Original Article

Pharmacovigilance: Awareness and Practice of Nurses and Midwives in Monitoring and Reporting Adverse Drug Reactions in a Selected University Teaching Hospital, Rwanda

David Ryamukuru[1*,2], Joselyne Mukantwari[1,3], Emmanuel Munyaneza[4], Timothee Shahidi Twahirwa[5], Vedaste Bagweneza[1], Adeline Nzamukosha[6], Valens Musengamana[5], Dancilla Nyirasebura[4], Omondi Lilian[7]

[1]*Department of General Nursing , College of Medicine and Health Sciences , University of Rwanda, Kigali, Rwanda*
[2]*School of Nursing, University of Michigan, Ann Arbor, Michigan, United States*
[3]*Arthur Labatt Family School of Nursing, University of Western Ontario, London, Ontario, Canada*
[4]*Operating Theatre, University Teaching Hospital of Kigali, Kigali, Rwanda*
[5]*Quality Assurance Directorate, University Teaching Hospital of Kigali, Kigali, Rwanda*
[6]*Department of Pharmacy, University Teaching Hospital of Kigali, Kigali, Rwanda*
[7]*University of Nairobi, Nairobi, Kenya*

***Corresponding author:** David Ryamukuru. Department of General Nursing , College of Medicine and Health Sciences , University of Rwanda, Kigali, Rwanda. Email: daviramu@yahoo.fr

Abstract

Background

Adverse drug reactions result in thousands of deaths, disabilities, and other serious outcomes. Nurses and midwives administer drugs, monitor both therapeutic and adverse drug reactions, and are on the front line of safety reporting. This study aimed to assess awareness of nurses and midwives about pharmacovigilance and their practice in monitoring and reporting adverse drug reactions at the University Teaching Hospital of Kigali .

Methods

We conducted a cross-sectional study on 147 randomly selected nurses and midwives. Self-administered questionnaires were used to collect data. We analyzed data using SPSS version 22 computer software for descriptive and inferential statistics.

Results

Concerning the awareness of nurses and midwives, 88% had heard about pharmacovigilance, and 22.3% were aware of Rwanda Food and Drug Authority. Nearly two-thirds (62.3%) reported inadequate practice in monitoring adverse drug reactions. Their practice was associated with having heard about pharmacovigilance (p=0.004) and knowing the hospital's adverse drug reactions reporting system (p=0.005). Concerning practice in reporting adverse drug reactions, 66.2% had observed adverse drug reactions, and 18.2% filled out adverse event notification forms.

Conclusion

Few nurses and midwives were aware of the pharmacovigilance system in Rwanda, and many of them reported inadequate practices toward monitoring and reporting adverse drug reactions .

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Keywords: Pharmacovigilance, adverse drug reactions, nurses, midwives, awareness, practice

Background

According to the World Health Organization (WHO), pharmacovigilance is science and activities related to detecting, assessing, understanding, and preventing adverse drug effects or any other possible drug-related problems.[1] The WHO also defines Adverse Drug Reactions(ADRs) as a harmful and unexpected response to medicines at normal doses.[2]

In 1961, thousands of children were born with congenital malformation due to using thalidomide in pregnant women.[3] With this background, the pharmacovigilance system emerged to detect medicine's previously unknown or poorly understood adverse effects.[3] In 1968, the WHO created a system that facilitates the international collection of suspected ADR reports. The vigilance is the WHO database, which is operated by the Uppsala Monitoring Centre (UMC) in Sweden, receives ADR reports from national Pharmacovigilance Centres (PVCs). The PVCs collect case reports from all possible sources, including health care professionals, patients, and marketing authorization holders.[2] In line with this system, in law 003/2018 of 09/02/2018, the Government of Rwanda established the Rwanda Food and Drug Authority (Rwanda FDA). One of Rwanda FDA's missions is to conduct pharmacovigilance and post-marketing surveillance for safety and quality of drugs.[4]

