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Pharmacovigilance: Knowledge Attitude and Practice within the Public Health actors in Yaounde, Cameroon

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Abstract

The drug discovery and development processes is designed to ensure that medicines have the right quality, are safe and efficacious. However, the number of patients who are exposed to drugs at approval is only a fraction of the target final patient population. Therefore, understanding the safety of medicines can only be finally achieved after the drug is on the market through post marketing surveillance or pharmacovigilance (PHV). Pharmacovigilance is defined by WHO as "the science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problems". Health professionals, patients, drug manufacturers and drug regulatory authorities are therefore highly involved in the practice of PHV. Cameroon imports 95 % of drugs and health care products. Therefore, an effective understanding of the knowledge, attitude and practice of PHV could help to elaborate the development of the PHV and adverse drug monitoring systems in Cameroon.

Objective: This study had as aim; to investigate the knowledge, attitude and practice of pharmacovigilance among the public health actors.

Methodology: A cross sectional, descriptive and analytical study was conducted in the Yaoundé Central Hospital, 50 pharmacies of the Mfoundi District in Yaoundé. The study focused on Health professionals (General Practitioners, specialists, pharmacists, dentists, nurses and midwives). The survey was conducted using a pre- tested self- administered questionnaire. The questionnaires for health professionals comprised of questions on knowledge (6), questions on attitude (5) and questions on practice (5). The data for health professionals and pharmaceutical companies was entered and analyzed using Epi-Info Version 3.5.4 statistical software and presented using Microsoft Excel spreadsheet.

Results: A total of 162 professionals composed of 101(62.3%) Hospital personnel and 50(30.9%) Pharmacy personnel and 11 (6.8%) Pharmaceutical companies' representative office supervisors not reported in this paper. These populations were further subdivided into Hospital personnel comprising 8(4.9%) Specialists, 47(29%) General practitioners, 10(6.2%) Dentists, 30(18.5%) Nurses and 6(3.7%) midwives. Pharmacy personnel comprised of; 4(2.5%) Advanced level, 3(1.9%) HND (Higher National Diploma) or pharmacy technicians, 4(2.5%) bachelors holders and 39(24.1%) pharmacists. In the general appreciation of knowledge, 58% of pharmacy personnel, 52.9% of hospital

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personnel. For attitudes, 52% of pharmacy personnel, 43.4% of hospital personnel had the expected results. For practice, 25.1% of pharmacy personnel, 17.5% of hospital personnel had the right practice.

Conclusion: The study showed that there was little applicable knowledge which determined the poor attitudes developed towards PHV among the health professionals leading to poor practice. Given that these are key actors in the PHV system, these results are seen to cause the problem of underdevelopment in our PHV systems. If these three principal elements are improved upon, there will be an evident turn of events regarding the development of our PHV system as a whole.

Keywords: Adverse drug reactions; Knowledge; Attitude; Practice; Health professional; Pharmacy personnel; Hospital personnel; Pharmaceutical company representative office

Abbreviations: ADRs: Adverse Drug Reactions; UMC: Uppsala Monitoring Centre; WHO: World Health Organization

Introduction

The drug discovery and development process holds pharmacovigilance as the final stage. It comprises three main steps presented in chronological order are; Discovery; where target identification and toxicity studies are carried out in test tubes and rodent animals. Pre-clinical phase; where pharmacokinetics, safety and toxicology studies are the main focus in animals [1,2]. Clinical trials are divided into 4 phases with the last phase being during marketing. Clinical trials have the phase 1 which has as target question "is it safe?" comprising short term dose-response and tolerability studies in a small group of healthy volunteers (20-100) [2,4]. The phase 2 focuses on "does it work?" which entails the evaluation of drug effectiveness and safety in 100 – 500 patients, followed up for 48 weeks. The phase 3; here 1000-5000 people can be involved for at least 48 weeks with the aim of observing safety, and efficacy versus standard of care [3,4]. Finally, the phase 4 comes in after marketing authorization has been granted. Here larger and more diverse populations are involved to observe efficacy and adverse effects which are rare or occur from long term use [5,7].

Pharmacovigilance is therefore defined by WHO as "the science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problems" [5,6] The reasons for pharmacovigilance surveys can be explained by the fact that the tests in animals are insufficiently predictive of human safety, patients in clinical trials are selected and limited in number, the conditions of use differ from those in clinical practice and the duration of trials is limited. Information about rare but serious adverse reactions, chronic toxicity, and use in special groups (such as children, the elderly or pregnant women) or drug interactions is often incomplete or not available [8,9].

The goal of pharmacovigilance is to protect patients and the public wherever possible and to disseminate knowledge among the relevant professional communities and to patients in order to minimize risk [9]. This was coined following the tragedies which occurred in the mid twentieth century. The thalidomide tragedy in the mid twentieth century triggered a chain of activities that were part of a global effort to avert a recurrence. Australia, Canada, several European countries, New Zealand and the United States of America established monitoring schemes based on reporting of suspected adverse drug reactions (ADRs) [10]. From these beginnings emerged the practice and science of pharmacovigilance. Systems were developed in Member States for the collection of individual case histories of ADRs and evaluation of them [6,11]. In 2007, national manufacturers held less than 5% market share on the amount of drugs produced by Cameroon [11,39]. This therefore means that Cameroon consumes more foreign supply of drugs, than locally manufactured drugs. These drugs manufactured by different Pharmaceutical companies are subjected to regulatory authorities external to Cameroon.

