

## **Evaluation of the Adverse Drug Reactions Reporting Systems in Hospitals and Health Centers IV and III in Bushenyi District.**

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### **ABSTRACT**

Currently, adverse drug reactions are the 6th global leading cause of death. In sub-Saharan Africa, 6.3% of hospital admissions are a direct result of adverse drug reactions. The aim of this study was to evaluate adverse drug reaction reporting systems in hospitals and health centers IV and III in the Bushenyi district, Uganda. This study employed a cross-sectional study among 225 health professionals including pharmacists, intern pharmacists, nurses, midwives, intern nurses, doctors, intern doctors, and then the clinical officers. Data was collected with the help of questionnaires entered into SPSS version 25 for analysis. The analyzed information was presented in the form of tables and graphs. A great number of 80 (35.6%) were from Kampala International University Teaching Hospital, the majority 132(58.7%) were aged 26-45 years, many 121(53.8%) were females and 104 (45.3%) were males. The majority 98(43.6%) were certificate holders and 117 (52.0%) were adverse drug reaction nurses. The majority 164 (72.9%) of the health facilities had adverse drug reaction reporting systems and 50(22.2%) said they didn't have. 160 (71.1%) respondents had ever detected drug adverse reactions. Of these 133(83.1%) reported these reactions and 27(19.9%) didn't report the adverse drug reaction. Most 95(59.4%) of the adverse drug reaction cases are reported to doctors, 30(18.6%) were reported to pharmacists and lastly 3(2.3%) were reported to the National drug authority (NDA). According to the study, the adverse drug reaction reporting system was in existence with adverse drug reaction reporting forms being the commonest adverse drug reaction reporting tool. Health workers who had heard about adverse drug reactions were 12 times more likely to report adverse drug reaction reactions compared to their counterparts. In addition, the lowest rate of reporting adverse drug reactions was seen at Ishaka Adventist Hospital and Comboni Hospital. Most of the health workers had ever detected adverse drug reactions and 83.1% of them reported adverse drug reactions but to the wrong authorities (doctors and pharmacists) using majorly phone calls. Therefore, NDA, Pharmacovigilance Center, pharmacovigilance coordinators at regional hospitals, and online platforms were not properly utilized.

**Keywords:** Adverse drug reactions, Health centers, Health professionals, Pharmacists, Pharmacovigilance.

### **INTRODUCTION**

An adverse drug reaction (ADR) is an unintended and undesired response to a drug at the normally required doses in human beings for prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function [1-3]. Adverse drug reaction results in increased morbidity, mortality, and hospital and health centers admission which affects the economy and health care systems [4, 5]. Severe adverse drug reactions have made some patients resort to the use of herbal alternatives due to mild adverse effects [6-8]. In most cases, discomforts associated with ADR do compel patients to discontinue medications and hospital check-ups [9-11]. Thus, healthcare professionals should consider ADR reporting as their professional duty to protect patients from the adverse effects of medications [12]. The 16<sup>th</sup> World Health Assembly accepted the resolution that confirmed the need for early detection and rapid dissemination of information on ADRs due to medicines and hence led to the creation of the WHO Program for international drug monitoring. Pharmacovigilance (PV) is a system of activities that relates to the detection,

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assessment, understanding, and prevention of ADRs and other drug-related problems [13]. The aims of ADR reporting systems are to improve patient care and safety in relation to the use of medicines. To support public health programs by providing information about effective assessment of the risk-benefit profile of medicine [14, 15]. Reporting in Uganda relies heavily on spontaneous reporting whereby the reports are voluntarily done, forms filled in, and submitted by the health professionals, pharmaceutical companies, patients, and any member of the public to the national drug authority pharmacovigilance Center. Suspected ADRs to any therapeutic agent should be reported, including drugs, blood products, vaccines, complementary herbal products, and radiological contrast media. Currently, adverse drug reactions are the 6th global leading cause of death, in the sub-Saharan Africa 6.3% of hospital admissions are a direct result of adverse drug reactions [16]. In Uganda, 4.5% of admissions to the medical ward in Kabale regional referral hospital were suspected to be due to adverse drug reactions. 1.5% was the reason for hospitalization [17]. Spontaneous and voluntary reporting of suspected ADRs generates signals about rare, delayed, and unexpected drug reactions that are undetected in the initial phases of drug development. But underreporting is a major limitation. This low rate of ADR reporting undermines efforts to identify and estimate the magnitude of drug risk, confirmation of actionable issues, and possible regulatory action [17]. This study, therefore, evaluated the adverse drug reaction reporting systems in hospitals and health centers IV and III in the Bushenyi district to determine their existence, use, and effectiveness.