Reporting the ADRs via pharmacovigilance systems helps protect patients from harm unidentified during the pre-approval period of drugs. Adverse event reporting system in the US from 2006 to 2014 revealed that 902,323 serious outcomes resulted from approved drugs. Those outcomes include 244,408 deaths, 72,141 disabilities, and 585,774 other serious outcomes.[5] However, developing countries underreport ADRs.[6,7] In East Africa, less than one percent of the health facilities in each country report medicine-related harm.[8] In Rwanda, until December 2018, no suspected medicine-related harm was submitted to the national pharmacovigilance unit.[8]

The reporting of ADRs between 1950 and June 2015 resulted in withdrawing 353 medicinal products from the market.[9] Health professionals are a significant source of ADR reporting, [7,12] and they also render the national pharmacovigilance system successful.[12,13] However, studies found that health professionals lack awareness of pharmacovigilance and knowledge about ADRs reporting.[12–14] A systematic review also revealed that 67.1% of nurses observed ADRs during their professional experience; only 21.2% reported ADRs; lack of knowledge/ training was the leading cause of this low ADRs reporting practice. [15] Thus, healthcare professionals should know pharmacovigilance systems and develop the necessary knowledge, attitudes, and skills that enhance their ability to report adverse drug reactions.

Nurses and midwives are drug administrators at all levels of the healthcare system in Rwanda. They administer drugs and monitor both therapeutic and adverse drug reactions. They are the last defense line for patient safety compromises, and they are on the frontline of safety reporting. Therefore, their involvement in ADRs reporting or any patient safety initiative toward medication might protect patients from harm and optimize positive outcomes. Hence it is wise for Rwanda FDA to rely on the nurses and midwives to successfully report the ADRs and protect the patients from medical product-related harms. However, effective ADRs reporting depends on how knowledgeable they are about pharmacovigilance and the ADRs reporting system, which are still unknown among Rwandan nurses and midwives. This study aimed to assess the awareness of nurses and midwives about pharmacovigilance and their practice in monitoring and reporting ADRs at the University Teaching Hospital of Kigali (UTHK).

Methods

Design, setting, and population

We conducted a cross-sectional study to assess awareness of nurses and midwives about pharmacovigilance and their practice in monitoring and reporting adverse drug reactions at the UTHK from April to June 2020. The hospital is widely known as CHUK, the French acronym "Centre Hospitalier Universitaire de Kigali." UTHK is located in Nyarugenge district, Kigali city, Rwanda. It is the biggest hospital in Rwanda, with 519 beds. UTHK offers inpatient and outpatient services and treats patients referred from district hospitals across the country. The number of nurses and midwives employed at UTHK is 503, of whom 450 (study population) are deployed in inpatient departments. They are holders of advanced diploma (A1), bachelor's degree (A0), and master's degree (MSN). The study was conducted in the inpatient departments, namely medical, surgical, pediatric, neonatal, maternity, emergency and accident, intensive care, and the renal unit. The criteria to participate in the study included being a registered nurse or midwife working in the inpatient department and providing direct care to patients. Registered nurses or midwives working elsewhere in the hospital and with no responsibility for drug administration and monitoring were excluded from the study.

Sample size and sampling procedure

The study involved 210 nurses and midwives. We calculated the sample size using the proportion formula considering the population size of 450.The proportion (p) was set at 0.5 and at 95% confidence interval , the standard score (z)= 1.96 and margin of error (MOE) = 0.05.[16] Therefore, $n= z^2\ p\ (1-p)\ /MOE^2= z^2\ 0.5(1-0.5)/MOE^2= z^2(0.25)/MOE^2$, thus, $n= (1.96)^2\ (0.25)/(0.05)^2= 384$. However, the adjustment for the population size was calculated to obtain the sample size for this study. Sample size adjusted for the population size (n)= n=n'/[1+(n'-1/N)],[16] thus, n= 384/[1+(383/450)]=207.6 ≈210.

