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Educational intervention to improve the knowledge, attitude and practice of healthcare professionals regarding pharmacovigilance in South-South Nigeria

Abimbola O. Opadeyi, Annie Fourrier-Réglat and Ambrose O. Isah

Abstract

Background: Our aim in this study was to evaluate the effect of a combined educational intervention and year-long monthly text message reinforcements *via* the Short Messaging System (SMS) on the knowledge, attitude and practice (KAP) of healthcare professionals (HCPs) towards pharmacovigilance.

Methods: Six randomly selected teaching hospitals in the South-South zone of Nigeria were randomized in 1:1 ratio into intervention and control groups. The educational intervention consisted of delivering a seminar followed by sending monthly texts message reinforcements *via* SMS over 12 months. Then a semi-structured questionnaire regarding the KAP of pharmacovigilance was completed by HCPs working in the hospitals after the intervention. Data was analysed descriptively and inferentially.

Results: A total of 931 HCPs participated in the post intervention study (596 in the intervention and 335 in the control). The M:F ratio was 1:1.5. According to the KAP questionnaire, a significant difference was observed between the intervention and control groups, regarding knowledge of the types of adverse drug reactions (ADRs). ADR resulting from pharmacological action of the drug (85.6% *versus* 77%, $p = 0.001$), the fact that ADRs can persist for a long time; (60.1% *versus* 53.4%, $p = 0.024$) and a higher awareness of the ADR reporting form (48.7% *versus* 18.8%, $p < 0.001$). Most respondents in the intervention group (68.5% *versus* 60.6%, $p = 0.001$) believed they should report ADRs even if they were unsure an ADR has occurred, a greater proportion of HCPs from the intervention group had significantly observed an ADR (82% *versus* 73.4%, $p = 0.001$). Furthermore, of the 188 who had ever reported an ADR, 41% from the intervention group used the national ADR reporting form compared with 19.8% from the controls ($p < 0.001$).

Conclusion: This educational intervention and the use of SMS as a reinforcement tool appeared to have positively impacted on the knowledge and practice of pharmacovigilance in South-South Nigeria with a less-than-impressive change in attitude. Continuous medical education may be required to effect long-lasting changes.

Keywords: adverse drug reaction reporting, attitude and practice, educational intervention, healthcare professionals, knowledge, Nigeria, pharmacovigilance, SMS

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Correspondence to:
Abimbola O. Opadeyi
Department of Clinical Pharmacology and Therapeutics, University of Benin, PMB 1151, Ugbowo Lagos Road, Benin-City, Edo State 300001, Nigeria
felabimbola@yahoo.com

Annie Fourrier-Réglat
Pharmacoepidemiology, Université de Bordeaux, Bordeaux, France
Bordeaux PharmacoEpi, INSERM CIC1401, Bordeaux, France
CHU de Bordeaux, Pôle de santé publique, Bordeaux, France

Ambrose O. Isah
Department of Clinical Pharmacology and Therapeutics, University of Benin, Benin-City, Nigeria Department of Medicine, University of Benin Teaching Hospital, Benin-City, Nigeria
National Agency for Food and Drug Administration and Control, Federal Ministry of Health, Abuja, Nigeria

Abimbola O. Opadeyi
Department of Medicine, University of Benin Teaching Hospital, Benin-City, Nigeria

Introduction

The scope of pharmacovigilance has increased over the years from reporting mainly adverse drug reactions (ADRs) to reporting cases of medication errors, misuse of medicines, drug dependence, and lack of effectiveness, among others.[1] Product concerns have also been expanded to include herbal medicines, biologics,

and vaccines, as well as blood products.[1] The main form of reporting remains the spontaneous method, which has been beset with the issue of under-recognition and under-reporting of ADRs, especially with the increased scope and newer product concerns.[2] The scenario may be worse in Africa where the recognition of drug-related events appears to be poor, as medicines are associated only with the benefits they render and not the harmful effects that may ensue from them.[3]

