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# KNOWLEDGE, ATTITUDE AND PRACTICES TOWARDS PHARMACOVIGILANCE AMONG HEALTHCARE PROFESSIONALS IN MUKONO GENERAL HOSPITAL,MUKONO DISTRICT. A CROSS-SECTIONAL STUDY.

**Nancy Rose Byogero, Harrison Sida*
*Kampala School of Health Sciences*

## Abstract

### Background
Adverse Drug reactions are an important contributor to patient morbidity and hospitalization in Uganda. This may be linked to under reporting of ADRs among patients. Reporting adverse drug reactions is a professional responsibility crucial for patient safety in Pharmacovigilance. The study was aimed at assessing the knowledge, attitude, and practices of pharmacovigilance among health care professionals at Mukono General Hospital.

### Methodology
A descriptive cross-sectional study was adopted, with a purposive sampling technique to obtain a sample of 50 participants. Data was collected with the help of questionnaires. The collected data was further analyzed and presented in the form of tables and graphs.

### Results
Findings reveal that the majority (68%) were females, (32%) were males, and (52%) were aged 31-40 years. Professionally, (60%) were nurses, while the least, (2%) were from other professions. There was moderate knowledge about pharmacovigilance, as only (58%) could define it. ADRs reporting was seen as an obligation of health workers, (86%) had ever heard about adverse drug reaction reporting, and (68%) of the respondents knew the regulatory body responsible for monitoring ADRs. Furthermore**,** 88% had a good attitude towards reporting of ADRs since they thought reporting adverse drug reactions was necessary. In addition, the practice towards pharmacovigilance was poor, where (88%) had never reported ADRs to the Pharmacovigilance center, and (74%) of respondents had never been trained on how to report ADRs.

### Conclusion
There was moderate knowledge and a good attitude towards reporting of ADRs, while the practice towards pharmacovigilance was poor.

### Recommendation
The government, the Ministry of Health, and hospital administrators should organize educational seminars to encourage ADR reporting and provide knowledge on ADRs and ADR reporting**.**

***Keywords:*** Knowledge, attitude, practice, pharmacovigilance, Mukono General Hospital, Mukono District.

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***Corresponding author:*** *Nancy Rose Byogero*
***Email:*** *nancyrose533@gmail.com*
*Kampala School of Health Sciences*

## BACKGROUND
Pharmacovigilance, according to the World Health Organization, refers to activities relating to the detection, probing, analysis, and interdiction of adverse reactions to medicines or any other medicine-related problems (WHO, 2024). Furthermore, medicines have changed life by controlling and managing diseases.

Despite their tremendous benefits, worldwide, significant evidence continues to emerge on adverse drug reactions; for example, they may cause ailments, disability, and even death. Adverse drug reactions are also common for patient -related morbidity and mortality and are recognized to cause an extended duration of hospital stay and poor therapeutic outcomes (Ali et al., 2018).

Globally, drug efficacy and corresponding safety are key. While drug efficacy can be feasibly quantified, the same cannot be for safety. This is due to uncommon adverse effect of a drug (but very serious), and many patients may be affected or subjected to a potential risk before the relationship with the drug is established. Adverse Drug Reactions (ADRs) affect patients irrespective of the age group of patients, with a varying magnitude of causing morbidity and mortality (Ganesan et al., 2016).

In history, the Thalidomide disaster is a major catastrophic event that affected the development of medicine regulation. The establishment of safety committees and voluntary adverse drug reaction reporting systems emanated from the latter. To date,

pharmacovigilance systems are essential, and health workers and consumers are obliged to report adverse events to regulatory agencies (Nambasa, 2017).

Pharmacovigilance (PV) evolved because of the thalidomide tragedy in Europe in the late 1960s. Its focus was on studying adverse drug reactions (ADRs) to medicines after their authorization for use. The most commonly used classification of these adverse effects are augmented (Type A) or bizarre (Type B) reactions, which was the original classification of ADRs primarily distinguishing between pharmacological outcomes and super sensitivity reactions (Patton & Borshoff, 2018).

Research on medicine- related hospitalizations carried out over the past 35 years has demonstrated that approximately 50% of medicine-related patient harms leading to hospitalization are preventable, that is, are not only linked to the intrinsic properties of the medical product itself, but also with its prescription, dispensation, and administration or use (Olsson *et al*., 2017).

