

Evaluation of the Adverse Drug Reaction Reporting System at IV and 111 Hospitals and Health Centers in Bushenyi District

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ABSTRACT

Currently, adverse drug reactions are the 6th leading cause of death worldwide. In sub-Saharan Africa, 6.3% of hospitalizations are a direct result of adverse drug reactions. This study aimed to evaluate the adverse drug reaction reporting system at Hospitals and Health Centers IV and III in Bushenyi District. A cross-sectional study was conducted on 225 health professionals including pharmacists, trainee pharmacists, nurses, midwives, trainee nurses, physicians and internists, followed by agents clinical. Data collected using questionnaires were entered into SPSS version 25 for analysis. The analyzed information is presented in tables and graphs. The results indicated that 80 (35.6%) were from Kampala International University Teaching Hospital, the majority 132 (58.7%) were between the ages of 26 and 45, of which 121 (53.8%) were female and 104 (45.3%) were male. The majority, 98 (43.6%) were certified and 117 (52.0%) were nurses. The majority of medical facilities, 164 (72.9%), had a system for reporting adverse drug reactions and 50 (22.2%) said they did not have this system. 160 (71.1%) respondents discovered side effects of the medication. Of these, 133 (83.1%) reported these reactions and 27 (19.9%) did not report adverse drug reactions. Almost 95 (59.4%) adverse drug reactions were reported to physicians, 30 (18.6%) to pharmacists, and finally 3 (2.3%) to NDAs. In summary, adverse drug reaction reporting systems exist, with adverse drug reaction reporting forms being the most common adverse drug reaction reporting tool. Healthcare professionals who had heard about an adverse drug reaction were 12 times more likely than other healthcare professionals to report an adverse drug reaction. Additionally, the lowest adverse drug reaction reporting rates were recorded at Ishaka Adventist Hospital and Comboni Hospital. Most medical staff have detected adverse drug reactions and 83.1% of them reported adverse drug reactions but sent them to the wrong authorities (doctors, pharmacists), mainly through phone. As a result, the National Drug Authority (NDA) pharmacovigilance center, pharmacovigilance coordinators at regional hospitals and online platforms were not used properly.

Keywords: Drugs, NDA, pharmacovigilance and health workers

INTRODUCTION

An adverse drug reaction is an unintended and undesired response to a drug at the normal required doses in human beings for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function [1].

Adverse drug reaction results in increasing morbidity, mortality and hospital and health centers admission which affects the economy and health care systems. Health care professionals should consider ADR

reporting as their professional duties to protect patients from adverse effects of medications [2].

The 16th 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 WHO Program for international drug monitoring. Pharmacovigilance (PV) is a system of activities that relates the detection,

assessment, understanding and prevent of ADRs and other drug related problems [3]. Aims of ADR reporting systems are to improve patient care and safety in relation to use of medicines. To support public health programs by providing information about effective assessment of the risk-benefit profile of medicine [4]. 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 [4]. Suspected ADRs to any therapeutic agent should be reported, including drugs, blood products, vaccines, complementary herbal products and radiological contrast media (Informa *et al.*, n.d.). 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 [3][4][5][6]. Of the 46 countries in Africa whose Pharmacovigilance system was assessed, 24 were incapable and only 4 countries had a good pharmacovigilance center [3]. In Uganda, 4.5% of admissions on medical ward in Kabale Regional Referral Hospital were suspected to be due to adverse drug reactions. 1.5% was the

reason for hospitalization [5][7-9]. 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. However, 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 [5][9-11]. Currently, adverse drug reactions are the 6th global leading cause of death, in sub-Saharan Africa 6.3% of hospital admissions are direct results of adverse drug reactions [3][12-15]. 23 per 100 hospitalization episodes of drug reactions occur at referral hospitals in Uganda [6][16-20]. As Uganda's pharmacovigilance mainly relies on spontaneous reporting, healthcare professionals may not be compelled to report expected adverse reactions especially if the symptoms are not serious [3][21]. This study has therefore assessed the Hospitals and health centers IV and III in Bushenyi district on the existence and usage of ADR reporting System since ADR reporting entirely depends on whether reporting tools are available and properly used.