After determining the sample size, we selected respondents using simple random sampling. We only considered a list of nurses and midwives who work in the inpatient departments. After checking the list of nurses and midwives for eligibility and removing duplicated names, we assigned numbers from one through 450 to all names of nurses and midwives on the list. Then we used an online research Randomizer at www. randomizer.org to generate 210 random numbers. Then we identified the names of participants corresponding to generated random numbers. A randomly selected nurse or midwife was contacted and requested consent to participate in this study.

Data collection procedures

We used a self-administered questionnaire to collect data. The questionnaire was adapted from similar studies [17–20]. First, we tested the questionnaire for content validity by the consensus of the research team members. Then pretested the questionnaire on 11 nurses and midwives. As the results of the pretest, we transformed open questions into closed-ended questions mainly in the sociodemographic section of the questionnaire, such as age and years of experience, because some participants skipped these questions.

Moreover, we rephrased some questions to reflect the context; for example, the yellow card for reporting suspected adverse drug reactions was replaced by an incident reporting form and an adverse event notification form available in the hospital. We only computed the Cronbach's coefficient alpha for the Likert scale for practice toward monitoring ADRs because we summed up the scores on each item to find the overall scores in practice toward monitoring ADRs. We found Cronbach's coefficient alpha of 0.90 for these 17 Likert scale items.

Finally, the items to assess awareness of pharmacovigilance and practice of ADRs reporting were yes, no, and not sure questions.

We did not sum up the scores on each item for an overall score. Therefore, we reported the percentage and frequency of response of each item for our study findings. After pretesting , the questionnaire comprised four sections: The first section was about the respondents' sociodemographic characteristics.

The second section comprised six questions related to the awareness of the nurses and midwives about pharmacovigilance in the Yes, No, Not sure answer format. The third section consisted of 17 Likert scale statements related to the practice of nurses and midwives in monitoring of ADRs. Finally, the fourth section includes six questions about the practice of nurses and midwives in reporting adverse drug reactions.

We collected data from Monday to Friday. All randomly selected nurses were contacted in their working service and were given the questionnaire with study information to read and complete the questionnaire at their convenient time. Answering the questionnaire lasted between 20-30 minutes.

Data analysis

We used the Statistical Package for Social Sciences (SPSS) version 22 computer software for data analysis. After coding, data entry, and cleaning, we ran descriptive statistics and presented frequency and percentage in tables. The seventeen items were used to assess practices of nurses and midwives in monitoring adverse drug reactions on a Likert scale of 1 to 5 points whereby 1 stands for never, 2 for rarely, 3 for sometimes, 4 for often, and 5 for always. Each respondent's scores on the Likert scale were summed up and converted to over 100 points. The overall score was categorized as a binary variable (inadequate and good practice) based on Bloom's cut-off scores.[21] A score of less than 80% was classified as inadequate practice, and a score of 80% and above was categorized as good practice. We also used the chi-square test to assess the relationship between different sociodemographic characteristics and the practice of nurses and midwives in monitoring adverse drug reactions. We considered a p-value <0.05 as a cut-off point for a statistically significant relationship.

Ethical considerations

We obtained ethical clearance from the UTHK before data collection. We also explained to the respondents the purpose of the study. The respondents voluntarily signed a written consent to participate in the study before completing the questionnaire. We informed the respondents about their right to withdraw from the study without consequence if they felt uncomfortable. The questionnaires were anonymous to ensure the confidentiality of respondents. We stored the completed questionnaires and informed consent forms in a locked cupboard. We saved the data on a computer protected with a password, and we did not associate any participant's identifiers with the data to maintain confidentiality.

