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KNOWLEDGE, ATTITUDE AND PRACTICE TOWARDS ADVERSE DRUG REACTION REPORTING BY HEALTH CARE SERVICE PROVIDERS WORKING IN AIVEEN PHARMACIES WITHIN CENTRAL DIVISION KAMPALA DISTRICT. A CROSS SECTIONAL DESCRIPTIVE STUDY.

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Abstract

Purpose of the study:

The purpose of the study was to assess the adverse drug reaction reporting among healthcare service providers in Aiveen pharmacies

Objectives of the study: The specific objectives of the study were; to determine the level of knowledge of reporting ADR"s among healthcare providers, to determine the attitude of reporting ADR"s and to determine the practices of reporting ADR"s among healthcare service providers in Aiveen pharmacies.

Research methodology:

The study employed the descriptive cross-sectional study to assess the specific objectives on a sample of 19 respondents using the simple random sampling.

Results of the study:

From the study findings, 76.5% of respondents were not trained on drug safety and ADR reporting, 57.9% were not aware of national ADR reporting guidelines, 78.3% have never seen ADR reporting forms, 84.2% said reporting ADR"s is professional obligation, 94.7% revealed reporting ADR"s benefit public health, 84.2% had positive attitude towards ADR reporting, 63.2% ever diagnosed on ADR, 78.9% have never reported ADR"s and 73.6% did not report ADR"s to any center neither to pharmacovigilance center , pharmaceutical company nor in hospital DTC and 63.0% revealed that there was lack of reporting forms.

Conclusion:

In conclusion the research study clearly indicates a relatively better attitude but limited knowledge and practice towards ADRs reporting among healthcare professionals working in Aiveen pharmacies.

Recommendation:

The Ministry of Health through National Pharmacovigilance and Medicine Information Centre (NPMIC) should create awareness of healthcare professionals through regular trainings, continuous education and refresher courses in Pharmacovigilance and ADR reporting system. This training could be incorporated into the Continuous Professional Development (CPD) program for the doctors, nurses and pharmacists as part of license requirement for the doctors, nurses and pharmacists in Aiveen pharmacies.

Keywords: attitude, practice, ADR, Aiveen pharmacies, Health care service providers, Submitted: 2023-07-06 Accepted: 2023-08-17

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1. Background study

The World Health Organisation defines an adverse drug reaction (ADR) as „a response to a medicinal product which is noxious and unintended, and occurs at doses normally used in humans(Canbera,2022) for the prophylaxis, diagnosis, or therapy of disease, or for modification of physiological function (Julie Samyde, 2016). Adverse effects usually predict hazard from future administration and warrant prevention, or specific treatment, alteration of dosage regimen, or withdrawal of the product. Since 2012, the definition has included reactions occurring as a result of error, misuse or abuse, and to suspented reactions to medicines that are unlisenced or being used off-label in addition to the authorised use of a medicinal product in normal doses. (Jacoline C Bouvy, 2015)

Adverse drug reactions (ADRs) remains a major public health concern for most policy makers, clinicians and patients because they impact treatment adherence and increase healthcare costs, mortality. ADRs may range from mild to life-threatening, with short or long-term effects of which the ADR will necessitate linkage for that specific drug of assault. ADRs are broadly defined as Type A reactions which refer to augmented reactions which are dose-dependant and Predictable on the basis of the pharmacology of the drug. Type B reactions Bizarre reactions which are idiosyncratic and not predictable on the basis of the pharmacology (Sumeshni Birbal, 2016) The ADR might also occur even after the correct utilisaton of medications, such that there has been a range of factors, which either predispose or contribute to the development of ADR (WA Adedeji, 2013)

Globally occurrence of ADRs is multifactorial. These factors include the irrational utilization of medications, poor patterns of medication prescriptions, the promotional activities and campaigns considered by the pharmaceutical industries, the inadequate access to the objective resources of information, and unhealthy pharmaceutical practices (Marc L Berger, 2014)The ADR might be predicted and related to dose, time(delayed reactions), the withdrawal reactions, and the unexpected reactions due to the failure of treatment. (Mai Fujimoto, 2014)

In sub-Saharan Africa, the need for Monitoring ADRs has been important in Africa with reference to chronic illnesses notably HIV/AIDS.The prevalence of HIV infections and the usage of antiretroviral therapy gave more to relevance of pharmacovigilance over the years. Although Africa contributes to 69% of the world"s patients, are on ARVs. (Yohanna Kambai Avong, 2018) There is little information as to what extent adverse drug reactions (ADRs) influence patients" health related quality of life. From a pharmacovigilance perspective, capturing and making the best use of this information remains a challenge (Sieta T de Vries, 2019)despite the fact that Africa registers an average 6.3% of total hospital admissions are a direct result of adverse drug reactions. (Appiah, 2012)

Appropriate reporting and capturing of ADRs across all the spans of service delivery is essential for reducing the risk of morbidity and mortality following the administration of drugs., the healthcare professionals need to achieve competence in the handling of ADRs within the clinical practice not only for safety of patients but also for the monitoring of drug safety level at the level of the population (Rike van Eekeren, 2018)

One of the studies superficially hinted that some of Uganda"s healthcare workers were unfamiliar with formal pathways for reporting ADRs with about 16.6% under reporting rate linked to inadequate knowledge, attitude and practices towards Adverse Drug Reaction reporting by Health care service providers at Mulago National Referral and Teaching Hospital with a variety of factors cited to deter healthcare workers from reporting ADRs including inadequate knowledge about the reporting , fear of extra workload, failure to differentiate clinical symptoms from ADRs, among-several other factors (Katusiime et al, 2015).