Pharmacovigilance is an important and gradually developing discipline in Nigeria that has been strengthened by the development of key policy documents such as the National Drug Policy and recently, the National Pharmacovigilance Policy.[4,5] To encourage this growth, the National Pharmacovigilance Centre (NPC) has been active by engaging the media to disseminate awareness to the general public, organizing pharmacovigilance training to various cadres of healthcare professionals (HCPs) over the years and in different tiers of institutions since joining the international drug monitoring programme in 2004.[6,7] The growth of the pharmacovigilance system rests basically on the capacity development of the HCPs, as well as education of the public.[1]

In Nigeria, preliminary single-institutional studies have also shown ignorance of procedures in reporting, lack of knowledge of the Nigerian national reporting forms, as well as difficulty in determining the occurrence of an ADR or lack of willingness in reporting a well-known reaction were some of the factors that may be responsible for under-reporting.[8–10] Furthermore, according to NPC's guide to reporting ADRs,[11] all HCPs can forward ADR reports. Education of the HCPs on recognition and reporting of the drug related events is essential towards ensuring increased numbers as well as improving the quality of ADR reports.[12]

Educational strategies towards improving the knowledge and attitude of the HCPs have been carried out in different parts of the world using different methods. These include the use of didactic lectures, presentations, posters relating to pharmacovigilance and ADR reporting, different modes of reminders, use of safety bulletins and safety newsletters among others.[13–17] Rates of success of the strategies varied depending on the type of HCP. It has also been shown that a multidimensional approach to changing provider behaviour is key to a successful intervention.[18]

In resource-constrained settings, interventional strategies which are easily delivered such as the use of the short messaging system (SMS) in sending reminders may be useful for improving knowledge of pharmacovigilance in HCPs.[16,19] In Nigeria, mobile phone penetration is quite high and no study has evaluated the impact of training and SMS monthly reinforcements on improving the knowledge, attitude and practices (KAPs) pertaining to pharmacovigilance, despite findings which suggest that increased awareness and training may improve the practice of pharmacovigilance.[13] In this study, we therefore set out to evaluate the effect of a combined educational seminar and year-long monthly SMS reinforcements on the KAP of pharmacovigilance of HCPs practising in the South-South zone.

Methods

Setting

The study was conducted in teaching hospitals that are tertiary care centres in the South-South geopolitical zone of Nigeria, located in the coastal region of Nigeria and home to about 21 million residents (national census 2006). The zone comprises six states: Akwa-Ibom, Bayelsa, Cross-Rivers, Delta, Edo and Rivers State. All hospitals have a complement of doctors, pharmacists and nurses to cater to the health needs of the populace.

Design

A repeated cross-sectional study with teaching hospitals randomized to intervention and control sites was conducted from January 2016 to April 2017. This design was selected in view of the high probability of loss to follow up, exit of resident doctors from the programme and posting of some other members of staff to outstations.[20] The study now consisted of two sets of participants, both before and 12 months after the intervention, to account for the dynamics in a teaching-hospital setting.

Selection of facilities and randomization. A sampling frame of all tertiary hospitals in the zone was obtained to include teaching hospitals, federal medical centres, as well as specialist hospitals that have a particular focus for treatment such as neuro-psychiatric hospitals. Teaching hospitals were selected for the study, as they provided the widest access to both patient and HCP complement and were also in a position to train different

cadres of undergraduates and postgraduates. There were eight teaching hospitals in the zone and then six teaching hospitals were randomly selected using a table of random numbers, with one teaching hospital representing a state. Other tertiary hospitals in the zone were excluded from the study as they were not teaching hospitals. To be included in the study, ethical and institutional approval was required from the ethics and research committee and the chief medical director of the institution, respectively. Six institutions were included in the study, namely: University of Benin Teaching Hospital Benin-City, Edo State, (UBTH); Delta State University Teaching Hospital Oghara, Delta State (DELSUTH); Niger Delta University Teaching Hospital Okolobri, Bayelsa State, (NDUTH); University of Port Harcourt Teaching Hospital, Port Harcourt, Rivers State, (UPTH); University of Uyo Teaching Hospital, Uyo, Akwa-Ibom State (UUTH); and University of Calabar Teaching Hospital, Calabar Cross-River State, (UCTH). They were randomized in a 1:1 ratio into either intervention or control groups prior to commencement of the study following ethical and institutional approval.

