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# KNOWLEDGE, ATTITUDE, AND PRACTICES OF HEALTH CARE PROFESSIONALS TOWARDS PHARMACOVIGILANCE AT KAYUNGA REGIONAL REFERRAL HOSPITAL, KAYUNGA DISTRICT. A CROSS-SECTIONAL STUDY.

*Daniel Baliraine*[*]*, Dr. Mulodokayi Niwagiira*
*Kampala School of Health Sciences P.O. Box 14263 Kampala – Uganda.*



## ABSTRACT.

### Background:
Purpose of the study: The study was to assess the knowledge, attitude, and practices of healthcare professionals towards pharmacovigilance at Kayunga Regional Referral Hospital, Kayunga district.

### Methodology:
The study employed a cross-sectional descriptive study design, simple random sampling technique was used. Data was collected from a sample size of 50 respondents. A semi-structured questionnaire was used as a data collection tool. Data was analyzed manually and entered in a computer using Microsoft Excel computer program to generate tables, pie charts, and bar graphs.

### Results:
Most of the respondents were 58% females while the least were 42% males. 48% knew the correct definition of pharmacovigilance, 54% had ever heard about adverse drug reaction reporting, 78% thought ADR reporting is a professional obligation, 76% knew that National drug authority was the regulatory body responsible for monitoring ADRs, 44% had ever heard of a pharmacovigilance program in Uganda, 98% said pharmacovigilance should be taught in detail to health care professionals, 68% had ever experienced ADRs in their patients during their professional practice, 84% had never reported ADRS to the pharmacovigilance center, 78% had never been trained on how to report ADRs.

### Conclusions:
Generally according to the findings, the respondents had some knowledge of pharmacovigilance and their attitudes toward reporting the ADRs encountered by patients were good however their practice was poor.

### Recommendations:
The government, Ministry of Health, and the hospital administration should organize seminars to encourage ADR reporting and provide knowledge on ADRs, more researchers should carry out more research regarding the same topic to cover up the unfilled gaps, and ADR reporting should be encouraged and promoted, especially through financial support.

***Keywords:*** *Knowledge, Attitude, Practices, Healthcare Professionals, Pharmacovigilance, Kayunga Regional Referral Hospital*
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***Corresponding author:*** *Daniel Baliraine*[*]
*Email: balirainedaniel3@gmail.com*
*Kampala School of Health Sciences P.O. Box 14263 Kampala – Uganda.*

## BACKGROUND OF THE STUDY.

The World Health Organization defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problems (WHO, 2024). Medicines have changed the lives of people by controlling and managing diseases. Besides their benefits all over the world, ample evidence continues to show that they cause adverse drug reactions which may lead to illness, disability, and even death. Adverse drug reactions are also common reasons for patient-related morbidity and mortality and are recognized to cause an extended duration of hospital stay and increased therapy costs (Hassan. Y, 2018).

Worldwide safety and efficacy are two major concerns about a drug. The efficacy of a drug can be quantified with relative ease, but safety cannot be easily determined. This is because adverse effects of a drug may be uncommon

(but very serious) and many patients may be affected or subjected to a potential risk when the drug is established. The Thalidomide disaster in history is one of the catastrophes that influenced the development of medical regulation. This disaster led to the establishment of safety committees and voluntary adverse drug reaction reporting systems up to today, the need for pharmacovigilance systems is considered important and health workers and consumers are encouraged to report adverse effects to regulatory agencies (Nambasa. V, 2019).

When pharmacovigilance first developed as a consequence of the thalidomide tragedy in Europe in the 1960s, the focus was on studying adverse drug reactions to medicines after they have been authorized for use primarily distinguishing between pharmacological effects and hypersensitivity reactions. Research on medicine-related hospitalization carried out over the past 35 years has demonstrated that approximately 50% of medicine-related patient harms leading to hospitalization are preventable i.e., are associated not with the intrinsic properties the medical product itself, but with the way it has been prescribed, dispensed, administered, or used (Olsson.S and Miraharrison, 2018).