METHODOLOGY

Study Design

This was a cross sectional study which will involve descriptive quantitative methods of data collection.

Study setting

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 Rubirizi district to the northwest, Sheema district to the east, Mitooma district to the south and Rukungiri district to the west

Study population

Study population comprised of all health professionals working in hospitals and health centers III and IV in Bushenyi

district who consented and include Doctors, intern doctors, pharmacist, intern pharmacist, clinical officers, nurses, midwives and intern nurses.

Selection criteria

The following criteria was 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 and intern doctors and 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 the Solven's Formula:

$$n = \frac{N}{1 + N(e^2)}$$

$$n = \frac{510}{1 + 510(0.05)^2} = 225.0$$

$$n = 225 \text{ health professionals}$$

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 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 number 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 method available and can be effective in exploring anthropological situations where the discovery of meaning can benefit from natural approach. With this method the researchers considered all the three hospitals and 2 health center IV in the district but only used 5 health center III of 9 nine health center III.

Simple random sampling technique (SRS)

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 center 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 back-up copies of data on compact discs (CDS) were made.
- Results were presented in the form of pie charts and graphs.

Ethical considerations

- The research proposal was submitted to school of pharmacy and research ethics committee of Kampala international university for approval.
- Permission was sought from the Research ethics committee of Kampala international university, school of pharmacy, hospital and health centers administrators to carry out the study.
- The consent of the participant was sought and consent form filled. The participant had the right to accept or refuse to participate in the study.
- Confidentiality was ensured at all stages of data collection, analysis, report writing and dissemination of results. Each questionnaire had a code for identification.

Study limitations

The study was carried out in hospitals and health centers in Bushenyi district and the results obtained may not therefore be used to generalize for all hospitals country wide.

RESULTS

Socio-demographic findings

Table 1 indicates the socio demographic findings

Variables	Frequency (n)	Percent (%)
Name of facility		
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 center 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
Age		
18- 25 years	86	38.2
26- 45 years	132	58.7
Above 45 years	7	3.1
Gender		
Female	121	53.8
Male	102	45.3
Level of education		
Bachelors	54	24.0
Diploma	73	32.4
Certificate	98	43.6
Profession		
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 80(35.6%) were from Kampala International University Teaching Hospital, majority 132(58.7%) were aged 26- 32

years, many 121(53.8%) were females and 104 (45.3%) were males. 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.

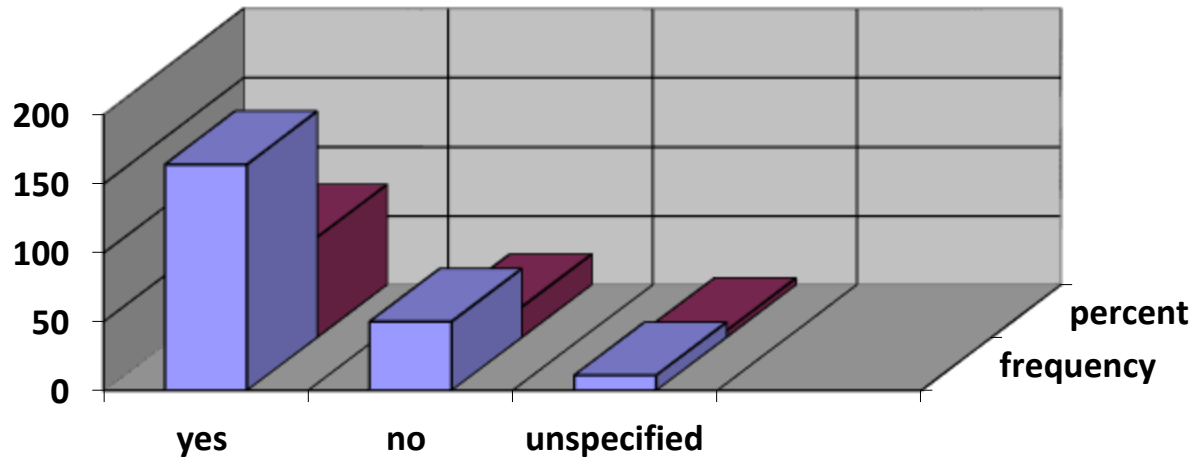


Figure 1 shows the existence of adverse drug reaction reporting system at health facilities