## METHODOLOGY

### Study Design

This was a cross-sectional study that involved descriptive quantitative methods of data collection.

### Area of Study

The study was carried out in hospitals and health centers III and IV in Bushenyi district which is located in western Uganda. These hospitals are located in the Bushenyi district which is approximately 295 kilometers by road, southwest of the capital of Uganda, Kampala. It is bordered by the Rubirizi district to the northwest, the Sheema district to the east, the Mitooma district to the south, and the Rukungiri district to the west.

### Study population

The study population comprised all health professionals working in hospitals and health centers III and IV in Bushenyi district who consented and include Doctors, intern doctors, pharmacists, intern pharmacists, clinical officers, nurses, midwives, and intern nurses.

### Selection criteria

The following criteria were used in selecting the subjects that were eligible for the study.

### Inclusion criteria

The healthcare professionals in hospitals in the Bushenyi district include pharmacists, intern pharmacists, nurses, midwives, intern nurses, doctors, intern doctors, and then clinical officers. The healthcare professionals who consented were eligible to participate in the study.

### Exclusion criteria

Health practitioners who did not consent did not participate in the study.

### Sample Size determination

The sample size in this cross-sectional study was calculated using Sloven's Formula:

$$n = N / (1 + N(e^2))$$

$$n = 510 / (1 + 510(0.05^2)) = 225.0 = 225 \text{ health professionals}$$

Where n = sample size, N = Population, 1 = constant, e = error margin of 0.05

### Sampling technique

#### Purposive sampling technique

This technique was used to select health facilities and the number of study participants in each health facility to take part in the study. With this sampling technique, the researchers relied on their own judgment when choosing health facilities and the number of study participants in each health facility to participate in the study. This method was preferred because it is one of the most cost and time-effective sampling methods available and can be effective in exploring anthropological situations where the discovery of meaning can benefit from a natural approach. With this method, the researchers considered all three hospitals and 2 health centers IV in the district but only used 5 health centers III of 9 nine health centers III.

#### Simple random sampling technique (SRS)

A simple Random sampling method was used to obtain/select respondents until the sample size was achieved. With this method, every health worker in the hospitals, health centers III and IV had an even chance and likelihood of being selected as a study participant. The method of the lottery was used in this study where each member who meet the inclusion had to number systematically and in a consequent manner which was assigned by the researcher

written on a separate piece of paper. These pieces of paper were mixed and put into a box and then numbers are drawn out of the box in a random manner. The participants who selected odd numbers took part in this study.

#### **Data collection methods**

Pre-tested questionnaires were used to interview participants about adverse drug reporting systems. The questionnaires were designed to capture all the information required in the study.

#### **Data analysis**

- Data was analyzed using the SPSS computer software, version 25.0, and Excel software.
- Electronic backup copies of data on compact discs (CDS) were made.
- Results were presented in the form of pie charts and graphs.

#### **Ethical considerations**

Ethical clearance was obtained from the faculty of clinical medicine and dentistry, the district health officer, and the hospital administration of KIU, Ishaka Adventist.