In Africa, there is little information as to what extent adverse drug reactions influence a patient`s health-related quality of life. From a pharmacovigilance perspective, capturing and making the best use of this information remains a challenge (Eugene. P., 2016). Therefore, healthcare professionals are frontline stakeholders in detecting and reporting adverse drug reactions occurring in patients (Katusime. B., 2015). However, there is limited literature on the magnitude and factors associated with adverse drug reporting among healthcare workers in Uganda.

Nevertheless, a study carried out at Mulago National Referral and Teaching Hospital superficially hinted that some of Uganda`s healthcare workers were familiar with formal pathways for reporting adverse drug reactions. Additionally, a variety of factors deter healthcare workers from reporting adverse drug reactions including inadequate knowledge about the purpose of reporting, fear of extra workload, and failure to differentiate clinical symptoms from ADRS, among several other factors (Katusime. B, 2015).

### General objective.

To assess the knowledge, attitude, and practices of health care professionals towards Pharmacovigilance at Kayunga Regional Referral Hospital, Kayunga District.

### Specific objectives.

- To determine the knowledge of health care professionals on Pharmacovigilance at Kayunga Regional Referral Hospital, Kayunga district.
- To find out the attitude of health care professionals towards pharmacovigilance at Kayunga Regional Referral Hospital, Kayunga district.
- To assess the practices of health care professionals on pharmacovigilance at Kayunga Regional Referral Hospital, Kayunga district.

## METHODOLOGY.

### Study design.

A cross-sectional descriptive study was applied because the study was conducted across participants over a short period and follow-ups of participants were not done. Both qualitative and quantitative data were collected.

### Study area.

The study was carried out at Kayunga Regional Referral Hospital which is located in Kayunga district, Eastern Uganda. The health center offers several health services in different departments to both inpatients and outpatients. The health center receives patients from most parts of Kayunga district and the neighboring districts. The study was carried out from September 2023 to October 2023

### Study population.

The study population included all healthcare professionals who were involved in prescribing, dispensing, and administering drugs to the patients attending Kayunga Regional Referral Hospital. These include doctors, clinicians, midwives, nurses, pharmacists, and pharmacy technicians.

### Inclusion criteria.

The study only included healthcare professionals at Kayunga Regional Referral Hospital, who were present, not busy, not sick, and mentally stable, and those who had consented to participate in the study.

### Exclusion criteria.

The study excluded mentally unstable healthcare workers.

### Sample size determination.

A sample size of healthcare professionals was determined using Burton's formula (Burton 1965) given below.

S=2 (QR) O:
Where:
S=required sample size
Number of days the researcher spent collecting data maximum number of respondents per day

Maximum time the interviewer spent on each respondent And; Q=10 days
R=5 respondents O=0.5 hour, Therefore; S=2*10*5*0.5
Therefore, the study used 50 respondents.

## Sampling technique.

A simple random sampling was employed. This technique was used because it gives all participants equal opportunity participation and it is easy to administer.

## Sampling procedure.

The population of interest was determined by specific characteristics, a sample size of 110, a sample frame was created, numbers were assigned to the units and then selected randomly from the sample frame using a lottery, and the required sample size was obtained.

## Data collection method.

A semi-structured questionnaire was administered to the healthcare professionals. Each interview lasted for as long as necessary (enough time to answer all the relevant questions).

## Data collection tool.

A well-organized semi-structured questionnaire, with both open-ended and close-ended questions, prepared in English was used and some questions were interpreted to the respondents where necessary. This tool was utilized because it was easy to administer, quick in data collection, and less expensive while collecting data for analysis to address a research problem.

## Data collection procedure.

A letter of introduction was obtained from Kampala School of Health Sciences and it was taken to Kayunga Regional Referral Hospital, Kayunga district, and permission was obtained from the facility administration. Before administering the questionnaires, the researcher introduced himself, explained the purpose of the study, and sought informed consent from the participants (health care professionals). The administration of questionnaires was conducted only after consent had been obtained from the respondents.

## Study variables.

Both independent and dependent variables were used in this study.

## Independent variables.

The independent variables were; level of education, profession, age, and working experience.

## Dependent variables.

The dependent variables were; knowledge, attitude, and practices of health care workers towards pharmacovigilance.