Figure 1 shows that majority 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 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	26	11.6
Email	1	0.4
Unspecified	53	23.6

Table 2 indicates that the commonest adverse drug reaction reporting system were adverse drug reaction reporting

forms suggested by majority 145(64.4%) participants 26(11.6%) suggested phone calls and only 1(0.4%) suggested email.

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

Table 3 bivariate analysis of factors affecting the reporting of existence of adverse drug reaction reporting system at health facilities.

		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 reaction must be reported	YES	0.294	2.698
	NO		
Have you heard about drug reaction	YES	0.080	1.824
	NO		
Where did you hear it from	Health facility	0.999	0.000
	School		
	Friends		
	Others		

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

Table 4 shows multivariate analysis of factors affecting the reporting of existence of adverse drug reaction reporting system at health facilities.

		p-value	OR (95%CI)
Have you ever heard about adverse drug reaction	YES	0.000	12.39(4.52- 33.98)
	NO		

Table 4 above shows that respondents who heard about adverse drug reaction were significantly related to reporting of adverse drug reaction reporting systems.

That is those respondents who had heard about adverse drug reaction were 12 times more likely to report adverse drug reaction reporting systems.

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

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

Name of facility		Is there an adverse drug reaction system		p-value
		Yes	No	
Name of facility	KIUTH	52 (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 centre 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 (20%)	
	Nyabubare health center III	4 (80%)	1 (20%)	
	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 ≥ 0.05 , thus no significant relationship was revealed at this stage. Regardless of that, the lowest rate of reporting that there is 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 systems exist. Since only one pharmacist participated in the study, response from him was negligible

thus we did consider that finding. Therefore, the highest rate of not reporting that there is existence of adverse drug reaction reporting system was seen among midwives (27.6%) and clinical officers (25%).

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

Usage of adverse drug reaction reporting system in hospitals or health center IV and III in Bushenyi district

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

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

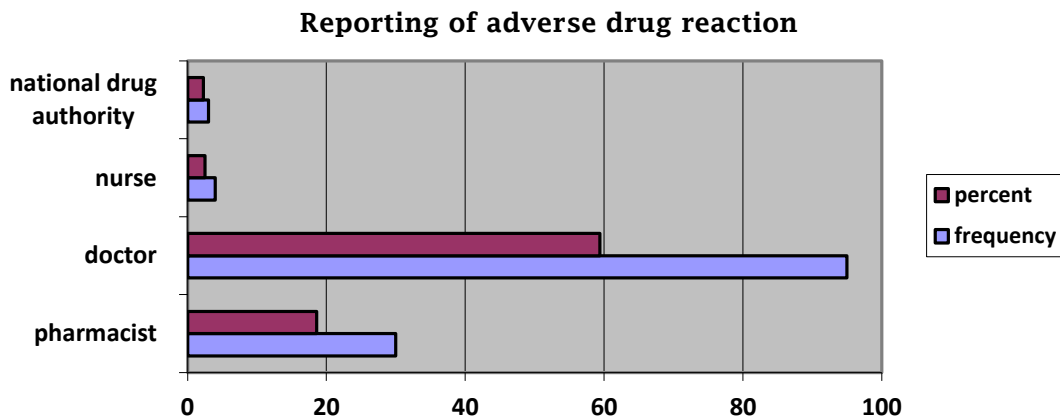


Figure 2 shows to who adverse drug reaction systems cases are reported.

The figure above shows most 95 (59.4%) of the adverse drug reaction cases are reported to doctors, 30 (18.6%) were

reported to pharmacists and only 3 (2.3%) were reported to NDA.