Therefore, it is important to determine the possible causes of the under reporting by Health professionals. The aim of this study is to evalu-

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ate Knowledge, Attitude and practices of Adverse Drug Reaction reporting among Health Professionals in Aiveen Pharmacies in Central division in Kampala District.

1.1. General objectives:

To assess the level of Knowledge, attitude and practices of Adverse Drug Reaction reporting among Healthcare Professionals working in Aiveen Pharmacies in Central division, Kampala district.

1.2. Specific Objectives:

- To determine the level of Knowledge of ADR reporting among healthcare professionals working in Aiveen Pharmacies in the Central division, Kampala district.
- To determine the attitude of ADR reporting among healthcare professionals working in Aiveen Pharmacies in the Central division, Kampala district.
- To determine the practice of ADR reporting among healthcare professionals working in Aiveen Pharmacies in the Central division, Kampala district.

2. METHODOLOGY

2.1. Study design:

The study employed a cross-sectional descriptive study design which employed both quantitative and qualitative methods of data collection.

2.2. Study area

The study was conducted in Aiveen pharmacies which are found in Central division Kampala district in the southern region of Uganda which will be chosen for the study with the reason that it was easy to reach. It is located within the city center mainly William Street which was one of the busy places in Kampala City.

2.3. Selection criteria

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

2.3.1. Inclusion criteria

Only healthcare professionals from Aiveen pharmacies in the central division, Kampala district consented to answer the questionnaires.

2.3.2. Exclusion criteria

Healthcare professionals who didn"t consent to participate in the study.

2.4. Study population:

All the Healthcare providers working within Aiveen pharmacies were considered for data collection right from the dispensers regardless of qualification whether registered midwives, nurses, clinical officers, pharmacy technicians, and pharmacists. The Healthcare professionals involved as the source of data to be collected must be able to decide and consent by themselves.

2.5. Sample size determination:

The sample size was determined using Slovene formula Sample size: $n = N/(1+Ne^2)$,

n= 24/(1+24(5%)2)

n= 24/(1+24(5/100)2) n= 24/(1+24* 0.0025) n= 24/(1+0.06)

n= 24/(1.06) n= 22.6415

n=23

Where n is the sample size, N is the population size and e is the level of precision/marginal error which is 5% while 1 is a constant

(Source; Guilford J.P. and Frucher B.; 1973)

Aiveen(U) Limited is the mother company which consists of ;

- Two Vita care pharmacies along Johnson Road and Bombo Road.
- Four Aiveen pharmacies along Wilson Road.
- One Supermedic Pharmacy along Wiliam Street at Gaza land.

This sums up to about Seven Aiveen pharmacy outlets with a sum of about 24 Healthcare service providers

2.6. Sampling technique.

Using randomization, random numbers were generated for each healthcare professional category were sampled.

2.7. Data collection procedures.

The healthcare professionals were explained to concerning the essence and significance of the study and then asked to consent by signing a consent form for their participation in the study.

Each participant will be required to indicate their profession on the questionnaires for the purpose of identification. A pretested questionnaire will be used. The questionnaires were written in English and kept in lock and key.

After each of the healthcare professionals has answered the questionnaires in private with the help of the researcher or assistant where necessary.

2.8. Data management.

Original questionnaires were stored in a self-locked place for future reference and as a backup to the electronically stored data. Electronic backup copies of data on compact discs (CDS) were made. They were kept in a self-locked place for future reference and as a backup to the electronically stored data. Electronic backup copies of data on compact discs (CDS) were made.

2.9. Data analysis.

Data analysis is a process of inspecting, cleansing, transforming, and modeling data with the goal of discovering useful information, and informing conclusions. It can also be defined as the practice of working with data to glean useful information, which can then be used to make informed decisions.

The data filled on the questionnaires were analyzed by statistical, descriptive, and inferential methods of data analysis tallied, and entered into both tabular and graphic presentations which include Bar graphs, circles, and pie charts which were created using Microsoft Excel which was used to encapsulate the quantitative data.

2.10. Quality Control

Questionnaires were designed such that they are coherent, legible, and easy to understand and typed so as to emphasize important points (e.g., using capitals, bold letters, or underlining)

The questionnaires were pre-tested on 20 participants who met the inclusion criteria and modifications shall make to ensure the collection of good-quality data.

Appropriate software for data entry and analysis was selected including the data diary which was continuously filled so as to facilitate convenient follow-up of the sample received, analyzed, required re-analysis, and protocol adherence enhancement.

Profound and minor errors were checked while subjects are still accessible, Data was entered in doubles as soon as possible after collection so as to minimize bias or missing data in case of misplacement of tools. Back-up of data electronically and in hard copy was kept.

