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Original Research Article

Evaluation of Adverse Drug Reaction Reporting Among Traditional Medicine Practitioners in Zaria Kaduna State Nigeria

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ABSTRACT

The wide use of traditional medicines has remained a serious concern particularly when it comes to safety. This study was aimed at assessing the knowledge, perception and barriers for Adverse Drug Reaction (ADR) reporting among traditional medicine practitioners (TMPs). This study was a cross sectional study among TMPs in Zaria Nigeria using a structured questionnaire. A response rate of 87.5% (105) was recorded. The TMPs were mostly males 86 (81.9%) with a mean age of 40.8 ± 12.9 years. Majority of the TMPs have never come across ADR 64 (61.0%), didn't know how to report ADR 62 (59.0), with no training on ADR reporting 61 (58.1%). The TMPs believed that pharmacovigilance is not only ADR reporting 67 (63.8%), ADR reporting will improve the healthcare 87 (82.9%), and ADR reporting is as important as treating patient 78 (74.3%). The TMPs reported updating their knowledge 84 (80.0%), belonging to professional bodies 80 (76.2%), and willing to implement ADR reporting in their practice 85 (81.0%). The overall mean scores for the knowledge, perception and barriers were 3.57 ± 2.10, 4.99 ± 1.42 and 4.44 ± 1.52, respectively. There was association between knowledge and age, ownership, rank and years of experience (p < 0.05), between perception and age (p < 0.05), and between barriers and practice setting (p < 0.05). This study revealed deficiency in knowledge with a positive perception of ADR reporting among TMPs. However, barriers were not significant. This suggests the need for advocacy and training of the TMPs on ADRs.

Keywords: Adverse drug reaction, ADR reporting, Traditional medicine, TM practitioners.

Introduction

The use of traditional medicines (TM) continue to expand rapidly worldwide. There is tremendous surge in acceptance and use of natural therapies, with herbal remedies being available not only in pharmacies and patent medicine stores, but also in food stores and supermarkets.[1] It is estimated thatup to 80% of the world's population rely on herbal products as a primary source of healthcare.[2, 3]Safety has always been a fundamental principle in the provision of any medical intervention.[4]Several herbal medicines are reported to be quite potent, but may be associated with adverse effects.[5]

Despite promising potential, many herbal medicines remain scientifically untested and their use not monitored.[6] This makes knowledge of their potential adverse effects very limited and identification of the safest and most effective therapies more difficult.[6]

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It is also common that the safety of most herbal products is further compromised by lack of suitable quality controls, inadequate labeling, and the absence of appropriate information.[7] The most common sources of information on adverse events and reactions to medicines are clinical trials and spontaneous reports. The latter ordinarily far exceed the former in numbers and type, especially serious reports, over the lifetime of a product.[8] Given the reality of global use of TMs, monitoring safety of such medicines becomes a priority for all stakeholders. Traditional medicines are not always safe, particularly when used in combination with other medicines.[5]

An Adverse drug reaction (ADR) is defined as a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.[6] Adverse drug reactions are a leading cause of morbidity and mortality globally.[9] It was reported that up to 20% of patients on drug therapy experience ADR.[10] It is therefore important that medication monitoring systems like pharmacovigilance (PV) are put in place to ensure safety. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.[11] Reporting ADRs constitutes an integral part of PV process. Spontaneous reporting helps to detect serious and unusual adverse effects previously undetected during clinical trials.[10]

In many countries, providers of herbal medicines other than physicians, dentists, pharmacists and nurses are excluded from reporting systems.[12] If adequate coverage of herbal medicines is to be achieved, national reporting schemes should be developed to include all

providers of herbal medicines, and providers of traditional, complementary and alternative medicines, according to national circumstances.[5] There is no doubt that the increasing cases of poisoning associated with the use of particularly the unregistered herbal medicines in many parts of the world in recent times, is necessitating the need to ensure thorough toxicity assessment alongside active pharmacovigilance on such products.[13] The aim of this study was to assess the knowledge, perception and barriers for adverse drug reaction reporting among traditional medicine practitioners.

Materials and Methods

Study Setting
This study was carried out in Zaria Metropolis of Kaduna State Nigeria. Zaria was chosen because it is one of the biggest heterogeneous cities in Nigeria with numerous traditional medicine practitioners who are the target population for the study.