The need for pharmacovigilance is therefore paramount given that there is no legislation allowing the sampling of imported products for analysis in Cameroon [8, 21]. PHV should not be perceived as a burden put upon the pharmaceutical product development industry by the regulating bodies. Once a drug is developed and approved, PHV is essential to establish full safety data guaranteeing its survival in the market place [12,25]. Cameroon who joined the WHO Program for International Drug Monitoring, known as the Uppsala Monitoring Centre (UMC) in 2010, is making little effort to get involved in PHV [13,14,38]. In a bid to solve some of the problems caused by the inactivity in PHV, the Minister of Health has been taking actions to quarantine drugs which have proven to have serious adverse reactions and withdraw from the market, drugs or batches of drugs with

doubtable quality. An example occurred recently in January 2018 when Co-arinate tablets for Adults and children were quarantined for precautionary reasons, after a suspected serious adverse reaction was associated to administration of the drug [14-16]. Pharmacovigilance is therefore a public health problem in Cameroon, due to lack of good knowledge and practice of prescribers. Physicians, pharmacists, nurses, and dentists are not always aware of an existing PHV system in Cameroon [7, 18].

Pharmacovigilance information should be of great importance in this study. Health care providers, patients are therefore needed for the collection of data. This study focuses on the knowledge, attitude and practices of the public health actors in PHV. This study had as general objective; to investigate the knowledge, attitude and practice of PHV in some pharmaceutical companies and among the public health actors.

Methodology

Site of study

The research took place in 3 different environments precisely; Yaoundé Central Hospital, and 50 Community Pharmacies in the Mfoundi district, Hospitals were chosen following the Cameroon National Health System pyramid. Pharmacies which have been functional for at least 1 year were chosen from the list of pharmacies in the Mfoundi area.

Duration of study

The timeline for the study was approximately 8 months, from October 2017 till May 2018. The study design was a cross sectional descriptive study.

The study population

This study targeted health care professionals (medical doctors, nurses, midwives, pharmacists, dentists).Our sample population was derived from health professionals of Yaoundé Central Hospital, 50 Community Pharmacies in the Mfoundi Division of the Centre Region. Those included in the study were health professionals having had at least 1 year working experience and gave their consent and willingness to participate in the study.

Sample size

The sample size was intended to be exhaustive of the population at hand, having estimated 60 pharmacies from the list of 112 pharmacies found on the pharmacy call list in Yaounde, 120 hospital personnel were approximated.

Tools for data collection

This cross sectional questionnaire study was done with the acquisition of three data plans. The questionnaire for health professionals contains 15 questions, 6 to test knowledge, 5 to test the attitude, 3 to test practice. Study was initiated after obtaining clearance from the Institutional Ethics Committee. The study participants consisted of all the practicing healthcare professionals (medical doctors, specialists, dentists, nurses and midwives) who gave their informed consent and who are working at the hospital during the study period.

The questionnaire filled by Community pharmacy personnel contains 14 questions with 6 questions on knowledge, 5 questions on attitude and 3 questions on practice. The questionnaire for Pharmaceutical companies had a slightly different format presenting more questions on practice since they have a major role to play in processing the reports gotten and also in making available Adverse Drug Reaction report forms. The questionnaire contains 22 questions with 11 questions being based on Practice, 4 questions based on attitude, and 7 questions with knowledge as focus. From the contact with the health professionals, eligibility was sought. The objectives of the study and the modalities of participation were subsequently presented to the eligible professionals in order to obtain consent. Only those that freely consented were administered the questionnaire.

The model for data collection for hospital personnel indicating score and appreciation is shown in Table 1.

Score (number of points)	Appreciation
Less than 25 %	Bad
Between 25 and 50 %	Insufficient
Between 50 et 70 %	Average
More than 70 %	Good

Table 1: Model for Hospital Personnel.

Data analysis

The data collected was entered into a microcomputer using the Epi-Info version 3.5.4 statistical software and then analysis done still on the Epi-info software and the Microsoft Excel spreadsheet. This was done following the three different populations of interest. Assembling the distinct data for each of them concerning the various variables of knowledge, attitude and practice. Considering the different groups, different roles and professions, they are all grouped separately, analyzing each variable in each population set which gave rise to results from which a conclusion was drawn. A positive response was

considered as a correct answer and a negative or un-attempted response will be considered as an incorrect answer. Qualitative variables were expressed by percentages and the Chi-square test was used to compare the difference in correct responses for each question.

The model for community pharmacy personnel and pharmaceutical companies was different from that used for hospital personnel as seen in Table 2. This was as a result of the expected difference in exposure to pharmacovigilance principles.

Score (number of points)	Appreciation
Less than 50 %	Bad
Between 50 and 65 %	Insufficient
Between 65 et 85 %	Average
More than 85 %	Good

Table 2: Model for Community Pharmacy personnel and Pharmaceutical Companies.

Ethical consideration

After obtaining the ethical clearance of from the ethics committee of the Faculty of Medicine and Biomedical Sciences, the administrative authorizations were obtained from the directors of the structures involved in our study (the hospital, pharmacies selected for the study). Each health professional, pharmacist and representative of the pharmaceutical companies participating in the study signed a written informed consent form before answering the questionnaire.

Results

Socio-demographic profile

Out of a total of 190 people given questionnaires, 162 questionnaires were properly filled and thus could be exploited which made up a percentage of 85.3 % questionnaires exploited. Of the 162 participants, there were 50(30.9 %) pharmacy personnel, 101(62.3 %) hospital personnel and 11(6.8 %) PCRSs. When analyzing the possible associated factors which could influence Pharmacovigilance practice, these socio-demographic factors were considered. Significant p-values considered were values lower than 0.05 gotten through the Chi-square test. Qualification had an influence on pharmacovigilance knowledge and gave significant p-values of 0.010 in pharmacists, 0.010 in specialists, 0.000 in general practitioners and 0.000 in nurses. The influence of qualification on pharmacovigilance attitudes gave a significant p-value of 0.010 in specialists and 0.040 in dentists. The qualification of personnel involved in the study showed hospital personel 101 (62.3%) very highly represented as shown in Table 3.

