documentation of ADR in Sokoto, to analyze the extent to which clinicians appreciate factors that could affect reporting ADRs.

Materials and Methods: Four hospitals within Sokoto metropolis were selected by convenient sampling. Pre-validated questionnaires containing questions on demographic and professional characteristics, and questions that evaluate attitudes as listed in the so-called "deadly sins" of Inman were self-administered by physicians. Data from respondents were analyzed by logistic regression.

Results: Of 61 physicians interviewed, 43 (70.5%) had encountered potential ADRs in the 12 months before the study but only 3 (7.0%) of these were reported. Fifty eight (95.1%) of the respondents were not aware that an ADR reporting system was available in Sokoto but all the 3 respondents who were aware of the existence of a reporting system had reported an ADR. Generally, there was no significant relationship between demographic and professional attributes and scores obtained on each of the Inman's attitude measured except that more experienced physicians tend to believe that ADRs are not impossible to identify and female physicians were more reluctant to engage representatives of pharmaceutical companies on ADRs related to their drugs. Additional attitudes that may influence ADRs reporting were identified.

Conclusion: Adverse drug reactions are under-reported in Sokoto. Lack of physicians' awareness of channels for reporting appears to be the major cause.

Keywords: Adverse drug reactions, attitudes, pharmacovigilance, physicians

Résumé

Fond/objectifs: Effets indésirables des médicaments (EIM) sont les principales causes de morbidité. Il est important de surveillance de l'innocuité des médicaments déjà sur le marché de déclaration volontaire de l'ADR. Par conséquent, cette étude visait à évaluer la documentation actuelle de l'ADR de Sokoto, pour analyser l'étendue à laquelle cliniciens apprécient les facteurs qui pourraient influer sur la déclaration des effets indésirables.

Méthode: Quatre hôpitaux dans la métropole de Sokoto ont été sélectionnés par la pratique d'échantillonnage. Les questionnaires DETECTEURS contenant des questions sur les caractéristiques démographiques et professionnels et des questions permettant d'évaluer les attitudes répertorié dans le soi-disant « péché mortel » du Inman ont été auto-administré par les médecins. Répondants sous forme de données ont été analysées par régression logistique.

Résultats: De 61 médecins interrogés, 43 (70,5%) avait rencontré EIM potentiels dans les 12 mois précédant l'étude, mais seulement 3 (7,0%) d'entre eux ont été signalés. Cinquante huit (95,1%) des répondants n'étaient pas au courant qu'un ADR système de déclaration était disponible en Sokoto, mais tous les 3 répondants qui étaient au courant de l'existence d'un système de déclaration avaient signalé un ADR. En général, il y n'avait aucune relation significative entre les attributs démographiques et professionnels et des scores obtenus sur chacun de l'attitude de

la Inman mesuré sauf que les médecins plus expérimentés ont tendance à croire que les EIM n'est pas impossibles à identifier et femmes médecins étaient plus réticents à s'engager les représentants des sociétés pharmaceutiques sur les effets indésirables liés à leurs médicaments. Attitudes supplémentaires qui peuvent influer sur la déclaration des EIM ont été identifiés.

Conclusion: Effets indésirables des médicaments sont sous-déclarées dans Sokoto. Manque de sensibilisation des médecins des canaux pour avoir signalé semble être la principale cause.

Mots clés: Effets indésirables des médicaments, les attitudes, les pharmacovigilance, les médecins

Introduction

Paracelsus' statement that 'all drugs are poison' underscores the need for care and vigilance with drug use. The incidence of adverse drug reaction (ADR) due to established drugs have been reported to range from 3.1% in children, 6–8.5% in the young adult and middle age, and 20% in the geriatric group.[1] Although studies in sentinel centers have reported rates as high as 32%,[2] it is estimated that only 6% of ADRs are reported worldwide,[3] which implies that ongoing evaluation of the risk-benefit ratio of medications in the market is largely unavailable. Voluntary ADR reporting is a fundamental tool of drug safety surveillance. It is, therefore, important to identify knowledge and attitudes relating to under-reporting because this would enable targeted educational strategies that is expected to stimulate ADR reporting. The model known as the "seven deadly sins" developed by Inman[3,4] to explain the reason for under-reporting of ADR are essential tools for educational strategies. This study was, therefore, conducted with the following objectives: (1) to appraise the current documentation of ADR in Sokoto, the state capital of Sokoto State in north-western Nigeria (2) to analyze the extent to which clinicians appreciate factors that could affect reporting ADRs, and (3) to identify novel factors that could hinder reporting.