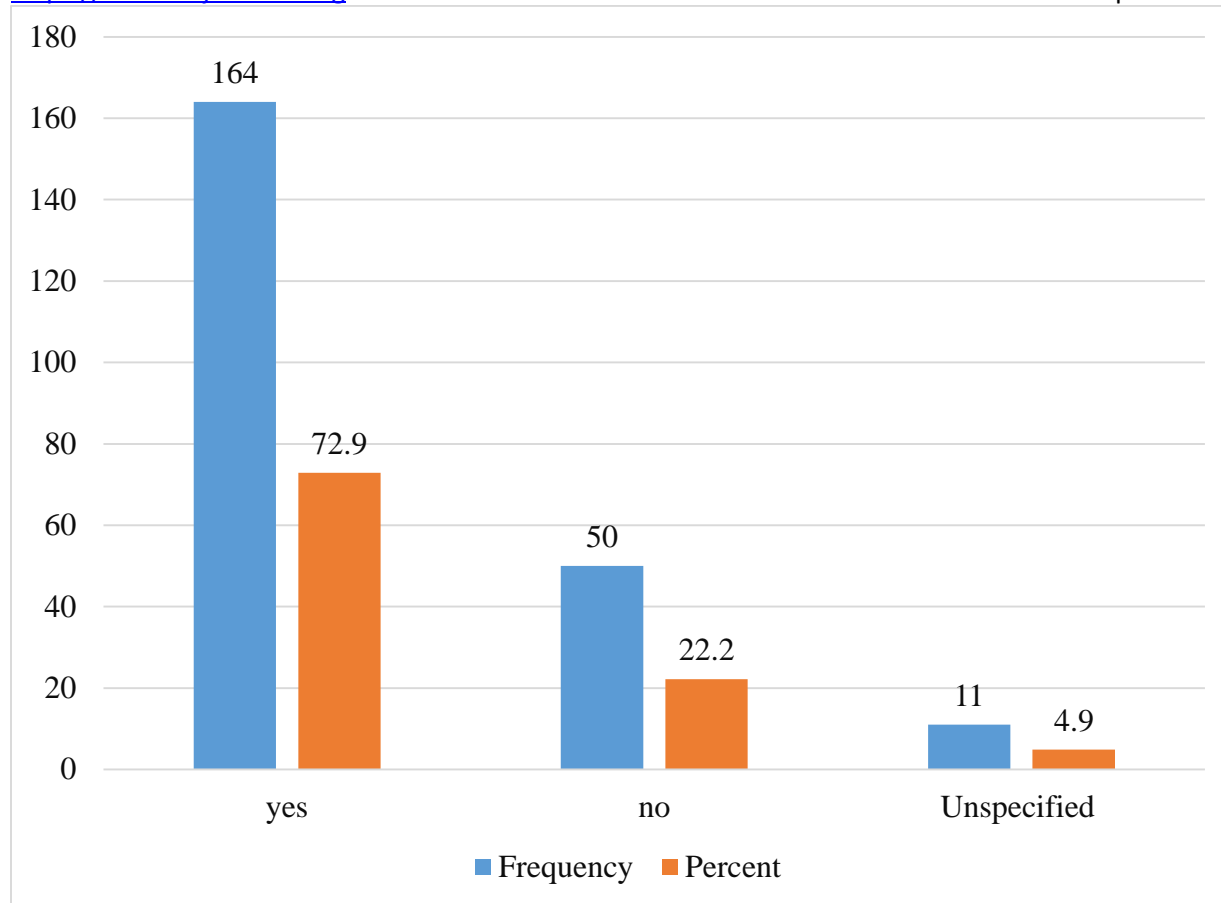
**RESULTS**  
**Socio-demographic findings**  
**Table 1: indicates the socio-demographic findings**

