International Journal of Sciences: Basic and Applied Research (IJSBAR)

ISSN 2307-4531
(Print & Online)

http://gssrr.org/index.php?journal=JournalOfBasicAndApplied

Knowledge, Attitudes, and Practices Towards Pharmacovigilance Amongst Healthcare Providers at Edward Francis Small Teaching Hospital in the Gambia.

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Abstract

Background: According to the World Health Organization, pharmacovigilance is the research and practices involved in the identification, evaluation, comprehension, and mitigation of side effects or any other hazard relating to medications or immunizations. Adverse Drug Reactions (ADRs) are a major public health concern in today`s world. As a result, ADR reporting in The Gambia must be taken seriously because drug-drug interactions, drug-disease interactions, or food-drug interactions can exacerbate ADRs that occur in the patient without the Healthcare providers' knowledge. More importantly, this research should support the need for legislation to prevent ADRs. This research was aimed to assess healthcare professionals' understanding, attitudes, and pharmacovigilance practices at The Gambia's Edward Francis Smalls Teaching Hospital. **Methods**: Healthcare providers from the Edward Francis Smalls Teaching Hospital in The Gambia participated in an observational, descriptive, and cross-sectional, questionnaire-based study to understand the extent of their knowledge, attitudes, and practices towards PV. The independent variables in the study were the socio-demographic factors used to characterize healthcare providers from the EFSTH. The sample size was calculated using software Epi info version7.Inclusion criteria was certified or licensed health care provider but those who are not willing to participate will not be included in the study. The data analysis was performed using Epi info version7. 2, Microsoft excel, MAXQDA and SPSS version 20. All statistical tests conducted were considered significant at 95% confidence interval with a p-value less than 0.05. **Results:** The response rate based on this sample size was 51% (n=102).

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A total of 102 participants were included in the final analysis, of which by profession the majority were Nurses 66 (64. 2%) and by gender most were female 58(56. 9%). Majority of the participants belong to the age of ranging from 20-37 years 89(87.5%).102(100%) of the respondents all agreed reporting ADR was necessary. Majority of the respondents 86(84.7%) had moderate knowledge score but however within the professions the pharmacist had a high score of 3(60%) amongst the participants. Most subjects 86(84.3%) had a positive level of attitude amongst the profession the nurses scored highest 57(86.4%). Most of the participants 81(79.4%) scored inadequate towards practices. By profession, Nurses had the most inadequate practices 55(53.9%), Doctors 22(21.6%), Pharmacist 3(2.9%) and physiotherapist 1(1%). In general, the practice towards pharmacovigilance was inadequate amongst most of the participants at the tertiary care Centre. The study found out a statistical significance between profession and Adverse Drug Reactions reporting training at p=0. 009. **Conclusion**: The study found out a statistical significance between profession and Adverse Drug Reactions reporting training at p=0. 009 which expose that most of the participants have not undergone training in area of pharmacovigilance and ADR Reporting alarming a need to include pharmacovigilance in undergraduate curriculum for healthcare providers. However, these findings are not surprising given the sample population in this study from low- and Middle-Income Countries (LMICs) like The Gambia is much more deprived of adequate education about Adverse Drug Reactions and pharmacovigilance activities compared to the general population in the developed nations. Therefore, there is a need for a national KAP study regarding the use of National Pharmacovigilance guidelines to be conducted in order to identify the key factors spurring low Adverse Drug reaction reporting rates within The Gambia.

Keywords: Pharmacovigilance (PV); Adverse Drug Reactions (ADR).

1. Introduction

1.1. Background

According to the World Health Organization, pharmacovigilance is the research and practices involved in the identification, evaluation, comprehension, and mitigation of side effects or any other hazard relating to medications or immunizations [1].

The World Health Organization (WHO) describes an adverse drug reaction (ADR) as "any unpleasant, unplanned and undesirable effect of a medicine which occurs at levels utilized in humans for prophylaxis, diagnosis or therapy of disease, or for the alteration of physiologic function [1]. Pharmacovigilance is considered a major public health concern in these modern days. Adverse drug reactions are among the important causes of morbidity and mortality worldwide (The WHO) [1]. PV study started following the disaster caused by thalidomide in pregnant women in 1961.Pharmacovigilance studies are gaining more significance as new drugs are entering at an unprecedented rate. There is also increase in number of drugs withdrawn because of ADRs [2]. Gupta and his colleagues ***(2016***) found out that ADRs not only pose a risk to the patient's safety, but also adversely affect their quality of life and likely increase the healthcare cost [3].

In order to promote ADR reporting and stakeholder involvement, the Pharmacovigilance team of WHO had empowered Low- and Middle-income Countries (LMICs) to adapt a smart phone based ADRs reporting app,

named the Med Safety App in partnership with the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and the WHO collaborating Centre, Uppsala Monitoring Centre (UMC).The Med Safety App has also been updated in response to the COVID-19 pandemic to aid in the reporting of adverse events associated with medicines and vaccines used during the pandemic [1].

In 2016, The Gambian Government through the Ministry of health has established Medicine Control Agency tasked (MCA) with several duties including but not limited to:

- Regulate all matters relating to efficacy, quality and safety of medicines and related product
- Ensure that evidence of existing and new adverse events, interactions and information about pharmacovigilance of products being monitored globally, are analyzed and acted upon
- Attend to and where possible, take legal measures on complaints made by consumers against manufacturers of products regulated under the MCA act. Unfortunately, the Medicine Control Agency cannot do much to ensure drug safety without public cooperation and appropriate reporting of ADRs in all healthcare facilities across The Gambia [5].

The pharmacy council of The Gambia (PCG), through its acts 2014, is mandated to regulate pharmacy practice including pharmaceutical care and related affairs like pharmacovigilance activities, by ensuring that pharmacist, and various classes of drug dispensers' practice in adherence to the National Pharmacovigilance guidelines [5].

1.2. pharmacovigilance background

Adverse Drug Reaction (ADR) is known by the WHO, as "any noxious, unintended and undesired effect of a drug which occurs at dosages used in humans for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function [1]." ADRs cause a great burden to healthcare systems and create economic burden worldwide. ADR monitoring is the mainstay of Pharmacovigilance. PV study started following the disaster caused by thalidomide in pregnant women in 1961(WHO), [1]. The formation of the International Society of Pharmacoepidemiology (ISPE) in 1984 and of the European Society of Pharmacovigilance (ESOP) which later transformed into the International Society of Pharmacovigilance (ISP) in 1992 signified the introduction of pharmacovigilance formally into the research and academic world, and its increasing integration into clinical practice [1]. Post marketing surveillance (PMS) of drugs is significant for the identification of unseen ADRs and should be an integral part of clinical practice.

In 2016, The Gambian Government through the Ministry of health established the Medicine Control Agency (MCA) with several duties including but not limited pharmacovigilance and development of the National Pharmacovigilance Guidelines [5].

In order to encourage ADR reporting and stakeholder involvement, the pharmacovigilance team of WHO had empowered LMICs (Low- and Middle-Income Countries) to adapt a smart phone based adverse reactions reporting app, named the Med Safety App in partnership with the MHRA and the WHO Collaborating Centre, Uppsala Monitoring Centre (UMC). In wake up to the COVID-19 pandemic, the Med Safety App has also been

adapted to help the reporting of adverse events associated with medicines and vaccines used during the COVID19 pandemic.

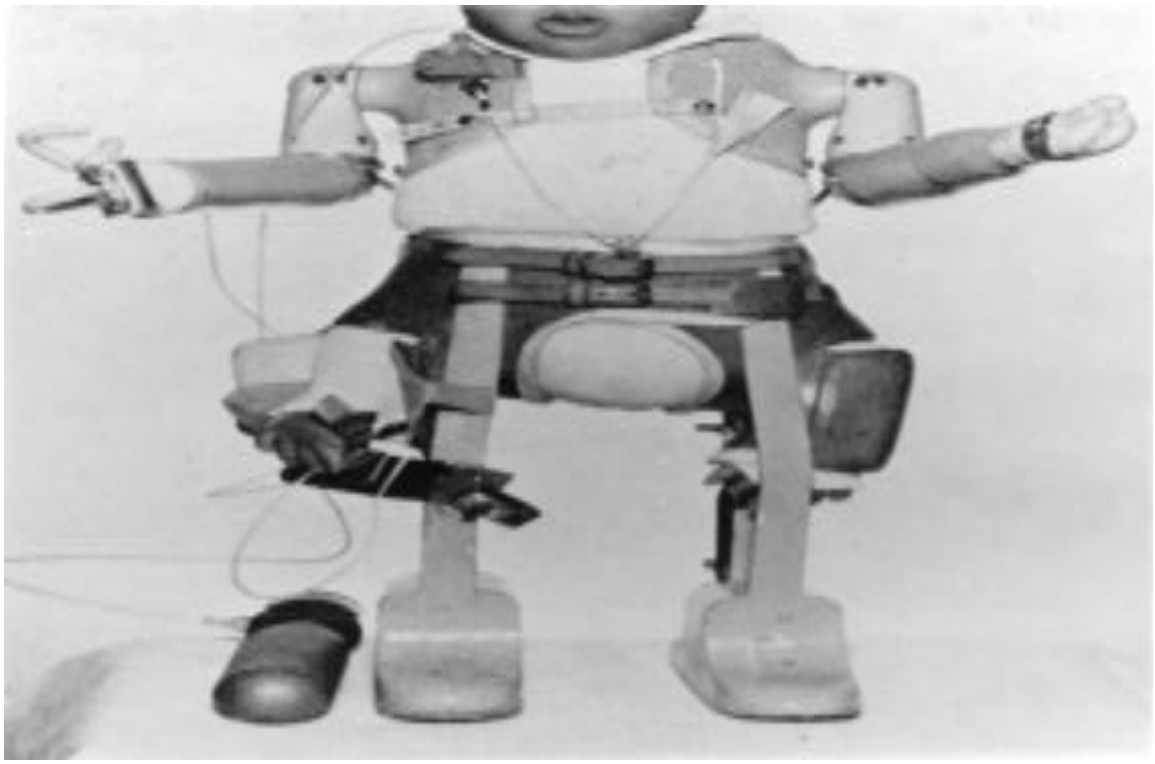


Figure 1: A child with Thalidomide-induced deformity of upper and lower limb. Adapted from **Ronald D. Mann &Elizabeth B. Andrews 2nd edition on Pharmacovigilance.**

The picture above depicts the genesis of pharmacovigilance study when children were born with abnormalities caused by thalidomide consumed by their mothers [6].

1.3. pharmacovigilance significance

Pharmacovigilance is related to discovery; assessment monitoring and prevention of adverse effects with pharmaceutical product **[1]** and the main importance are:

- Improve patient care and safety in relation to the use of medicines in all medical and paramedical interventions
- Improve public health and safety in relation to the use of medicines.
- Contribute to the examination of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and cost-effective use.
- Promote comprehension, education and clinical training in pharmacovigilance and its effective communication to the public [7].

Post-marketing surveillance (PMS) is done as part of Pharmacovigilance during phase-4 clinical trial; for example, in Korea, Sun woo S and his colleagues (2005) investigated the safety and potency of sildenafil

prescribed in primary care via PMS amongst a total of 651 men with erectile dysfunction (ED) and revealed only 6(1.0%) patients stopped sildenafil as a direct result of adverse events. This proofs that sildenafil prescribed by primary care physicians was well tolerated and improved erectile dysfunction **[8]**. The expansion of scientific knowledge in drug safety is tied to greater awareness and academic interest in pharmacovigilance with institutes of pharmacology and pharmacy playing a vital role via tutoring, policy development, clinical research, ethics committees and clinical services [9].