Results

Sociodemographic characteristics of the respondents

Out of 210 distributed questionnaires, 147 nurses and midwives completed and returned questionnaires, corresponding to a response rate of 70%. Nearly a half of the respondents (n=68, 46.3%) were aged between 30 and 39 years old. Most of the respondents (n= 116, 78.9%), were female. Nearly two-thirds of respondents (n= 90, 61.6%) were educated to the level of advanced diploma (A1). More than a quarter of respondents (n= 42, 28.6%) were working in surgical wards, and more than a third of respondents (n=50, 34.7%) had between six to ten years of experience. (Table 1)

Table 1. Demographic characteristics of the respondents

Variable	Category	Frequency	%
Age	< 30 years	13	8.8
	30-39 years	68	46.3
	40- 49 years	52	35.4
	More than 50 years	14	9.5
Gender	Male	31	21.1
	female	116	78.9
Level of education	Advanced diploma	90	61.6
	Bachelor	51	34.9
	Masters	5	3.4
Department	medical	20	13.6
	surgical	42	28.6
	pediatrics	31	21.1
	maternity	28	19.0
	Accident and Emergency	15	10.2
	ICU	11	7.5
Experience	5 years and below	26	18.1
	6-10 years	50	34.7
	11-15 years	40	27.8
	16-20 years	19	13.2
	Over 20 years	9	6.3

Awareness of nurses and midwives about pharmacovigilance

This study revealed that most respondents (n=130, 88.4%) had heard about pharmacovigilance. More than three-quarters of respondents (n=113, 79.0%) had heard about pharmacovigilance from nursing and midwifery schools. Three-quarters of the respondents (n=110, 75.9%) learned pharmacovigilance topics in nursing and midwifery schools. Less than a third of the respondents (n=42, 29.0%) were aware of a committee responsible for pharmacovigilance in the hospital.

About half of the respondents (n=76, 52.1%) were aware of policy about pharmacovigilance in the hospital. Close to sixty percent of the respondents (n=85, 58.2%) knew the ADRs reporting system in the hospital. Most respondents (n=139,94.6%) thought pharmacovigilance is important for patient safety. Less than a quarter of respondents (n=29,22.3%) were aware of the National agency to which Adverse drug reactions are reported in Rwanda (Rwanda FDA) (Table 2).

Table 2. Awareness of nurses and midwives about pharmacovigilance

Variable	category	Frequency	%
heard about pharmacovigilance	Yes	130	88.4
	No	9	6.1
	Not sure	8	5.4
Source of pharmacovigilance information	Nursing School	113	79.0
	Workshop/training	11	7.7
	Others	6	4.2
	Not heard	13	9.1
Topic learned in nursing and midwifery school	yes	110	75.9
	no	17	11.7
	Do not remember	18	12.4
Presence of committee responsible for pharmacovigilance in the hospital	Yes	42	29.0
	No	24	16.6
	Not sure	79	54.5
Presence of policy about pharmacovigilance in your hospital	Yes	76	52.1
	No	9	6.2
	Not sure	61	41.8
Awareness about ADRs reporting system in the hospital	Yes	85	58.2
	No	23	15.8
	Not sure	38	26.0
Awareness about pharmacovigilance importance for patient safety	Yes	139	94.6
	No	1	0.7
	Not sure	7	4.8
Aware of National agency to which Adverse drug reactions are reported in Rwanda	Yes	29	22.3
	No	7	5.4
	Not sure	94	72.3

The practice of nurses and midwives toward monitoring adverse drug reactions

This study found that 81(62.3%) respondents had inadequate practice in monitoring adverse drug reactions. Having heard about pharmacovigilance (p=0.004) and being aware of the ADR reporting system in the hospital had a statistically significant association with the practice of nurses and midwives toward monitoring adverse drug reactions (p=0.005).