	Pharmacy		Hospital		PCRSs		Total
Population	50(30.9 %)		101(62.3 %)		11(6.8 %)		162
Qualification/ Profession	Advanced level	4(8 %)	Midwife	6(5.9 %)	Supervisor	11(100 %)	
	Pharm tech	3(6 %)	Nurse	30(29.7 %)			
	Bachelors	4(8 %)	Dentist	10(9.9 %)			
	Pharm D	39(78 %)	G.P	47(46.5 %)			
			Specialist	8(7.9 %)			

Table 3: Population and Qualification.

The work experience registered for the health personnel was elaborated in table 4 where nurses and midwives have the greatest number of years of experience. The influence of work experience on pharmacovigilance knowledge gave a significant p-value of 0.010 where work experience was <5 years among pharmacy personnel and 0.040 where work experience was between 10 to 14 years among hospital personnel.

	Work experience	<5years	5-10 years	11-15 years	16-20 years	>20 years	All
	Pharmacist	35	1	2		1	39
Pharmacy	Bachelors	2	1	1			4
	Pharmacy tech	2	1				3
	A/L	1	2	1			4
	Total	40	5	4		1	50
Hospital	Specialist	1	7				8
	G. P	44	3				47
	Dentist	8				2	10
	Nurse	8	10	6	1	5	30

	Midwife	1	2	1		2	6
	Total	62	22	7	1	9	101
Pharm company	Supervisor	3	1	5	1		11

Table 5: Work experience of the Population An appreciation of study area.

The health professionals were questioned on where they got their training. The idea was based on a presentation of either in country (local) or out of the country (foreign). Site of study influenced pharmacovigilance attitudes gave a significant p-value of 0.030 when pharmacy personnel studied locally, 0.030 when pharmacy personnel studied in another country, 0.030 when hospital personnel studied in another country, and 0.030 when they studied locally. Pharmacovigilance practice was influenced by site of study giving a significant p-value of 0.030 where the pharmacy personnel studied in another country.

The illustration of the study area of the health professionals is shown in Figure 1.

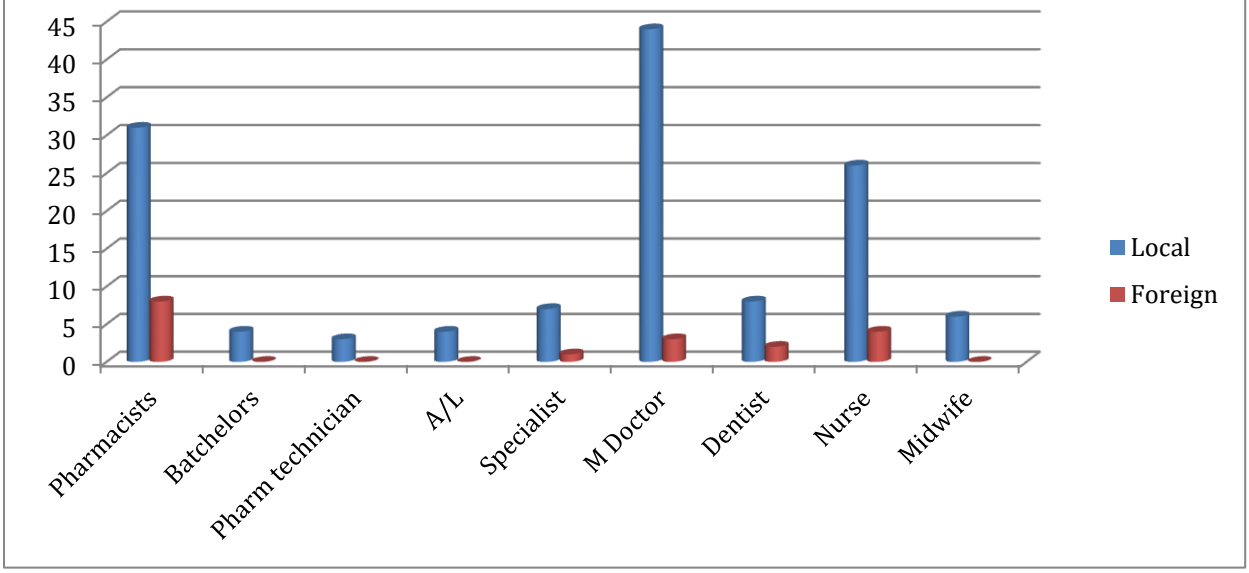

Figure 1: Study area of Hospital and Pharmacy personnel.

Descriptive analysis of questionnaires

General knowledge among study populations: The results of a detailed analysis of the Knowledge questions among the three study populations, is demonstrated in Table 6 with the percentage of correct responses seen in each case.

	Hospital	Pharmacy	PCRS	All
Def of Pharmacovigilance	78(77 %)	41(82 %)	10(90.90 %)	129(79.6 %)
Actors in Pharmacovigilance				
Pharmacist	88(87.1 %)	48(96 %)	10(90.9 %)	146(90.1 %)
Physician	64(63.4 %)	31(62 %)	10(90.9 %)	105(64.8 %)
Dentist	62(61.4 %)	28(56 %)	9(81.8 %)	99(61.1 %)
Nurse	54(53.5 %)	27(54 %)	7(63.6 %)	88(54.3 %)
Patient	53(52.5 %)	26(52 %)	5(45.5 %)	84(51.9 %)
Sales representatives	49(48.5 %)	24(48 %)	5(45.5 %)	78(48.1 %)
Total	370(61.1 %)	184(61.3 %)	46(69.7 %)	600(64 %)