Table 1: Drugs withdrawn in the United Kingdom over safety concerns. Adapted from **Ronald D. Mann &Elizabeth B. Andrews 2nd edition on Pharmacovigilance [6].**

Brand name (drug substance)	Year action taken	Major safety concerns
Secholex (polidexide)	1975	Safety concerns because of impurities
Eraldin (practolol)	1975	Oculomucocutaneous syndrome
Opren (benoxaprofen)	1982	Hepatotoxicity, serious skin reactions
Devryl (clomacran phosphate)	1982	Hepatotoxicity
Flosint (indoprofen)	1982	Gastrointestinal toxicity
Zomax (zomepirac)	1983	Anaphylaxis
Osmosin (indomethacin-modified release)	1983	Small intestine perforations
Zelmid (zimeldine)	1983	Neurotoxicity
Flenac (fenclofenac)	1984	Lyell's syndrome
Methrazone (feprazone)	1984	Serious skin reactions, multi-system toxicit
Althesin (alphaxolone plus alphadolone)	1984	Anaphylaxis
Pexid (perhexilene)	1985	Hepatotoxicity, neurotoxicity
Suprol (suprofen)	1986	Nephrotoxicity
Merital (nomifensine)	1986	Haemolytic anaemia
Unicard (dilevalol)	1990	Hepatotoxicity
Glauline eye drops 0.6% (metipranolol)	1990	Uveitis
Halcion (triazolam)	1991	Psychiatric reactions
Micturin (terodiline)	1991	Arrhythmias
Teflox (temafloxacin)	1992	Multi-system toxicity
Centoxin (nebacumab)	1993	Mortality
Roxiam (remoxipride)	1994	Aplastic anaemia
Volital (pemolin)	1997	Hepatotoxicity
Romazin (troglitazone)	1997	Hepatotoxicity
Serdolect (sertindole)	1998	Arrhythmias
Tasmar (tolcapone)	1998	Hepatotoxicity
Ponderax (fenfluramine)	1998	Cardiac valvular disease
Adifax (dexfenfluramine	1998	Cardiac valvular disease
Posicor (mibefradil)	1998	Drug interactions
Trovan (trovafloxacin)	1999	Hepatotoxicity
Grepafloxacin (Raxar)	1999	QT interval prolongation
Prepulsid (cisapide)	2000	QT interval prolongation
Alec (pumactant)	2000	Adverse comparative trial results
Droleptan (droperidol)	2001	Increased cardiac risks
Lipobay (cerivastatin)	2001	Rhabdomyolysis
Kava-Kava	2001	Liver toxicity
Anorectic agents (amfepramone, phentermine)	2000	Heart valve disorders
Vioxx (rofecoxib)	2004	Increased cardiovascular event risks
Non-proprietary (co-proxamol)	2005	Use in suicide
Bextra (valdecoxib)	2005	Stevens–Johnson syndrome

1.4. Adverse Drug Reactions Reporting

An ADR is any harmful effect suspected to be caused by a drug. Aside effect is an unintended outcome that seems to be associated with both negative or positive effects [10] and" life-threatening" means "serious" in context of an event in which the patient was at risk of death at the time of the event; it does not refer to an event, which hypothetically might have resulted to death if it was more severe. Serious adverse reaction is any untoward medical occurrence that at any dose causes death, is life threatening, needs or prolongs patient hospitalization, results in persistent incapacity, or is a congenital anomaly according to International Conference on Harmonization (ICH) [1]. Traditionally, ADRs can be classified into two types namely: Type A reactions which are dose dependent and predictable by Pharmacology of the drugs and Type B reactions which are bizarre reactions or otherwise idiosyncratic or not predicted by the drug pharmacology[11].The study of adverse drug reactions (ADRs) is an integral part of the field known as Pharmacovigilance (PV).There are numerous other pharmacovigilance tools which include: Suspected Adverse Drug Reaction Form, ADR Severity Assessment Scale, Causality Assessment Categories, patient Alert Card, Criteria for issue of a Patient Alert Card, Checklist for investigation procedure and Poor Quality Medicinal Product Reporting Form[5].

ADR reporting is the most important tool in pharmacovigilance which includes the process of assessing, investigating and reporting an ADR. There are two major types of ADR reporting:

- Spontaneous Reporting is a process whereby case reports of adverse drug reactions are willingly submitted by the healthcare provider from both the public and private health facilities and the general public to the National Pharmacovigilance Centre.
- Active ADR reporting is looking to ascertain completely the number of adverse events via a continuous Pre-organized process using Sentinel Sites, Drug Event Monitoring and Registries [5].

The UK uses yellow card to report ADR while USA uses Med-watch form and The Gambia uses the ADR reporting form. Statistically, it has been estimated that only 6-10% of all the ADRs are reported although ADRs are among the significant causes of morbidity and mortality worldwide, yet they are under reported in LMICs like The Gambia [12]. The overall aim of ADR reporting is to ensure patient safety and reduce events of therapeutic failure which may impose significant economic burden on both the patient and the healthcare system.

After the thalidomide disaster in 1961, the WHO established the International Drug Monitoring Program in Geneva in 1968; it was later moved to Uppsala, Sweden in 1978 which is now known as the UMC (Uppsala Monitoring Centre) where a hundred- and thirty-four-members Countries are connected to report to UMC through their National PV Centers [13,14].

In Namibia, an open-access mobile data-gathering platform (Epicollect5®) impregnated with the data contained in the ADR form is used by healthcare workers to collect and report ADRs to Therapeutic Information and Pharmacovigilance Center. The reporting instrument can be installed on mobile devices of healthcare workers. The data-frame was invented by researchers at the School of Pharmacy, Faculty of Health Sciences at the

University of Namibia in February 2019 and tested by the researchers prior to face validity, to check for any inconsistency and improve the flow of information [8]. In India, the Pharmacovigilance Program of India (PvPI) aimed at sensitizing the healthcare providers towards strengthening the Spontaneous reporting system in order to protect many lives reported over a million ADRs from April 2011 to March 2016 to National Coordination Center (NCC).These program is to encourage and empower the healthcare providers to substantiate the PvPI to assess the knowledge, attitude, and practice (KAP) of pharmacovigilance among practicing healthcare professionals with focus on the under-reporting of ADR and Multi-modality intercessions[15] .

Adapted from **Sanvidhan Suke** ,Research Gate.

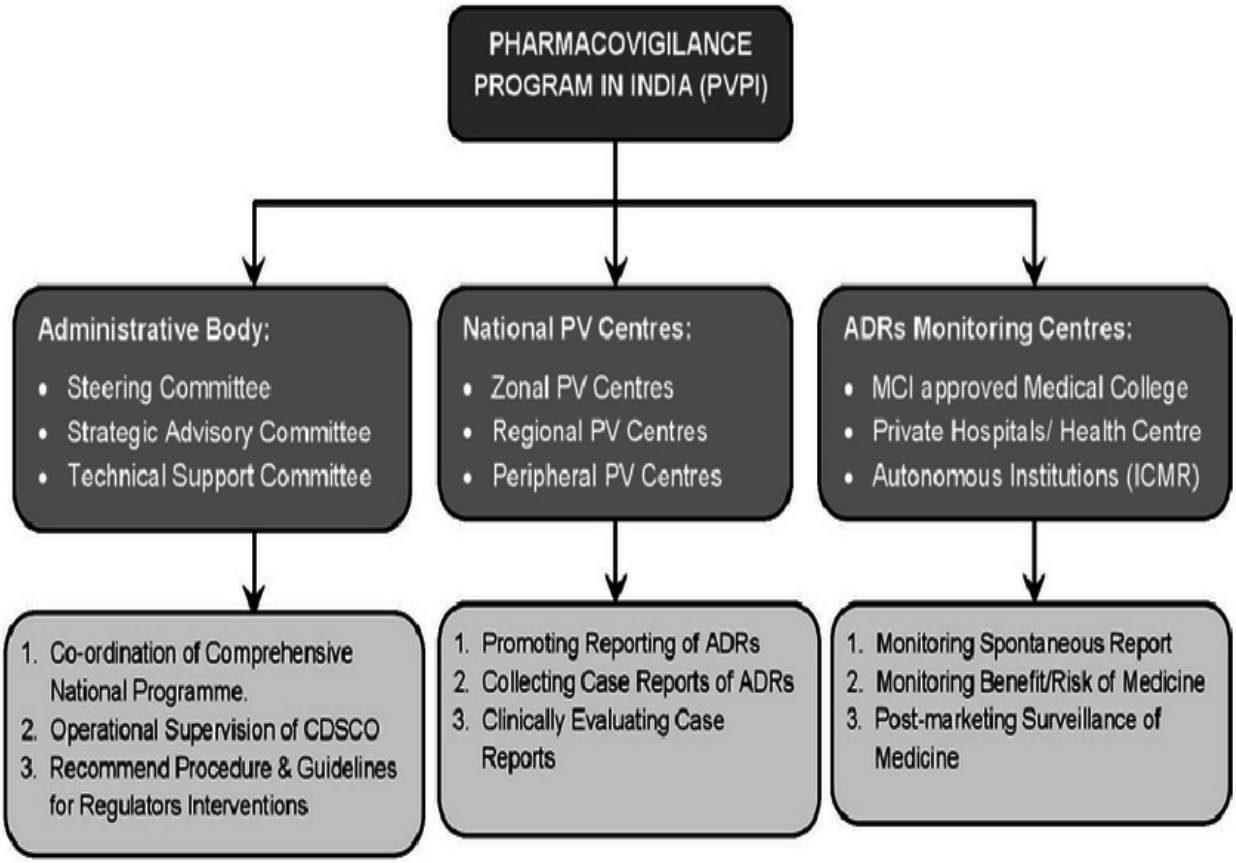


Figure 2: Hierarchical system of Pharmacovigilance Program of India (PvPI)

1.5 problem statement

It is critical to address the issues of ADRs in the Gambia as newer drugs which are imported into the country are rapidly increasing. Even after quality control by the relevant public health stakeholders like the Medicine Control Agency which regulates products and Pharmacy Council of The Gambia which regulates practices, many patients still experience ADRs. There is a need to follow up with the medication that reach the patient who is the main consumer and most important in the supply chain. This cross-sectional questionnaire-based

survey study will serve to help understand the knowledge, attitudes and practices towards pharmacovigilance in The Gambia. The study can also help to emphasize ADR monitoring across all health facilities in the Gambia as legislation to ensure safety of the patient by institutionalizing post-marketing surveillance of drugs, especially those drugs with toxicity concerns and narrow therapeutic window.

1.6 significance of the study

Self-medication, irrational prescription and importation of substandard medical substances are becoming problems to most Low- and Middle-income Countries (LMICs) therefore; ADR reporting has to be taken seriously in The Gambia because drug-drug interactions, drug-disease interactions or food -drug interactions can exacerbate an adverse drug reaction which happens to the patient without the healthcare provider's notice. More importantly, this study should affirm the need for legislation for prevention of ADRs.

1.7 aim of the study

- To determine the knowledge, attitude and practices of pharmacovigilance amongst healthcare providers at Edward Francis Small Teaching Hospital in The Gambia

1.8 specific objectives

- To determine the status quo of the information about to the knowledge, practices and attitude relate to pharmacovigilance amongst healthcare providers in the available and current literature.
- To determine the extent of pharmacovigilance guidelines usage amongst healthcare providers at EFSTH.
- To determine the relationship between level of knowledge, attitudes, and practices of pharmacovigilance with socio-demographic factors.

1.9 research questions

- What is the pharmacovigilance level of knowledge, attitude and practices amongst healthcare providers at Edward Francis Small Teaching Hospital in The Gambia?
- Is there any relationship between level of knowledge, attitudes, and practices of pharmacovigilance with socio-demographic factors?
- What tools do they use to report ADR?
- How often are ADR cases reported?

1.9.1 study outcome

- Interpret the degree of significance in which socio-demographic influence the levels of knowledge, attitudes and practices amongst the participants.
- Outline the participant's barriers to adequate ADR reporting.
- Interpret the knowledge, Attitudes and Practices scores.

2. Materials and methods

2.1 Study setting and design

Healthcare providers from the EFSTH in The Gambia participated in an observational, descriptive, and cross-sectional, questionnaire-based study to understand the extent of their knowledge, attitudes, and practices towards pharmacovigilance. The study was completed anonymously on paper at the request of the participant. The survey period was from 10th, July 2022 to 23rd, July 2022 for a total of two weeks. Only complete responses were recorded and counted.

2.2 Study variables

The independent variables in the study were the socio-demographic factors used to characterize healthcare providers from the EFSTH. These included age, gender, educational level, nationality, marital status, religion, and role. Also looked at were, knowing someone who had a serious adverse reaction from a vaccine or medicine, and lifetime ADR history. The dependent variables were the participants' in pharmacovigilance knowledge and attitudes scores as well as their reported practices towards Pharmacovigilance.

2.3 Study population and sample size

The sample size was calculated using software **Epi info version7.2** on population survey and the proportionate stratified sampling size method. The size of the sample drawn from each cluster will be proportionate to the relative size of that cluster in the total population. The sampling fraction used will be 50%. Once proportionate stratified sampling size method has been applied, simple random sampling will occur within each cluster to remove bias when choosing the final participants of the study by assigning each eligible participant with a number with a random number table. Eligible Healthcare providers including doctors, pharmacist, nurses and physiotherapist presently at EFSTH, The Gambia will be included in the study given by Human Resource(table2). In order to practice in the tertiary care Centre, one must be a certified, licensed or a degree holder of at least a bachelor's degree and over 18 years.

Inclusion criteria:

- Age >18years
- Sex -male or female
- Profession-certified or licensed health care provider
- Ability to give informed consent

Exclusion criteria:

- Healthcare providers who are not willing to participate will not be included in the study.
- Age<18years
- Profession -not a certified or licensed healthcare provider

- Inability to give an informed consent.

Table2: List of Eligible healthcare providers.

DEPARTMENT	HEALTHCARE PROVIDERS	NURSES	DOCTORS	PHARMACIST	PHYSIOTHERAPIST
Internal Medicine	109	26	80	0	3
Obstetrics & Gynecology	100	59	41	0	0
Pediatrics	111	80	29	1	1
Surgery	91	38	50	0	3
Pharmacy	4	-	-	4	0
Accident& Emergency/IU	95	95	Interdepartmental	1	2
Total	510	298	200	6	9

The sample size was calculated using Epi **info version7.2** on population survey was 222 participants using 95% confidence interval and 6 clusters each cluster had 37 participants.