Good PV helps to identify the uncertainties associated with medicines in a short period, and when effectively communicated, information allows for intelligent, evidence-based use of medicines, which will potentially prevent many adverse reactions. The WHO and its regional offices support countries in promoting the establishment and setting up of sustainable monitoring systems. It acts as a repository for PV information and dispatches this information appropriately.

In Africa, scarce information concerning the influence of adverse drug reactions (ADRs) on the quality of life and health of patients has been recorded. From a Pharmacovigilance perspective, capturing and making the best use of this information remains a challenge (Eugene, 2016).

Health care professionals are therefore frontliners in the prompt detection and reporting of adverse drug reactions among patients. However, literature on the magnitude and factors affecting ADR reporting among healthcare workers in Uganda is limited. One of the studies superficially hinted that some of Uganda's healthcare workers were unfamiliar with formal pathways for reporting ADRs. In addition, several factors have hindered healthcare workers from reporting ADRs, including low knowledge on the importance of reporting, phobia of extra workload, and inability to differentiate clinical symptoms from ADRs, among others (Katusiime *et al*, 2015). Therefore, this study aimed to assess the knowledge, attitude, and practices towards pharmacovigilance among health care professionals in Mukono General Hospital.

## METHODOLOGY

### Study design

The study employed a descriptive cross-sectional design with quantitative methods of data collection.

### Study area

The study was carried out in Mukono General Hospital along the Jinja-Kampala highway in the North Central region, Mukono District, approximately 20 kilometers east of Kampala. The hospital is staffed with about 80 health workers who provide a comprehensive range of medical services that include inpatient care, emergency services, maternal and child health services, and specialized treatments.

### Study population

The study population comprised all health care practitioners in Mukono General Hospital: both male and female with different professional backgrounds, that is to say, doctors, Pharmacists, Pharmacy Technicians, Nurses, clinical officers, and any other auxiliary medical staff.

### Sample size determination

According to Mugenda's formula (2003), the sample size was determined by n= N/[1+N(e)2]

Where N is the study population, e=at 5 % level of significance or margin of error. n= sample size required

Considering a population of 57 n=57/ (1+57(0.1)2) =50

50 respondents will be used in this study.

### Sampling technique

Respondents who had knowledge, experience, and skills about pharmacovigilance were sampled using a purposive sampling technique.

### Sampling procedure

Healthcare professionals who had knowledge and experience about pharmacovigilance and adverse drug reactions were identified. They were selected and requested to consent, and those who agreed to participate in the study were given questionnaires to answer.

### Data collection method

Questionnaires were used to collect data, which were filled out by respondents. Respondents were interviewed using structured questionnaires for quantitative data. The structured questions were written in English and were given to the respondents, who replied in English.

### Data collection tools

A structured questionnaire was designed to allow respondents tick the most appropriate answer as a way to express their views and opinions without explanation by the interviewer. This, therefore, helped the researcher to reduce the possibility of bias from the respondents and also saved time.

### Data collection procedure

Respondents who had knowledge and skills about pharmacovigilance participated in the data collection exercise, where they were interviewed using structured questionnaires. The structured questions were written in English, and respondents replied in English. The participants were chosen at their own convenience.

### Study variables

***Table 1: Showing the study variables***

| Objectives | Variables | Indicators |
|---|---|---|
| Knowledge of health workers on pharmacovigilance | Knowledge | • Awareness of pharmacovigilance<br>• Practice of pharmacovigilance |
| Attitude of health workers towards pharmacovigilance | Attitude | • Availability of reporting tools<br>• Use of ADR reporting tools |
| Practice of pharmacovigilance | Magnitude of reporting | • Frequency of reporting of adverse drug reaction<br>• Effectiveness of pharmacovigilance |

### Quality control
Quality control involved training of a research assistant, pretesting of the research tool, and clear inclusion and exclusion criteria.

### Training research assistants
A literate individual was trained through briefing them about the topic of the study and was given instructions on how to and to whom to distribute questionnaires. This gave aid in the fast collection of data in the anticipated period of time.

### Pre-testing of data collection tools
The questionnaire was first approved by the supervisor, together with the proposal. It was pretested on 2 clinics, specifically targeting nurses and a few doctors, to check out any ambiguous questions and errors that were corrected.