Objective of Pv	88(87.1%)	49(98%)	11(100%)	148(91.4%)
Def of ADR	61(60.4%)	33(66%)	5(45.5%)	99(61.1%)
AE Qualification for reporting				
Unexpected AE	61(60.4%)	28(56%)	6(54.5%)	95(58.6%)
All supected AE	30(29.7 %)	19(38 %)	6(54.5 %)	55(33.9 %)
Severe AE	12(11.9 %)	9(18 %)	1(9.1 %)	22(13.6 %)
Expected AE	12(11.9 %)	1(2 %)	1(9.1 %)	14(8.64 %)
Total	115(28.5 %)	57(28.5 %)	14(31.8 %)	186(29.6 %)
Awareness of a Drug Reg Authoriy	69(68.3 %)	44(88 %)	11(100 %)	124(76.5 %)
Name: DPML	20(19.8 %)	27(54 %)	10(90.9 %)	57(35.2 %)
Constant supply of ADR forms to medical personnel			11(100 %)	11(100 %)
ADR form Supplier				
Pharmaceutical sales representatives			10(90.9 %)	10(90.9 %)
Ministry of Health representatives			2(18.2 %)	2(18.2 %)
Total	801(52.9 %)	435(58 %)	130(65.7 %)	1366(55.4 %)

Table 6: Knowledge.

The results above can be summarized by analyzing the percentage response in each of the study populations. This gave 52.9 % in hospital personnel, 58 % in pharmacy personnel and 65.7 % in PCRSs. This can be illustrated comparatively as seen in Figure 2 below.

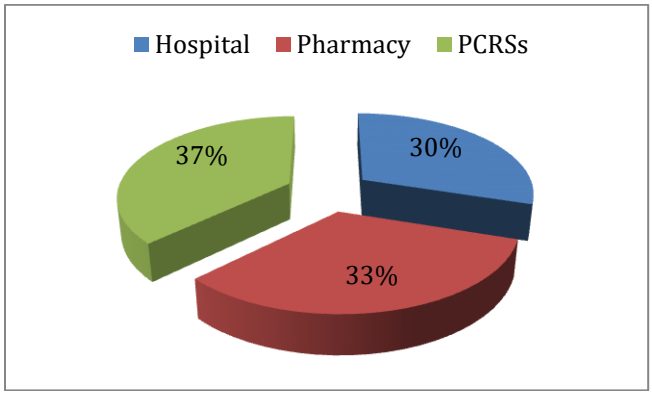

Figure 2: General Plot of Knowledge among Study Populations.

General Attitudes among study populations: The correct responses for attitudes questions among hospital personnel, pharmacy personnel, and PCRSs although not the same for all the populations, is presented in Table 8.

	Hospital	**Pharmacy**	**PCRS**	**ALL**
Appreciation of ADR form	29(28.7 %)	26(52 %)		55(36.4 %)
In Possession of ADR forms	5(5.0 %)	9(18 %)		14(9.3 %)
Importance of Pv	98(97.0 %)	49(98 %)		147(97.4 %)
Causal Relationship	90(89.1 %)	46(92 %)		136(90.1 %)
Reaction as a Health Professional				
Stop administration of drug	70(69.3 %)	44(88 %)	6(54.5 %)	120(74.1 %)
Change treatment therapy	36(35.6 %)	14(28 %)	1(9.1 %)	51(31.5 %)

Fill and submit ADR forms	13(12.9 %)	11(22 %)	10(90.9 %)	34(21 %)
Inform drug rep	10(9.9 %)	9(18 %)	2(18.2 %)	21(12 %)
Total	**129(31.9 %)**	**778(39 %)**	**19(43.2 %)**	**226(38 %)**
Drug representatives sensitize on Pv			11(100 %)	11(100 %)
Type of ADR forms made available				
Company forms			10(90.9 %)	10(90.9 %)
Ministry of Public health forms			2(18.2 %)	2(18.2 %)
Frequency of ADR form supply				
Made available after a request			6(54.5 %)	6(54.5 %)
Constantly supplied without specific request			5(45.5 %)	5(45.5 %)
Total	**351(43.4 %)**	**208(52 %)**	**53(53.3 %)**	**612(46.8 %)**

Table 7: Attitudes.

In view of evaluating the attitudes of the hospital personnel, pharmacy personnel and PCRSs, the response rates were taken into consideration and analyzed giving a total 43.4 % for hospital personnel, 52 % for pharmacy personnel, and 53.3 % for PCRSs. Figure 3 illustrates these differences elaborately.

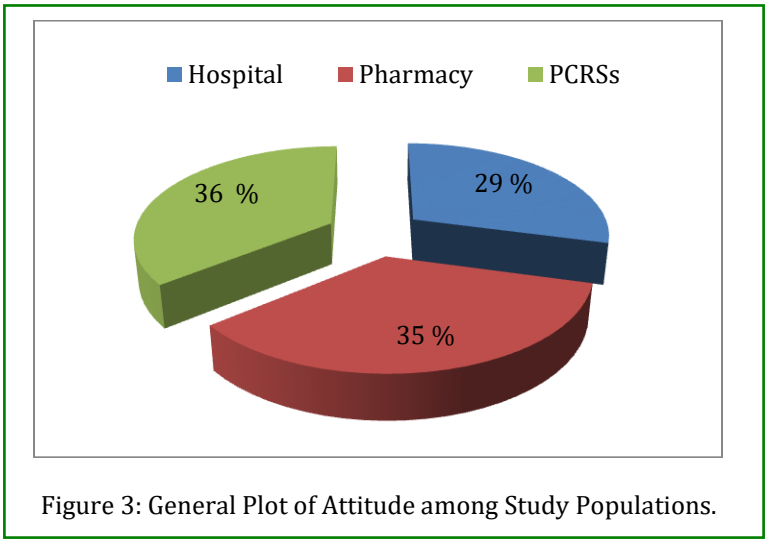

Figure 3: General Plot of Attitude among Study Populations.

General practice among all study populations: Analysis of the correct responses for practice questions among hospital and pharmacy personnel yielded the results presented in Table 8.