2.4 Study procedure

An ethical clearance letter was sent to EFSTH from AIUWA which after it was reviewed and approved, the questionnaires were printed and I proceeded to meet the various departments and units to recruit willing healthcare providers to participate. A follow-up visit was made to participants who had not yet responded. The self-administered questionnaire did not require informed consent according to EFSTH REC (Research Ethics Committee Guidance) Attached in APPENDIX[C], in which the respondents who answered and returned questionnaire have automatically consented. The answered questionnaire was then collected and only the completely filled was sent to be coded into the SPSS software for data analysis.

2.5 Data collection tool: questionnaire

The data was collected using an adapted questionnaire (see Appendix B) from previous PV KAP studies [21]. It was divided into four sections: demographics, knowledge, attitudes, and practices. KAP section had 21 questions. The questionnaire was pilot tested amongst 10 respondents who did not participate in the study. This was done in order to test the nature of the questions [25].

The correct changes were applied to the questionnaire [21]. Two hundred pretested questionnaires were printed, administered and finally disseminated among the healthcare providers. A time of 1 day or 24 hours was given for collection of the anonymously filled forms.

2.5.1 Socio-demographic

These questions included information related to age, gender, marital status, educational level, place of residence, nationality, religion, work schedule (full-time or part-time), profession, years of working experience, and involvement in patient care both prescription and administration of medication.

In addition, they were asked about their previous history with ADR (Have your patient ever had ADRs?), (Have you seen ADRs in all your lifetime?), whether they (monitor ADR?), and whether they know anyone who had fatal ADRs?'

2.5.2 Knowledge

The knowledge section consisted of 7 statement items and were answered. Correct responses were given a score of 1 and incorrect responses were given a score of 0. The total score of knowledge ranged from 0 to 7, with higher scores indicating better knowledge. The overall knowledge was categorized, using Bloom's cut-off point, High knowledge >60% (5-7points), moderate knowledge >50% (3-4points), and low knowledge < 50% (0-2 points). This section also included information about pharmacovigilance by which they were to select all that applied to them, as well as whether they were aware that the PV? Items were evaluated for internal reliability, using Cronbach's alpha coefficient was 0.761, indicating satisfactory internal reliability.

2.5.3 Attitudes

This section is made of 5 statement items with questions the number 1 indicated correct response and 0 indicated incorrect responses. The total score for each participant was calculated by adding the scores of each answer given per item and ranged from 8 to 12. Lower scores indicated negative attitudes towards the pharmacovigilance. The overall attitude level was categorized with Bloom's cut-off point, as positive if the score was between 80% and 100% (4-5 points), neutral if the score was between 60 and 79%(2-3points), and negative if the score was less than 60% (0-2 points). Items were evaluated for internal reliability, using Cranach's α (alpha) which was 0.761, indicating acceptability.

2.5.4 Practices

The practice section consisted of 9 binary items regarding participants' acceptance of the pharmacovigilance as clinical practice was coded with 1-yes 2-No 3-can't say and 4-Maybe and 0 indicated incorrect responses. These included: whether they have seen ADR reporting form, if they ever reported ADR to PV and so on. Then 21 was analyzed with MAXQDA to reduce bias.

A score of 3 below was considered Inadequate and above 4 was Adequate. These items were evaluated for internal reliability, with Cronbach's (alpha). 0.816.

2.6 Statistical analysis

The data analysis was performed using **Epi info version7.2, Microsoft excel, MAXQDA** and **SPSS version 20**. **Epi info version7.2** was used to calculate sample size for random sampling, the collected questionnaire was

then coded and imported into **SPSS software.** Descriptive statistics were used to describe the data. During the analysis, frequencies of different variables were obtained, followed by cross-tabulation to compare the frequencies and presented the graphs with **Microsoft excel**. Chi square and V tests were performed to determine significant relationships between knowledge and attitudes scores with socio-demographic information. Spear man's correlation was used to determine any relationship between training of pharmacovigilance and reporting ADR.**MAXQDA software** was used to analyze question 21. All statistical tests conducted were considered significant at 95% confidence interval with a p-value less than 0.05[21].

2.7 Ethical consideration

The proposed study was reviewed and approved by the Research and Ethics Committee at AIUWA and EFSTH REC.

Potential study participants were provided with a detailed description of the study and were assured of confidentiality. They were also informed of the voluntary nature of the study, and that rejection of participation would carry no negative consequences

3. Results

3.1 Response rate

The survey targeted all eligible healthcare providers at the EFSTH.A total of 200 Questionnaires were distributed to be submitted after 24hours, 8 submitted after the stipulated time and the remaining 45 either never provided correspondence back or submitted an incomplete survey. 46 questionnaires were invalid because the answers were duplicated. The response rate based on this sample size was 51% (n=102).

3.2 Socio-demographic characteristics

A total of 102 participants who completed their questionnaire were included in the final analysis of which by profession the majority were nurses 66 (64.7%), majority by gender were female 39(38.2%) and in general, the majority of the participants were female 58(56.9%).

Majority of the participants were in the age group 20-37 years 89 (87.3%), those married were 54(52.9%), Gambian nationals were 86 (84.3%), those who practiced Islam 86(84.3%), 93(91.2%) had work experience ranging 1-15years, the educational level 98(96.1%) had attended college or university,101 (99%) had full-time job(figure3).

Table 3: Distribution of the Health Workers by Socio-demographic Characteristics.EFSTH. 20th June to 24th July. 2022. n=102.

Socio-demographic characteristics	Profession								Total	%
	Nurse	%	Doctor	%	Pharmacist	%	Physiotherapist	%		
Gender										
Male	27	26.5	15	14.7	1	1.0	1	1.0	44	43.1
Female	39	38.2	15	14.7	4	3.9	0	0.0	58	56.9
Age										
20 to 37	58	56.9	26	25.5	4	3.9	1	1.0	89	87.3
38 to 55	7	6.9	2	2.0	1	1.0	0	0.0	10	9.8
56 to 73	1	1.0	2	2.0	0	0.0	0	0.0	3	2.9
Religion										
Christian	6	5.9	8	7.8	1	1.0	0	0.0	15	14.7
Muslim	60	58.8	21	20.6	4	3.9	1	1.0	86	84.3
others	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
Work experience										
1 to 15	61	59.8	27	26.5	4	3.9	1	1.0	93	91.2
16 to 30	4	3.9	1	1.0	1	1.0	0	0.0	6	5.9
31 to 44	1	1.0	2	2.0	0	0.0	0	0.0	3	2.9
Marital status										
Single	26	25.5	15	14.7	4	3.9	0	0.0	45	44.1
Married	38	37.3	14	13.7	1	1	1	1	54	52.9
Widowed	0	0	1	1	0	0	0	0	1	1
Divorced	2	2	0	0	0	0	0	0	2	2

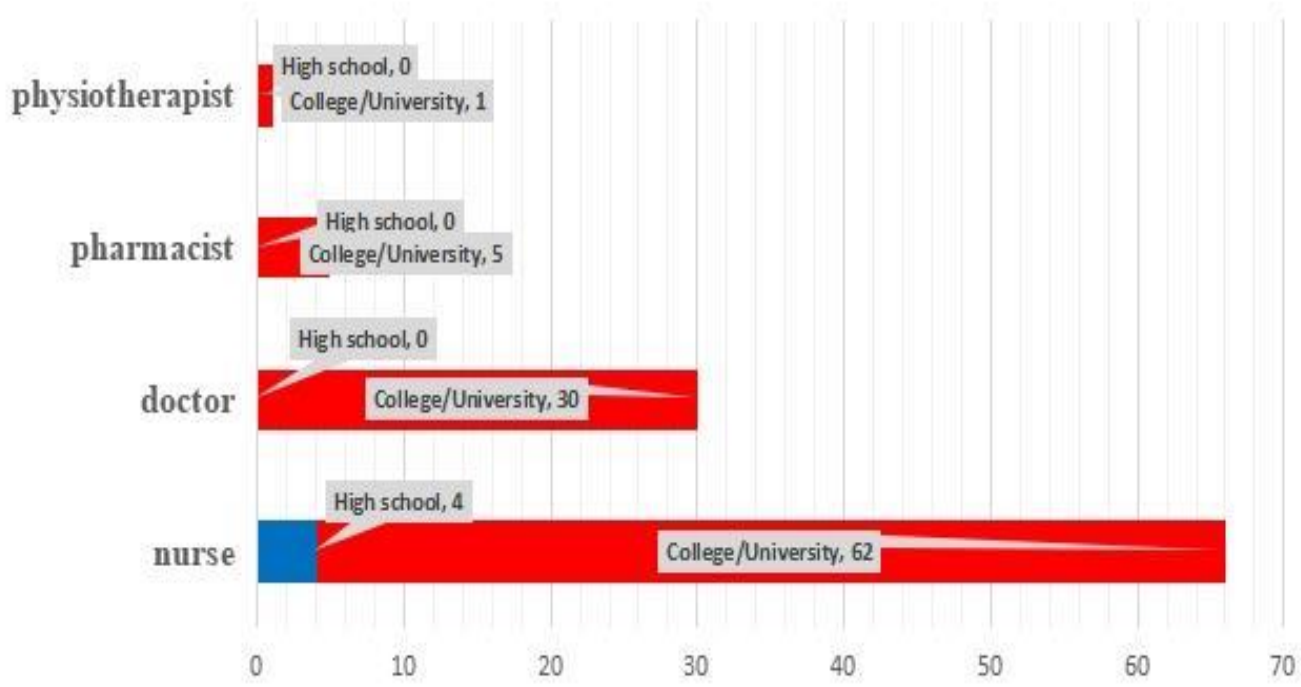
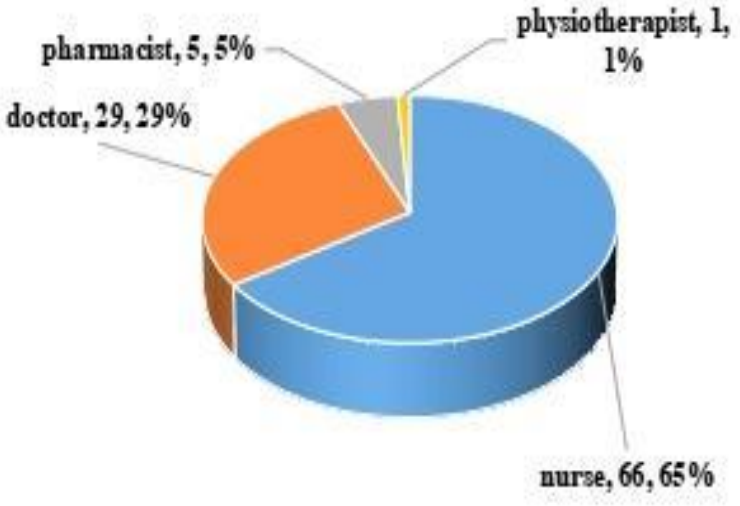


Figure 3: Distribution of the Health Workers by Socio-demographic Characteristics (Educational level). EFSTH. 20th June to 24th July. 2022. n=102.

Full-time



Part time

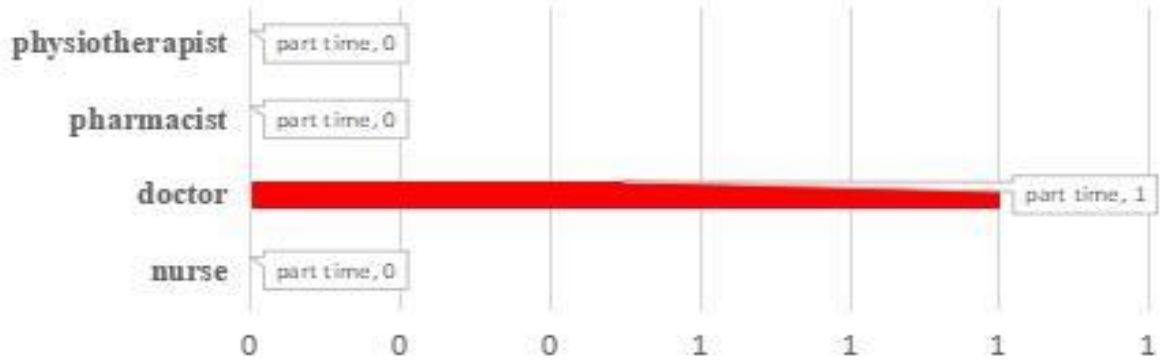
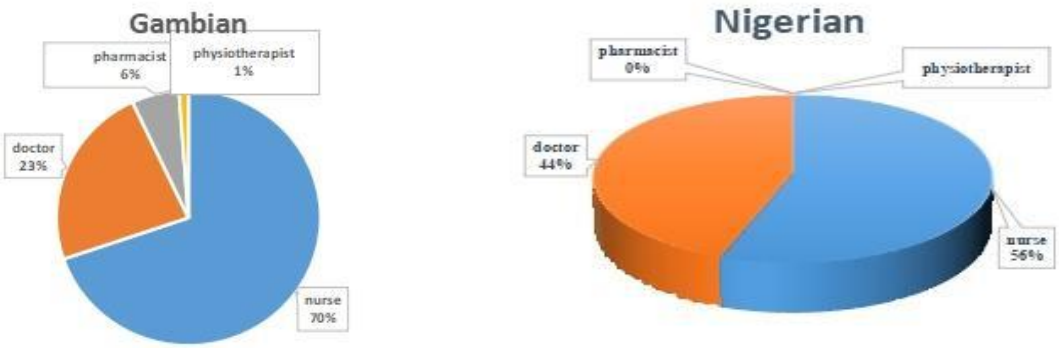


Figure 4: Distribution of the Health Workers by Socio-demographic Characteristics at EFSTH. 20th June to 24th July. 2022. n=102.