### Inclusion Criteria
Healthcare professionals, that is, Doctors, Pharmacy Technicians, nurses, and pharmacists, participating directly in inpatient care and having been in practice for at least one year, were included in the study. These professionals were thought to have knowledge and the responsibility of assessing patients, documenting findings, and reporting suspected ADRs to the hospital and/or the national pharmacovigilance Centre.

### Exclusion criteria
Healthcare professionals who did not have the knowledge about pharmacovigilance and had not practiced for at least one year were not included in the study.

### Data analysis and presentation
Analyzing data was done manually; the responses were tallied, frequencies counted, and converted into percentages using a calculator. Data was presented in tables and then put in representative figures like pie charts, graphs, to ease the interpretation of results.

### Ethical considerations
A letter of introduction was obtained from the Kampala School of Health Sciences research committee, introducing the researcher and seeking permission to carry out the study with assurance of confidentiality.
Participation in the study was voluntary, and informed consent was obtained from all study participants before being handed the questionnaires. Data collection forms were anonymous, and all information was kept with strict confidentiality.

## RESULTS

### Social Demographic data of the respondents

***Table 2: Showing the distribution of respondents according to demographic data, (N=50)***

| **Response** | **Frequency (f)** | **Percentage (%)** |
|---|---|---|
| **Gender** | | |
| Female | 34 | 68 |
| Male | 16 | 32 |
| **Total** | **50** | **100** |
| Age | | |
| 20-30 | 22 | 44 |
| 31-40 | 26 | 52 |
| 41-50 | 2 | 4 |
| **Total** | **50** | **100** |
| **Profession** | | |
| Doctor | 4 | 8 |
| Pharmacy technician | 2 | 4 |
| Nurse | 30 | 60 |
| Mid wife | 4 | 8 |
| Clinical officer | 9 | 18 |
| Others | 1 | 2 |
| Total | 50 | 100 |
| **Years of Experience** | | |
| 1-5 | 35 | 70 |
| 5-10 | 14 | 28 |
| 10-15 | 1 | 2 |
| **Total** | **50** | **50** |

From Table 2, the majority of the respondents (68%) were females, while the minority (32%) were males. More than half of the respondents (52%) were aged 31-40 years, whereas the least (4%) were aged 31-40 years. The majority of the respondents (60%) were nurses, while the minority (2%) were other professionals.

## Knowledge of health care professionals towards Pharmacovigilance

***Table 3: Shows the distribution of respondents according to their knowledge about the term pharmacovigilance, (N=50).***

| **Response** | **Frequency(f)** | **Percentage (%)** |
|---|---|---|
| Pharmacovigilance is | | |
| The study of medicines | 14 | 28 |

| | | |
|---|---|---|
| The detection, assessment, understanding and prevention of adverse effects | 28 | 56 |
| None of the above | 8 | 16 |
| **Total** | **50** | **100** |

From Table 3, more than half of the respondents (56%) knew the correct definition of pharmacovigilance, and the minority (16%) did not know the definition of PV.

***Table 4: Table showing the distribution of respondents according to who had ever heard about adverse drug reaction reporting, (N=50).***

| **Response** | **Frequency (f)** | **Percentage (%)** |
|---|---|---|
| Yes | 43 | 86 |
| No | 7 | 14 |
| If yes from question no.2, where did you hear it from | | |
| Television | 08 | 18.6 |
| Radio | 1 | 2 |
| Seminars and training | 12 | 27.9 |
| Other health care professionals | 22 | 44 |
| **Total** | **50** | **100** |