Interventions

An intervention was implemented both at the level of the hospital and to individuals in the hospitals belonging to the intervention, namely UBTH; UUTH and UCTH.

Educational intervention

The design and effectiveness of an educational intervention in changing behaviour of healthcare workers has been discussed in various studies.[18,21,22] The design here consisted of an active intervention with a seminar presentation followed by a passive year-long regular intervention (monthly broadcast of text messages). The positive impact of a mixed effect of continuous medical education and other forms of intervention in changing healthcare workers' behaviour has also been described.[23] All postregistration HCPs working in the selected teaching hospitals were eligible to be recruited into the study if they consented to participate in either the baseline study or the repeat cross-sectional study. The HCPs gave consent by completing the questionnaire and indicated their willingness for future contact. We also allowed for those who attended the seminar to receive text messages if they so indicated. House officers, pharmacy interns and students were excluded from the study as they were undergoing supervised training at the time. Only consenting HCPs were recruited into the study after stratification into the various professional cadres.

The seminar was an hour-long presentation delivered to the HCPs at specially organized meetings. It was in two parts: first, the scope and aims of pharmacovigilance were outlined using the World Health Organization (WHO) documents on pharmacoviglance.[1,11,24] The definitions of the different key items of ADRs,[25,26] the historical aspect of ADRs, and relevant history of pharmacovigilance in Nigeria was described. The number of reports presently in the Nigerian database with the system organ classification and pharmacological classification was made known.

Second, emphasis was laid on ADR reporting, types of reports, reasons to report, how to report and other reporting modalities. The submission processes and consequences, as well as frequently asked questions in ADR reporting were presented. Finally, an algorithm of the ADR reporting process was explained and the contacts of relevant persons and institutions listed. Posters and handbills regarding pharmacovigilance from the NPC were shared after the lecture. Short text messages reminding the HCPs to report all ADRs and the contacts details of the local pharmacovigilance centre personnel were sent to the HCPs in the institutions monthly over 12 months after the educational intervention. This commenced immediately after the educational seminars (Supplemental information 1).

The educational seminar took place between January 2016 and March 2016 in the three intervention hospitals. The presentation was given by one of the researchers (AOO).

The participants in the control institutions received news from the NPC as usual and they could also report ADRs to their local pharmacovigilance centres.

Questionnaire

A semi-structured questionnaire that was developed after a bibliographic and literature search from previous studies in this area[8,9,22,27–34] to evaluate their KAP of pharmacovigilance, specifically ADR reporting, was used.

The questionnaire had been pretested in 25 health professionals from different hospitals who

were attending a workshop on pharmacovigilance. They were asked about the relevance, wording and layout of the questionnaire, and modifications were made to the final questionnaire which contained 40 questions, including some open-ended questions. It was also reviewed by other clinical pharmacologists in the area. The answers to the open-ended questions were synthesized and analysed thematically.

The questionnaire contained demographics of the HCPs such as age, duration of practice, sex, institution. Also, knowledge of ADR definitions, reporting schemes, questions regarding the location of the pharmacovigilance centre was equally sought. Perception of pharmacovigilance, such as determining the occurrence of ADRs, willingness to receive incentives for reporting, belief that ADR reporting may place a career at risk, among others, were also sought. Furthermore, they were also asked about previous ADR reporting, process of handling the ADR reporting form and other ADR reporting practices in their hospitals.

There were 12 questions for the assessment of the health professionals' knowledge, 10 questions relating to the attitude and 18 questions regarding their practice of ADR reporting.

In both intervention and control sites, the questionnaire was initially (preintervention) administered to HCPs to evaluate their baseline KAP of pharmacovigilance, specifically ADR reporting, at the onset of the study; it was also administered at the end of the intervention, a year after the lecture and receipt of SMS (postintervention).