Study Design
This study was a cross-sectional study among TMPs randomly selected and administered a structured questionnaire by a trained research assistant under supervision of the principal investigator between July and September 2018. All practicing TMPs during the period of data collection within the study area and who were willing to participate were included in the study.

Study Tool
A self or interviewer administered (depending on the literacy status of the respondents) structured questionnaire was developed based on previous studies.[14-19] The questionnaire content was agreed by a panel of experts with backgrounds in clinical pharmacy, pharmacovigilance, traditional medicine and academia. The face validity of the questionnaire was tested in a pilot study using a convenience sample of 20 TMPs. Minor modifications were made to some of the questions after the pilot study to improve clarity.
The questionnaire was composed of four sections, consisting a total of 34 questions that covered socio-demographics (A, 10 questions), knowledge (B, 8 questions), perception (C, 8 questions) and barriers (D, 8 questions). Apart from section A that contained open ended and mostly closed multiple choice questions, all other sections had a 'yes' or 'no' options coded for correct and incorrect answers respectively. Knowledge, perception and barriers were finally weighted according to the total scores recorded by the TMPs in each of the section.

Ethical Consideration
Ethical approval was sought from Ahmadu Bello University Committee for use of human subjects for research (ABUCUHSR) for the conduct of the study with an approval number ABUCUHSR/2018/UG/004. Informed consent was clearly stated inferred by voluntarily filling and submitting the questionnaire. All information provided on the questionnaire was held in strict confidentiality.

Data Presentation and Analysis
All data retrieved were sorted and presented in tables as frequencies, percentages and as mean ± standard deviation. The level of knowledge, perception and barriers for ADR reporting among the TMPs were scored one point for each 'yes' answer with a maximum score of 8. For the knowledge, a total score of ≥ 4 was graded as 'good' and < 4 was graded as 'poor', while for perception, a total score of ≥ 4 was graded as 'positive' and < 4 was graded as 'negative' and barriers were counted as such.
Chi-square test was used to determine association between socio-demographics and knowledge, perception, and barrier-based parameters. Data was analyzed using the Statistical Package for Social Science (SPSS) Software, version 23.0. $p \leq 0.05$ was considered statistically significant.

Results and Discussion

Adverse drug reaction reporting especially on traditional medicines remains a big challenge particularly in the less developed countries.[19,20] There is currently no study that assessed ADR reporting among TMPs in Nigeria. This study therefore assessed the level of knowledge, perception and barriers for ADR reporting among TMPs in Zaria. The TMPs were evaluated because they are presumed to be the most vulnerable healthcare professionals when it comes to safety of traditional medicines. The WHO encourages all stakeholders in the healthcare system to report and document ADRs resulting from all kinds of therapeutic products.[20]
A total of 105 completed questionnaires were retrieved from eligible TMPs, which gave a high response rate of 87.5%. Similar studies in Ireland, Bhutan, Nepal, Saudi Arabia and Nigeria had response rates of 8, 65, 75, 65 and 36 respectively.[19-23] Majority of the TMPs were males 86 (81.9%), aged between 30 -49 years 59 (56.2%), and were mostly Hausas 96 (91.4%). Most of the TMPs had informal education 47 (44.8%) and are operating a stationed business 69 (65.7%). Majority of the TMPs are the real owners of the business 60 (57.1%) with ≤ 5 years of experience 34 (32.4%). The mean age and years of experience were 40.8 ± 12.9 years and 10.9 ± 7.7, respectively. Details of the demographics are shown in Table 1. The characteristics of the TMPs identified from this study could be supported by the fact that the study was conducted in one of the major cities in Northern Nigeria where informal education is still preferred. Reports have shown that such category of people engage into several kind of businesses both to earn a living and serve their community while preserving their cultures and beliefs.[24]
Poor knowledge of ADR reporting among the TMPs was identified in this study. This was evident by the low value in the overall mean score for knowledge (3.57 ± 2.10). Among the TMPs, 64 (61.0%) have never come across ADR, 62 (59.0%) didn't know how to report ADR, and 55 (52.4%) have not heard of ADR reporting. Majority of the TMPs stated that ADR is not life threatening 75 (71.4%), 61 (58.1%) have not had training on ADR reporting, and 60 (57.1%) have never heard about pharmacovigilance. These are summarized in Table 2. Association was also established between knowledge and age (p = 0.016), practice ownership (p = 0.035), rank (p = 0.048) and years of working experience (p = 0.048) as shown in Table 5. The knowledge deficiency identified may be attributed to the lack of formal education, advocacy, awareness, as well as the non-integration of the TM practices into the conventional health care systems.[25] A study have identified that lack of awareness lead to under-reporting of ADRs among residents in Nigeria.[26] Similar studies have also reported compromised ADR reporting among healthcare professionals due to inadequate awareness.[17, 27-29]
This study revealed positive perception of ADR reporting identified by a high overall perception mean score (4.44 ± 1.52). Majority of the TMPs believed that pharmacovigilance is not only ADR reporting 67 (63.8%), TMs are not devoid of ADRs 67 (63.8%), and patients' ADR must always be reported 63 (60.0%). In addition, 52 (49.5%) believed that not all medicines are safe, 87 (82.9%), ADR reporting will improve the healthcare system, and 78 (74.3%) believed that ADR reporting is as important as treating the patient. These are summarized in Table 3. Association was found between age and perception (p = 0.045) as shown in Table 5. Studies have shown that perception and understanding of health cases are greatly informed within the lived experience.[18, 29] Similarly, another study showed positive perception of HCPs on ADR reporting.[30] while on the contrary other studies in Malaysia and the UK reported negative perception of ADR reporting.[31,32] The overall mean score for barriers for ADR reporting was 4.99 ± 1.42. Majority of the TMPs reported keeping records of patients 59 (56.2), follow-up their patients 74 (70.5%), do update their knowledge of medicines 84 (80.0%), and belong to professional bodies 80 (76.2%). They also reported remuneration for ADR reporting not necessary 71 (67.6%) and are willing to implement ADR reporting in their practice 85 (81.0%). These are summarized in Table 4. There was association between type of practice setting and barriers (p = 0.027) as shown in Table 5. A study suggested that interventional educational programs