2.11. Ethical considerations.

Ethical clearance to execute data collection among healthcare professionals working within Aiveen pharmacies will be obtained by getting an introductory letter from the principal of Kampala School of Health Sciences addressed to the Managing Director of Aiveen Pharmacies who granted me an intern permit me to reach out to the various Healthcare professionals working within these pharmacies; to allow me to go ahead with my research study. The photocopy of the letter was carried along by me to assure respondents of legal permission to carry out data collection and the questionnaires were kept under key and lock.

3. RESEARCH FINDINGS AND DISCUSSION

3.1. Demographic characteristics of respondents.

Table 1 shows that the majority of the respondents were in the age group of 21-30 52.6%while only 2(10.5%) were above the age of 40 years of age. The gender of respondents was approximately evenly distributed with 55% female and 45% male. The respondents were mainly nurses, clinical officers, pharmacy technicians, and pharmacists representing 26.3%, 21.1%, 15.8%, and 36.8% respectively. Looking into years of work experience, the most respondents 60.0% had less

Table 1: Demographic profile of respondents

Variables	Frequency (N=19)	Percentage of respondents
Age		
21-30	10	52.6
31-40	7	36.9
41- above	2	10.5
Gender		
Female	11	55
Male	8	45
Profession		
Nurse	5	26.3
Clinical officers	4	21.1
Pharmacy Technicians	3	15.8
Pharmacist	7	36.8
Years of experience		
Below 5 years	11	60
5 to 12 years	8	40

than 5 years of experience while the rest of them 40.0% were in the range of 5 to 12 years of experience.

in table 2, it indicates that only 23.5% of respondents were trainedin drug safety and ADR reporting. The minority of the respondents 42.1% were aware of national

ADR reporting scheme and guideline. Among participants, only 4 health workers 21.7% had ever seen the ADR reporting form. Focusing on reporting of ADRs, only 26.3% of respondents knew how to report ADRs. The life-threatening reaction was correctly reported by the most respondents 42.1% as the kind of reaction needs to be reported compared to others. Besides, the mail has been answered correctly as the format used to report ADRs by 21.1% of respondents. Finally, a small number of respondents 26.3% reported having documented ADRs at some point in 12 months.

Overall, the respondents had inadequate knowledge with regard to ADR reporting. Figure 2 shows that among 19 respondents, only 36.8% had adequate knowledge while 63.2% of them had poor knowledge with questions assessing the training, awareness of reporting scheme, awareness of reporting form, knowledge on how to report, kind of ADR to report, the format used to report and documentation about ADRs.

3.2. The attitudes of healthcare professionals towards ADR reporting

Table 3 shows the attitudes of respondentstoward reporting ADRs. The findings indicate a positive attitude toward ADR reporting among respondents, with most having the opinion that ADR reporting is a professional obligation 84.2% and that ADR reporting can benefit the public health 94.7%. And then they felt that one report can make a difference of 63.2%, that filling the ADR reporting form is useful 89.5%, and that reporting of ADR should be compulsory 84.7%. The minority 15.8% reported that ADR reporting should be voluntary.

Figure 2 indicates the majority of the respondents (82.5%) had a positive attitude toward reporting ADRs while the minority (17.5%) had a negative attitude

3.3. The practices of healthcare professionals on ADR reporting.

Table 4 shows; 19 healthcare professionals, nearly two-thirds of them 63.2% reported having ever diagnosed an ADR and only 4 respondents

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Table 2: **shows the Knowledge of respondents about ADR reporting**

Variables	Frequency(N=19)	Percentage of Respondents
Trained in drug safety and ADR reporting		
No	15	76.5
Yes	4	23.5
Aware of national ADR reporting scheme/guideline		
No	11	57.9
Yes	8	42.1
Ever seen the ADR reporting form(AE notiftcation form)		
No	15	78.3
Yes	4	21.7
Know how to report ADRs		
No	14	73.7
Yes	5	26.3
Kind of ADRs needed to be reported		
Don't know	3	15.8
Unknown reaction	4	21.1
Known reaction	4	21.1
Life-threatening Reaction	8	42.1
The way used to report ADRs		
Telephone/E-mail/Don't Know	15	78.9
Mail	4	21.1
Ever read an article related to ADR in the last 12 months		
No	14	73.7
Yes	5	26.3t

21.1% claimed to have ever reported an ADR to any reporting center. These results showed that there was under reporting of ADRs to reporting places among healthcare professionals sampled. It seems that most of the reported ADR cases were actually not formal written reports, but oral reports made during an informal conversation because they were not reported to any reporting place. Thus, the most respondents 73.6% did not submit any ADR report to responsible bodies. Most of the ADRs detected have been reported to Hospital DTC 15.8%, Pharmacovigilance center 5.3%, and Pharmaceutical company 5.3%. Finally, the majority of respondents 63.2% had provided counseling on ADRs to patients.

Figure 3 shows that the majority of the respondents (73.6%) do not report the ADRs to any center while the minority (5.3%) report to both the pharmaceutical company and pharmacovigilance center.

3.4. The reasons for not reporting adverse drug reactions.

From Figure 4, the respondents that reported an ADR to any reporting center were 63.2%, those that reported the ADR to any reporting center were 21.1%, the majority of the respondents 73.6% did not report to any center, and 63.2% of the respondents ever counseled patient about ADRs in the last 12 months.