## Quality control.

The questionnaires were thoroughly checked by the supervisor to ensure that it is properly designed, valid, reliable, and relevant to the study.
The sample size was determined using the approved formula.
There was pretesting of data collection tools before the actual data collection. Two research assistants were trained and ample time for data collection and analysis was provided. A pre-visit to the study area for the exercise with authorities was conducted.
There was optimum adherence to the standard operating procedures while conducting this research.

## Data analysis and presentation.

Data was analyzed manually by use of tally sheets, processed and analyzed using a simple electronic computer to compute frequencies and percentages (using the Excel computer program); then was presented in terms of percentages, distribution tables, pie charts, and bar graphs for easy interpretation of the study findings.

## Ethical considerations.

Before the collection of data for the study, an introductory letter was obtained from the Kampala School of Health Sciences which introduced the researcher to the hospital administration. The researcher then sought permission from the administration of the facility to collect data from the health facility. A consent form was filled out by the respondents after explaining the purpose of the study to them. The respondents were assured of confidentiality as no name of the respondent appeared on the questionnaire instead numbers were used. No participant was forced to participate in the study and all the study materials used were safely kept under lock and key accessible by the researcher only.

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## RESULTS. Demographic data of the respondents.

**Table 1: Table illustrating social demographic data. (N=50)**

| Variables | Frequency (f) | Percentage (%) |
|---|---|---|
| **Gender** | | |
| Female | 29 | 58 |
| Male | 21 | 42 |
| **Age** | | |
| 20-30 | 30 | 60 |
| 31-40 | 13 | 26 |
| 41-50 | 5 | 10 |
| Missing | 2 | 4 |
| **Profession** | | |
| Doctor | 2 | 4 |
| Clinical officer | 4 | 8 |
| Pharmacy technician | 2 | 4 |
| Nurse | 33 | 66 |
| Mid-wife | 8 | 16 |
| Lab technician | 1 | 2 |
| **Level of education** | | |
| Certificate | 25 | 50 |
| Diploma | 15 | 30 |
| Degree | 6 | 12 |
| Any other | 4 | 8 |
| **Years of work experience** | | |
| >5 | 19 | 38 |
| >=5 | 31 | 62 |

From Table 1, most respondents were 29(58.0%) females while the least 21(42.0%) were males. The majority 30(60%) were aged 20-30 years, 13(26%) were aged 31-40 years and the minority 5(10%) were aged 41-50 years. The majority of the respondents 33(66%) were nurses, 8(16%) were mid-wives, 4(8%) were clinical officers, 2(4%) were pharmacy technicians, 2(4%) were medical doctors and 1(2%) was a lab technician.

Most of the respondents 25(50%) were certificate holders, 15(30%) were diploma holders, 6(12%) were degree holders, and at least 4(8%) had any other qualifications. The majority of the respondents 31(62%) had a work experience of more than 5 years and the minority 19(38%) had a work experience of fewer than 5 years.

### Knowledge of health care professionals on pharmacovigilance.

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**Table 2: Table illustrating knowledge of pharmacovigilance. (N=50)**

| Variable | Frequency (f) | Percentage (%) |
|---|---|---|
| **Pharmacovigilance is** | | |
| Missing | 1 | 2 |
| The detection, assessment, understanding, and prevention of adverse effects | 24 | 48 |
| The study of medicines | 18 | 36 |
| None of the above | 7 | 14 |
| **Have you heard about adverse drug reaction reporting** | | |
| Don`t know | 4 | 8 |
| NO | 19 | 38 |
| YES | 27 | 54 |
| **If yes from question no.2, where did you hear it from** | | |
| Television | 11 | 22 |
| Radio | 1 | 2 |
| Friends | 22 | 44 |
| Others | 16 | 32 |

From the table 2;
The majority of the respondents 24(48%) knew the correct definition of pharmacovigilance, 18(36%) defined pharmacovigilance as the study of medicines, and the minority 8(16%) didn`t know the definition of pharmacovigilance.

The majority of the respondents 27(54%) had never heard about adverse drug reaction reporting and 19(38%) had never heard about adverse drug reaction reporting. Of those who heard about adverse drug reaction reporting the main source of information was friends accounting for 22(44%), television accounting for 11(22%), radio 1(2%), and 16(32%) heard from other sources.