Variable	Hospital	Pharmacy	ALL
Participated in Pv	7(6.9 %)	13(26 %)	20(13.2 %)
Available forms			
Pharm Company forms	6(5.9 %)	5(10 %)	11(7.3 %)
Min of Health forms	1(1 %)	8(16 %)	9(6 %)
Actors Involved			
Pharm sales representatives	6(5.9%)	5(10%)	11(7.3%)
Public Health Rep	1(1%)	5(10%)	6(4%)
Other sources		3(6 %)	3(2 %)
Expectations after Pv reporting			
Instructions from NCPV	43(42.6 %)	30(60 %)	73(48.3 %)

Information about the drug	35(34.7 %)	24(48 %)	59(39.1 %)
Safety Alert	19(18.8 %)	13(26 %)	32(21.2 %)
Withdrawal of the product	15(14.9 %)	9(18 %)	24(15.9 %)
Modification of the leaflet	12(11.9 %)	9(18 %)	21(13.9 %)
Total	**124(24.6 %)**	**85(34 %)**	**209(29.3 %)**
Pharmacovigilance Sensitization	49(48.5 %)	14(28 %)	63(41.7 %)
Total	**194(17.5 %)**	**138(25.1 %)**	**332(20 %)**

Table 8: Practice of Hospital and Pharmacy Personnel.

In comparing the practice rates among the pharmacy personnel, hospital personnel and PCRSs, 25.1 % was observed for pharmacy personnel, 17.5 % for hospital personnel and 44.6 % for PCRSs. This could be better understood as demonstrated on Figure 4 below.

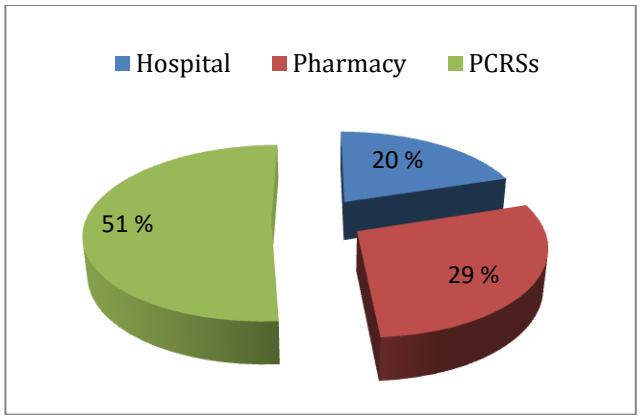

Figure 4: General Plot of Practice among Study Populations.

General skills : In a bit to demonstrate the skills in pharmacovigilance for each population, the hospital personnel were seen to have 39.1 %, pharmacy personnel 45.9 %, and PCRSs 54.1 %. A comparative illustration was made in Figure 5 which better describes this.

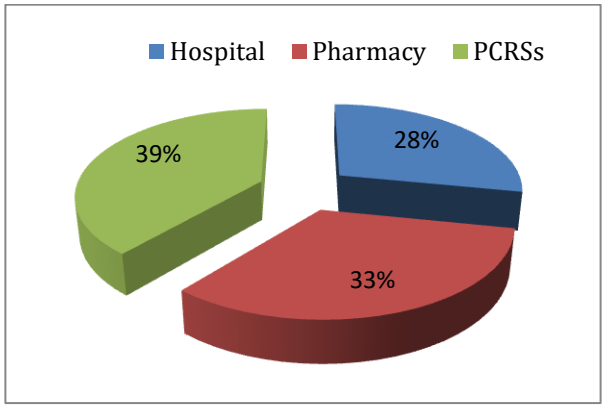

Figure 5: General Plot of Skills among Study Populations.

Practice of community pharmacy and hospital personnel: Practice was assumed to be very timid among pharmacy personnel since 49 people (98 %) of the population scored very low and 1 person (2 %) had inadequate practice. The pie chart below demonstrate the practice of pharmacovigilance to be seen to consist of 88 people (87 %) having a poor practice, and 12 people (11.9 %) with inadequate practice. These two scores sum to give 100 people or 99 % of the population presenting poor practice (Figure 6). Only 1 person had an average performance.

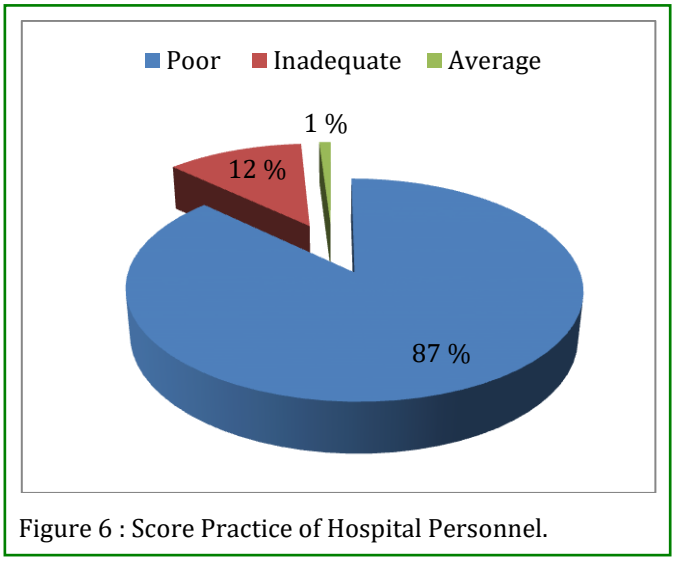

Figure 6 : Score Practice of Hospital Personnel.

Skills: Almost half of the population of pharmacy personnel particularly 45.4 % had very weak level of skills in Pharmacovigilance; 23.4 % had inadequate skills; 21.2 % of the population had average or acceptable skills and only 10 % of the population had good pharmacovigilance skills. As seen in figure 6,7.

In Figure 6 and 7, an average of 45% and 32.7 people respectively had very weak level of skills in Pharmacovigilance; 24% and 37.3 people had inadequate skills; about 21% and 17% people had average or acceptable skills and only an average of 10% 14% had good pharmacovigilance skills (Figure 6 and & 7).