Different reasons that contributed to ADR underreporting are described in the table 5 as provided by respondents. The majority of participants identified unavailability of reporting forms 63%, uncertain of how to report 47.4%), ADR was well known 37%, lack of feedback 32%, no report

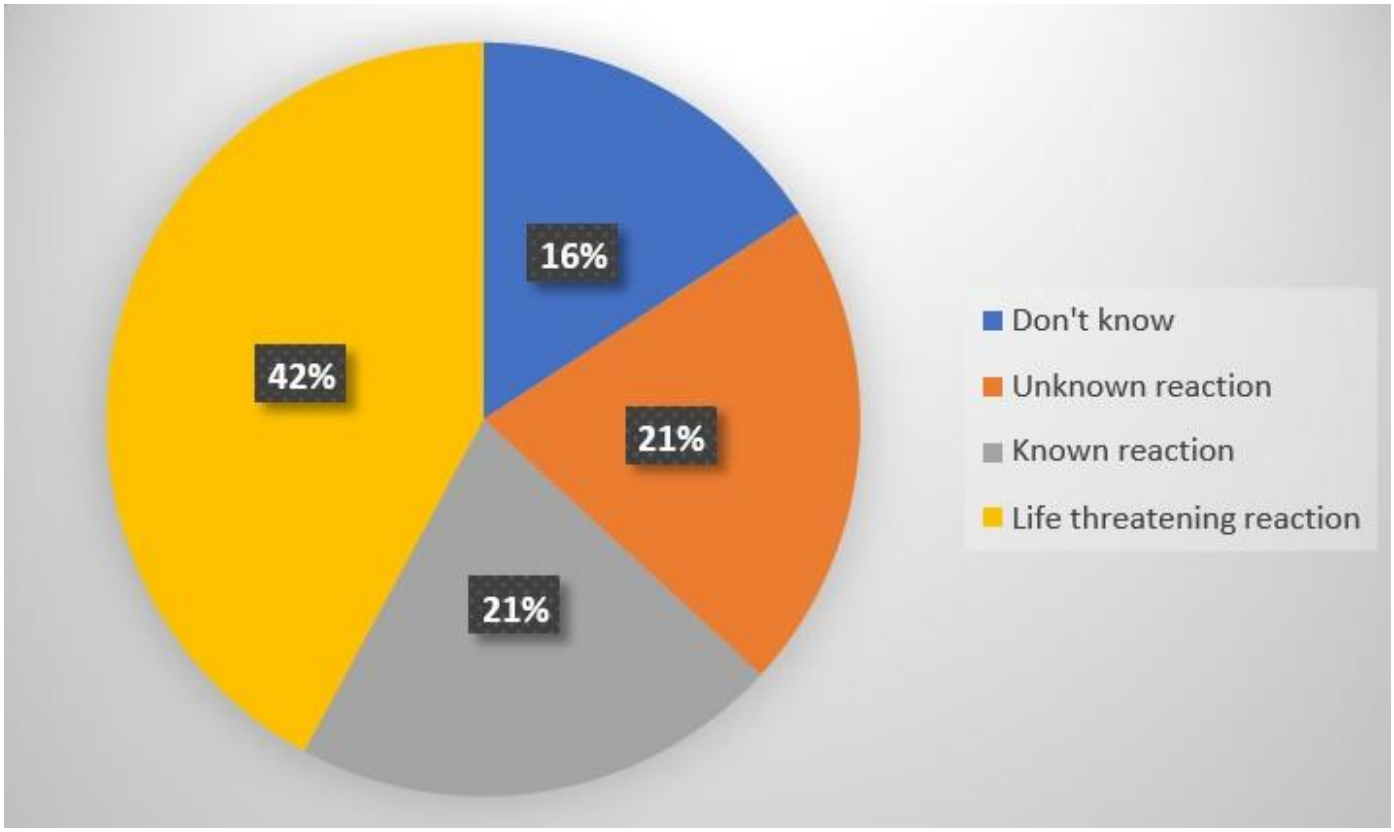

Figure 1: Shows the measure of the respondents who know the kind of ADRs to be reported as expressed in a pie chart.

Table 3: **Attitudes of respondents towards ADR reporting**

Variables	**Frequency (N=19)**	**Percentage of respondents**
Reporting of ADR is a professional obligation		
No	3	15.8
Yes	16	84.2
Reporting of ADR can beneftt the public health		
No	1	5.3
Yes	1	94.7
One report of ADR can make a difference		
No	7	36.8
Yes	12	63.2
Filling out ADR reporting form is useful		
No	2	10.5
Yes	17	89.5
Reporting of ADR should be compulsory		
No	3	15.8
Yes	16	84.2