Settings, Population and Sample

The three major state government hospitals in Sokoto and one teaching hospital were selected by convenient sampling. These hospitals are easily identifiable as the gold standard for practice in the state, having the highest number of physicians and the highest patient load. The government hospitals have clinical departments of medicine, surgery, obstetrics and gynecology, pediatrics and a pharmacy. All clinical departments and units are manned by physicians with varying levels of experience and headed by a principal medical officer. In addition, all departments are supervised by appropriate visiting consultants from the nearby teaching hospital. Physicians that work in these hospitals, either full time or on part time were the target population. The teaching hospital has all standard departments. The pre-specified sample size was calculated as at least 45 physicians.

Questionnaire design and Validation

The questionnaire (supplementary 1) was designed after the method of Herdeiro *et al*.[5] except that it included an open section for free comments aimed at identifying new factors. Also, additional demographic variables derived using the Delphi Protocol[6] were included. The questionnaire was designed to be easy to complete and comprised four sections. Section 'A' sought to obtain information of personal and professional nature including age, sex, marital status, medical specialization, area of practice, estimated patient load and estimated prescription volume. Section 'B' comprised 15 questions that sought information about knowledge and attitudes regarding spontaneous ADR reporting based on Inman's "seven deadly sins" and non-Inman factors identified from other studies.[7-9] Against each question in this section was a four-point Likert item[10] (strongly disagree, disagree, agree and strongly agree). We preferred this over the Five-point Likert item (which contains the point "Neither agree nor disagree") in order to evoke the forced choice method and reduced the so-called central tendency bias. Section 'C' contained three questions relating to the physician's use of voluntary reporting system within the 12 calendar months before the study. Section 'D' is an open space requesting information which the interviewee considers to have hindered him/her from reporting observed ADR but are not addressed in the questionnaire.

The questionnaire was validated in interpretative and linguistic terms by appropriate experts. Content validity was performed by selected pharmaco-vigilance experts in Nigeria and Egypt. Test–retest reliability was performed by a pilot administration of the questionnaire to six doctors in Sokoto, and repeated after 4 weeks.

Data Collection

Each questionnaire was delivered in person by one of the investigator (TMU) who reassured the interviewees of confidentiality. The questionnaire was completed in the presence of the interviewer for immediate collection. Interviewees who preferred to complete and/or send the questionnaires were allowed 24 hours after which the interviewer

re-visited for collection. The first questionnaire was administered on 14/10/2009 and the last one administered was collected on 21/11/2009.

Statistical Analyses

We calculated crude descriptive analyses for all components of the questionnaire and used multinomial logistic regression analysis to model relationships between demographic and professional parameters versus each of the "major sins" of Inman and other factors in the questionnaire (extended Inman). We calculated the overall score of each interviewee on the extended Inman (minimum = 15, i.e. strongly disagreed with all the items; maximum = 60, i.e. strongly agreed with all the items) and classified the score into low scores (15–29) and high scores (30 and above). We subsequently used binary logistic regression to model relationships between demographic and professional parameters versus scoring low or high. All analyses were performed using SYSTAT 13 statistical software (SYSTAT software Inc.)

Results

Sixty one physicians were interviewed of whom 50 (82%) were male and 11 (18%) were female. Twenty five (41%) of the interviewees were medical officers. Six (9.8%), 1 (1.6%), 7 (11.5%), 4 (6.6%), 4 (6.6%), 10 (16.4%), 1 (1.6%) were consultants, chief medical officers, principal medical officer, senior registrars, senior medical officers, registrars, and house officers, respectively. Of all respondents, only 3 (4.9%) medical officers at the specialist hospital had reported ADRs they encountered, although 43 (70.5%) respondents had encountered a potential ADR in the 12 months before the study which translated to a reporting rate of 3 in 43 or 7%. All those who have reported ADRs were medical officers working with the specialist hospital. Fifty eight (95.1%) respondents were not aware that an ADR reporting system was available in Sokoto. The percentile scores on each question on attitude are as shown in Table 1. The distribution of summed scores on the extended Inman is as shown in Figure 1. Seventy percent of physicians studied had scores in the range 30–40. The lowest score per physician was 24 while the maximum score was 44. Generally, no significant relationship was found between demographic or professional characteristic and absolute scores on each item on attitude. Respondents with chronological age (above 35 yrs) tend to disagree that "It is nearly impossible to determine whether a drug is responsible for a particular adverse reaction" (parameter estimate: 30 ± 0.485, 95% CI: 27–33, $Z = 20.4$, $P = 0.047$) and female responds tend not to engage pharmaceutical companies