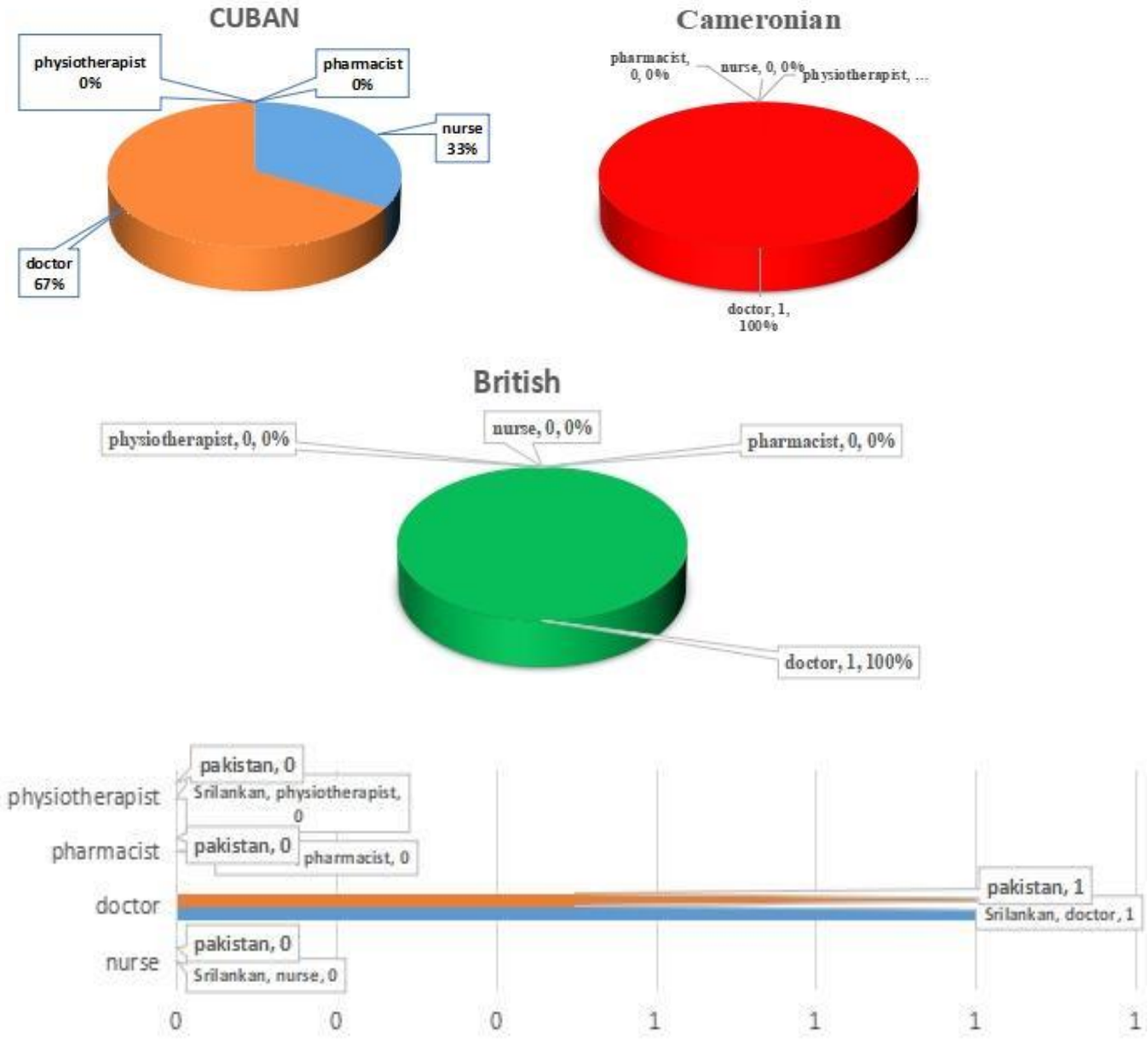


Figure 5: Distribution of the Health Workers by Socio-demographic Characteristics (Nationality). EFSTH. 20th June to 24th July. 2022. n=102.

3.3 The health workers experiences related medication and Adverse Drugs Reactions

In the questions concerning experience related medication and adverse drugs reactions

(Table4**), majority** of the respondents 102 (100%) were involved in patient care (figure6). 56 (54.9%) of the participants prescribe medications (figure7), administer medication to patient 93 (95.1%), monitor ADR 85(83.3%), ADRs observed 87(83.5%), participants have equally seen or not seen fatal ADR? 54(52.5%) have had patients with ADR.

Table 4: Distribution of the Health Workers by Experience Related Medication and adverse drugs reactions.at EFSTH. 20th June to 24th July. 2022. n=102.

Experiences related medication and adverse drugs reactions	Profession								Total	%
	Nurse	%	Doctor	%	Pharmacist	%	Physiotherapist	%		
Do you administer medication to patient?										
yes	66	64.7	26	25.5	1	1.0	0	0.0	93	95.1
no	0	0.0	4	3.9	4	3.9	1	1.0	9	4.9
Do you monitor Adverse Drug Reaction?										
YES	59	57.8	21	20.6	4	3.9	1	1.0	85	83.3
NO	7	6.9	9	8.8	1	1.0	0	0.0	17	16.7
Have you observed Adverse Drug Reaction in all your lifetime?										
YES	57	55.9	26	25.5	3	2.9	1	1.0	87	83.5
NO	9	8.8	4	3.9	2	2.0	0	0.0	15	14.7
Do you know anyone that have had fatal Drug Reactions?										
YES	34	33.3	14	13.7	2	2.0	1	1.0	51	50
NO	32	31.4	16	15.7	3	2.9	0	0.0	51	50
Has your patient ever had Adverse Drug Reactions?										
YES	37	36.3	14	13.7	3	2.9	0	0.0	54	52.9
NO	29	28.4	16	15.7	2	2.0	1	1.0	48	47.1

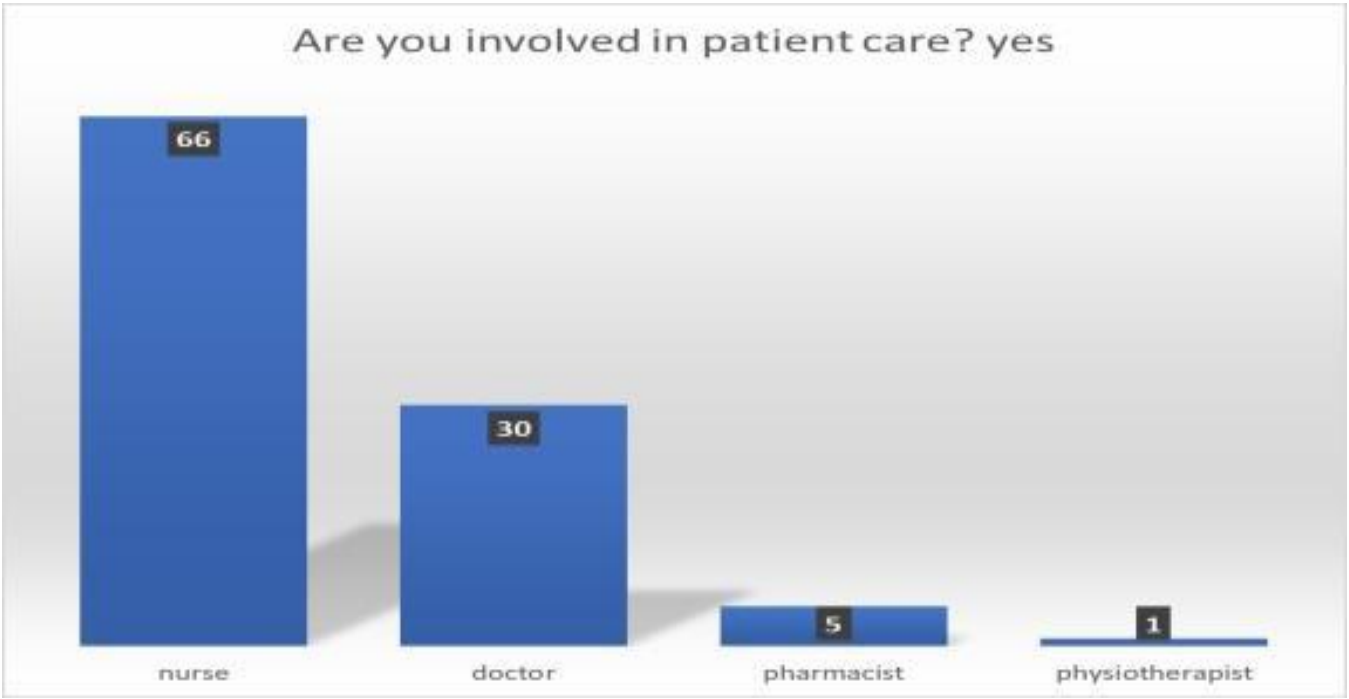


Figure 6: Distribution of the Health Workers by Socio-demographic Characteristics (Involved in patient care). EFSTH. 20th June to 24th July. 2022. n=102.

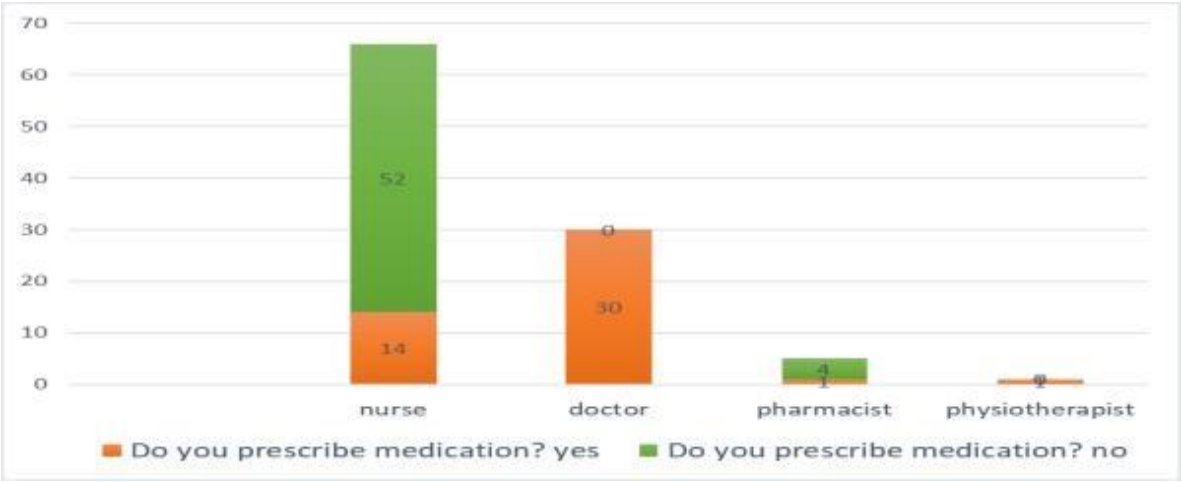


Figure 7: Distribution of the Health Workers by Socio-demographic Characteristics (prescribers and non-prescribers). EFSTH. 20th June to 24th July. 2022. n=102.

3.4 Knowledge on the pharmacovigilance

Table 5: Distribution of the Health Workers by Questions/Answers Related to Pharmacovigilance Knowledge. EFSTH. 20th June to 24th July. 2022. n=102.

Questions related to pharmacovigilance knowledge	**Answers by Profession**								**Total**	**%**
	Nurse N	**%**	**Doctor N**	**%**	**Pharmacist N**	**%**	**Physiotherapist N**	**%**		
What is pharmacovigilance?										
correct	41	40.2	21	20.6	1	1.0	1	1.0	64	62.7
Incorrect	25	24.5	9	8.8	4	3.9	0	0.0	38	37.3
The most important purpose of pharmacovigilance is?										
correct	50	49.0	18	17.6	3	2.9	0	0.0	71	69.6
Incorrect	16	15.7	12	11.8	2	2.0	1	1.0	31	30.4
Do you think ADR reporting is professional obligation for you?										
correct	57	55.9	29	28.4	3	2.9	1	1.0	90	88.2
Incorrect	9	8.8	1	1.0	2	2.0	0	0.0	12	11.8
The healthcare professionals responsible for reporting ADRs in a hospital is/are?										
correct	51	50.0	28	27.5	2	2.0	1	1.0	82	80.4
Incorrect	15	14.7	2	2.0	3	2.9	0	0	20	19.6
Do you know regarding the existence of a National Pharmacovigilance Program in The Gambia?										
correct	10	9.8	3	2.9	4	3.9	0	0.0	17	16.7
Incorrect	56	54.9	27	26.5	1	1.0	1	1.0	85	83.3
In the Gambia which regulatory is responsible for monitoring ADRs?										
correct	21	20.6	10	9.8	4	3.9	0	0.0	35	34.3
Incorrect	45	44.1	20	19.6	1	1.0	1	1.0	67	65.7
Where the international center for adverse drug reaction monitoring is located?										
correct	10	9.8	9	8.8	2	2.0	1	1.0	22	21.6
Incorrect	56	54.9	21	20.6	3	2.9	0	0.0	80	78.4

Table 6: Distribution of the Health Workers by level of knowledge. EFSTH. 20th June to 24th July. 2022. n=102.