Table 1: Socio-demographic characteristics of the traditional medicine practitioners.

Variable	Category	Frequency	Percentage (%)
Gender	Male	86	81.9
	Female	19	18.1
Age (Years)	< 20	3	0.01
	20 - 29	19	18.1
Mean (± SD)	30 - 39	31	29.5
40.8 (± 12.9)	40 - 49	28	26.7
	50 - 59	14	13.3
	≥ 60	10	9.5
Tribe	Hausa	96	91.4
	Yoruba	2	1.9
	Others	7	6.7
Educational status	Tertiary	10	9.5
	Secondary	33	31.4
	Primary	15	14.3
	Informal	47	44.8
Practice ownership	Family	38	36.2
	Partnership	21	20.0
	Sole proprietorship	46	43.8
Practice Setting	Ambulatory	16	15.2
	Stationed	69	65.7
	Both	20	19.1
Position/rank	Manager/owner	60	57.1
	Sales representative	45	42.8
Years of experience	< 5	34	32.4
	6 - 10	19	18.1
	11 - 15	31	29.5
Mean (± SD)	16 - 20	10	9.5
10.9 (± 7.7)	> 20	11	10.5

Total number of traditional medicine practitioners, n = 105

effectively improve barriers to ADR reporting by increasing knowledge and perception.[33,34] Traditional medicine of proven quality, safety, and efficacy contributes to the goal of ensuring that all individuals have access to care. Many countries now identify the need to develop an integrative approach to healthcare that allows governments, healthcare practitioners including TMPs to improve on prevailing safety of TMs thus preventing any possible barrier to ADR reporting.[35]

Nigerians have a deep belief and reliance on the services of the TMPs for their health care needs.[36] An estimated 75% of the population still prefers to solve their health problems by consulting the traditional healers despite not yet integrated into the conventional healthcare system.[37] Many western countries have advanced in integrating the traditional medicine practices.[38-40] There is no doubt that traditional medicine remains important in meeting the health needs of the people despite expansion of orthodox medicine. The Nigerian government should therefore make do with its promise 'to see both health care delivery systems are empowered to deliver good quality care.[25]

Strength and Limitations of the study
There is poor knowledge of ADR reporting among healthcare professionals with this present study establishing that of the TMPs. The study is the first to report ADR reporting among TMPs in Nigeria. The information generated will therefore serve as evidence in promoting the regulations and good policies towards traditional medicines, as well as paving way for subsequent integration of such care. The findings also suggest the need for advocacy, education and training of the TMPs on identification and reporting ADRs. The main limitation of our study was the relatively small number of respondents and unwillingness of most of those approached to participate. They felt the investigators are trying to police them. In addition, some other factors that are associated with self-reporting such as accuracy of recall and personal bias could also have affected, in some ways, the results of this study.