Statistical analysis

Sample size. To calculate sample size for this randomized study and to get the required sample size per s with a power of $1-\beta$, (80%) and to detect a difference of d, the sample size (n) we estimated the sample size for individual randomized study comparing two proportions using Epi Info™ version 7 software (Centers for Disease Control).[35] The proportion of those who had used the national form to ever report an ADR was about 26% in a previous study,[9] and we hoped that the intervention would improve the prevalence by 40% at a power of 80% and a 95% confidence interval. The estimated sample size for each of the studies was 178 HCPs and cumulatively, 356. A 15% nonresponse rate was anticipated, and this increased the sample size to 410 persons (205 per arm).

Data analysis. The study was analysed descriptively using frequencies and proportions. In defining an ADR, the key elements (noxious and unintended) had to be present to be regarded as a correct answer. Partially correct answers may contain one or the other and an incorrect answer need not contain any of the key elements or related synonyms. The various answers from open-ended question were synthesized thematically, and similar answers merged (multiple responses were accepted). The chi-square test was used to assess categorical variables and the significance value set at 0.05. SPSS (IBM SPSS Statistics for Windows, Version 21.0, Armonk, NY: IBM Corp) version 21 was used for the analysis of the study.

Ethical consideration

Ethical approval was obtained from the research and ethics committee of all the selected institutions: DELSUTH: DELSUTH/HREC/2015/024; NDUTH: NDUTH/REC/0005/2015; UBTH: UBTH:ADM/E22/2/VOL.VII/1245; UCTH: UCTH/HREC/33/360; UPTH: UPTH/ADM/90/S.II/VOL.X/668; and UUTH: UUTH/AD/S/96/VOL.XIV/357. Written Informed consent was obtained from each individual in the study. The participants were assured that their responses would be kept confidentially and not shared with third parties. All ethical considerations were observed. A further institutional approval was obtained from the management of the hospitals.

Results

The approximate number of postregistration HCPs working in the selected hospitals who were eligible for inclusion in the study as at January 2016 were 4912, with 2085 doctors (42.4%), 2662 nurses (54.2%) and 165 pharmacists (3.4%). There were 3099 HCPs in the intervention arm and 1813 in the control arm. Only about one-third of HCPs in the intervention arm participated in the intervention despite invitation being sent to all HCPs.

In all, a total of 811 HCPs (65% intervention and 35% control arms) participated in the preintervention study in 2016 (response rate of 70.8%) and 931 HCPs in the repeated cross-sectional study with a response rate of 77.6 % (64% intervention and 36% control). The HCPs who participated in the pre- and postintervention surveys were very similar. However, mean age was slightly

Table 1. Characteristics of HCPs between the intervention and control groups, *n* (%).

Characteristics	Preintervention			Postintervention		
	Intervention (*n* = 524)	Control (*n* = 287)	*p* value[1]	Intervention (*n* = 596)	Control (*n* = 335)	*p* value[1]
Age, years, mean (SD)	38.9 (7.9)	39.1 (8.4)	0.825	37.4 (7.9)	39.8 (7.9)	**<0.001**
Years of practice (SD)	12.5 (8.3)	12.8 (8.1)	0.604	9.8 (6.8)	9.6 (6.9)	0.737
Sex						
Women	292 (55.7)	181 (63.1)		339 (56.9)	168 (50.1)	
Men	203 (38.7)	94 (32.8)	0.122	232 (38.9)	156 (46.6)	0.072
Unknown	29 (5.5)	12 (4.2)		25 (4.2)	11 (3.3)	
Type of HCP						
Doctors	238 (45.4)	135 (47.0)	0.938	281 (47.1)	165 (49.4)	**0.005**
Nurses	224 (42.7)	119 (41.5)		270 (45.3)	131 (39.2)	
Pharmacists	53 (10.1)	27 (9.4)		31 (5.2)	35 (10.5)	
Unknown	9 (1.7)	6 (2.1)		14 (2.3)	3 (0.9)	

[1]*p* value from Pearson chi-square test.
Bold numerals indicate significance.
HCP, healthcare professional; SD, standard deviation.

higher in the control group and there were more doctors participating (Table 1).