Level of knowledge	Answers by Profession								Total	%
	Nurse N	%	Doctor N	%	Pharmacist N	%	Physiotherapist N	%		
High	12	18.1	8	26.7	3	60	0	0.0	23	22.5
Moderate	42	63.8	21	70	1	20	1	1.0	65	64.7
Low	12	18.1	1	3.3	1	20	0	0.0	14	13.8
Total	66	100	30	100	5	100	1	1.0	102	100

3.4 Knowledge analysis

The knowledge domain consisted of 7 Pretested. Questions Most of the participants scored moderately 65(64.7%) in the knowledge score but however within the professions the pharmacist had a high score of 3(60%) amongst the participants.

3.4.1 Socio-demographic characteristics associated with better knowledge level

Table 11: Relationship between Level of Knowledge and Socio-demographic Characteristics. At EFSTH. 20th June to 24th July. 2022. n=102.

Socio-demographic characteristics	Level of knowledge /Profession							
	Nurse		Doctor		Pharmacist		Physiotherapist	
	X^2	V	X^2	V	X^2	V	X^2	V
Gender	.192[b]	.054	1.929[c]	.254	1.875[d]	.612	-	-
Religion	2.675[b]	.201	6.803[c]	.476	1.875[d]	.612	-	-
Work experience	30.154[b]	.478	16.238[c]	.520	10.000[d]	1.000	-	-
Marital status	2.632[b]	.141	1.442[c]	.155	1.875[d]	.612	-	-
Nationality	5.164[b]	.198	36.696[c]	.782	-	-	-	-
Educational level	2.433[b]	.192	-	-	-	-	-	-
Age	47.283[b]	.599	46.622[c]	.881	10.000[d]	1.000	-	-

Legend (-) means no statistical outcome due to constant or same variable.

The study did not find any significant relationship between the socio-demographic and the levels of knowledge towards Pharmacovigilance.

Only one physiotherapist participated in the study therefore bringing statistical bias.

3.5 Attitudes towards pharmacovigilance

Table 7: Distribution of the Health Workers by Questions/answers Related to pharmacovigilance Attitude.at EFSTH. 20th June to 24th July. 2022. n=102.

Questions related to pharmacovigilance attitude	**Answers by Profession**								**Total**	**%**
	Nurse	**%**	**Doctor**	**%**	**Pharmacist**	**%**	**Physiotherapist**	**%**		
Do you think reporting of adverse drug reaction is necessary?										
correct	66	64.7	30	29.4	5	4.9	1	1.0	102	100
Why is it necessary?										
correct	40	39.2	23	22.5	2	2.0	1	1.0	66	64.7
Incorrect	26	25.5	7	6.9	3	2.9	0	0.0	36	35.3
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?										
correct	64	62.7	29	28.4	4	3.9	1	1.0	98	96.1
Incorrect	2	2.0	1	1.0	1	1.0	0		4	3.9
Have you anytime read any article on prevention of adverse drug reactions?										
correct	51	50.0	20	19.6	4	3.9	0	00.0	75	73.5
Incorrect	15	14.7	10	9.8	1	1.0	1	1.0	27	26.5
What is your opinion about establishing ADR monitoring center in every hospital?										
correct	61	59.8	27	26.5	4	3.9	1	1.0	93	91.2
Incorrect	5	4.9	3	2.9	1	1.0	0	0.0	9	8.8

Table 8: Distribution of the Health Workers by Attitude Classification.EFSTH. 20th June to 24th July. 2022. n=102.

Attitude classification	**Answers by Profession**								**Total**	**%**
	Nurse	**%**	**Doctor**	**%**	**Pharmacist**	**%**	**Physiotherapist**	**%**		
Positive	57	86.3	25	83.3	3	60	1	100	86	84.3
Neutral	9	13.7	5	16.7	2	40	0	0.0	16	15.7
Negative	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Total	66	100	30	100	5	100	1	100	102	100

3.51 Attitude analysis

The attitude domain consisted of 5 Pretested questions.102(100%) of the respondents all agreed reporting ADR was necessary(figure10). Majority of the respondents 86(84.3%) had a positive level of attitude amongst the profession the nurses scored highest 57(86.35) while Doctors scored 25(83.3%), the pharmacist 3(60%). The only physiotherapist who participated scored high but statically biased

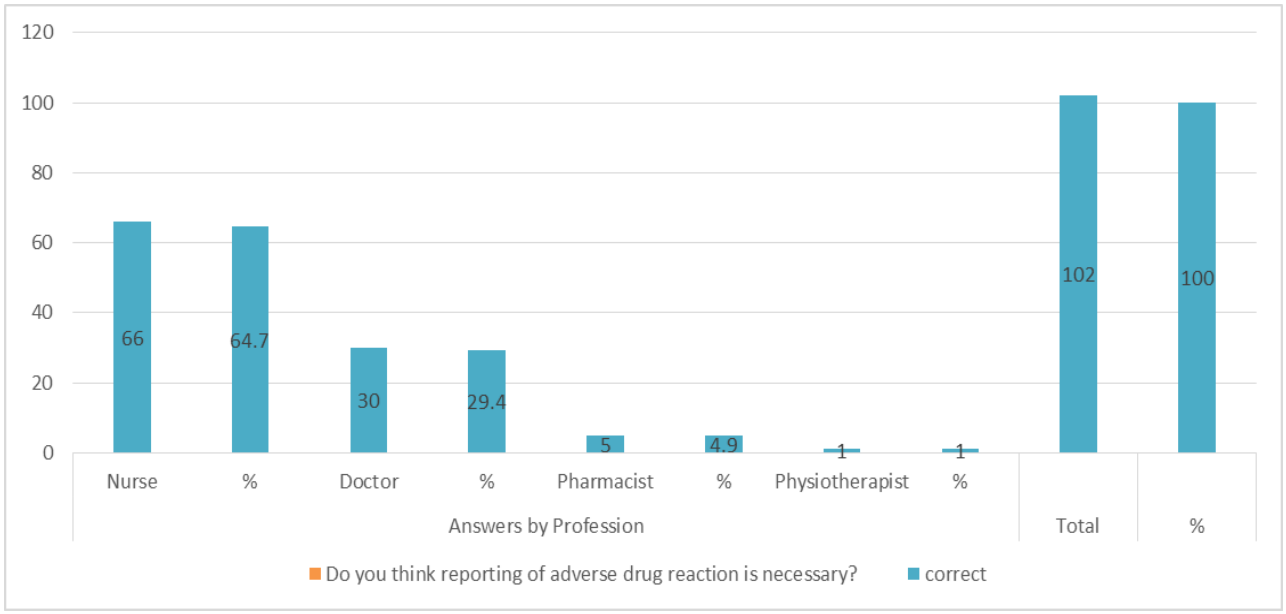


Figure 10: Do you Think Reporting of ADR is Necessary? EFSTH. 20th June, 2022 to 24th Jufjuly2022. (n - 102).

All participants 102(100%) agreed it was necessary to report ADR

3.5.2 Socio-demographic characteristics associated with attitude

The study did not find any significant relationship between the socio-demographic and the classifications of attitudes towards Pharmacovigilance. (table12)

Table 12: Relationship between Attitude Classification and Socio-demographic Characteristics.EFSTH. 20th June to 24th July. 2022. n=102.

Socio-demographic characteristics	**Attitude classification /Profession**							
	Nurse		**Doctor**		**Pharmacist**		**Physiotherapist**	
	X^2	*V*	X^2	*V*	X^2	*V*	X^2	*V*
Gender	6.681[b]	.318	2.040[c]	.261	.833[d]	.408	-	-
Religion	1.042[b]	.126	3.016[c]	.224	5.000[d]	1.000	-	-
Work experience	60.119[b]	.675	3.955[c]	.257	6.667[d]	.816	-	-
Marital status	16.762[b]	.356	2.401[c]	.200	.833[d]	.408	-	-
Nationality	1.042[b]	.089	20.940[c]	.591	-	-	-	-
Educational level	33.688[b]	.714	-	-	-	-	-	-
Age	54.155[b]	.641	45.500[c]	.871	10.000[d]	1.000	-	-

Legend (-) means no statistical outcome due to constant or same variable.

3.6 Practices towards pharmacovigilance

Table 9: Distribution of the Health Workers by Questions/Answers Related to Pharmacovigilance practices. EFSTH. 20th June to 24th July. 2022. n=102.

Questions related to pharmacovigilance practices	Answers by Profession								Total	%
	Nurse	%	Doctor	%	Pharmacist	%	Physiotherapist	%		
Have you ever experienced adverse drug reactions in your patients during your professional practice?										
yes	45	44.1	18	17.6	2	2.0	0	0.0	65	63.7
no	21	20.6	11	10.8	3	2.9	1	1.0	36	35.3
Can't say	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
Have you ever reported ADR to the Pharmacovigilance center?										
correct	10	9.8	5	4.9	1	1.0	0	0.0	16	15.7
Incorrect	56	55.0	25	24.5	4	3.9	1	1.0	86	84.3
Have you ever seen the ADR reporting form?										
correct	8	7.8	4	3.9	3	2.9	0	0.0	15	14.7
Incorrect	58	56.9	26	25.5	2	2.0	1	1.0	87	85.3
Have you ever been trained on how to report Adverse Drug Reaction (ADR)?										
correct	6	5.9	4	3.9	2	2.0	1	1.0	13	12.7
Incorrect	60	58.9	26	25.5	3	2.9	0	0.0	89	87.3
A serious adverse event in The Gambia should be reported to the regulatory body within?										
correct	13	12.7	10	9.8	1	1.0	1	1.0	25	24.5
Incorrect	53	52.0	20	19.6	4	3.9	0	0.0	77	75.5
Rare ADRs can be identified in the following phase of a clinical trial?										
correct	9	8.8	5	4.9	2	2.0	0	0.0	16	15.7
Incorrect	57	55.9	25	24.5	3	2.9	1	1.0	86	84.3
Which of the following methods is commonly employed by healthcare professional to monitor adverse drug reactions of new drugs once they are launched in the market?										
correct	24	23.5	14	13.7	4	3.9	1	1.0	43	42.2
Incorrect	42	41.2	16	15.7	1	1.0	0	0.0	59	57.8
Is there any Pharmacovigilance Committee in your Hospital?										
correct	4	3.9	4	3.9	1	1.0	0	0.0	9	8.8
Incorrect	62	60.8	26	25.5	4	3.9	1	1.0	93	91.2
Which of the following factor discourage you from reporting ADRs?										
No remuneration	18	17.6	7	6.9	3	2.9	1	1.0	29	28.4
lack of time to report ADR	8	7.8	10	9.8	1	1.0	0	0.0	19	18.6
A single unreported case may not affect ADR Database	4	3.9	2	2.0	0	0.0	0	0.0	6	5.9
Difficult to decide whether ADR has occurred or not.	36	35.3	11	10.8	1	1.0	0	0.0	48	47.1

Table 10: Distribution of the Health Workers by Practices Classification. EFSTH. 20th June to 24th July. 2022. n=102.

Practices classification	Answers by Profession								Total	%
	Nurse N	%	Doctor N	%	Pharmacist N	%	Physiotherapist N	%		
Adequate	11	10.8	8	7.8	2	2.0	0	0.0	21	20.6
Inadequate	55	53.9	22	21.6	3	2.9	1	1.0	81	79.4
Total	66	64.7	29.4	29.4	5	4.9	1	1.0	102	100

3.61 Practices analysis

The practices domain consisted of 9 pretested questions which 8 were included in the level of practices score and 1(question 21) was excluded and analyzed with MAXQDA due to bias as about 7(6.8%) of the participants did not find a suitable option. Majority of the participants in the practice domain 81(79.4%) scored inadequate towards practices. By profession, Nurses had the most inadequate practice 55(53.9%), Doctors 22(21.6%), Pharmacist 3(2.9%) and physiotherapist 1(1%). (figure11).

In general, the practice towards pharmacovigilance was inadequate amongst the participants of the tertiary care center.