Variables	Frequency (n)	Percent (%)
<b>Name of facility</b>		
Kampala International University Teaching Hospital	80	35.6
Comboni hospital	42	18.7
Ishaka Adventist hospital	38	16.9
Bushenyi health center IV	19	8.4
Kyabugimbi health center IV	19	8.4
Kyeizooba health enter III	4	1.8
Kyamuhunga health center III	6	2.7
Ryeishe health center III	7	3.1
Nyabubare health center III	5	2.2
Kakanju health center III	5	2.2
<b>Age</b>		
18-25years	86	38.2
26-45years	132	58.7
Above 45 years	7	3.1
<b>Gender</b>		
Female	121	53.8
Male	102	45.3
<b>Level of education</b>		
Bachelors	54	24.0
Diploma	73	32.4
Certificate	98	43.6
<b>Profession</b>		
clinical officer	33	14.7
Medical officer	39	17.3
Nurse	117	52.0
Midwife	31	13.8
Pharmacy technician	4	1.8
Pharmacist	1	0.4

Table 1 above indicates that a great number of 80 (35.6%) were from Kampala International University Teaching Hospital, the majority 132(58.7%) were aged 26-32 years, many 121(53.8%) were females and 104 (45.3%) were males. The majority 98(43.6%) were certificate holders and 117 (52.0%) were nurses.

**Existence of adverse drug reaction reporting systems in hospitals and health centers in Bushenyi district.**

**Existence of an adverse drug reaction reporting system at health facilities**



**Figure 1: shows the existence of an adverse drug reaction reporting system at health facilities**

Figure 1 shows that the majority of 164 (72.9%) of the health facilities had adverse drug reaction reporting systems and 50(22.2%) said they didn't have.

**Adverse drug reaction reporting systems**

**Table 2: Indicates adverse drug reaction reporting systems**

Adverse drug reaction reporting systems	Frequency (n)	Percent (%)
Adverse drug reaction reporting form	145	64.4
phone call	26	11.6
Email	1	.4
Unspecified	53	23.6

Table 2 indicates that the commonest adverse drug reaction reporting system were adverse drug reaction reporting forms suggested by the majority of 145(64.4%) participants. 26(11.6%) suggested phone calls and only 1(0.4%) suggested email.

		P-value		Odd Ratio
Definition of adverse drug reaction	the study of medicine	0.310		4.338
	are unintended and undesired			
	the study of drugs			
	none of the above			
Adverse drug reactions must be reported	Yes	0.294		2.698
	No			
Have you heard about a drug reaction	Yes	0.080		1.824
	No			
Where did you hear it from	health facility	0.999		0.000
	School			
	Friends			
	Others			

**Factors affecting the reporting of the existence of adverse drug reaction reporting systems at health facilities**

**Table 3: bivariate analysis of factors affecting the reporting of the existence of adverse drug reaction reporting systems at health facilities**

Table 3 indicates that none of the factors was significantly related to reporting adverse drug reaction reporting systems.

**Table 4: shows a multivariate analysis of factors affecting the reporting of the existence of adverse drug reaction reporting systems at health facilities**

		P-value	OR(95% CI)
Have you heard about an adverse drug reaction	Yes	0.000	12.39(4.52-33.98)
	No		

Table 4 above shows that respondents who had heard about adverse drug reactions were significantly related to reporting of adverse drug reaction reporting systems. That is those respondents who had heard about adverse drug reactions were 12 times more likely to report adverse drug reaction reporting systems.

**Relationship between health facilities and health professions with reporting of the existence of adverse drug reaction reporting system**

**Table 5: Relationship between health facilities and health professions with reporting of the existence of adverse drug reaction reporting system**