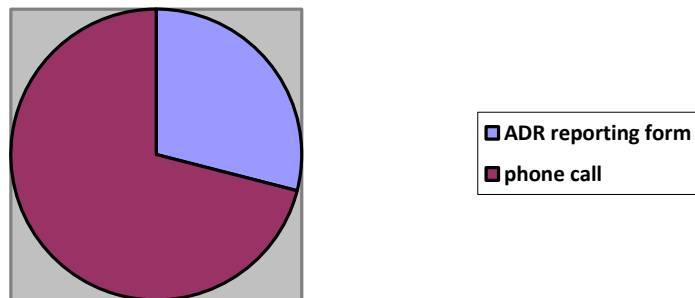


Figure 3 shows the reporting systems of adverse drug reactions used by health workers.

It shows that the most commonly used reporting system by health workers was phone call suggested by 71% of the

respondents and ADR reporting form used by 29% of the respondents.

Relationship between profession and reporting methods of ADR used by health workers

Table 7 shows the relationship between profession and reporting methods of ADR used by health workers.

Profession	How did you report	
	ADR reporting form	Phone call
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 (100%)

According to table 7 above, most of pharmacy technicians (66.7%) used ADR

reporting forms followed by clinical officers (44.4%).

Reporting system of adverse drug reactions used by health facilities

Table 8 indicates the reporting system of adverse drug reactions used by health facilities

Reporting system of adverse drug reactions	Frequency	Percent
ADR reporting forms	115	51.1
Phone calls	71	31.6
Email	14	6.2
Unspecified system	25	11.1

Table 8 above shows that the commonly used system by health facilities for reporting adverse drug reactions were ADR

reporting forms suggested by 115 (51.1%) of the respondents followed by phone calls suggested by 71 (31.6%).

DISCUSSION

According 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 study were adverse drug reaction reporting forms suggested by 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 reaction were 12 times more likely to report adverse drug reaction reporting systems compared to those who didn't hear about adverse drug reaction. This is in line with a study done in Napel among 185 health practitioners by Palaian et al (2011) [7] 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 reaction and 83.1% of them reported adverse drug reaction. Of those who reported adverse

drug reaction, most (59.4%) of the adverse drug reactions cases were reported to doctors and only 2.3% of the adverse drug reactions cases were reported to NDA. Yet, according Wa et al, (2011) [5] health professionals in Uganda must report Adverse Drug Reactions immediately to National Drug Authority (NDA) Pharmacovigilance Center in Kampala that 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 majority reported the adverse drug reactions cases, most of those cases were reported to 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

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followed by phone calls. suggested by 71(31.6%) respondents. This agrees with Wa et al. (2011) [5] who showed that health professionals in Uganda must report Adverse Drug Reactions immediately to National Drug Authority (NDA) Pharmacovigilance Center in Kampala that was established in 2015 using ADR reporting forms. Though contradicting results were showed in this study where the commonly used reporting method of adverse drug reaction cases by health

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 reaction were 12 times more likely to report adverse drug reaction reporting systems compared to their counter parts. 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 reaction and 83.1% of them reported adverse drug reaction but to wrong authorities (doctors and pharmacists) using majorly phone calls.

CONCLUSION

workers was phone call suggested by 71% of the respondents. Yet, in Uganda the alternative of ADR reporting forms, is online. Which could be because rural the doctor /health workers have little knowledge regarding the purpose, operation and usefulness of the adverse drug reaction reporting system and can't assume the responsibility of human's drug safety as suggested by Deye et al, (2016) [8] in China.

Therefore, National Drug Authority (NDA) Pharmacovigilance Center, pharmacovigilance coordinators at regional hospitals and online platforms were not properly utilized.

Recommendations

Based on the study findings the researcher recommends the following:

- Posters, socio media groups among others should be adopted to make health workers aware of adverse drug reaction.
- Seminars, and education platforms should put in place to educate health workers on where to report and what to use when reporting adverse drug reaction.

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