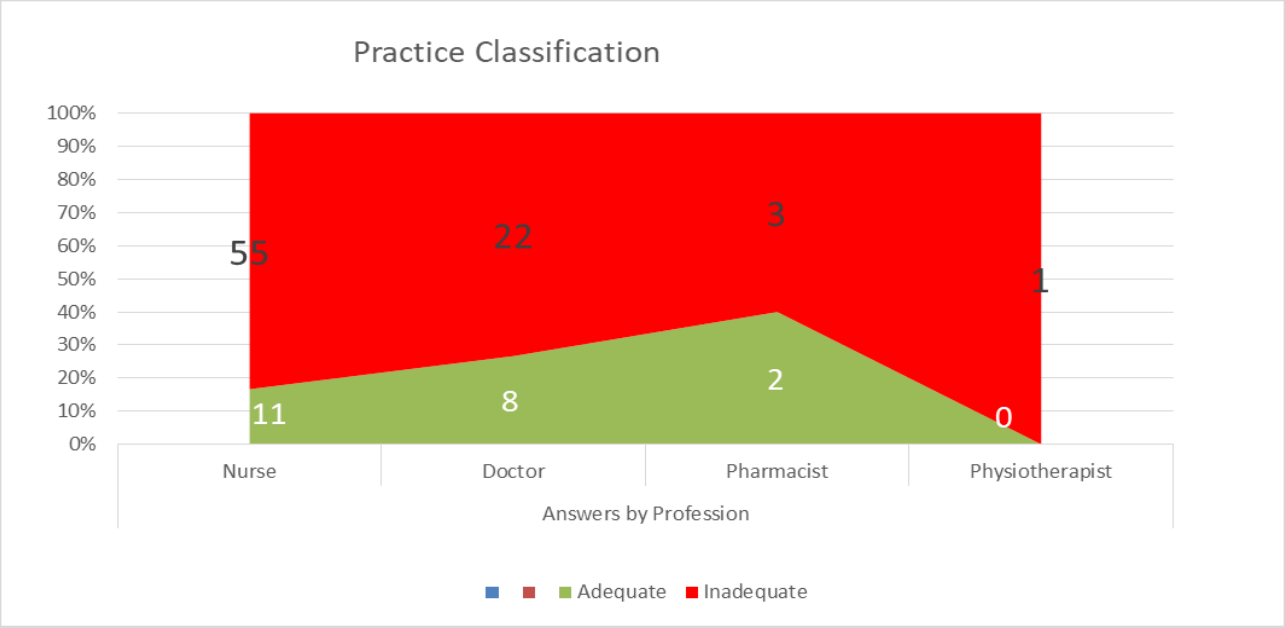


Figure 11: Distribution of inadequate level of practices.

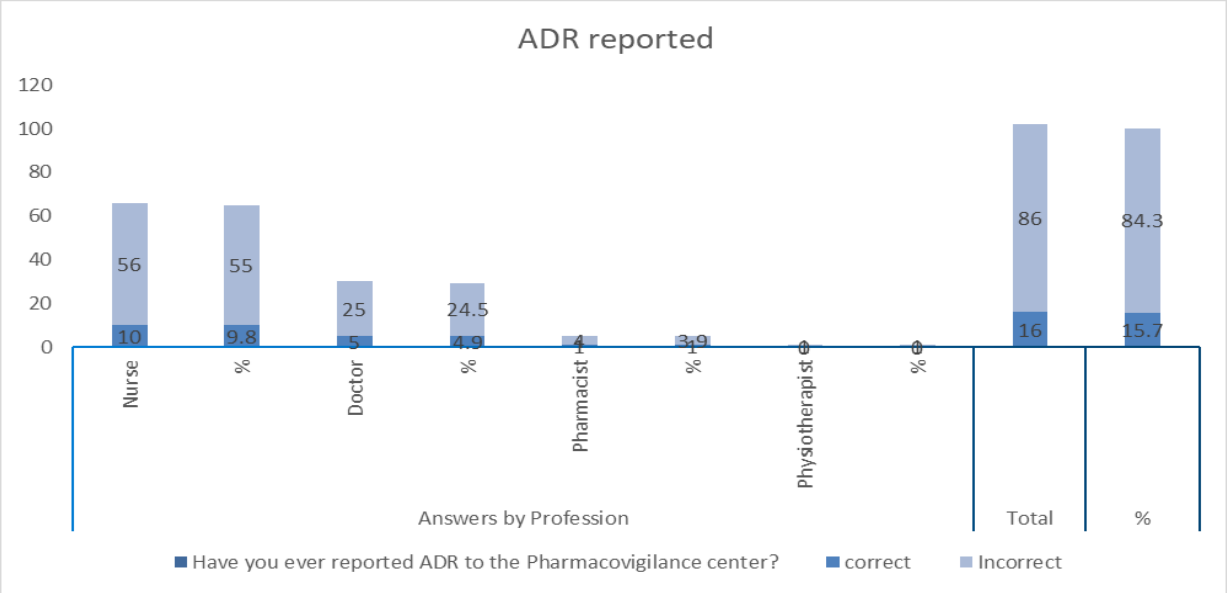


Figure 12: Distributions of healthcare providers who reported ADR.

majority of the participants 86(84.3%) have never reported any ADR, only 16(15.7%) have reported ADR.

3.6.2 Socio-demographic characteristics associated with inadequate practices

The study did not find any significant relationship between the socio-demographic and the classifications of practices towards Pharmacovigilance(table13).

Table 13: Relationship between Practice Classification and Socio-demographic Characteristics.at EFSTH. 20th June to 24th July. 2022. n=102.

Socio-demographic characteristics	**Practice classification /Profession**							
	Nurse		**Doctor**		**Pharmacist**		**Physiotherapist**	
	X^2	*V*	X^2	*V*	X^2	*V*	X^2	*V*
Gender	.113[c]	.041	000[d]	.000	.833[e]	.408	-	-
Religion	1.320[b]	.141	3.853[d]	.358	.833[e]	.408	-	-
Work experience	23.360[b]	.595	12.614[c]	.648	5.000[d]	1.000	-	-
Marital status	2.060[b]	.177	3.117[c]	.322	1.875[d]	.612	-	-
Nationality	5.160[b]	.280	7.244[c]	.491	-	-	-	-
Educational level	.213[c]	.057	-	-	-	-	-	-
Age	21.814[b]	.575	19.773[c]	.812	5.000[d]	1.000	-	-

Legend (-) means no statistical outcome due to constant variable

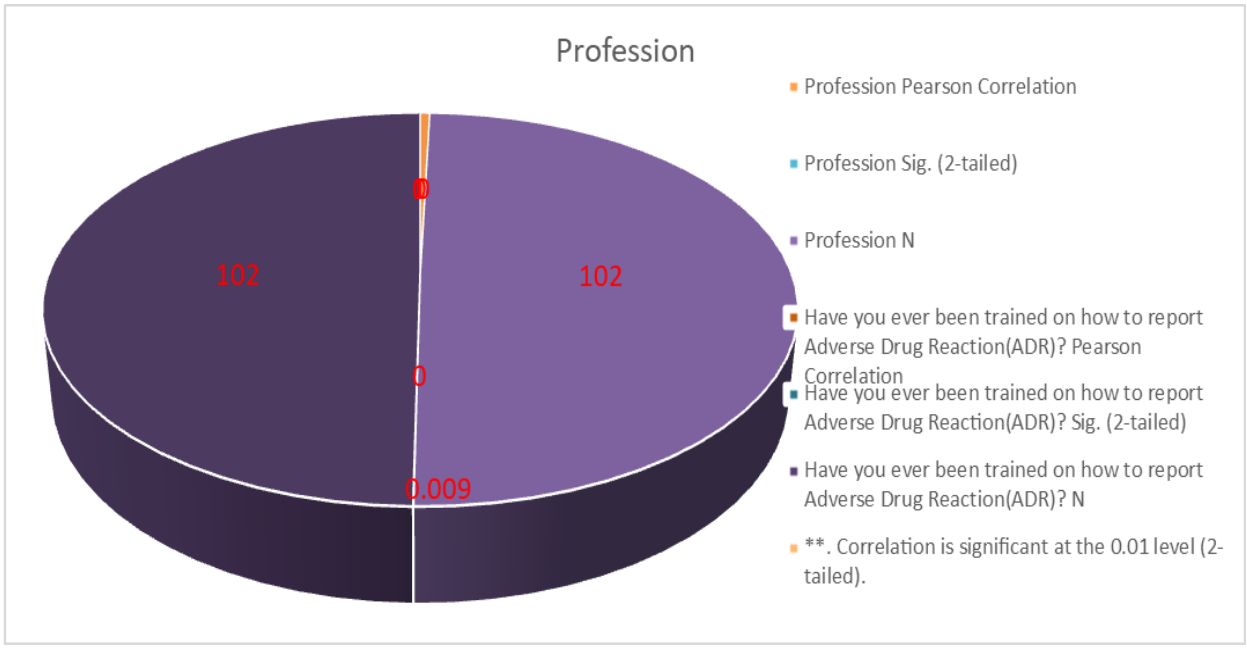


Figure 8: Correlations Between Profession and ADR Reporting Training. At EFSTH. 20th June to 24th July. 2022. n=102.

The study found a statistical significance between Profession and training for ADR reporting at (p=0.009) showing that most participants have not undergone formal training on pharmacovigilance(figure8).

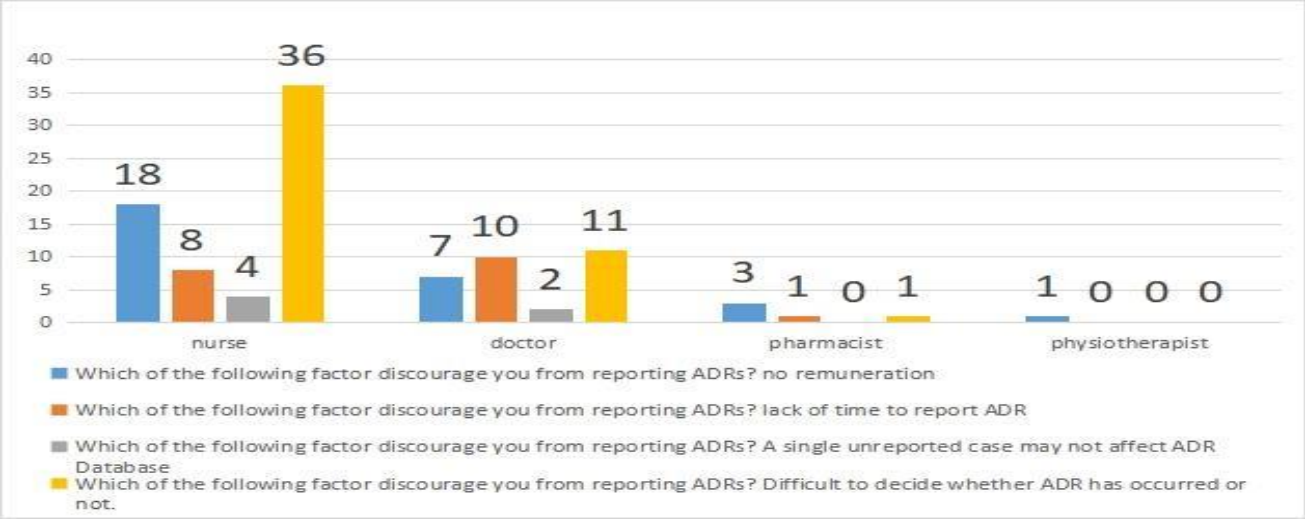


Figure 9: Distribution of Factors that Discourage ADR reporting.at EFSTH. 20th June to 24th July. 2022. n=102.

In the Question 21 of the practice domain displayed in (figure9) about factors that discourage ADR reporting Majority of the participants 48(47.1%) agreed it was difficult to decide whether ADR has occurred or not but however, by profession 36 (54%) nurses,11 (37.7 %) doctors and 1(20%)

5. Conclusion

5.1 Discussion

This is one of The Gambia's first studies of healthcare providers' knowledge, attitudes, and practices regarding ADR reporting. Patient and medication safety are top priorities in public health. As a result, community and hospital healthcare providers must work hard to ensure patient acceptance and trust, because undetected ADR and delays in interventions can endanger patients' well-being. This can have a negative impact on the efforts of public health and healthcare system of any nation. Thus, there is the need to look into how to prevent and manage adverse drug events. This research examined at the knowledge, attitudes, and practices of health care providers at a tertiary care center, Edward Francis Smalls Teaching Hospital, in The Gambia. The KAP is the most effective tool to examine ADR reporting among healthcare providers and their perception towards PV and patient's safety [7,36,19].

5.1.1 Response rate and socio-demographic

The response rate based on this sample size was 51% (n=102). 200 questionnaires were distributed. A total of 102 participants were included in the research which featured 21 questions. The different sets of questions were as follow: 7 for knowledge, 5 for attitudes and 9 for practices and 1 question to inquire general opinion. By profession the majority were nurses 66 (64.7%), between the Nurses the majority by gender were female 39(38.2%). In general ,the majority of the participants were female 58(56.9%).Majority of the participants belong to the age groups 20-37 years 89(87.3%) ,married 54(52.9%), Gambian 86(84.3%), practiced Islam 86(84.3%), 93(91.2%) had work experience ranging 1-15years, the educational level 98(96.1%) most had attended college or university, 101(99%) had full-time jobs. The study did not find any significant relationship between the socio-demographic and the levels of knowledge, attitudes and practices towards PV.