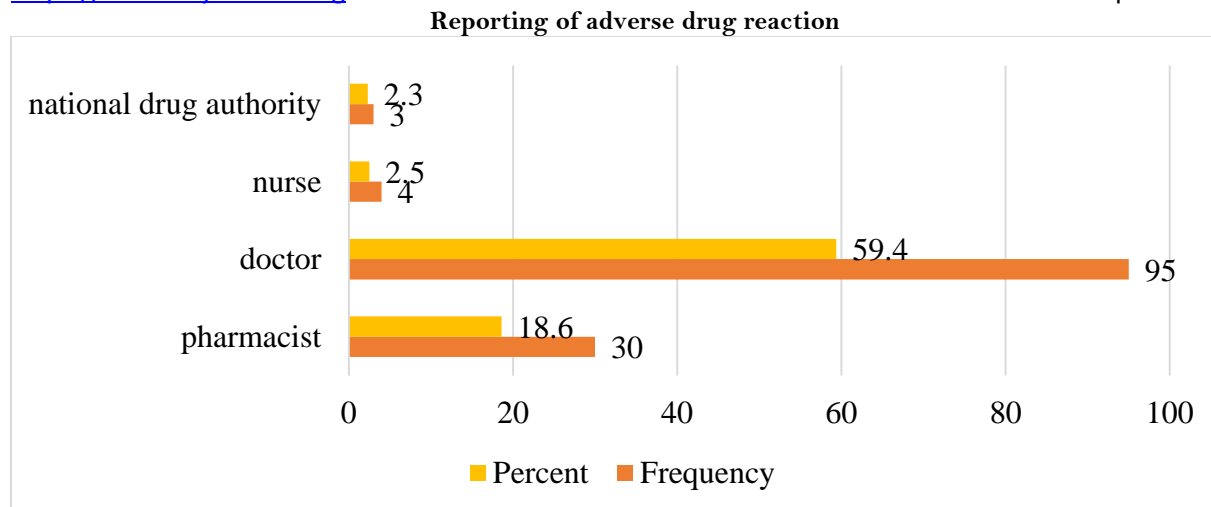
		Is there an adverse drug reaction systems		P-value
		yes	no	
Name of facility	KIUTH	54 (72%)	21 (28%)	0.133
	Comboni hospital	33 (82.5%)	7 (17.5%)	
	Ishaka Adventist hospital	23 (60.5%)	15 (39.5%)	
	Bushenyi health center IV	15 (83.3%)	3 (16.7%)	
	Kyabugimbi health center IV	17 (89.5%)	2 (10.5%)	
	Kyeizoba health center III	4(100%)	0 (0%)	
	Kyamuhunga health center III	5 (100%)	0 (0%)	
	Ryeishe health center III	4 (80%)	1 (0%)	
	Nyabubare health center III	4 (80%)	1 (0%)	
	Kakanju health center III	5(100%)	0 (0%)	
profession	Clinical officer	24 (75%)	8 (25%)	0.550
	Medical officer	29 (76.3%)	9 (13.7%)	
	Nurse	87 (79.1%)	23(20.9%)	
	Midwife	21 (72.4%)	8 (27.6%)	
	Pharmacy technician	3 (75%)	1 (25%)	
	Pharmacist	0 (0%)	1 (100%)	

Table 5 indicates that all the P-values  $\geq 0.05$ , thus no significant relationship was revealed at this stage. Regardless of that, the lowest rate of reporting that there is the existence of adverse drug reaction reporting systems was seen at Ishaka Adventist Hospital with 60.5% reporting that systems exist and Comboni Hospital 72% reporting that the systems exist. Since only one pharmacist participated in this study, the response from him was negligible thus we did consider that finding. Therefore, the highest rate of not reporting that there is the existence of adverse drug reaction reporting systems was seen among midwives (27.6%) and clinical officers (25%).

Usage of adverse drug reaction reporting system in hospitals or health centers IV and III in Bushenyi district  
**Table 6 indicates the usage of the adverse drug reaction reporting system in hospitals or health centers IV and III in the Bushenyi district.**

Variables	Frequency	Percent
<b>Have you detected adverse drug reaction</b>		
Yes	160	71.1
No	65	28.9
<b>Have you reported adverse drug reaction</b>		
Yes	133	83.1
No	27	16.9