However, no statistically significant relationship between age, gender, level of education, working department, and years of experience of nurses and midwives and their practice of monitoring adverse drug reactions. (Table 3)

Table 3. Practice of nurses and midwives toward monitoring adverse drug reactions

Variables	Practice towards monitoring ADRs		P-value [a]
Age in years, n (%)			
<30	5(50)	5 (50)	
30-39	37(63.8)	21(36.2)	0.87
40- 49	31(63.3)	18(36.7)	
> 50	8 (61.5)	5(38.5)	
Gender, n (%)			
Male	21(77.8)	6 (22.2)	0.06
Female	60(58.3)	43(41.7)	
Level of education, n (%)			
Advanced diploma	51(63.0)	30(37.0)	0.30
Bachelor	28(63.6)	16(36.4)	
Masters	1(25.0%)	3(75.0%)	
Working department, n (%)			
Medical ward	10(55.6)	8(44.4)	0.42
Surgical ward	21(55.3)	17(44.7)	
Pediatric ward	15(57.7)	11(42.3)	
Maternity	19(73.1)	7(26.9)	
Accident and Emergency	10(83.3)	2(16.7)	
Intensive care Unit	6 (60.0)	4(40.0)	
Experience, n (%)			
5 years and below	10 (47.6)	11(52.4)	0.29
6-10 years	30(71.4)	12(28.6)	
11-15 years	21(55.3)	17(44.7)	
16-20 years	13(72.2)	5(27.8)	
Over 20 years	5(62.5)	3(37.5)	
Have you heard about pharmacovigilance before, n (%)			0.004
Yes	73(62.9)	43(37.1)	
No	1(14.3)	6(85.7)	
Not sure	7(100.0)	0(0.0%)	
Are you aware of the adverse drug reaction reporting system in your hospital, n (%)			0.005
Yes	40(53.3)	35(46.7)	
No	14 (60.9)	9(39.1)	
Not sure	27(87.1)	4(12.9)	
Total, n (%)	81(62.3)	49(37.7)	

a: P-value compares inadequate and good practices using the chi-square test

The practice of nurses and midwives toward ADRs reporting

Table 4. Practice of nurses and midwives toward adverse drug reaction reporting

Variable	Category	Frequency	%
Observation of any adverse drug reaction during/after drug administration	Yes	96	66.2
	No	49	33.8
Report form filled	Yes	81	84.4
	No	15	15.6
Report form used	Incident reporting form	52	78.8
	Adverse event notification form	12	18.2
Other ways of Reporting ADR	Matron	21	6.1
	Unit manager	56	16.2
	Team leader	45	13.0
	Pharmacist	17	4.9
	Nurses in pharmacy	12	3.5
	Pharmacovigilance unit in the hospital	7	2.0
	Patient's file	59	17.1
	Handover report	59	17.1
	physician	64	18.5
	Others	6	1.7
Motivations to report ADR	I know that all the drugs available on the market are not safe	48	15.3
	Reporting adverse drug reactions helps to identify unrecognized ADR	56	17.9
	Reporting adverse drug reactions may improve patient safety	88	28.1
	Reporting helps to calculate the incidence of ADR	58	18.5
	Reporting might help to identify predisposing factors	63	20.1
Barriers to reporting adverse drug reactions	There is no system of reporting	21	21.4
	It is not important	3	3.1
	Fear of punishment	7	7.1
	Heavy workload	11	11.2
	Insufficient knowledge in pharmacology	10	10.2
	Fear of blame	9	9.2
	It was not so serious	7	7.1
	Fear of being reported as a poor performer	5	5.1
	It was a normal side effect of the drug	12	12.2
	Hard to point out the responsible drug	4	4.1
	It is not in my scope of practice	4	4.1
	Not necessary to report every adverse drug reaction	3	3.1
	Others, specify	2	2.0

The study found that two-thirds (n=96, 66.2%) of respondents had observed an adverse drug reaction during or after drug administration, and most of them (n=81, 84.4%) filled the reporting form. Nearly a fifth (n=12, 18.2%) of respondents filled out adverse event notification forms. Concerning the other ways of reporting adverse drug reactions, the most common ways were to report to a physician (n=64, 18.5%), to document adverse drug reactions in patient's file (n=59, 17.1%), and to report adverse drug reactions during handover report (n=59, 17.1%). More than a quarter (28.1%) of respondents are motivated to report the ADR based on the knowledge that reporting ADRs may improve patient safety. The barriers mostly reported were lack of a system of reporting in the hospital (n=21, 21.4%), considering the adverse drug reactions as normal side effects (n=12, 12.2%), heavy workload (n= 11, 11.2%), and Insufficient knowledge in pharmacology(n= 10, 10.2%). (Table 4)