In the questions concerning experiences related medication and adverse drugs reactions, majority of the respondents 102(100%) were involved in patient care.56(54.9%) of the participants prescribe medications, administer medication to patient 93(95.1%),monitor ADR 85(83.3%),have seen ADR 87(83.5%), majority of the participant had come across an ADR which was synonymous to other studies[21,2].The participants have equally seen or not seen fatal ADR 51(50%) and 54(52.5%) have had patient with ADR but few of the study participants played a role in ADR reporting which was in contradiction to other studies[21,33,25].

5.1.2 Healthcare providers knowledge towards pharmacovigilance

Most participants scored moderately 65(64.7%) in the knowledge score but however within the professions, Pharmacists had a highest score of 3(60%) amongst the participants which shares a different view with a research conducted by Suman Kanwar and his colleagues (2020) with response rate of 80. 15 % amongst medical officers showing satisfactory knowledge of aim of pharmacovigilance and who can report an ADR but limited facts about existence of national PvPI. [39,20,41,42]. These researches demanded for urgent educational interventions like input of pharmacovigilance related activities in the undergraduate practical, CME, and workshop on pharmacovigilance [33] to the healthcare providers because continuous sensitization is essential

for ADR reporting. The study found a statistical significance between profession(healthcare providers) and training for ADR reporting at (p=0.009) showing that most participants have not undergone formal training on pharmacovigilance which highlights the findings of a study in Iran [16]that concurs to a systematic review by Bhagavathula and his colleagues (2016) showing that 74.5% of Indian healthcare providers inclusive of nurses never reported any ADRs [5,16] because they were not trained on areas of pharmacovigilance guidelines. The National Pharmacovigilance Guidelines of The Gambia mandates ADR monitoring and reporting as a professional responsibility for all health care providers [5].

5.1.3 Healthcare providers attitudes towards pharmacovigilance

Majority of the respondents 86(84.3%) had a positive level of attitude. The nurses scored highest 57(86.35) while doctors scored 25(83.3%), the pharmacist 3(60%). The only Physiotherapist score was statically biased. All healthcare providers 102(100%) agreed it was necessary to report ADRs which shares different view with other studies where the nurses almost similarly assumed that ADR reporting should be mandatory or voluntary, but however, it is generally believed that spontaneous reporting programs, where the reports are given out voluntarily, are linked to fairly low levels of ADR reporting [7]. The respondents 86(84.3%) had a positive level of attitude which contradicts a study in India [37] that most of the nurses accepted that ADR reporting improves the patient safety, but their attitude towards it was poor because it is time exhausting with no outcome. Thus, the researcher demanded an educational remedy to change their attitude towards ADR reporting.

The study also figured out that all the nurses who completed the questionnaire shared their thought that pharmacovigilance should be taught in detail to healthcare practitioners. Most participants 93(91.2%) agreed that ADR monitoring center should be present in every hospital which is in accordance with the study conducted by Gupta and his colleagues about 92% of the nurses accepted [21].

5.1.4 Healthcare providers practices towards pharmacovigilance

Majority of the participants who are practicing at the EFSTH,81(79.4%) had inadequate score towards practices. By profession, nurses had the most inadequate practice 55(53.9%), doctors 22(21.6%), pharmacist 3(2.9%) and physiotherapist 1(1%).

In general, the practice towards pharmacovigilance was inadequate amongst the participants of the tertiary care Centre, the poor practice of ADR reporting among doctors was reported in another systematic review [6] by S Palaian and his colleagues which agrees with results of the study.

In Question 21 of the practice domain displayed in (figure9) about factors that discourage ADR reporting, majority of the participants 48(47.1%) agreed it was difficult to decide whether ADR has occurred or not which disagrees with evidence from various studies which majority stated that lack of time M Bishit and his colleagues [42] and lack of awareness of where and how to report the suspected ADRs [3,6]. There are other contributing factors such as: lack of recognition of the significance of ADR reporting [41], uncertainty about the ADR investigations [38,39], fear of legal liabilities [40], complexity in filling out the ADR form [41], and lack of access to the ADR forms [41] resulted to under-reporting of ADRs by healthcare providers in the Gambia as

well as globally. ADRs are under reported at the tertiary care center because most participants 86(84.3%) had a negative response to reporting an ADR to the Pharmacovigilance Centre. Globally, only about 6-10% of all ADRs are reported [44].Generally, our findings coincide with findings of Gupta and his colleagues (2017), who demonstrated that the participating students in their study exhibited better attitude but poor practice and limited knowledge towards pharmacovigilance [43] which agreed with the findings of other studies [45]. The respondents were healthcare professionals including doctors, nurses and pharmacist whose sound demographic details were assessed and also given a KAP questionnaire which was designed according to previous studies [8,31,32,33,34,35]. The main focus of the pharmacovigilance is to improve the safe and the rational use of medicines. It has played a significant role in detection of ADRs but previous studies suggest that under-reporting of ADRs is one of the main problems associated with pharmacovigilance scheme [46]. Main reason for under reporting ADRs is limited knowledge and skill about PV program, which was reflected in these studies, and is consistent with the findings of other studies [13,14]. Furthermore, the review by T Salehi and his colleagues showed that more than two-thirds of nurses believed that ADR reporting is necessary and important for patient safety. In summation, Nurses almost equally believed that ADR reporting should be mandatory or voluntary. It is normally assumed that spontaneous reporting programs, where reports are submitted willingly, are associated with fairly low levels of ADR reporting [56,57] which is in accordance with the findings of the study by Rehan and his colleagues which stated that more than half of the Nurses and resident Doctors believe that PV activities like ADR reporting should be a mandatory practice to ensure and improve patient safety [58] because a climax rate of under-reporting of ADRs can delay signal detection thus endangering the patients' well-being[59]. Therefore, it is essential for spontaneous reporting practice among healthcare providers to be encouraged as a visionary goal aiming to cement the practice of PV [54].

5.2 Strengths of the study

The study has been conducted at different sites globally and the reviewed literatures were from Iran, India, Turkey, Namibia and Nigeria enforcing the significance of pharmacovigilance involvement in clinical and pharmaceutical care. This was the first of its kind as a study to be conducted at EFSTH, The Gambia. Most healthcare providers were interested in getting knowledge about patient and medication safety, drug interactions and drug allergy in order to improve patient safety. The EFSTH provided their standard ethical research guideline which strictly conforms to WHO standard guidance which made the study appropriate and valid.

Limitations of the studies

The major limitation of this study was the smaller number of participants (low response rate) and there were other limitation factors that are associated with self-reporting studies which includes; Accuracy of recall, personal bias may also have affected the results of this study in some ways as such as:

- Doctors were on very tight work schedule so they couldn't find time to complete the questionnaire within the stipulated time.
- Question 21(APPENDIX A) even after pilot testing on 10 participants pretest during the study period an estimate of 7participants did not find suitable option as answer because they had discouragement

about ADR reporting, therefore it was analyzed with MAXQDA software to reduce bias as displayed in figure9.

- The study was done amongst healthcare providers at only one Hospital, EFSTH so it is impossible to generalize the findings to the general Gambian population of healthcare providers. The number of pharmacists and physiotherapist that participated was low compared to other professions in number bringing statistical bias.

5.3 Recommendations

The study found a statistically significant correlation between profession and training on reporting of ADR at (p=0.009). Thus, I recommend further research and training to be done to explore knowledge on areas of pharmacovigilance and ADR reporting in The Gambia with inclusion of PV activities in undergraduate curriculum. The respondents 81(79.4%) scored inadequate towards practices, which clearly indicates the need for pharmacovigilance education and training of healthcare providers practice. The government through ministry of Health (Medicine Control Agency) to put up a good and standard pharmacovigilance guideline to health promote appropriate pharmaceutical delivery for a better patient outcome. Based on the results of my study where the answers given by the respondents for the practice domain was Inadequate, I found it quite necessary the need to encourage ADR reporting electronically by creation of a WhatsApp network called WHATSAPPVIGILANCE(attached in APPENDIX E) built to give easy access to ADR forms, encourage, educate and guide healthcare providers in reporting of ADRs observed daily according to National PV guidelines.

5.3.1 Suggestions to improve ADR reporting

(a) Addition of pharmacovigilance in the undergraduate (UG) curriculum for healthcare providers [31, 48].

(b) Regular training on basic principles of pharmacovigilance including ADR reporting [49].

(c)Establishment of a national Pharmacovigilance Center

(d) Easy access to ADR reporting forms [50]

(e). Regular e-mail update on the safety of drugs [51]

(f) Small remuneration and granting of sabbatical to ADR reporters [46, 52, 54]

(g) Spontaneous reporting of ADR via electronic submission [53]

5.4 Conclusion

The study found a statistical significance between profession and adverse drug reactions reporting training at p=0.009, which shows most of the participants have not undergone training in the area of pharmacovigilance and ADR Reporting. Thus, this indicates the need to include pharmacovigilance in the undergraduate curriculum

for healthcare providers in training as well. Participants showed moderate levels of knowledge, generally positive attitudes, and significantly inadequate levels of practices of pharmacovigilance. However, these findings are not surprising given the small sample size population in this study. The Gambia is much more deprived of adequate education about Adverse Drug Reactions and pharmacovigilance activities compared to the general population in the developed nations. The UNESCO report 2015 stated that The Gambia has a literacy rate of 50.8% among those 15 years and older [55], which affects patients' awareness of pharmacovigilance tools like the patient alert card. Therefore, there is a need for a national KAP study regarding the use of National Pharmacovigilance Guidelines to be conducted in order to identify the key factors spurring low Adverse Drug reaction reporting rates within The Gambia. Willingness to report an ADR can be improved electronically by taking advantage of WHATSAPPVIGILANCE, social media and community influencers to spread accurate facts about the use of National Pharmacovigilance Guidelines [5].

Acknowledgements

Special thanks to the Vice Chancellor Prof Makie. Taal for giving me the chance to complete my education after I dropped out for almost three years due to no financial constraint, the Provost of AIUWA medical college,Prof. Kassama,Professor Stephen Allen The Head of Pediatric Department and Chairman EFSTH Ethics Committee,H.O.D clinical pharmacy Sankung Jobarteh, Dr Philomena Akpoveso,my former HOD,Dr Maria Rosa,Dr Youdubagha Dinipre,Dr Chijioke Nwaigwe,Justice I.O Nwabuike Esq.and the supporting staffs of EFSTH Pharmacy Department especially Dr Ibrahima Jaiteh, Pharmacists Camara and Pharmacist. Eliza Barber. The National Human Rights Commission especially Mrs.Aminatta Ceesay, Lords Chambers senior counsel Bar.Sunbo Akimbo, the Registrar Pharmacy Council Dr. Omar Gaye, The Honorable Ambassador of Nigeria to The Gambia. Finally, I will like to thank God Almighty, Pastor Chris Lawrence, Prophets Francis and Ogegere for fervent prayers. Thanks to all healthcare givers at EFSTH that participated in the study and my Mauritanian friend Mr. Abdul Wahab who provided me with free internet during this research. I am grateful. Special thanks to Tamdi Isaac Sammani for helping me review my work. I am deeply grateful.

References

[1] Who.int. [Online]. Available: https://www.who.int/publications/i/item/10665-42493. [Accessed: 27-Oct-2022].

[2] A. R. Abubakar, N. B. Simbak, and M. Haque, “A systematic review of knowledge, attitude and practice on adverse drug reactions and pharmacovigilance among doctors,” J. Appl. Pharm. Sci., vol. 4, no. 10, pp. 117–127, 2014.

[3] R. Gupta, D. Sharma, and P. Malhotra, “assessment of knowledge, attitude and practice of pharmacovigilance among the undergraduate medical students in a Northern Indian tertiary care teaching hospital-an observational study,” international journal of pharmaceutical sciences and research, vol. 8, pp. 2654–2659, 2017.

[4] A. S. Bhagavathula, A. A. Elnour, S. Q. Jamshed, and A. Shehab, “Health professionals’ knowledge,

attitudes and practices about Pharmacovigilance in India: A systematic review and meta-analysis," PLoS One, vol. 11, no. 3, p. e0152221, 2016.

[5] Mca.gm. [Online]. Available: https://www.mca.gm. [Accessed: 28-Oct-2022].

[6] R. D. Mann and E. B. Andrews, Pharmacovigilance, 2nd ed. Wiley, 2007.

[7] B. Hugman, "The Erice declaration: the critical role of communication in drug safety," Drug Saf., vol. 29, no. 1, pp. 91–93, 2006.

[8] S. Sunwoo et al., "Post-marketing surveillance study of the safety and efficacy of sildenafil prescribed in primary care to erectile dysfunction patients," Int. J. Impot. Res., vol. 17, no. 1, pp. 71–75, 2005.

[9] N. Moore, "The role of the clinical pharmacologist in the management of adverse drug reactions," Drug Saf., vol. 24, no. 1, pp. 1–7, 2001.