Knowledge of pharmacovigilance (scope and product concerns; Table 2). In evaluating HCP knowledge of pharmacovigilance, no significant difference was found between the groups with regards the preintervention questionnaire.

From the postintervention questionnaire, there was a significant increased knowledge for several items between the groups. The following were better known by the HCPs from the intervention group: 'ADR can result from the pharmacological action of the drug'; 'ADRs can persist for a long time'; 'ADRs can occur with newly marketed medicines, vaccines, biological medicines' and 'reports of cases of drug abuse or drug dependence'. Furthermore, regarding knowledge of what to report, most respondents in the intervention group would more likely submit reports of life-threatening ADRs.

Knowledge of reporters and pharmacovigilance centres (Table 3). There was a significant increased awareness of the existence of the South-South Zonal Pharmacovigilance Centre as well as the national ADR reporting form between the intervention and control groups according to the postintervention questionnaire. In the preintervention survey, most of the respondents believed all cadres of HCPs could report ADRs, with doctors being the preferred group from the preintervention. However, from the postintervention questionnaire, it appeared that only those in the control still preferred doctors to report.

Attitude of healthcare workers (Table 4). Attitude before the intervention was not significantly different between the groups. According to the postintervention questionnaire, respondents in the control group had a significantly higher proportion of positive attitudes than in the intervention group, for most of the items regarding ADR reporting apart from reporting when not certain an ADR has occurred. However, belief about the importance of reporting ADRs was not different between the groups.

HCPs' practice of ADR reporting (Table 5). The proportion of HCPs in the intervention group who had received training in ADR reporting increased statistically compared with those in the control group after the intervention (24.3% *versus*

Table 2. Knowledge of types of ADR and product concerns of pharmacovigilance of HCPs between the intervention and control groups, before and after the intervention, *n* (%).

Knowledge items	Preintervention			Postintervention		
	Intervention (*n* = 524)	Control (*n* = 287)	*p* value	Intervention (*n* = 596)	Control (*n* = 335)	*p* value
	Yes *n* (%)	Yes *n* (%)		Yes *n* (%)	Yes *n* (%)	
Correct definition of ADR	111 (21.2)	59 (20.6)	0.894	47 (7.9)	19 (5.7)	0.123
Resulting from normal pharmacological action of drug	424 (80.9)	239 (83.3)	0.790	510 (85.6)	258 (77.0)	**<0.001**
New and unexpected ADRs	455 (86.8)	237 (82.6)	0.360	478 (80.2)	248 (78.0)	0.056
ADRs persisting for a long time	316 (60.3)	164 (57.1)	0.437	358 (60.1)	179 (53.4)	**0.024**
ADRs delayed for a long time	189 (36.1)	99 (34.5)	0.369	228 (38.3)	104 (31.0)	**0.028**
ADRs occurring in the following						
At the end of use of medicines	303 (57.8)	161 (56.1)	0.798	372 (62.4)	202 (60.3)	0.257
A newly marketed medicine	486 (92.7)	270 (94.1)	0.843	542 (90.9)	267 (79.7)	**<0.001**
An established medicine and vaccine	436 (83.2)	238 (82.9)	0.090	480 (80.5)	244 (72.8)	**<0.001**
Herbal medicine	343 (65.5)	203 (70.7)	0.319	406 (68.1)	241 (71.9)	0.183
Biological medicine	358 (68.3)	203 (70.7)	0.267	386 (64.8)	240 (71.6)	**0.046**
Complementary medicine	349 (66.6)	197 (68.6)	0.414	397 (66.6)	224 (66.9)	0.454
Vaccine	426 (81.3)	228 (79.4)	0.889	447 (75.0)	247 (73.7)	**0.030**
Over-the-counter preparations	411 (78.4)	223 (77.7)	0.995	433 (72.7)	287 (85.7)	**<0.001**
When used by children	393 (75.0)	213 (74.2)	0.823	431 (72.3)	253 (75.5)	0.604
Medicines misused or used with error	319 (60.9)	171 (59.6)	0.538	399 (66.9)	225 (67.2)	**0.030**
In cases of drug abuse	279 (53.4)	170 (59.2)	0.370	388 (65.1)	205 (61.2)	**0.024**
In cases of drug dependence	286 (54.6)	170 (60.3)	0.471	376 (63.1)	196 (58.5)	**0.037**
Reporting mild ADRs	172 (32.8)	88 (30.7)	0.227	226 (37.9)	100 (29.9)	0.082
Reporting life-threatening ADRs	346 (66.0)	169 (58.9)	0.242	436 (73.2)	218 (65.1)	**<0.001**