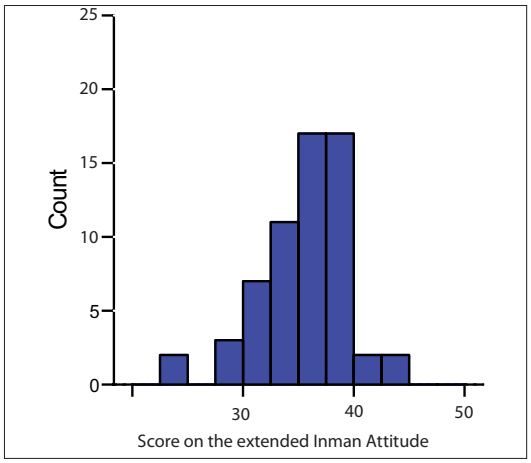

Figure 1: On the extended Inman attitude, the best score, which suggests full compliance with pharmacovigilance, would be 15, while the worst score would be 60. The distribution of attitude scores in the sample studied is clustered at 30-40 and is roughly binomial suggesting high group similarities.

Table 1: Percentile scores on attitudes on voluntary adverse drug reaction reporting

Attitude	Percentile score		
	25	50	75
Really serious ADRs are well documented by the time a drug is marketed	2	2	3
It is nearly impossible to determine whether a drug is responsible for a particular adverse reaction	2	2	3
I would only report an ADR if I were sure that it was related to the use of a particular drug	2.75	3	4
The one case an individual doctor might see could not contribute to medical knowledge	1	1	2
When I read medical literature I am interested in articles about ADRs	3	3	4
I would be more likely to report ADRs if there were an easier method	3	3	4
I think that the most correct way to report an ADR is in medical literature	2	2	3
I should be financially reimbursed for providing the ADR service	1	2	2
I have a professional obligation to report ADRs	3	3	4
Reporting ADRs puts my career at risk	1	1	2
It is only necessary to report serious or unexpected ADRs	1.75	2	3
I do not have time to complete the yellow card	2	2	3
I do not have time to think about the involvement of the drug or the other causes of ADRs	1	2	2
I do not know how the information reported in the yellow card is used	2	2	3
I talk with pharmaceutical companies about possible ADRs with their drugs	2	3	3

representatives about possible ADRs with their drugs female (parameter estimate: 26 ± 1.205, 95% CI: 24–28, $Z = 22$, $P = 0.011$). The relationships between personal and professional characteristics on obtaining low summed scores versus high summed scores are as shown in Tables 2 and 3, respectively.

Additional attitudes deducted from the comments of the interviewees include (1). "Even if I report ADR, I do not trust the responsible authority to use the information properly", (2). "I do not feel competent to identify ADR" and (3) "Reports of ADRs by patients are unreliable for documentation".

Discussion

The ADR reporting rate of 7% found in this study is close to the 6% ADR reporting rate reported worldwide[3] but much lower than the 32% reported in Ibadan.[2] However, this study has revealed staggering lack of awareness of ADR reporting channel in Sokoto by the majority of physicians interviewed. Nevertheless, the finding that all the physicians that were aware of this channel had reported ADRs they encountered is re-assuring and is a strong indication that attitudes towards ADR reporting could be favorable and that targeted educational strategies that emphasize knowledge of available ADR reporting pathway should result in dramatic improvement. However, the finding that 70% of the population studied had scores in the range 30-40 on the extended Inman questionnaire suggests that significant issues on attitudes that may require global educational strategies exist. Even when robust and well-known ADR reporting channels are available, attitudes towards reporting are known to influence actions taken by physicians.[3] It is therefore interesting that physicians above the age of 35 years tend to disagree with statements that suggest that ADRs are impossible to detect and that this was not confounded by duration of practice as would be expected. This may mean that difference in opinion due to age-dependent cognate view of issues may influence ADR reporting more than professional hierarchy [Table 3]. On the other hand, it may be consistent with known non-assertiveness of the female[11] that this study revealed that female physicians are less willing to engage representatives of pharmaceutical companies on ADRs. In this regard, our finding supports the report by Bartels *et al*.[12] that the female gender tends to choose less assertive behaviors in clinical scenarios. It is reassuring that other demographic and professional characteristics evaluated showed no significant influence on attitudes but it is possible that characteristics that influence attitudes were not evaluated in this study. Other attitudes that may affect ADR reporting in this study suggest that physicians may be uncertain of information flow and that this uncertainty begins from information given by patients on ADRs, information processing by the physician and then by authorities responsible for processing of ADRs. These biases may not be unrelated to a general feeling of system failure in Nigeria, especially in the health services.[13,14] These suggest that educational strategies aimed at improving ADR reporting may need to include patients and physicians in formal and targeted settings like halls, and also in broader settings like the mass media.