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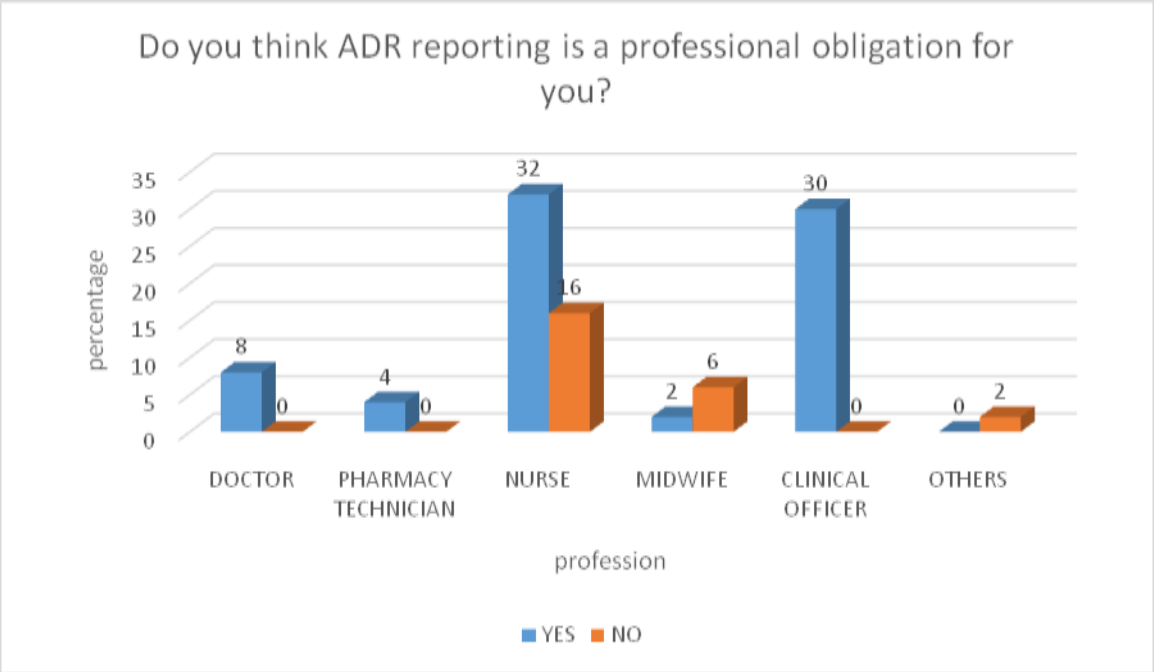
From Table 4, the majority of the respondents (86%) had ever heard about adverse drug reaction reporting, and the minority (14%) had never heard about adverse drug reaction reporting. Of those who heard about adverse drug reaction reporting, the main source of information was from other healthcare professionals, accounting for (44%) and radio, accounting for (2%).

***Figure 1: Showing the distribution of respondents according to the knowledge on whose obligation is it to report ADRS, N=50.***




From Figure 1: the majority of the respondents (76%) thought ADR reporting is a professional obligation, and the minority (24%) thought it is not their professional obligation to report ADRs.

***Table 5: Shows the distribution of respondents according to their knowledge on which profession is responsible for reporting ADRs in a hospital, (N=50).***

| **Response** | **Frequency(f)** | **Percentage (%)** |
|---|---|---|
| Doctor | 5 | 10 |
| Pharmacy technician | 8 | 16 |
| Nurse | 12 | 24 |
| All professionals | 25 | 50 |
| Don't know | 0 | 0 |
| **Total** | **50** | **100** |

From table 5, half of the respondents (50%) believed that all health care professionals are responsible for reporting ADRs, and the minority (10%) believe it is a responsibility of the doctors.

***Table 6: Showing the distribution of respondents according to their knowledge about which regulatory body is responsible for monitoring ADRs,(N=50).***

| **Response** | **Frequency(f)** | **Percentage(%)** |
|---|---|---|
| National drug authority | 34 | 68 |

| | | |
|---|---|---|
| World health organization | 16 | 32 |
| **Total** | **50** | **100** |

From table 6: The majority (68%) knew that the National Drug Authority was the regulatory body responsible for monitoring ADRs, whereas (32%) knew that the World Health Organization was the regulatory body responsible for monitoring ADRs.