**Table 3: Shows whose professional obligation it is to report ADRs. (N=50)**

| **Do you think ADRS reporting is a professional obligation for you?** | | | | |
|---|---|---|---|---|
| | | **NO (%)** | **Yes (%)** | **Total** |
| **PROFESSION** | Lab technician | 1(100) | 0(00) | 1 |
| | Midwife | 3(37.5) | 5(62.5) | 8 |
| | Nurse | 6(18.18) | 27(81.81) | 33 |
| | Doctor | 0(00) | 2(100) | 2 |
| | Pharmacy technician | 0(00) | 2(100) | 2 |
| | Clinical officer | 1(25) | 3(75) | 4 |
| **Total** | | **11(22)** | **39(78)** | **50** |

From Table 3, the majority of the respondents 39(78%) thought ADR reporting is a professional obligation and the minority 11(22%) thought it is not a professional obligation.

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**Figure 1: A graph illustrating whose obligation to report ADRS against the profession. (N=50)**

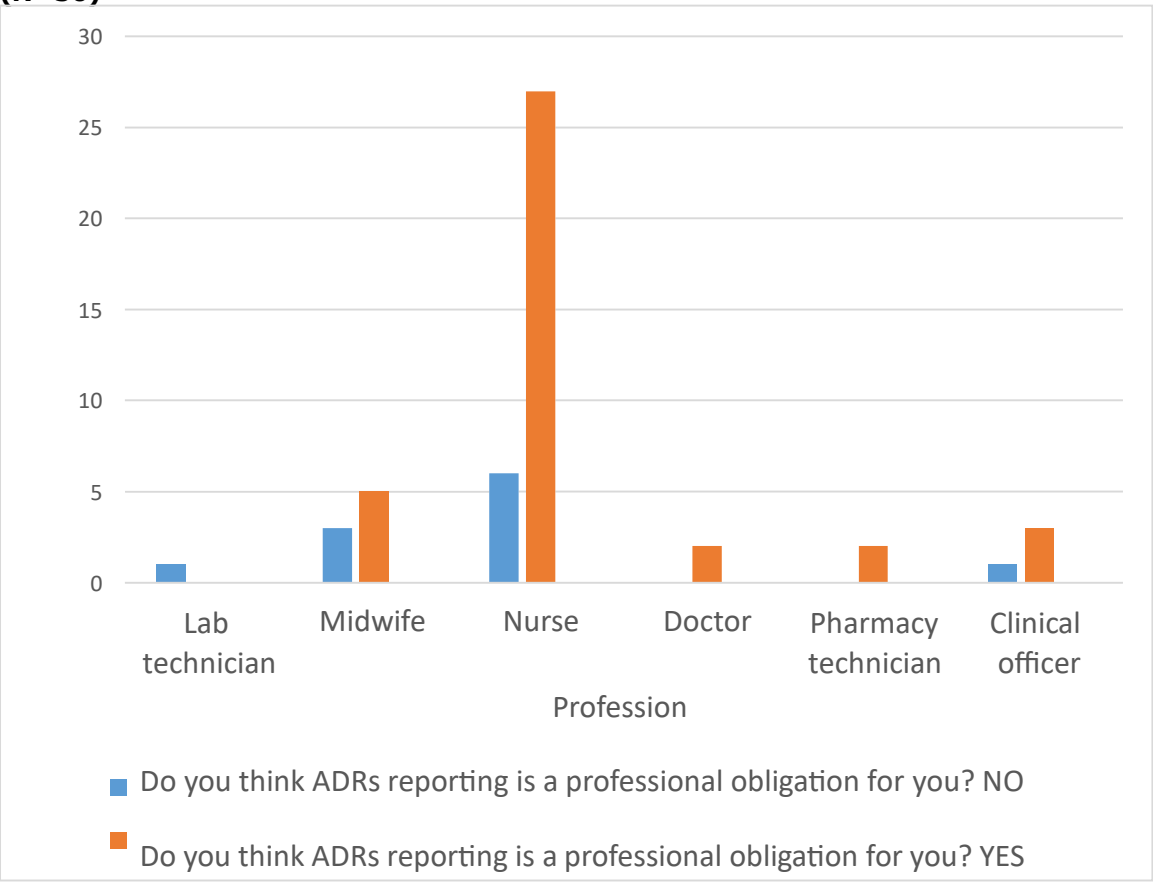

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**Table 4: Table illustrating ADRS reporting. (N=50)**