A shortcoming of this study is that convenient sampling was used. This may compromise generalization of the result but the findings may still be sufficient to give an idea of trends.

ADR reporting in Sokoto is poor. Reasons found in this study appear to be easy to address using methods that include awareness campaigns that target physicians and patients.

Table 2: Influence of personal characteristics on voluntary adverse drug reaction (ADR) reporting

Personal Characteristic	Odds Ratio	Standard error	*P*-value	95% CI	
				Lower	Higher
Sex	0.870	1.018	0.906	0.088	8.635
Age	0.238	0.021	0.421	0.901	1.269
Marital Status	4.100	3.942	0.138	0.623	26.988

Table 3: Influence of professional characteristics on voluntary adverse drug reaction (ADR) reporting

Professional Characteristic	Odds Ratio	Standard error	*P*-value	95% CI	
				Low	High
Medical specialization	1.123	0.327	0.688	0.634	1.987
Highest Medical Qualification	1.833	2.200	0.518	0.175	19.252
Rank/Level of Practice	1.020	0.386	0.959	0.485	2.142
Years in Practice	0.394	0.053	0.222	0.874	1.482
Estimated number of patients seen per weeks in the last 12 months	1.000	0.001	0.623	0.998	1.002
Estimated number of prescriptions written per day in the last 12 months	1.001	0.003	0.643	0.995	1.007

Questionnaire on ADR Reporting

Section A

Age..... Sex..... Marital Status.....

Department/Unit..... Specialization.....

Qualification..... Rank/Level of Practice.....

Years in Practice.....

Estimated number of patients seen per weeks in the last 12 months.....

Estimated number of prescriptions written per day in the last 12 months.....

Section B

Pls √ against the option that best fits your position against each question below

1. Really serious ADRs are well documented by the time a drug is marketed. .....
   1. Strongly disagree, 2. Disagree, 3. Agree, 4.Strongly agree
2. It is nearly impossible to determine whether a drug is responsible for a particular adverse reaction.....
   1. Strongly disagree, 2. Disagree, 3. Agree, 4.Strongly agree
3. I would only report an ADR if I were sure that it was related to the use of a particular drug..... .....
   1. Strongly disagree, 2. Disagree, 3. Agree, 4.Strongly agree
4. The one case an individual doctor might see could not contribute to medical knowledge.....
   1. Strongly disagree, 2. Disagree, 3. Agree, 4.Strongly agree
5. When I read medical literature I am interested in articles about ADRs.....
   1. Strongly disagree, 2. Disagree, 3. Agree, 4.Strongly agree
6. I would be more likely to report ADRs if there were an easier method.....
   1. Strongly disagree, 2. Disagree, 3. Agree, 4.Strongly agree
7. I think that the most correct way to report an ADR is in medical literature.....
   1. Strongly disagree, 2. Disagree, 3. Agree, 4.Strongly agree
8. I should be financially reimbursed for providing the ADR service.....
   1. Strongly disagree, 2. Disagree, 3. Agree, 4.Strongly agree
9. I have a professional obligation to report ADRs.....
   1. Strongly disagree, 2. Disagree, 3. Agree, 4.Strongly agree
10. Reporting ADRs puts my career at risk.....
    1. Strongly disagree, 2. Disagree, 3. Agree, 4.Strongly agree
11. It is only necessary to report serious or unexpected ADRs.....
    1. Strongly disagree, 2. Disagree, 3. Agree, 4.Strongly agree
12. I do not have time to complete the yellow card .....
    1. Strongly disagree, 2. Disagree, 3. Agree, 4.Strongly agree
13. I do not have time to think about the involvement of the drug or the other causes of ADRs..... .....
    1. Strongly disagree, 2. Disagree, 3. Agree, 4.Strongly agree
14. I do not know how the information reported in the yellow card is used .....
    1. Strongly disagree, 2. Disagree, 3. Agree, 4.Strongly agree
15. I talk with pharmaceutical companies about possible ADRs with their drugs.....
    1. Strongly disagree, 2. Disagree, 3. Agree, 4.Strongly agree

Section C

Please answer Yes or No

1. Are you aware of the ADR reporting system in Sokoto.....
2. Have you encountered a potential ADR within the last 12 months.....
3. Have you reported a potential ADR within the last 12 months.....

Section D

In the space below, Kindly give descriptions of what *may have hindered you or you consider may hinder you* from reporting ADR but have not been addressed in the questionnaire.

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