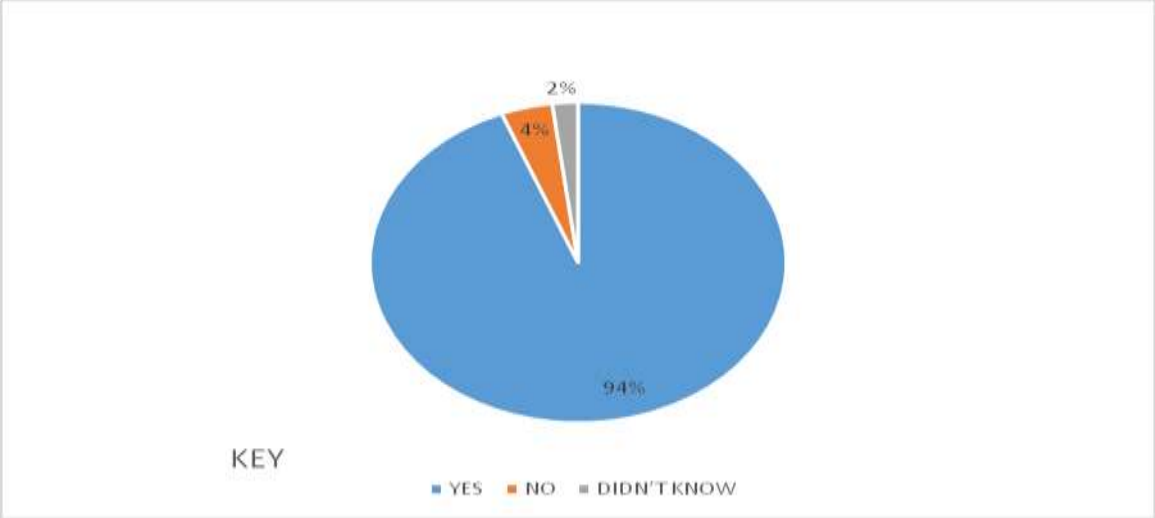
## Attitude of healthcare professionals towards Pharmacovigilance

***Table 7: Showing the distribution of respondents according to their perception towards the necessity of reporting ADRs, (N=50).***

| **Response** | **Frequency** | **Percentage** |
|---|---|---|
| Yes | 44 | 88 |
| No | 6 | 12 |
| **Total** | **50** | **100** |

From Table 7, the majority (88%) of the health care professionals thought reporting adverse drug reactions was necessary, while a minority (12%) of the health care professionals thought it was not necessary.

***Figure 2: Showing the distribution of respondents according to their perception whether pharmacovigilance should taught in detail to health care professionals, (N=50).***




From figure 2; Majority 94% agreed that pharmacovigilance should be taught in detail to healthcare professionals, whereas a minority 2% didn't know whether pharmacovigilance should be taught or not.

***Table 8: Table showing the distribution of respondents according to their opinions on establishing ADR monitoring system in their hospital (N=50).***

| **Opinion on establishing an ADRS monitoring system in your hospital** | | |
|---|---|---|
| **Results** | **Frequency(f)** | **Percentage(%)** |
| It would be of great importance | 45 | 90 |

| | | |
|---|---|---|
| It's not necessary | 1 | 2 |
| Gave no opinion | 4 | 8 |
| **Total** | **50** | **100** |

From table 8, the majority (90%) of the respondents gave an opinion that the ADR monitoring system would be of great importance, and the minority (2%) thought it was not necessary.

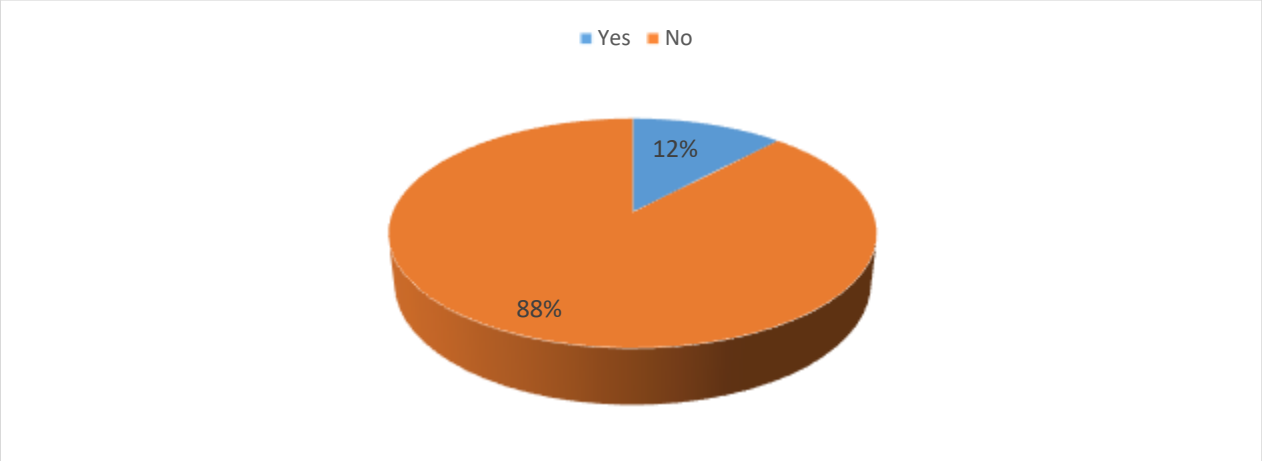
## Practice of health care professionals towards Pharmacovigilance