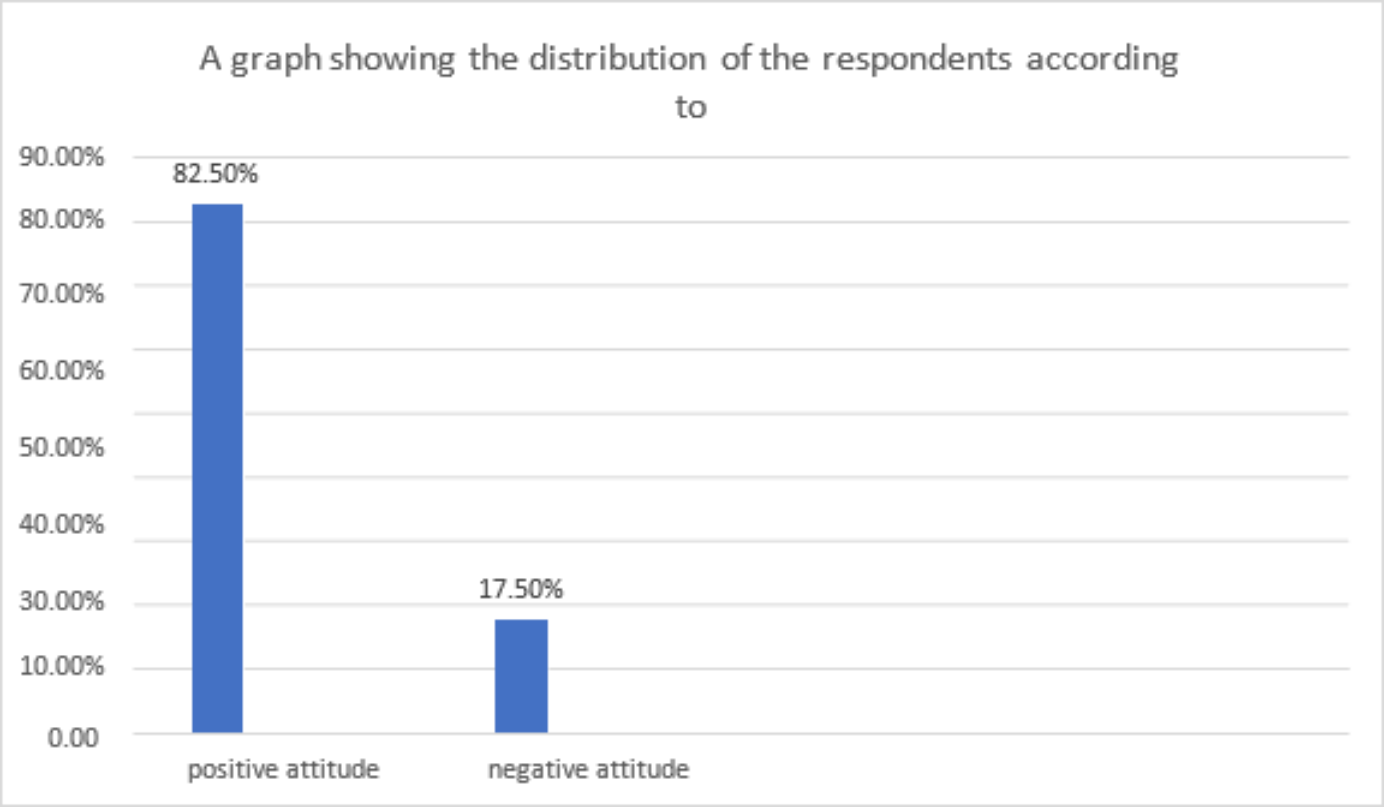

Figure 2: Shows the distribution of the respondents according to their attitude towards the ADRs reporting system.

Table 4: Practice of respondents regarding ADR reporting

	Frequency (N=19)	**Percentage of respondents**
Ever diagnosed an ADR		
Yes	12	63.2
No	7	36.8
Ever reported an ADR to anyreporting center		
Yes	4	21.1
No	15	78.9
Reporting the reaction to		
Hospital DTC	3	15.8
Pharmaceutical company	1	5.3
Pharmacovigilance center (NDA/MoH)	1	5.3
Not reporting to any center	14	73.6
Ever counseled patients aboutADRs in the last 12 months		
Yes	12	63.2
No	7	36.8