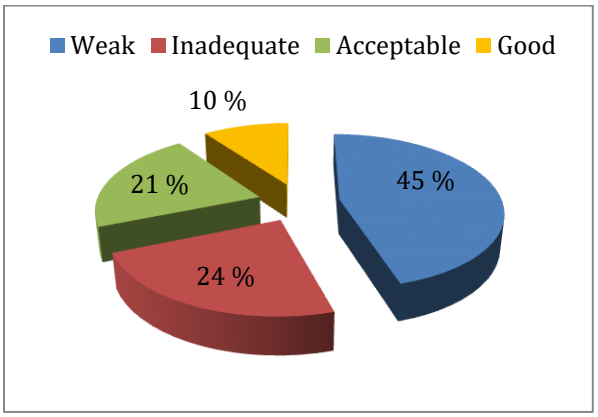

Figure 6: Pharmacy personnel.

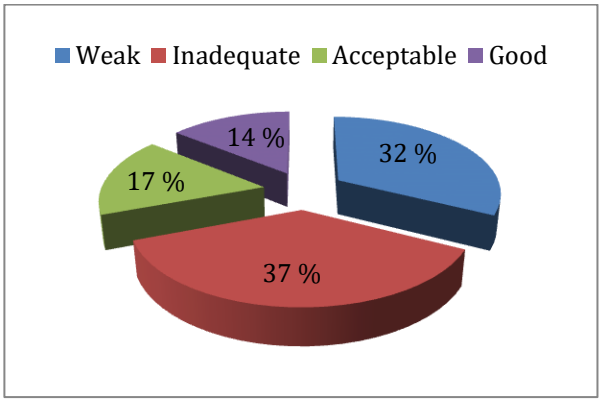

Figure 7: Hospital personnel.

Discussion

The study was focused on the appreciation of Pharmacovigilance by hospital personnel at Central Hospital Yaoundé and Pharmacy personnel in the Mfoundi district. In a bid to appreciate this behavior, a questionnaire comprising questions on knowledge, attitudes and practices was auto administered to public health actors who concerted to participate. This was done with the aim of involving a representative sample of all health care professionals. These populations were subdivided according to various qualifications. Hospital personnel comprised of 8 (7.9 %) Specialists, 47(46.5 %). General practitioners; constituting the highest number of participants. 10(9.9 %) Dentists, 30(29.7 %) Nurses and 6(5.9 %) midwives.

According to the appreciation of Fokunang *et al*. [40]. in 2017 in Cameroon, the required distribution proportions of personnel in hospitals was taken into consideration in this study but not at the same percentages. It was seen that 80 %(n=40) of the pharmacy population had below 5 years of work experience. The left over 20 %(n=10) was split in two with 10 % falling within the range of 5- 10 years' work experience, 8 % falling within the range 11-15 and 2 % having over 20 years work experience. Hospital personnel had 61.4 % (n=62) with less than 5 years of work experience, 21.8 % (n=22) falling within the range of 5- 10 years' work experience, 6.9 % (n=7) of the population falling within 11- 15 years of experience. 8.9 % (n=9) had over 20 years of experience and only 1 person had experience between 16-20 years. Pharmaceutical companies supervisors on the other hand had their highest population of 45.5 % (n=5) with 11-15 years' work experience, 27.3 % (n=3) had less than 5 years' work experience and 9.1 % fell within the 5-10 year range and the 16-20 year range.

The number of years in service was seen to affect the pharmacovigilance behavior particularly in the aspect of knowledge as seen in Toklou and Uysal [41]. in 2008 in Turkey where Pharmacy personnel had a significant p-value of 0.01 for those with less than 5 years of work experience. With regard to pharmacovigilance reporting, this study is one of the first to assess the knowledge, attitudes and practices of the Cameroonian health systems. The majority of people could define pharmacovigilance, precisely 77 % of Hospital personnel, 82 % of pharmacy personnel and 90% of PCRSs. The study conducted by Toklou and Uysal [41]. in 2008 in Turkey had contrary results with the minority being able to answer positively. The difference in responses can be attributed to the fact that they had open questions for pharmacists to reason out for themselves, thus raising difficulty. Our case served as a reminder to most of the professionals.

The Uppsala Monitoring Centre as well as the Ethiopian Pharmacovigilance center justifies the intervention of general practitioners and specialists, pharmacists, dentists, midwives, nurses, manufacturing companies and patients in pharmacovigilance reporting [17-21]. In our study 61.1 % Hospital personnel, 61.3 % of Pharmacy personnel and 69.7% PCRSs had the right appreciation of the actors involved. According to Fokunang *et al.* [40]. in 2014, 44.7 % of their population knew these actors. This has improved to 64 % in the present case. The DPML presented 3 actors as having participated in Cameroon in recent years. These were medical doctors, pharmacists and nurses. The objective of pharmacovigilance as seen in the study conducted by Wysowski and Swartz [22]. in 2005 was clear to the majority of personnel with a general appreciation of 91.4 %.

Less than half of the general population (29.6 %) was able to identify all the adverse events expected to be reported.

Results from Fadare *et al.*[43]. in Nigeria in 2011 show that; a majority (>70 %) of the respondents were aware of the adverse events to report. This was much higher than our case, probably because as seen in Uppsala records [13,24-27]. Nigeria who got implicated in reporting since 2004 is more mature than Cameroon who got involved only in 2010. About three quarters of the population (76.5 %) knew we have a drug regulatory authority in Cameroon, but only 35.2 % knew its name. In a study conducted by Srinivasan *et al* .[44].

In India in 2017, 59.5 % of their population knew their regulatory authority. The difference in level of activity of these authorities within the different countries defends these results Hospital personnel could be seen to have an above average score of 60 % though 6 % of the population have very poor knowledge, 34 % have insufficient knowledge, 25 % have mediocre and only 35 % have good knowledge. This appreciation is not bad but will improve drastically if there is more divulgation of pharmacovigilance [28-30].