***Table 9: Showing the distribution of respondents according to whether they had ever experienced ADRs in their patients during their professional practice, (N=50).***

| Response | Frequency(f) | Percentge(%) |
|---|---|---|
| Yes | 36 | 72 |
| No | 14 | 28 |
| **Total** | **50** | **100** |

From Table 9, the majority of the respondents (72%) had ever experienced ADRS in their patients during their professional practice, while the minority of the respondents (28%) had never experienced ADRs in their patients during their professional practice.

***Figure 3: Shows the distribution of respondents whether they had ever reported an ADR to the Pharmacovigilance center, (N=50).***



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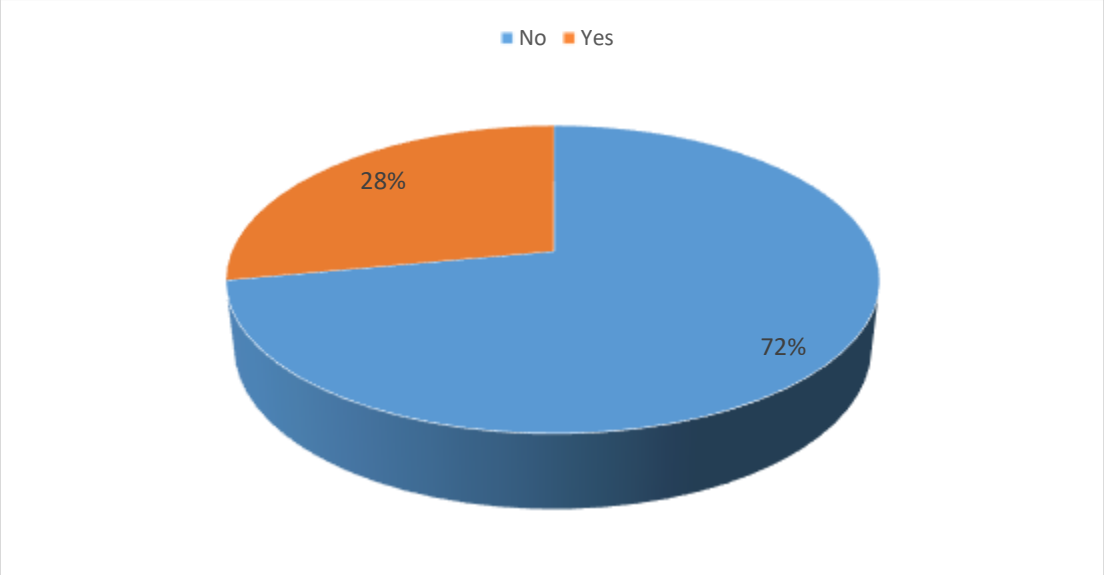
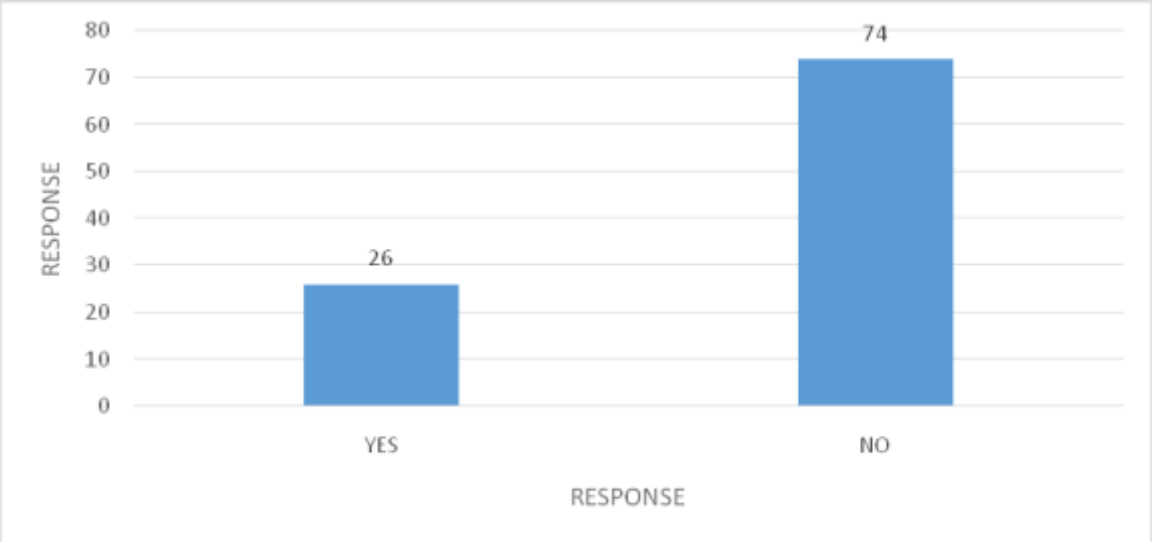
From Figure 3: The majority of the respondents (88%) had never reported ADRS to the Pharmacovigilance center, while a minority (12%) had ever reported ADRs to the Pharmacovigilance center.