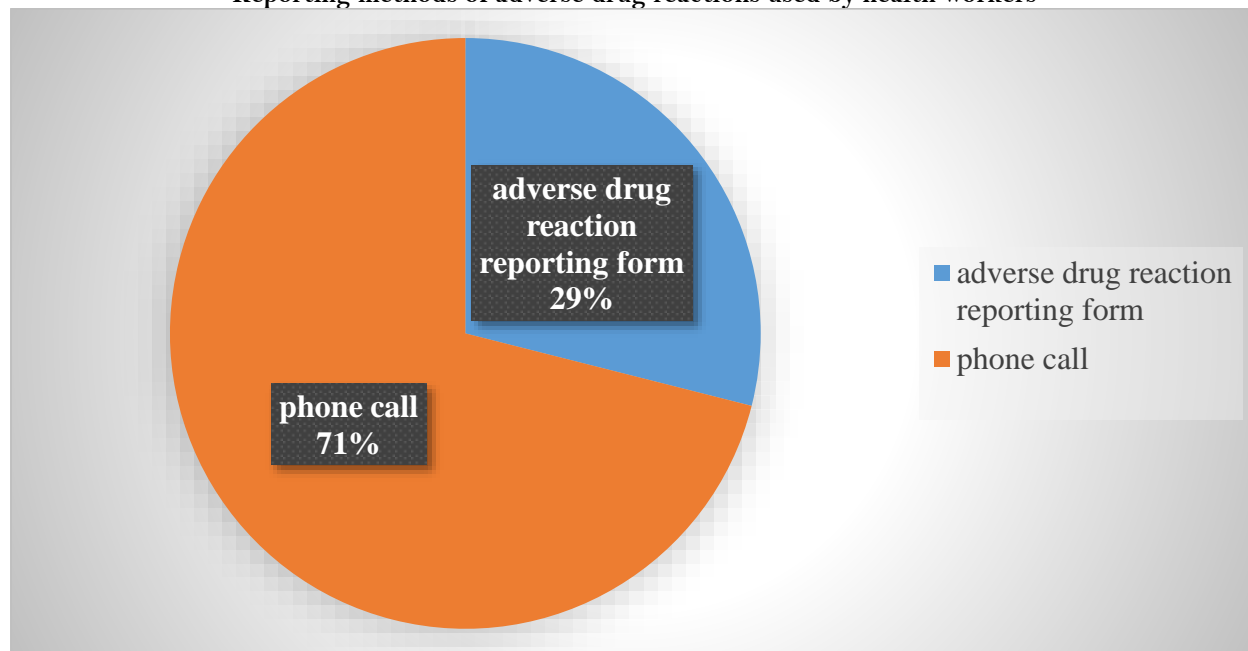
Table 5 indicates that 160 (71.1%) respondents had ever detected drug adverse reactions. Of these 133(83.1%) reported these reactions and 27(19.9%) didn't report the adverse drug reaction.



**Figure 2: Shows to whom adverse drug reaction systems cases are reported**

Figure 2 shows most 95(59.4%) of the adverse drug reaction cases are reported to doctors, 30(18.6%) were reported to pharmacists and lastly 3(2.3%) were reported to NDA.

**Reporting methods of adverse drug reactions used by health workers**



**Figure 3: Shows the reporting systems of adverse drug reactions used by health workers**

Figure 3 shows that the commonly used reporting system for adverse drug reaction cases by health workers was a phone call suggested by 71% of the respondents and an adverse drug reaction reporting form used by 29% of the respondents who had reported adverse drug reaction cases.



**Relationship between Profession and Reporting methods of adverse drug reactions used by health workers**

**Table 7: Relationship between profession and reporting methods of adverse drug reactions used by health workers**

		how did you report	
		adverse drug reaction reporting form	phone call
Profession	Clinical officer	8 (44.4%)	10 (65.6%)
	Medical officer	3 (37.5%)	5 (72.5%)
	Nurse	17 (25.8%)	49 (74.2%)
	Midwife	3 (16.6%)	15 (83.4%)
	Pharmacy technicians	2 (66.7%)	1 (33.3%)
	Pharmacist	0 (0%)	1 (1%)

According to table 7 above most pharmacy technicians (66.7%) used adverse drug reaction reporting forms, followed by clinical officers (44.4%) used adverse drug reaction reporting forms.