Over half the population of pharmacy personnel (58 %) present poor knowledge where bad knowledge constituted 30 % and insufficient knowledge was 28 %. 30 % of these personnel had an average score and finally just 12 % could present with good knowledge of pharmacovigilance. These results give a reason for their low intervention in pharmacovigilance activities contrary to what is expected. The attitudes regarding Pharmacovigilance in our respondents were appreciated as follows;

Only 36.4 % of the health professionals had been opportuned to see the pharmacovigilance form. Pharmacy personnel had more access to this than hospital personnel with an average of 52 % as compared to 28.7 % in hospital personnel. But only 9 out of 50 pharmacy personnel had pharmacovigilance forms in their disposal and even less (n=5) were in possession among hospital personnel. This spells out the underreporting in our society since the health personnel do not even know the pharmacovigilance form. The necessity of pharmacovigilance reporting was seen by almost every respondent with a percentage total of 97.4 %. This was similar to the results of Palaian *et al*.[45]. in 2011 in Nepal and Gupta et a [46]. l in South India who found 96.6 % and 97 % response respectively.

In this study, the question on the expected reaction of health professionals had very low response level of 38 %. Hospital personnel made up only 31.9 %, pharmacy personnel made 39% and PCRSs who were suggesting what should be done, made only 43.2 %. The majority of health professionals selected 'stop administration' which was the first basic thing they do when faced with an adverse event. The next considered proposition was 'change of treatment therapy' where 35.6 % of hospital personnel and 28 % of the pharmacy personnel participated.

The availability of the pharmacovigilance forms was also questioned. 54.5 % of the PCRSs supported the idea that the forms are to be made available after being requested. 45.5 % were for the idea that the forms need be supplied constantly or without a specific request. These responses can be seen as the center of the pharmacovigilance sensitization problem since, if the health professionals are constantly supplied with pharmacovigilance forms, the interest to know what to do with them will be raised. The forms could then be used as a first step to the sensitization of pharmacovigilance.

Attitude scores bring out the Pharmacy personnel having the best attitudes with only 48 % having poor attitudes in pharmacovigilance. They had 8 % with harmful attitudes, 40 % erroneous, 34 % average and just 18 % good attitudes. These are poor results but comparatively better than the other populations. Hospital personnel had a poor attitude score of 69 % which is considerably higher than pharmacy personnel. The details include 4 % being harmful, 65 % having erroneous attitudes, 23.8 % presenting average attitudes and only 6.9 % had good attitudes in pharmacovigilance. They are also much less exposed to pharmacovigilance so this could be expected [31-35].

The hospital personnel and pharmacy personnel who have participated in pharmacovigilance make up just 20(13 %) people out of the total 151 health professionals in the study with 13 pharmacy personnel and just 7 hospital personnel. In similar studies conducted by Srinivasan *et al.*[44]. in 2017, and Palaian *et al.*[45] in 2011, they had 36.5 % and 33.7 % respectively of their populations who had participated in Pharmacovigilance reporting. These were also below average but they could still be considered as double our present state. This therefore proves the level of underreporting in Cameroon is much higher than that in India and Nepal [36].

The ministry of public health forms were used by 9 respondents being downloaded from the internet for 3 of the respondents and supplied by ministry of public health representatives for the other 6 respondents. In a study conducted by Toklou and Uysal [41]. in 2008, the health professionals acknowledged that difficulty in accessing forms is a great factor for underreporting. This is acknowledged in our case since those without access to forms do not end up reporting.

Only 29.3 % of the population thought all the propositions were worth expecting. From the WHO guidelines [1,2,37], pharmacovigilance reporting is encouraged when a reporter receives feedback from the authorities. This highlights the problem of health professionals not being well informed about pharmacovigilance reporting. Less than half of the health professionals (41.7 %) were of the opinion that the pharmaceutical sales representatives sensitize them on pharmacovigilance as declared by most of the pharmaceutical companies. This result adds more justification to the idea that the pharmaceutical companies are not fully playing their role in the pharmacovigilance system.

Our study in Yaoundé was done in three structures, two of which are health structures having personnel of different trainings and educational levels, hence causing a difference in perception. To address this problem, evaluation and scoring had to be done differently taking into account the appreciated difference in training and exposure to the topic. This study was conducted in only one hospital which gives a rough appreciation of health professionals in other hospitals and hence difficult to extrapolate the study findings to the entire country.

Conclusion

The objective of the study was; the investigation of the knowledge, attitude and in some pharmaceutical companies and among the public health actors, assessing the practice and procedures put in place for documentation of adverse drug reactions among health personnel, pharmacy staff, pharmaceutical company representatives and our drug regulatory authority. From the results we got during our study the state of knowledge among hospital personnel, pharmacy personnel in our Country was above average but cannot be rated as good.

This knowledge, if improved will have a better manifestation in the general behavior of health personnel towards pharmacovigilance. The pharmacovigilance attitude observed in the study was generally below average. Attitudes which develop after knowledge has been gained, could not give better results than this seeing the level of knowledge the population had. Pharmacovigilance practice yielded results far below average for all the populations studied. This could be accounted for by the lack of legislation which could motivate pharmaceutical companies to do their part in improving the situation. The study therefore justified the hypothesis since little knowledge, gave rise to less attitudes and consequentially much less practice. At the end of this study, we can conclude that there is a great need for the pharmacovigilance system in Cameroon to be developed through a more rigorous sensitization programmes.