Conclusion

This study revealed deficiency in knowledge with a positive perception of adverse drug reaction reporting among traditional medicine practitioners. However, barriers towards ADR reporting were not significant. These findings suggest the need for advocacy, education and training of the TMPs on identification and reporting ADRs in order to improve healthcare regulations and service delivery.

Table 2: Knowledge of ADR reporting among traditional medicine practitioners.

Knowledge	Frequency (%)		Mean score ± SD
	Yes	**No**	
Know adverse drug reaction (ADR)	67 (63.8)	38 (36.2)	
Come across ADR	41 (39.0)	64 (61.0)	
Know how to report ADR	43 (41.0)	62 (59.0)	
Heard of ADR reporting	50 (47.6)	55 (52.4)	3.57 ± 2.10
ADR is not harmful and life threatening	30 (28.6)	75 (71.4)	
Training on ADR reporting	44 (41.9)	61 (58.1)	
Heard of Pharmacovigilance	45 (42.9)	60 (57.1)	
Heard of NAFDAC	85 (81.0)	20 (19.0)	

Table 3: Perception onADR reporting among traditional medicine practitioners.

Perception	Frequency (%)		Mean score ± SD
	Yes	No	
Pharmacovigilance is not only ADR reporting	67 (63.8)	38 (36.2)	
Traditional medicines are not devoid of ADR	67 (63.8)	38 (36.2)	
Traditional medicine practitioners can report ADR	24 (22.9)	81 (77.1)	
Patients ADR must be reported	63 (60.0)	42 (40.0)	4.66 ± 1.52
Not all my medicines are safe	52 (49.5)	53 (50.5)	
ADR reporting will improve the healthcare system	87 (82.9)	18 (17.1)	
ADR reporting is my professional obligation	51 (48.6)	54 (51.4)	
ADR reporting is as important as treating patient	78 (74.3)	27 (25.7)	

Table 4: Barriers for ADR reporting among traditional medicine practitioners.

Barriers	Frequency (%)		Mean score ± SD
	Yes	No	
Keep records of your patients	59 (56.2)	46 (43.8)	
Follow-up your patients	74 (70.5)	31 (29.5)	
Update knowledge of medicines	84 (80.0)	21 (20.0)	
Belong to professional organization	80 (76.2)	25 (23.8)	4.99 ± 1.42
Have registered medicines	30 (28.6)	75 (71.4)	
Time and resources for ADR reporting	41 (39.0)	64 (61.0)	
Remuneration for ADR reporting not necessary	71 (67.6)	34 (32.4)	
Willing to implement ADR reporting	85 (81.0)	20 (19.0)	

Table 5: Association between socio-demographics with knowledge, perception and barriers for ADR reporting.

Variable	Category	X^2–test(p – value)		
		Knowledge	Perception	Barriers
Gender	Male	0.565	0.784	0.553
	Female			
Age (Years)	< 20	0.016*	0.045*	0.487
	20 - 29			
	30 - 39			
	40 - 49			
	50 - 59			
	≥ 60			
Tribe	Hausa	0.174	0.054	0.429
	Yoruba			
	Others			
Educational status	Tertiary	0.101	0.473	0.926
	Secondary			
	Primary			
	Informal			
Practice ownership	Family	0.035*	0.141	0.961
	Partnership			
	Sole proprietorship			
Practice Setting	Ambulatory	0.078	0.387	0.027*
	Stationed			
	Both			
Position/rank	Manager/owner	0.048*	0.066	0.482
	Sales representative			
Years of experience	< 5	0.048*	0.528	0.345
	6 - 10			
	11 - 15			
	16 - 20			
	> 20			

* = $p ≤ 0.05$

Conflict of interest

The authors declare no conflict of interest.

Authors' Declaration

The authors hereby declare that the work presented in this article is original and that any liability for claims relating to the content of this article will be borne by them.

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