[10] A. Singh, K. Twomey, and R. Baker, "Global pharmacovigilance regulations: Call for re-harmonization," Clin. Trials, vol. 15, no. 6, pp. 631–632, 2018.

[11] M. D. Rawlins, "Clinical pharmacology. Adverse reactions to drugs," BMJ, vol. 282, no. 6268, pp. 974–976, 1981.

[12]. J. Feely, S. Moriarty, and P. O'Connor, "Stimulating reporting of adverse drug reactions by using a fee," *BMJ*, vol. 300, no. 6716, pp. 22–23, 1990.

[13]. "2. http://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/ -

GoogleSearch," *Google.com*[Online].Available:https://www.google.com/search?client=opera&q=2.%09http%3A%2F%2Fwww.who.int%2Fmedicines%2Fareas%2Fquality_safety%2Fsafety_+efficacy%2Fpharmvigi%2Fen%2F&sourceid=opera&ie=UTF-8&oe=UTF-8. [Accessed: 28-Oct-2022]

[14]. Gupta SK. Pharmacovigilance: Current status and future challenges. Indian Journal of Medical Specialties. 2013 Jun;4(1):1-4.

[15]. V. Srinivasan, D. Sheela, and D. Mridula, "Knowledge, attitude and practice of pharmacovigilance among the healthcare professionals in a tertiary care hospital-A questionnaire study," *Biomedical & Pharmacology Journal*, vol. 10, no. 3, pp. 1441–1447, 2017.

[16] T. Salehi, N. Seyedfatemi, M. S. Mirzaee, M. Maleki, and A. Mardani, "Nurses' knowledge, attitudes, and practice in relation to pharmacovigilance and adverse drug reaction reporting: A systematic review," *Biomed Res. Int.*, vol. 2021, p. 6630404, 2021

[17] Sharad AK. Pharmacists' knowledge, attitude and practice about adverse drug reaction in Basra/Iraq.

Int J Pharm Sci Res. 2017 May 1;8(5):2309.

[18] K. P. Osamene and M. Afolabi, "An evaluation of the knowledge and perceptions of pharmacy students on pharmacovigilance activities in Nigeria. BMC research notes," vol. 10, pp. 1–9, 2017.

[19] B. A. Adenuga, D. Kibuule, and T. W. Rennie, "Optimizing spontaneous adverse drug reaction reporting in public healthcare setting in Namibia," *Basic Clin. Pharmacol. Toxicol.*, vol. 126, no. 3, pp. 247–253, 2020.

[20] T. R. Bagle, V. A. Vare, R. C. Hire, and A. O. Shukla, "Knowledge, attitude and practice of undergraduate medical students and interns towards pharmacovigilance," *Int. J. Basic Clin. Pharmacol.*, vol. 6, no. 8, p. 1904, 2017

[21] S. K. Gupta, R. P. Nayak, R. Shivaranjani, and S. K. Vidyarthi, "A questionnaire study on the knowledge, attitude, and the practice of pharmacovigilance among the healthcare professionals in a teaching hospital in South India," *Perspect. Clin. Res.*, vol. 6, no. 1, pp. 45–52, 2015.

[22] K. K. Knapp, H. Katzman, J. S. Hambright, and D. H. Albrant, "Community pharmacist interventions in a capitated pharmacy benefit contract," *Am. J. Health. Syst. Pharm.*, vol. 55, no. 11, pp. 1141–1145, 1998.

[23] M. Bakare, A. I. Oreagba, and B. Adeniran, "Drug therapy problems: pharmacists' interventions and outcomes in Lagos state general hospitals, South West, Nigeria West African Postgraduate College of Pharmacists (Nigerian Chapter)," *Newsletter*, vol. 1, no. 4, pp. 10–29, 2011

[24] K. P. Osamene, M. I. Ayeni, and A. Mo, "The role of community pharmacists in monitoring adverse drug reactions in Nigeria," *Journal of Pharmaceutical Health Services Research*, vol. 3, no. 4, pp. 197–204, 2012.

[25] A. ;. S. Oparah, M. I. Ibrahim, and P. Mishra, "Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal. Pharmacy practice," vol. 9, 2010.

[26] E. O. Okezie and I. Fo, "Adverse drug reactions reporting by physicians in Ibadan, Nigeria," *Pharmacoepidemiology and drug safety*, vol. 17, pp. 517–522, 2008.

[27] E. Hristov *et al.*, "Effect of pharmacist involvement on patient reporting of adverse drug reactions in Bulgaria," *Journal of Advanced Research in Pharmaceutical Sciences and Pharmacology Interventions*, vol. 2, no. 2, pp. 1–6, 2019.

[28] F. Vural, S. Çiftçi, and B. Vural, "The knowledge, attitude and behaviours of nurses about pharmacovigilance, adverse drug reaction and adverse event reporting in a state hospital," *Northern clinics of Istanbul*, vol. 1, no. 3, 2014.

[29] A. Hammour and K. El-Dahiyat, *Abu Farha R. Health care professionals knowledge and perception of pharmacovigilance in a tertiary care teaching hospital in*, vol. 23. Amman, Jordan, 2017.

[30] F. Vural, S. Çiftçi, and B. Vural, "The knowledge, attitude and behaviours of nurses about pharmacovigilance, adverse drug reaction and adverse event reporting in a state hospital," *Northern clinics of Istanbul*, vol. 1, no. 3, 2014.

[31] S. A. Khan, C. Goyal, N. Chandel, and M. Rafi, "Knowledge, attitudes, and practice of doctors to adverse drug reaction reporting in a teaching hospital in India: An observational study," *Journal of natural science*, vol. 4, no. 1, 2013.

[32] P. Gupta and A. Udupa, "Adverse drug reaction reporting and pharmacovigilance: Knowledge, attitudes and perceptions amongst resident doctors," *Journal of pharmaceutical sciences and research*, vol. 3, no. 2, 2011.

[33] J. K. Bajaj and K. Rakesh, "A survey on the knowledge, attitude and the practice of pharmacovigilance among the health care professionals in a teaching hospital in northern India," *Journal of clinical and diagnostic research: JCDR*, vol. 7, no. 1, 2013.

[34] R. Rajesh, S. Vidyasagar, and D. M. Varma, "An educational intervention to assess knowledge attitude practice of pharmacovigilance among health care professionals in an Indian tertiary care teaching hospital," *Int J Pharm Tech Res*, vol. 3, no. 2, pp. 678–692, 2011.

[35] S. A. Pimpalkhute, K. M. Jaiswal, S. D. Sontakke, C. S. Bajait, and A. Gaikwad, "Evaluation of awareness about pharmacovigilance and adverse drug reaction monitoring in resident doctors of a tertiary care teaching hospital," *Indian J. Med. Sci.*, vol. 66, no. 3–4, pp. 55–61, 2012.

[36] P. Gupta, A. R. Anvikar, N. Valecha, and Y. K. Gupta, *Pharmacovigilance practices for better healthcare delivery: knowledge and attitude study in the national malaria control programme of India. Malaria research and treatment*. 2014.

[37] R. Rajalakshmi, B. V. Devi, T. D. Prasad, S. Swetha, and B. Dharini, "Knowledge, attitude and practice towards pharmacovigilance and adverse drug reaction reporting among nurses in a tertiary care hospital, tirupati," *International Journal of Pharmaceutical and Clinical Research*, vol. 9, no. 11, 2017.

[38] L. Hazell and S. A. W. Shakir, "Under-reporting of adverse drug reactions: A systematic review," *Drug Saf.*, vol. 29, no. 5, pp. 385–396, 2006.

[39] E. Lopez-Gonzalez, M. T. Herdeiro, and A. Figueiras, "Determinants of under-reporting of adverse drug reactions," *Drug safety*, vol. 32, pp. 19–31, 2009.

[40] C. Palleria *et al.*, "Limitations and obstacles of the spontaneous adverse drugs reactions reporting: Two

'challenging' case reports," *Journal of Pharmacology and Pharmacotherapeutics*, vol. 4, pp. S66-72, 2013.

[41] J. O. Fadare, O. O. Enwere, A. O. Afolabi, B. A. Chedi, and A. Musa, "Knowledge, attitude and practice of adverse drug reaction reporting among healthcare workers in a tertiary centre in Northern Nigeria," *Tropical Journal of Pharmaceutical Research*, vol. 10, no. 3, 2011.

[42] M. Bisht, S. Singh, and D. C. Dhasmana, "Effect of educational intervention on adverse drug reporting by physicians: A cross-sectional study," *ISRN Pharmacol.*, vol. 2014, pp. 1–8, 2014.

[43] R. Gupta, D. Sharma, and P. Malhotra, "assessment of knowledge, attitude and practice of pharmacovigilance among the undergraduate medical students in a Northern Indian tertiary care teaching hospital-an observational study," international journal of pharmaceutical sciences and research, vol. 8, pp. 2654–2659, 2017.

[44] C. C. Smith et al., "Adverse drug reactions in a hospital general medical unit meriting notification to the Committee on Safety of Medicines," British journal of clinical pharmacology, vol. 42, no. 4, pp. 423–429, 1996.

[45] M. B. Vora, N. P. Paliwal, V. G. Doshi, M. J. Barvaliya, and C. B. Tripathi, "Knowledge of adverse drug reactions and pharmacovigilance activity among the undergraduate medical students of Gujarat," International Journal of Pharmaceutical Sciences and Research, vol. 3, no. 5, 2012.

[46] S. Chatterjee, N. Lyle, and S. Ghosh, "A survey of the knowledge, attitude and practice of adverse drug reaction reporting by clinicians in eastern India," Drug Safety, vol. 29, no. 7, pp. 641–642, 2006.

[47] S. Kanwar, S. K. Mathur, and D. Yadav, "A questionnaire-based study on the knowledge, attitude and practice of pharmacovigilance among the medical officers working in peripheral areas of Ajmer District, Rajasthan (India)," Galore International Journal of Health Sciences and Research, vol. 5, no. 1, pp. 84–88, 2020.

[48] K. Rajarathna, D. Sreedhar, D. Basavalingu, and C. R. Jayanthi, Eds., "416 A questionnaire study to assess the knowledge, attitude and practice of Pharmacovigilance in a paediatric tertiary care centre *Sushma Muraraiah," J. Chem. Pharm. Res, vol. 3, no. 6, pp. 416–422, 2011.

[49] Q. Li et al., "Awareness and attitudes of healthcare professionals in Wuhan, China to the reporting of adverse drug reactions," Chinese medical journal, vol. 117, pp. 856–861, 2004.

[50] R. K. Dikshit, C. Desai, and M. K. Desai, "Pleasures and pains of running a pharmacovigilance center," Indian journal of pharmacology, vol. 40, 2008.

[51] C. Biagi, N. Montanaro, E. Buccellato, G. Roberto, A. Vaccheri, and D. Motola, "Underreporting in

pharmacovigilance: an intervention for Italian GPs (Emilia-Romagna region)," European journal of clinical pharmacology, vol. 69, no. 2, pp. 237–244, 2013.

[52] M. Bäckström and T. Mjörndal, "A small economic inducement to stimulate increased reporting of adverse drug reactions-a way of dealing with an old problem," European journal of clinical pharmacology, vol. 62, no. 5, pp. 381–385, 2006.

[53] J. H. Lee, K. H. Park, H. J. Moon, Y. W. Lee, J. W. Park, and C. S. Hong, "Spontaneous reporting of adverse drug reactions through electronic submission from regional society healthcare professionals in Korea," Yonsei medical journal, vol. 53, pp. 1022–1027, 2012.

[54] K. Wilbur, "Pharmacovigilance in Qatar: a survey of pharmacists," East Mediterr Health J, vol. 19, no. 11, pp. 930–935, 2013.

[55] Gambia. UNESCO Institute of Statistics. UNESCO; 2017. Available from: http://uis.unesco.org/en/country/gm

[56] S. Palaian, M. I. Ibrahim, and P. Mishra, "Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal," Pharmacy practice, vol. 9, 2011.

[57] H. S. Rehan, R. K. Sah, and D. Chopra, "Comparison of knowledge, attitude and practices of resident doctors and nurses on adverse drug reaction monitoring and reporting in a tertiary care hospital. Indian journal of pharmacology," vol. 44, 2012.

[58] C. K. Desai, G. Iyer, J. Panchal, S. Shah, and R. K. Dikshit, "An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital," Perspectives in Clinical research, vol. 2, no. 4, 2011.

[59] E. Hristov et al., "Effect of pharmacist involvement on patient reporting of adverse drug reactions in Bulgaria," Journal of Advanced Research in Pharmaceutical Sciences and Pharmacology Interventions, vol. 2, no. 2, pp. 1–6, 2019.

[60] S. Sivadasan and M. Sellappan, "A STUDY ON THE AWARENESS AND ATTITUDE TOWARDS PHARMACOVIGILANCE AND ADVERSE DRUG REACTION REPORTING AMONG NURSING STUDENTS IN A PRIVATE UNIVERSITY, MALAYSIA"," International Journal of Current Pharmaceutical Research, vol. 7, no. 1, pp. 84–89, 2015