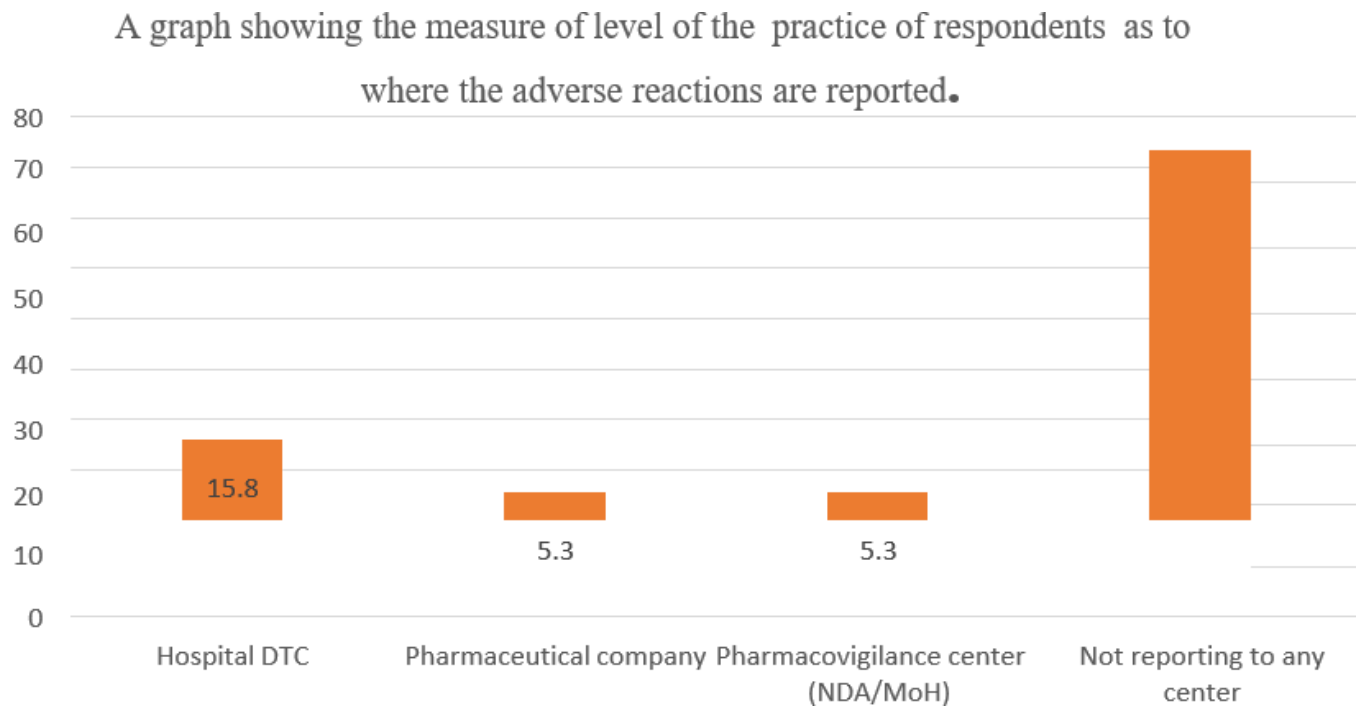

Figure 3: shows the practice of respondents as to where the adverse reactions are reported.

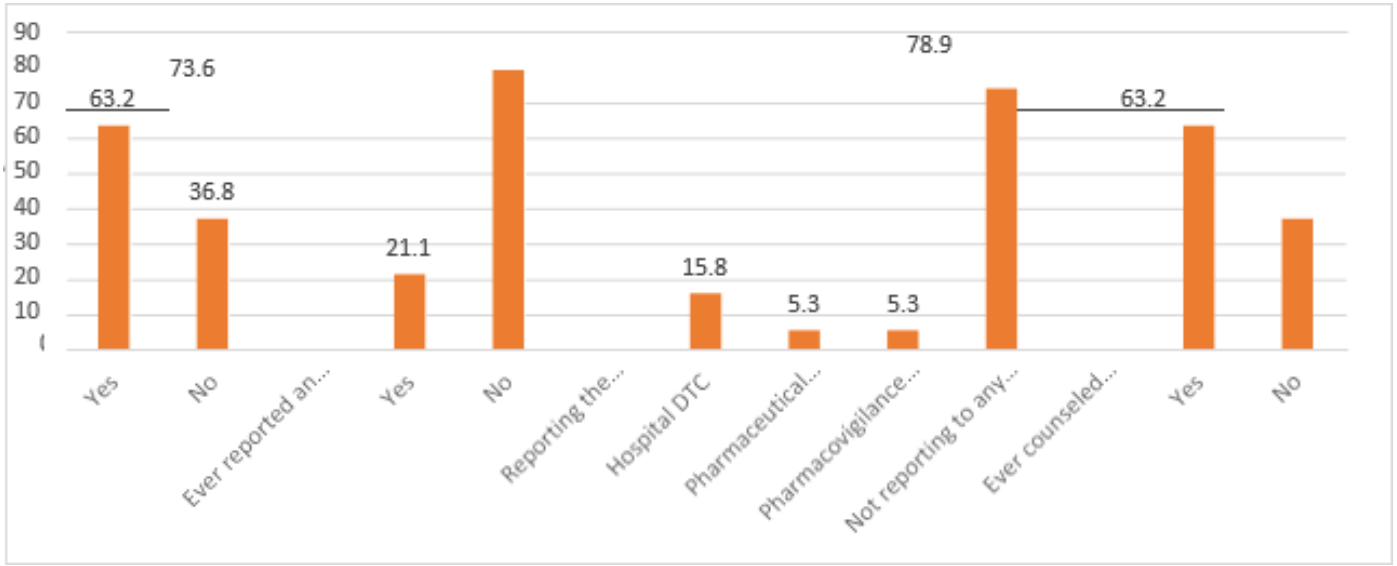

Figure 4: shows the measure of the practice levels regarding ADR reporting as for each

Table 5: Reasons for not reporting ADRs

Variables	Frequency (N=19)	Percentage(%)
ADR was well known	7	37
Fear of exposure to legal liability	2	11
Forgetfulness	5	26
Lack of feedback	6	32
Lack of time due to workload	5	26
No incentive or finacial compensation for the time spent on reporting ADRs	3	16
Time-consuming reporting process	3	16
Unavailability of reporting forms	12	63
Uncertain of how to report	9	47.4
No report because of no encountered cases of ADRs	5	26.3
Similar information is reported in other Reports	5	26.3
Other (Unaware of ADR reporting)	1	5

because of no encountered cases of ADRs 26.3%) and lack of time due workload 26%) as the major factors contributed to underreporting of ADR in Aiveen pharmacies. Unaware of ADR reporting has been mentioned by 5% of respondents as another reason for not reporting and finally no incentive or financial compensation for the time spent on reporting ADRs was 16% And monitoring ADRs.