**Reporting systems of adverse drug reactions used by health facilities**

**Table 8: Indicates the reporting systems of adverse drug reactions used by health facilities**

Reporting systems of adverse drug reactions	Frequency (n)	Percent (%)
Adverse drug reaction reporting forms	115	51.1
Phone calls	71	31.6
Email	14	6.2
Unspecified system	25	11.1

Table 8 shows that the commonly used system by health facilities for reporting adverse drug reactions was adverse drug reaction reporting forms suggested by 115(51.1%) of the respondents and followed by phone calls suggested by 71(31.6%) respondents.

**DISCUSSION**

According to the majority 76.6% of the health workers in this study, it was seen that adverse drug reaction reporting systems were in existence. The commonest adverse drug reaction reporting systems in the study were adverse drug reaction reporting forms suggested by the majority 64.4% of participants, 26(11.6%) suggested phone calls and only 1(0.4%) suggested email. This study found that health workers who had heard about adverse drug reactions were 12 times more likely to report adverse drug reaction reporting systems compared to those who didn't hear about adverse drug reactions. This is in line with a study done in Napel by Palaian *et al.* [18] who found that lack of information on how to report an ADR had the highest agreement among the respondents as the factor which influences them not to report an ADR. The findings in this study showed that most (71.1%) of the health workers had ever detected adverse drug reactions and 83.1% of them reported adverse drug reactions. Of those who reported adverse drug reactions, most (59.4%) of the adverse drug reaction cases were reported to doctors and only 2.3% of the adverse drug reaction cases were reported to NDA. Yet, according to Tumwikirize *et al.* [17] health professionals in Uganda must report Adverse Drug Reactions immediately to National Drug Authority (NDA), Pharmacovigilance Center in Kampala which was established in 2015 using ADR reporting forms. More to that all regional hospitals must have pharmacovigilance coordinators an indication of an alternative reporting point. The other recognized point where ADRs can be reported is using online platforms. Therefore, though the majority reported the adverse drug reactions cases, most of those cases were reported to the wrong authorities an indication that National Drug Authority (NDA) Pharmacovigilance Center is not potentially utilized. According to this study, health facilities were suggested to mostly have adverse drug reaction reporting forms suggested by 115(51.1%) of the respondents and followed by phone calls suggested by 71(31.6%) respondents. This agrees with Tumwikirize *et al.* [17] who showed that health professionals in Uganda must report Adverse Drug Reactions immediately to NDA and Pharmacovigilance Center using ADR reporting forms. Though contradicting results were shown in this study where the commonly used reporting method of adverse drug reaction cases by health workers was phone calls suggested by 71% of the respondents. Yet, in Uganda, the alternative to ADR reporting forms is online. This could be because rural doctors/health workers have little knowledge regarding the purpose, operation, and usefulness of the adverse drug reaction reporting system and can't assume the responsibility for human drug safety as suggested by Deye *et al.* [19] in China.

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## CONCLUSION

According to the study, the adverse drug reaction reporting system was seen to be in existence with adverse drug reaction reporting forms being the commonest adverse drug reaction reporting tool. Health workers who had heard about adverse drug reactions were 12 times more likely to report adverse drug reaction reporting systems compared to their counterparts. In addition, the lowest rate of reporting adverse drug reaction reporting systems was seen at Ishaka Adventist Hospital and Comboni Hospital. Most of the health workers had ever detected adverse drug reactions and 83.1% of them reported adverse drug reactions but to the wrong authorities (doctors and pharmacists) using majorly phone calls. Therefore, National Drug Authority (NDA) Pharmacovigilance Center, pharmacovigilance coordinators at regional hospitals, and online platforms were not properly utilized. Based on the study findings the researcher recommends that posters, socio media groups among others should be adopted to make health workers aware of adverse drug reactions. More so, seminars and education platforms should be put in place to educate health workers on where to report and what to use when reporting adverse drug reactions.

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