***Figure 4: Shows the distribution of respondents according to whether they had ever seen an ADR reporting form, N=50.***




From Figure 4: The majority of the respondents (72%) had never seen an ADR reporting form, while a minority (28%) had ever seen an ADR reporting form.

***Figure 5: Shows the distribution of respondents according to whether they had ever been trained on how to report ADRS, (N=50).***




From Figure 5, the majority of the respondents (74%) had never been trained on how to report ADRS, while the minority (26%) had ever been trained on how to report ADRS.

## DISCUSSION

### Knowledge of health care professionals on pharmacovigilance

The study findings revealed that more than half (56 %) of the respondents at Mukono General Hospital could define PV well. This implies that the outstanding percentage of study respondents were familiar with the study concept. This was attributed to the fact that some of the respondents were taught about pharmacovigilance during their training for their respective professions. These findings were in agreement with the study carried

out by Khardali (2024), where more than half of the respondents (55.2%) were able to define PV correctly.
The study revealed that the majority (86%) of the respondents had ever heard of adverse drug reactions. Such a response clearly shows that the study participants knew the concept of PV, which is adverse drug reactions. This was not in line with Baliraine & Molodokayi (2024), where findings showed that (54%) heard about adverse drug reactions.
Furthermore, when participants were assessed about their obligation to report ADRs, the study findings showed that the majority, 76% of the respondents, thought ADR reporting is a professional obligation. This was attributed to the fact that most health care professionals directly interact with the patients, which makes them responsible for reporting ADRs. These findings were in line with the study carried out by Hussain et al ( 2021), where the study findings showed that (77.7%) physicians,(75.7%) pharmacists, and (68%) nurses showed that ADR reporting is a professional obligation.
The study findings also revealed that the majority (68%) of the respondents knew the regulatory body responsible for monitoring ADRs is the National Drug Authority. These findings were not in line with Khardali (2024), where only (16%) of them were able to identify the system that is responsible for the ADRs report collection and analysis.

## Attitude towards pharmacovigilance among healthcare professionals

The study revealed that the majority (88%) of the respondents thought it was necessary to report adverse drug reactions. These findings indicate that respondents had a good attitude towards
Pharmacovigilance and ADR reporting. This was in line with Yawson et al (2022), where (85.8% ) of HCPs displayed positive attitudes towards ADR reporting.
The study findings showed that the majority (94%) of the respondents said PV must be taught further in detail to healthcare professionals. They thought this would help to enhance the knowledge and awareness of PV and promote its practice in the facility. This is in line with Baliraine & Molodokayi (2024), where (98%) of the respondents said pharmacovigilance should be taught in detail to healthcare professionals.
The study findings showed that the majority (90%) of the respondents said that establishing an ADR monitoring system would be of great importance to the facility. This implied that early detection, evaluation, and reporting of new ADRS that occur among patients would be made mandatory and compulsory for all healthcare workers. This was in line with the findings of Adebisi (2024), where (89%) of the pharmacists believed in the importance of reporting adverse drug reactions.