4. Discussion.

The findings from the study indicated that healthcare professionals had insufficient knowledge about ADR reporting. The majority of healthcare professionals had a positive attitude towards ADR reporting while reporting practice among them was generally low. This could be due to inadequate knowledge of how to report and awareness of the ADR reporting system among healthcare providers. The training on drug safety and ADR reporting is reflected in reporting practice of healthcare providers. The knowledge affects their practice towards ADR reporting. The unavailability of reporting forms could lead to ADR underreporting in Aiveen pharmacies.

4.1. The knowledge about ADR reporting among healthcare professionals

From these findings, most respondents had inadequate knowledge of the existing ADRS reporting system and how to report ADRs which is linked to inadequate knowledge. Similar findings have been reported in studies done in Malaysia (2021), Among the participants who had reported an ADR, only 39.1% reported all types of ADR. In contrast, a lack of knowledge on reporting ADR might discourage them from reporting ADR 50.6% (Roksanah Shaukat Ali, 2021) also similar study that was carried out in Johannesburg (2020), which revealed that the response rate was 87.7%, only half of these knew about Adverse drug reaction and although 58.9% had encountered adverse drug reaction, only 16.50% had reported (Yashmay Gordon, 2020) which was linked to inadequate knowledge

The relationship between knowledge and health worker factors that may affect reporting of ADRs is used. The age, sex, education background, and work experience of respondents are

factors that may affect their knowledge about reporting ADRs. It is expected that the health workers" age and years of practice are correlated

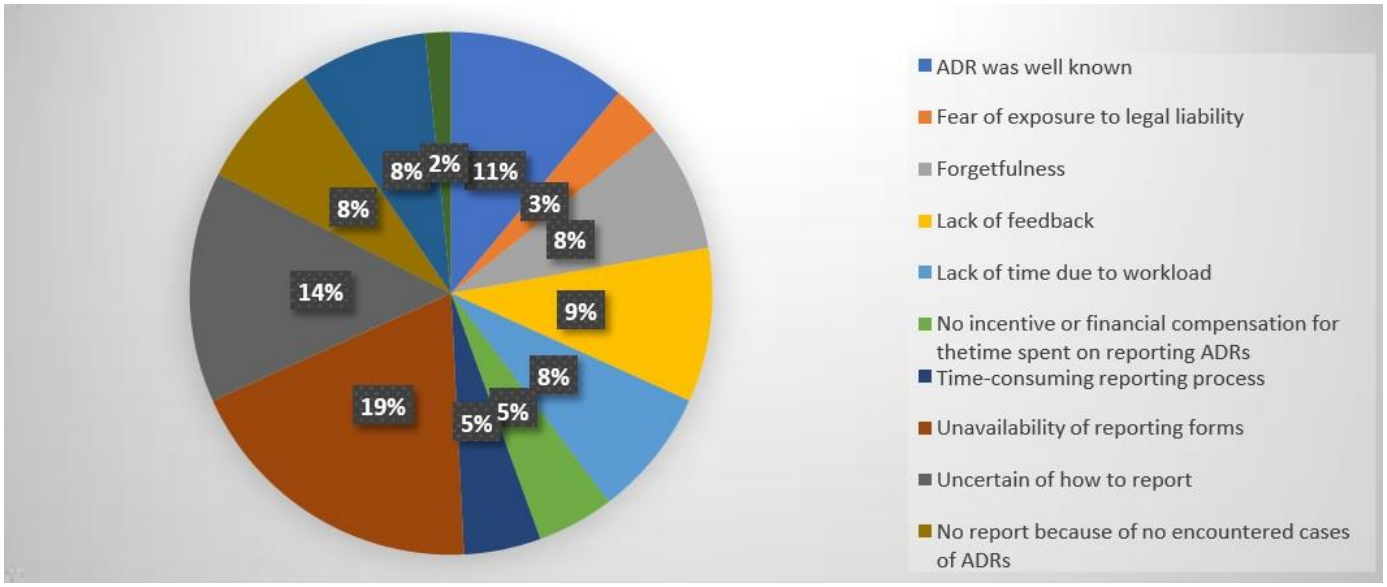

Figure 5: shows the measure of reasons respondents gave for not reporting ADRs expressed in a pie chart.

because the older the health worker, the more years of practice. The duration of practice may affect the knowledge of healthcare providers about the notification of ADRs. In practice, they gain knowledge from different sources of information. Hence, demographic factors are crucial in using medicine.

In the research study, the healthcare professionals had generally inadequate knowledge on ADR reporting. Among 19 respondents, only 23.5% of them were trained in drug safety and ADR reporting. The minority of the respondents were aware of the national ADR reporting scheme 42.1% and ADR reporting form 21.7%. Besides, only 26.3% of respondents knew how to report ADRs. The life-threatening reaction was correctly reported by the most respondents 42.1% as the kind of reaction needs to be reported among others. The mail has been answered correctly as the format used to report ADRs by 21.1% of respondents. A small number of respondents 26.3% reported having documented ADRs at some point in 1k2 months. The most respondents 63.2% had inadequate knowledge about ADR reporting.