Discussion

Awareness of nurses and midwives about pharmacovigilance

This study showed that most nurses and midwives (88.4%) who participated in the study had heard about pharmacovigilance. The findings of this study are relatively higher than what was reported in the studies conducted in Uganda and Turkey which indicated that the majority of healthcare professionals, 52% and 66%, respectively, had heard about pharmacovigilance. [18,22] The findings of this study may be explained by the fact that most nurses and midwives (79%) who participated in this study had heard about pharmacovigilance from schools of nursing and midwifery, and three-quarters of them (75.9%) had learned the pharmacovigilance as a topic in classrooms.

This study indicates that only 29% of respondents are aware of the committee responsible for the pharmacovigilance in the hospital. This may imply that the therapeutic drug committee responsible for pharmacovigilance in the hospital does not put much emphasis on pharmacovigilance aspects so as to involve nurses and midwives in its activities, which indicates that the committee may miss out on the most important stakeholders for patient safety. The results of this study revealed that about half of the respondents (52.1%) knew about the policy on pharmacovigilance in the hospital. About sixty percent (58.2%) of the respondents were aware of the ADR reporting system in the hospital. These findings are relatively higher than only 41% and 40% of respondents in a study conducted in Turkey who knew the pharmacovigilance contact point and pharmacovigilance system in the hospital, respectively.[18] The committee responsible for pharmacovigilance in the hospital needs to reach out to the bedside nurses and midwives to train them about policy and the ADR reporting system in the hospital to maximize the ADR reporting frequency.

This study reveals that 22.3% of respondents were aware of Rwanda FDA. The findings of this study are slightly less than what a study conducted in the Kingdom of Saudi Arabia , whereby only 27.2% of nurses knew the national pharmacovigilance system.[23] It is also less than 30% of health professionals in both Uganda and Turkey who were aware of national pharmacovigilance centers [18,22] and much lower than 71.4% reported in a Nigerian tertiary health facility.[24] However, the finding is relatively higher than studies conducted in Pakistan and India which found that 14.3% of healthcare professionals involved in the study were aware of the national pharmacovigilance center.[25,26] Rwanda FDA encourages everyone to report any suspected adverse drug reaction or event to prevent harm from medical products and promote their safe uses.[4] These findings suggest that though Rwanda FDA is still a young agency, it must reach out to the nurses and midwives to encourage the ADR reporting practice.

This study found that most respondents (94.6%) know that pharmacovigilance is important for patient safety. Similar findings of a study conducted in India among postgraduate students found that 92.08% of respondents reported that reporting adverse events increases patient safety. [17] These findings indicate that equipping nurses and midwives with knowledge and skills about pharmacovigilance might minimize drug harm among patients in healthcare systems.

The practice of nurses and midwives toward monitoring adverse drug reactions

The nurses and midwives independently administer medications to patients and monitor both therapeutic effects and adverse drug reactions. They record the signs and symptoms of patients for monitoring both therapeutic and detecting ADRs. This study indicates that 62.3% of respondents had inadequate practices towards monitoring and reporting ADRs. The results support the findings of the study conducted in Saudi Arabia, which found that 47.4% of respondents reported that difficulty in detecting ADR occurrence affected the ADR reporting practices.[27] They also support study findings that 96% of nurses need information on drugs causing adverse events and management strategies.[28] Moreover, this study found that having heard about pharmacovigilance and knowing the ADR reporting system in the hospital was associated with the practice of nurses and midwives toward monitoring ADRs. These findings suggest the need to train nurses in pharmacovigilance, monitoring, and reporting adverse drug reactions.