Bold numerals indicate significance.
ADR, adverse drug reaction; NPC, National Pharmacovigilance Centre; SSZPC, South-South Zonal Pharmacovigilance Centre.

11.6%, $p < 0.001$). Also, the proportion who had ever observed an ADR increased significantly (82% *versus* 73.4%, $p < 0.001$) in the HCPs from the intervention group. Use of the ADR reporting form was significantly different between the control and intervention groups from both the pre- and postintervention questionnaire.

Of the respondents who had ever reported an ADR using the national ADR reporting form, 18.6% were able to access the form in the intervention group compared with 9.9% in the control ($p = 0.02$). ADR reporting in the intervention group was also higher at 29.8% *versus* 18.7% ($p < 0.001$).

Table 3. Awareness of pharmacovigilance centres and reporting status of HCPs between the intervention and control groups, before and after the intervention, *n* (%).

	Preintervention			Postintervention		
	Intervention ($n = 524$)	Control ($n = 287$)	*p* value	Intervention ($n = 596$)	Control ($n = 335$)	*p* value
Awareness of the local pharmacovigilance centre	322 (61.5)	77 (26.8)	**<0.001**	345 (57.9)	135 (40.3)	**<0.001**
Awareness of the SSZPC	162 (30.9)	54 (18.9)	**<0.001**	273 (45.8)	78 (23.3)	**<0.001**
Awareness of the NPC	282 (53.8)	128 (45.1)	0.054	294 (49.3)	198 (59.1)	**0.009**
Awareness of the ADR reporting form	199 (38.0)	84 (26.6)	0.047	290 (48.7)	63 (18.8)	**<0.001**
Doctors to report	481 (91.8)	267 (93.0)	0.737	517 (86.7)	315 (94.0)	**0.006**
Nurses to report	467 (89.1)	258 (89.9)	0.755	498 (83.6)	305 (91.0)	**0.006**
Pharmacists to report	472 (90.4)	261 (90.9)	0.610	531 (89.1)	311 (92.8)	**0.030**

p value from Pearson chi-square test.
Bold numerals indicate significance.
ADR, Adverse Drug Reaction; HCPs, healthcare professionals; NPC, National Pharmacovigilance Centre; SSZPC, South-South Zonal Pharmacovigilance Centre.

Discussion

This study evaluated the effect of an educational intervention and reminders in improving the KAP of HCPs in the South-South zone of Nigeria towards pharmacovigilance in order to ultimately improve the number of reports from the zone. This was the first study, to our knowledge, in this resource-constrained setting to utilize a method of first, a didactic lecture, followed by monthly SMS reinforcement reminders for 12 months, on the necessity of reporting ADRs. The SMS was utilized due to its accessibility and the high mobile phone penetration in Nigeria. The HCPs showed improvement in some of the knowledge items, the perception and practice of pharmacovigilance. We also believe this method had an advantage of reaching a high proportion of HCPs, as the intervention was delivered both at the level of the institution and to consenting healthcare workers, which would also have allowed for dissemination between the members of the same institution.[36,37] Furthermore, the randomized nature of the study allowed for comparison of the effect of the intervention with centres that had not received the intervention and this further strengthened the study; other single-institutional pre–post studies had also suggested the positive impact of mixed educational strategies.[16,17]