4.2. The attitudes of healthcare professionals toward ADR reporting

In this study, the majority of the respondents 84.2% had a positive attitude This finding is consistent with other studies conducted in countries like Ethiopia, in which in one of the studies carried out in 2020, it was found that 60% of the respondents had a positive attitude on ADR reporting which was in contrast to the study carried out in Amhara region of Ethiopia in which 86% of the respondents had a positive attitude on ADR reporting (Mohammed Assen Seid, 2018) which was also in line with the study carried out in Pakistan (2021), of all the 77.7% of the physicians, 75.7% pharmacists and 68% of nurses had positive attitude It was therefore concluded that among all HCPs, pharmacists had better knowledge about ADR reporting and pharmacovigilance and all HCPs had positive attitude.

From the current study, the positive attitude of participants towards ADR reporting means that they considered reporting ADR as important. Thus, it is necessary for policymakers, regulatory authorities, and other stakeholders to put more emphasis on Pharmacovigilance, by providing appropriate guidelines and regular training to maintain this positive attitude of healthcare professionals.

4.3. The practices of healthcare professionals on ADR reporting.

Overall, the practice of healthcare professionals regarding ADR reporting was inadequate. Thus,

the majority of participants 63.2% reported having ever been diagnosed with ADRs but only a few of them 21.1% had reported an ADR to any reporting center at some point respondents for this study had submitted their reports to hospitals 15.8% of Pharmacovigilance center 5.3% and Pharmaceutical Company 5.3% respectively. Therefore, there was underreporting of ADR-detected cases to reporting centers. Most respondents 63.2% had ever counseled patients on ADRs about ADR during the last 12 months.

4.4. The reasons for not reporting adverse drug reactions

Unavailability of reporting forms 63%, uncertain of how to report 47.4%, ADR was well known 37%, lack of feedback 32%, no report because of no encountered cases of ADRs 26.3% and lack of time due workload 26% were the main reasons that might have contributed to underreporting of ADRs among the healthcare professionals in this research study.

5. Conclusions.

The research study clearly indicates a relatively better attitude but limited knowledge and practice towards ADR reporting among healthcare professionals working in Aiveen pharmacies.

- Despite positive attitudes towards ADR reporting, underreporting of ADRs by healthcare professionals was identified in this research study. Indeed, underreporting of ADRs was associated with insufficient training on ADR reporting, lack of awareness of national ADR reporting schemes and guidelines, and lack of awareness of reporting forms as well as inadequate knowledge on how to report and poor documentation about ADRs. Thus, inadequate knowledge of respondents was associated with underreporting of ADRs. Personal and professional factors had a little influence on ADR reporting. Besides, knowledge of how to report and reading articles related to ADRs as a source of information were found to be strongly associated with ADR reporting practice among healthcare professionals. There was an association between knowledge and practice towards ADR reporting in the present study.

5.1. Generalizability

The research was carried out only among healthcare professionals working within Aiveen pharmacies only within a central division, Kampala district, and findings that will be obtained may not therefore be used to generalize for all healthcare professionals working within all the community pharmacies country-wide.

6. Limitation to the study.

Finally, the main reasons that have influenced the respondents not to report were the lack of reporting forms, ADR was well known , the uncertainty of how to report, and the lack of feedback for cases reported.

7. Recommendations.

Based on the results of the study, the following recommendations are made to improve reporting of adverse drug reactions and overcome the underreporting of ADRs in Uganda.

The Ministry of Health through National Pharmacovigilance and Medicine Information Centre should create awareness of healthcare professionals through regular trainings, continuous education and refresher courses in Pharmacovigilance and ADR reporting system. This training could be incorporated into the Continuous Professional Development (CPD) program for the nurses and pharmacists and other auxillary staff as part of license requirement for the dispensers and pharmacists in Aiveen pharmacies.

NPMIC should ensure the availability of ADRs reporting forms and guideline by providing them to all medical offices, pharmacies, hospitals and other health facilities.

Every report submitted by a healthcare provider should be acknowledged and a timely feedback provided on the actions taken by regulatory authorities. The feedback provided encourages healthcare personnel participation in the

reporting process.The healthcare professionals are recommended to participate in reporting of ADRs and read the available guideline and articles related to ADRs to improve their knowledge in Pharmacovigilance.

The Hospital through Drug and Therapeutics Committee should play a major role in promoting the existing ADR monitoring and reporting program in the hospital. It should also allocate time for reporting ADRs and simplify the reporting process.

The healthcare professionals are recommended to participate in reporting of ADRs and read the available guideline and articles related to ADRs to improve their knowledge in Pharmacovigilance.

8. Acknowledgement.

Special thanks goes to the Almighty God for his infinite strength, wisdom, grace and peace throughout the whole complex trail of preparing this research report.

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A special thanks also goes to my research supervisor Dr. Julius Oluka for the technical support and time he has given me to ensure that I develop this research report.

9. Acronyms/Abbreviations.

ADR : Adverse Drug Reaction.
DCA : Drug Control Authority.
MOH : Ministry of health.
NDA : National Drug Authority.
NPRA : National Pharmaceutical Regulatory Agency.
PV : Pharmacovigilance.
UMC : Uppsala Monitoring Centre.
WHO : World Health Organization.
FDA : Food and Drug Authority

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