The practice of nurses and midwives toward ADRs reporting

In this study, 66.2% of respondents observed adverse drug reactions during or after drug administration, and 84.4% reported adverse drug reactions. These findings are relatively similar to 65.5% in Pakistan [26] and lower than 82.4% in the United Arab Emirates,[29] and 76% of healthcare professionals in Nigeria who observed adverse drug reactions during their practice.[30] ADR reporting rate in this study is much higher than 25% in Nigeria [30] and 57.4 % in% in Pakistan.[26] Nearly a fifth (18.2%) of respondents filled out adverse event notification forms. This rate of filling out reporting form is lower than 25.5% reported in Turkey [14] and much higher than 2.9% of participants in Nigeria who reported adverse drug reactions using reporting form.[24]

In this study, the nurses and midwives reported using other ways of reporting adverse drug reactions. The most common ways are to report to a physician, document adverse drug reactions in the patient's file, and report adverse drug reactions during the handover report. In contrast, a study conducted in the United Arab Emirates found that all nurses reported adverse drug reactions to the concerned medical doctors.[29] More than a quarter(28.1%) of respondents are motivated to report the adverse drug reaction by knowing that reporting adverse drug reactions may improve patient safety. This rate is much lower than 87.9% which reported patient safety as the first motivation to report ADRs.[29]

In this study, the barriers mostly reported were lack of a system of reporting in the hospital, considering the adverse drug reactions as normal side effects, heavy workload, and insufficient knowledge in pharmacology. Similar barriers to ADRs reporting were documented in different studies.[25,29,31] Lack of sensitization and insufficient knowledge about pharmacovigilance and ADRs are barriers to reporting ADRs.[17,25]

Limitations of the study

We conducted this study at one university teaching hospital, which may not represent the reality of all other University teaching hospitals or other healthcare facilities. No incentives were given to the respondents; therefore, the response rate was 70%. However, the rate is higher than in some similar studies.[32–34]

As the self-administered questionnaire was used, it may result in recall bias. Due to this bias related to retrospective data collection, the participants may not have reported the exact information they could do with prospective data collection. Finally, the study is descriptive , which limits its generalizability.

Conclusion and recommendations

This study found that most of the respondents heard about pharmacovigilance, and many of them heard it from schools of nursing and midwifery. However, 29% of the respondents knew the committee responsible for pharmacovigilance in the hospital. Only about a half (52.1%) were aware of policy about pharmacovigilance in the hospital. Most respondents (94.6%) thought pharmacovigilance is important for patient safety. Nevertheless, 58.2% of respondents knew the ADR reporting system and less than a quarter (22.3%) of respondents were aware of Rwanda FDA for reporting.

This study also revealed that nearly two-thirds (62.3%) of respondents had inadequate practice towards monitoring adverse drug reactions. Having heard about pharmacovigilance and knowing the ADR reporting system in the hospital had a statically significant association with the practice of nurses and midwives towards monitoring adverse drug reactions. Still, gender, age, experience, level of education, and working department of nurses and midwives were not significantly associated with their practice toward monitoring the adverse drug reactions.

Moreover, this study found that two-thirds (66.2%) of respondents had observed adverse drug reactions during or after drug administration, and most of them had filled out the reporting form. However, less than a fifth (18.2%) of respondents filled out adverse event notification forms though some had used other reporting methods, including reporting to physicians and documenting adverse drug reactions in patients' files.

Rwanda FDA encourages everyone to report any kind of suspected adverse drug reactions or events to ensure that consumers of medical products are prevented from any harm that may arise from their use. Therefore, Rwanda FDA, in collaboration with hospitals, should reach out and train nurses and midwives to detect, monitor, and report ADRs appropriately. The hospital administration should ensure that the committee responsible for pharmacovigilance is well functioning and that the reporting system is being used. Further studies shall find out factors associated with nurses' and midwives' awareness of pharmacovigilance monitoring and practice in monitoring and reporting ADRs.

Authors' contribution

DR, EM, JM, VB, TST, AN, VM, DN, and LO participated in the conception of this study, data analysis and interpretation, and writing of the manuscript.

Conflict of interest

No Author reported a conflict of interest

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