There was a difference in the knowledge of the health professionals after the intervention, especially in the items relating to the types of ADR; this is important, as recognition of the various types of ADR is the first step in ensuring that reports may ensue from such cases.[38] Under-recognition has been a major drawback in ADR reporting worldwide,[3] as HCPs may be unaware of the expanded scope and product concerns of pharmacovigilance, therefore this improvement is very important in tackling this issue. The knowledge of the scope of pharmacovigilance also improved after the intervention in this study, as seen in a similar study by Abu *et al.*[39] This is notable, as awareness of the scope will increase reporting of such cases and can stimulate targeted public health intervention, as a systematic review has also suggested that up to 50% of those sampled felt all medicines available in the market were safe and may not require surveillance.[40] Furthermore, the knowledge that cases of medication errors, drugs misused and abused should be reported are important considerations of public health importance, especially as health professionals are usually reluctant in reporting such cases.[41] In effect, understanding that such cases are to be reported constitutes a significant gain to the participating health professionals.

We also noted an improvement in the awareness of existence of the South-South Zonal Pharmacovigilance Centre following the intervention in this study. This is a key finding, as this

Table 4. Attitude to ADR reporting of HCPs between the intervention and control groups, before and after the intervention, *n* (%).

Attitude to ADR reporting items	Preintervention			Postintervention		
	Intervention (*n* = 524)	Control (*n* = 287)	*p* value	Intervention (*n* = 596)	Control (*n* = 335)	*p* value
Belief that all ADRs should be reported	481 (91.8)	262 (91.7)	0.191	520 (87.2)	306 (91.3)	0.051
No difficulty in determining occurrence of ADRs	303 (57.8)	153 (53.3)	0.671	346 (58.1)	212 (63.3)	**0.003**
Reporting when unsure if ADR has occurred	388 (74.0)	203 (70.7)	0.703	408 (68.5)	203 (60.6)	**<0.001**
Reporting when not sure it will make a difference	370 (70.6)	189 (65.9)	0.264	337 (56.5)	239 (71.3)	**<0.001**
Not expecting to receive incentives for reporting	375 (71.6)	239 (83.3)	**<0.001**	402 (61.1)	264 (78.8)	**<0.001**
Professional obligation to report	482 (92.0)	258 (89.9)	0.787	511 (85.7)	312 (93.1)	**0.005**
Reporting should be mandatory	468 (89.3)	260 (90.6)	0.335	525 (88.1)	307 (91.6)	**0.013**
ADR reporting does not put career at risk	479 (91.4)	260 (90.6)	0.510	505 (84.7)	310 (92.5)	**0.002**
ADR reporting should not be for publishing only	461 (88.0)	260 (90.6)	0.290	462 (77.5)	317 (94.6)	**<0.001**

Bold numerals indicate significance.
ADR, adverse drug reaction.

regional centre had been newly created, but as seen in the baseline results, the awareness of its existence was low, initially. Regionalization of ADR reporting centres has been shown to improve the number of reports and timeliness of those reports.[42] Therefore, increasing the awareness of this centre was one of the key components of the educational intervention in this study and this may be the initial step in improving reports. Similarly, there was an increased awareness of the ADR reporting form from baseline. A key determinant in reporting with the national form is the awareness of its existence, as previous studies have shown that although health professionals observe ADRs, they may report using other routine hospital processes and most ADRs go unreported.[9,38,43]

In this study, the respondents in the intervention group still believed they should report, even when unsure an ADR has occurred. This positive attitude may sustain the culture of reporting, as uncertainty of ADR occurrence has been suggested as a probable cause of under-reporting.[38] Other studies have also suggested that a negative attitude contributes to under-reporting.[40,43,44] However, we note the change in the positive attitudes in the control group. This may be because the respondents in this group were exposed to the baseline questionnaire, which may have stimulated interest in ADR reporting and this may have accounted for these changes. Also, we could not rule out repeated lectures on pharmacovigilance at those sites in the control arm due to the presence of enthusiastic HCPs encountered during the baseline assessment. Attitudinal changes that have been described as key components towards improving the behaviour of health professionals[23,37] are quite complex to evaluate, as studies have suggested several factors are responsible for behavioural changes.[45]

To attain the goal of increasing ADR reports at the NPC, it is recommended that the national ADR form be used in reporting ADRs. This was emphasized during the intervention and

Table 5. Practice of pharmacovigilance of HCPs between the intervention and control groups, before and after the intervention, *n* (%).