| **The healthcare professional responsible for reporting ADRs in a hospital?** | **Frequency (f)** | **Care professional responsible for reporting ADRs in a hospital? Frequency (f) Percentage (%) Percentage (%)** |
|---|---|---|
| All professionals | 25 | 50 |
| Doctors | 4 | 8 |
| Don`t know | 2 | 4 |
| Nurse | 11 | 22 |
| Pharmacist | 8 | 16 |
| **In Uganda which regulatory body is responsible for Monitoring ADRs?** | | |
| Didn`t know | 1 | 2 |
| National drug authority | 38 | 76 |
| World health organization | 11 | 22 |
| **Have you heard of any pharmacovigilance programs in Uganda?** | **Frequency (f)** | **Percentage (%)** |
| Missing | 2 | 4 |
| NO | 26 | 52 |
| YES | 22 | 44 |

From the table 4, most of the respondents 25(50%) believe that all health care professionals are responsible for reporting ADRs, 8(16%) believe it's a responsibility of pharmacists, 11(22%) believe it`s a responsibility of nurses, and 4(8%) believe it's a responsibility of doctors.
The majority 38(76%) knew that the National Drug Authority was the regulatory body responsible for monitoring ADRs whereas 11(22%) knew that the World Health Organization was the regulatory body responsible for monitoring ADRs.
Most of the respondents 26(52%) had never heard of any pharmacovigilance program in Uganda whereas the least of the respondents 22(44%) had ever heard of the pharmacovigilance program in Uganda.

**Table 5: Table illustrating awareness of the prevention of ADRs. (N=50)**

| **Have you ever read any article on the prevention of ADRs?** | **Frequency (f)** | **Percentage (%)** |
|---|---|---|
| Didn`t answer | 2 | 4 |
| N O | 30 | 60 |
| YES | 18 | 36 |
| **Total** | **50** | **100** |

From the table 5;
The majority, 30(60%) had never read any article on the prevention of ADRs while a minority of the respondents 18(36%) had at least read an article on the prevention of ADRs.

## The attitude of health care professionals towards pharmacovigilance.

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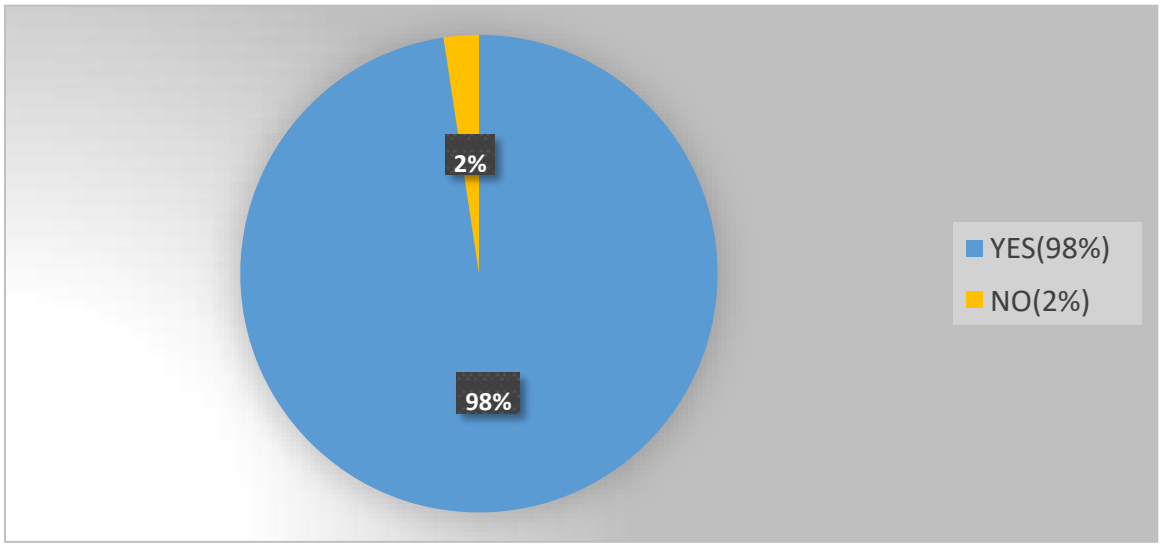
**Table 6: Table illustrating the necessity of ADRs. (N=50)**

| Do you think reporting adverse drug reactions is necessary? | Frequency (f) | Percentage (%) |
|---|---|---|
| Didn`t know | 1 | 2 |
| NO | 3 | 6 |
| YES | 46 | 92 |
| **Total** | **50** | **100** |