## Practice of pharmacovigilance among healthcare professionals

The study findings showed that the majority (72%) of the respondents had ever experienced ADRs in their professional practice. This was attributed to the fact that although medicines are formulated with a good safety profile, they also produce unintended effects on the body. This is compared with Maigetter et al (2015), where the study stated that in many developing countries, patients are not adequately safeguarded from accessing harmful and ineffective medicines due to poor PV systems.
The study also revealed that (88%) of the respondents had never reported ADRs to the pharmacovigilance center. This was attributed to the fact that most participants were not sure whether an ADR had occurred or not, a lack of training on how to report the ADRs, and a lack of reporting tools in their respective departments where they worked. These results were in line with Tukahirwa (2014), where it was revealed that despite the efforts of establishing 14 regional PV centers, conducting PV - training sessions for core teams of healthcare professionals, and ADR reporting forms, the reporting rate in Uganda is still low.
The study results also showed that (72%) of the health care professionals had never seen an ADR reporting form. This was attributed to the fact that reporting tools were not adequate in the health facility. This was in line with Assab et al (2024), where only (7%) of the health care professionals were aware of the official statement of ADR reporting.
The study findings also showed that the majority (74%) of the respondents had never been trained on how to report ADRS. This is because PV is not considered among the standard procedures enforced in the hospital. This was not in line with Srinivasan et al (2017), where (63.45%) of the respondents had ever been trained how to report an ADR.

## CONCLUSION

Based on the overall findings, the researcher concluded the following. The researcher noticed that respondents had moderate knowledge about pharmacovigilance, where (58%) could define PV, (86%) had ever heard about ADRs reporting, and (76%) knew that it was their professional obligation to report ADRs.
The researcher discovered that the majority (88%) had a good attitude towards reporting of ADRS since they thought reporting ADRs was necessary,(94%) of the respondents suggested teaching of PV in detail to HCPs, and (88%) gave an opinion that the ADR monitoring system would be of great importance to the health facility.
The researcher noticed that the practice of PV was poor since (88%) had never reported any ADRs to the pharmacovigilance center, although the majority (72%) had experienced ADRs in their patients during their professional practice, (72%) had never seen an ADR reporting form, and (74%) had never been trained on how to report ADRs.
Given these findings**,** the researcher discovered that respondents had moderate knowledge, a good attitude towards reporting the ADRs encountered by their patients, but their practices were poor.

## RECOMMENDATION

The government, the Ministry of Health, and hospital administrators should organize educational seminars to encourage ADR reporting and provide knowledge on ADRs.

The researchers need to carry out more research regarding the same topic to fill in the gaps.

ADRs reporting should be encouraged and promoted, especially through financial support by the government or Non-Government Organizations.

The facility administration should provide pharmacovigilance-reporting tools to all the departments of the hospital, as well as train the healthcare professionals about Adverse drug reporting through Continuous Medical education.

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| **ADR** | **:**Adverse Drug Reaction |
| **HCWs** | **:**Health care workers |
| **AE** | **:**Adverse event |
| **NDA** | **:**National Drug Authority |
| **ASHP** | **:**American Society of Health-system Pharmacists |
| **FDA** | **:**Food and Drug Administration |
| **GPs** | **:**General Practitioners |
| **HCPs** | **:**Health care professionals |
| **NPC** | **:**National Pharmacovigilance Centre |
| **PV** | **:**Pharmacovigilance |
| **SRS** | **:**Spontaneous Reporting Systems |
| **WHO** | **:**World Health Organization |

## SOURCE OF FUNDING

The study was not funded

## CONFLICT OF INTEREST

Author declares no conflict of interest

## AUTHOR CONTRIBUTIONS

**NRB**-Principal investigator
**HS**-Supervised the study

## DATA AVAILABILITY

Data is available upon request

## INFORMED CONSENT

There was full disclosure, total comprehension as well as voluntary consent from the respondents

## AUTHOR BIOGRAPHY

Nancy Rose Byogero is a student at Kampala School of Health Sciences, pursuing her Diploma in Pharmacy.

Harrison Sida is a research supervisor at Kampala School of Health Sciences.

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Address: Scholar's Summit Nakigalala, P. O. Box 166256, Entebbe Uganda, East Africa