Practice items	Preintervention			Postintervention		
	Intervention (*n* = 524)	Control (*n* = 287)	*p* value	Intervention (*n* = 596)	Control (*n* = 335)	*p* value
Training on ADR	84 (16.0)	43 (15.0)	0.821	145 (24.3)	39 (11.6)	**<0.001**
Observed ADR	423 (80.7)	240 (83.6)	0.222	489 (82.0)	246 (73.4)	**<0.001**
Reported ADR	166 (31.7)	78 (27.2)	0.394	188 (31.5)	91 (27.2)	0.256
Use of the national reporting form*	80 (49.4)	18 (23.4)	**<0.001**	77 (41.0)	18 (19.8)	**<0.001**
Easy access of ADR forms*	49 (29.5)	10 (12.8)	**<0.001**	35 (18.6)	9 (9.9)	**0.022**
Easy reporting with the ADR form*	84 (50.6)	16 (20.5)	**<0.001**	56 (29.8)	17 (18.7)	**<0.001**
Easy mode of returning ADR forms*	16 (9.6)	3 (3.8)	**0.003**	34 (18.1)	6 (6.6)	**<0.001**

*The number of respondents who had reported an ADR is the denominator.
p value from Pearson chi-square test.
Bold numerals indicate significance.
ADR, adverse drug reaction.

subsequent reminders sent to the HCPs. We observed an increase in the proportions of respondents who recalled having ever used the form to report, rather than other modes of reporting. This finding supports the possible influence of long-term reinforcement as seen in this study with the 12-month-long monthly SMS reminders, as well as education on improving ADR reports, and reiterates that frequent continuous medical education and possibly the use of mobile technology may serve as a means to improving the practice of pharmacovigilance.[12,16,23] The use of the SMS in this study served to buttress the need to tailor interventions to the respondents in a manner that could be reproducible and would not require excessive funding to execute in future.

Again, the cumbersome processes of accessing and returning ADR reporting forms are factors that have been linked to poor reporting rates.[12,46] Therefore, location and phone numbers of the local pharmacovigilance centres were made available to the HCPs in order to observe if this would ease the process of access or return. It was observed that the respondents still had some difficulty in accessing, reporting with and returning the forms, unlike similar studies that showed improvement in HCPs' understanding of the reporting processes.[15,47] This suggests that all aspects of the pharmacovigilance systems at the institutions in this study may need to be frequently evaluated and strengthened.[48,49]

Limitations: the control arm in this study may have had some external training on pharmacovigilance either from the NPC or the local pharmacovigilance committee conducted pharmacovigilance activities. We also could not evaluate the impact of the intervention in the respondents who participated in the first survey due to the logistics of accessing the HCPs and the possibility of a very high dropout rate. However, the repeat cross-sectional design has also been shown to give comparable results when applied in same group[50] and we did not expect the population of the hospitals to change much during the course of the study despite the dynamics of the teaching-hospital setting. We could also not rule out contamination in this study, despite all attempts to minimize it. Some respondents failed to answer all questions; this may be a reflection of poor knowledge of those HCPs and will require further evaluation. We also did not address the influence of factors such as specialty, area of practice or sex on the intervention results. Future interventions will

target various cadres and specialties in order to improve ADR awareness and practice. Again, we could not ascertain if the SMS were delivered to all those who participated or indeed, if they were read. The Nigerian health sector also underwent major industrial actions that may have impacted on the results.

Conclusion

There was an improvement in the knowledge and practice of pharmacovigilance and ADR reporting by the respondents following the educational intervention. However, attitudinal changes may require further targeted interventional strategies. SMS reminders as a reinforcement tool appear to have been useful in this setting. Further, an improvement in the reporting process may also improve the HCPs' practice of pharmacovigilance.

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Conflict of interest statement

The authors declare that there is no conflict of interest.

Supplemental material

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ORCID iD

Abimbola O. Opadeyi https://orcid.org/0000-0003-0630-2117

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