From Table 6, the majority 46(92%) of the health workers thought reporting adverse drug reactions was necessary while a minority 3(6%) of the health workers thought it was not necessary.

**Figure 2: A pie chart illustrating whether pharmacovigilance should be taught in detail to healthcare professionals. (N=50)**




From the figure 2;

The majority 49(98%) said pharmacovigilance should be taught in detail to healthcare professionals whereas the minority 1(2%) thought it was not necessary.

**Table 7: Table illustrating opinions on establishing ADR monitoring in your hospital.**

| Opinion on establishing an ADRs monitoring system in your hospital | | |
|---|---|---|
| | **Frequency (f)** | **Percent (%)** |
| Gave no opinion | 4 | 8 |
| It would be of great importance | 45 | 90 |
| It`s not necessary | 1 | 2 |
| **Total** | **50** | **100** |

From the table 7;

The majority 45(90%) of the respondents gave an opinion that the ADR monitoring system would be of great importance, 4(8%) gave no opinion and 1(2%) thought it was not necessary.

**Practices of health care professionals on pharmacovigilance.**

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**Table 8: Illustrating practices on pharmacovigilance among healthcare professionals.**

| Variables | Frequency (f) | Percentage (%) |
|---|---|---|
| **Ever experienced any ADRs in your patients during your professional practice** | | |
| Don`t know | 4 | 8 |
| NO | 12 | 24 |
| YES | 34 | 68 |
| **When did you last report an adverse drug reaction to the pharmacovigilance center?** | | |
| Month back | 2 | 4 |
| 2-3 months back | 6 | 12 |
| I have never | 42 | 84 |
| **Reasons not reported ADRs to the pharmacovigilance center** | | |
| The belief that a single unreported case may not affect the database | 7 | 14 |
| Difficult to decide whether an ADRs has occurred or not | 22 | 44 |
| Lack of time to report | 2 | 4 |
| No numeration | 19 | 38 |
| **Have you ever been trained on how to report ADRs?** | | |
| NO | 39 | 78 |
| YES | 11 | 22 |

From the table 8;
The majority of the respondents 34(68%) had ever experienced ADRs in their patients during their professional practice while the minority of the respondents 12(24%) had never experienced ADRs in their patients during their professional practice.
The majority 42(84%) had never reported ADRs to the pharmacovigilance center.
Of the respondents who had never reported ADRs to the pharmacovigilance center,
Most of the respondents 22(44%) said it`s difficult to decide whether an ADR has occurred or not, 19(38%) said there is no numeration, 7(14%) believed that a single unreported case may not affect the database and 2(4%) said there was no time to report.
The majority of the respondents 39(78%) had never been trained on how to report ADRs whereas a minority 11(22%) had never been trained on how to report ADRs.

## DISCUSSION.

### Knowledge of health care professionals on pharmacovigilance.

It revealed that only 48% of the respondents at Kayunga Regional Referral Hospital could define pharmacovigilance well, the rest 52% couldn`t give the most correct definition of pharmacovigilance however, 54% of the respondents had ever heard of adverse drug reactions and they could define ADRs correctly. These findings indicate that although the respondents couldn`t give a true definition of the subject matter, they knew pharmacovigilance, this could have been brought about by the fact that only 22% of the respondents at Kayunga Regional Referral Hospital had been trained in pharmacovigilance and ADRs reporting. These findings agree with (Mohamed. A, 2022), who conducted a study in Saudi Arabia where 42% were found to know the correct definition of pharmacovigilance.

Furthermore, when assessed about their obligation to report adverse drug reactions, the study showed that all pharmacy technicians 100% and all doctors 100% felt they must report adverse drug reactions, only 75% of the clinical officers and 62.5% of the midwives felt so, nurses 81.81% felt they should report ADRs. Nurses felt they should report ADRs because they are always in contact with patients who have been trained during the study and as well have attended seminars.

### The attitude of health care professionals towards pharmacovigilance.

It revealed that 82% of the respondents felt it necessary to report ADRs, 90% gave an opinion that ADRs monitoring system would be of great importance and 98% said pharmacovigilance should be taught in detail to health care professionals. These findings indicate that the majority of the respondents had a good attitude towards pharmacovigilance. These results compared to a study carried out by (Mustafa. Z, 2021) in Lahore, Pakistan showed that only 28.4% of the health workers had good attitudes towards pharmacovigilance and felt ADR reporting was important. This is because when they were asked about reasons for not reporting 51% of the health workers stated that ADRs reporting was very time-consuming, 54.9% stated that the identity of health care workers who report ADRs should be kept confidential, and 54.7% stated that reporting of just one ADRs would make no substantial contribution to ADRs reporting scheme.

**Practices of health care professionals on pharmacovigilance.**

It revealed that 68% of the healthcare workers had ever experienced ADRs in their patients during their professional practice though 84% had never reported ADRs to the pharmacovigilance center. 44% said it was difficult to decide whether an ADR had occurred or not, 4% said it was due to lack of time to report ADRs and 14% had a belief that a single unreported case may not affect the database. This could have been a result of the majority 78% not being trained on how to report ADRs and having never seen an ADRs reporting form. This compares with a study (Rabia. H, 2020) suggested that in many developing countries patients are not adequately safeguarded from accessing harmful and ineffective medicines due to poor pharmacovigilance systems.

## CONCLUSION.

The study established that 48% of the respondents could define pharmacovigilance correctly and ADR reporting was seen as an obligation of health workers. The National Drug Authority was a regulatory body responsible for ADR monitoring. A large percentage of 54% had never heard of ADRs and the main sources of information were friends, television, and other sources. A higher percentage of 82% had a good attitude towards reporting ADRs since they thought reporting adverse drug reactions was necessary. More to this majority 98% suggested teaching pharmacovigilance in detail to healthcare professionals. And 60% had never read an article on the prevention of ADRs. The majority 90% of health workers gave an opinion that the ADR monitoring system would be of great importance. The majority 68% of the health workers had ever experienced ADRs in their patients during their professional practice. 84% had never reported ADRs to the pharmacovigilance center and health workers who had never reported ADRs to the pharmacovigilance center, 44% found it difficult to decide whether an ADR had occurred or not, 4% said it was due to lack of time to report ADRs and 14% had a belief that a single unreported case may not affect the database. The majority 78% had never been trained on how to report ADRs.

Given these findings' respondents had some knowledge of pharmacovigilance. They knew about adverse drug reactions and their attitude towards reporting the ADRs encountered by the patients was good however their practice was poor and was affected by several factors which include remuneration, lack of time, and lack of expertise, to determine an adverse drug reaction and a thought that a single ADR would not affect the database. There is a need for great improvement in pharmacovigilance practice.

## STUDY LIMITATIONS.

The researcher faced a limitation of uncooperative health workers that is to say some of the respondents refused to give their full attention and also kept some information confidential, then other respondents provided wrong information while some had no time to fill out the entire questionnaire. Research study is a very lengthy and tiresome process and yet the researcher had limited time to conduct it. Financial shortages.

## RECOMMENDATIONS.

The government, Ministry of Health, and hospital administration should organize seminars to encourage ADR reporting and provide knowledge on ADRs
The researchers should carry out more research regarding the same topic to fill the gaps ADR reporting should be encouraged and promoted, especially through financial support.

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## LIST OF ABBREVIATIONS.

ADRS: Adverse Drug Reactions.
AE: Adverse Effect.
FDA: Food and Drug Administration.
HCP: Health Care Professional.
KSHS: Kampala School of Health Sciences.
MOH: Ministry Of Health.
NDA: National Drug Authority.
NPC: National Pharmacovigilance Center.
PV: Pharmacovigilance.
SRS: Spontaneous reporting system.
WHO: World Health Organization.

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