References

1. World Health Organization (2002) The Importance of Pharmacovigilance Safety Monitoring of medicinal products. World Health Organization 1-48.
2. World Health Organization (2015) WHO pharmacovigilance indicators A practical manual for the assessment of pharmacovigilance systems. World Health Organization 1-84.
3. Gagnon S, Schueler P, Fan Dachao J (2012) Global Clinical TRials Playbook. 1st ed ICON Clinical Research North Wales Pennsylvania USA 320 p.
4. Forbuzshi AF (2011) Republique du Cameroon Profil Pharmaceutique du Pays. Yaounde Cameroon 1-223.
5. Saurabh N, Vrish DA (2018) Pharmacovigilance: An Overview. Int J Pharmacovigi 1-6.
6. Hughes J, Rees S, Kalindjian S, Philpott K (2011) Principles of early drug discovery. Br J Pharmacol. 162(6): 1239-49.
7. US FDA (2017) US FDA Drug Definitions Registrar Corp.
8. 2015 Biopharmaceutical R&D: The Process Behind New Medicines.
9. Wenslow R, Newman A (2016) Drug Development-Don't Overlook Key Preclinical Research.
10. DiMasi JA (2002) The Value of Improving the Productivity of the Drug Development Process. faster times and better decisions. Pharmacoeconomics 20(3): 1-10.
11. Campbell J, Gossell-Williams M, Lee M (2014). A Review of Pharmacovigilance. West Indian Med J. 63(7): 771-774.
12. Minsante (2013) Guide de Bonnes Pratiques de Pharmacovigilance au Cameroon DPML Yaounde.
13. (2008) U S FDA FDA Approves Allegra-D, Manufacturer to Withdraw Seldane from Marketplace.
14. Wysowski DK, Swartz L (2005) Adverse Drug Event Surveillance and Drug Withdrawals in the United States, 1969-2002: The Importance of Reporting

Suspected Reactions. Arch Intern Med. 2005 165(12):1363–9.

15. ICH Harmonised Tripartite Guideline (2003) Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting E2D. Post-approval Safety Data Management: Definitions and Standards for Expedited Reporting E2D P 15.

16. (2011) Guideline on pharmacovigilance practice Module VI- Management and reporting of adverse reactions to medicinal products. European Medicines Agency Report No.: EMA/873138/2011.

17. Liebler JG, McConnell CR (2012) Pharmacovigilance. Management Sciences for Health Personnel. Management for Health Sciences 19.

18. (2018) Uppsala Monitoring Centre. UMC Glossary. Uppsala Monitoring Centre.

19. Botting J (2002) The History of Thalidomide. Drug News Perspect. 15(9):604–11.

20. Vargesson N (2015) Thalidomide-induced teratogenesis: History and mechanisms. Birth Defects Res. 105(2):140–56.

21. (2018) U S National Center for Biotechnology. Practolol.

22. Essi MJ, Njoya O (2013) L'Enquête CAP (Connaissances, Attitudes, Pratiques) en Recherche Médicale. Enquete CAP En Rech Médicale 14(2): 1-3.

23. Fokunang C, Djousse C, Kechia F, Ngadou P, Abondo RMN, et al (2017) Pharmacovigilance Adverse Drug Reactions reporting: Knowledge, Attitude and Practice study among Health Professionals in Yaoundé, Cameroon. J Anal Pharm Res 4(6): 5.

24. Waller P (2011) An Introduction to Pharmacovigilance. The Atrium, Southern Gate, Chichester, West Sussex, PO19 8SQ, UK: wiley-blackwell; 120 p.

25. Wright P (1975) Untoward effects Associated with Practolol Administration: Oculomucocutaneous Syndrome. Br Med J 1(5958): 595-8.

26. Abraham J, Davis C (2006) Testing times: The Emergence of the Practolol Disaster and its Challenge to British Drug Regulation in the Modern period. Soc Hist Med 19(1): 127-47.

27. Sibbald B (2004) Rofecoxib (Vioxx) voluntarily withdrawn from market. CMAJ Can Med Assoc J.171(9):1027–8.

28. (2009) WHO collaborating centre for international drug monitoring. Dictionary of Pharmaceutical Medicine 193-193.

29. Edwards IR, Aronson JK (2000) Adverse drug reactions: definitions, diagnosis, and management. Lancet 356(9237): 1255-9.

30. Doogue MP, Polasek TM (2013) The ABCD of Clinical Pharmacokinetics. Ther Adv Drug Saf 4(1): 5–7.

31. Malcom R, Thomas NT (2010) Fundamental Concepts and Terminology, in Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications Baltimore(Ed) P 17-45.

32. Fadare JO, Enwere OO, Afolabi AO, Chedi BAZ , Musa A (2011) Knowledge, Attitude and Practice of Adverse Drug Reaction Reporting among Healthcare Workers in a Tertiary Centre in Northern Nigeria. Trop J Pharm Res 10(3): 242.

33. Food, Medicine and Healthcare, Administration, Control Authority (2014) Guideline for Adverse Drug Events Monitoring (Pharmacovigilance). 3ed edition. Ethiopia P 37.

34. Bjornsson TD, Callaghan JT, Einolf HJ, Fischer V, Gan L, Grimm S, et al (2003) The Conduct Of In Vitro And In Vivo Drug-Drug Interaction Studies: A Pharmaceutical Research And Manufacturers Of America (PhRMA) Perspective. Drug Metab Dispos 31(7): 815-32.

35. Horn JR, Hansten PD, Chan LN (2007) Proposal for a New Tool to Evaluate Drug Interaction Cases. Ann Pharmacother 41(4): 674-80.

36. Srinivasan V, Sheela D, Mridula D (2017) Knowledge, Attitude, and Practice of Pharmacovigilance Among the Healthcare Professionals in A Tertiary Care Hospital - A Questionnaire Study. Biomed Pharmacol J 10(3).

37. Palaian S, Ibrahim MI, Mishra P (2011) Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal. Pharm Pract 9(4):228-35.

38. Perucca E (2006) Clinically relevant drug interactions with antiepileptic drugs. Br J Clin Pharmacol 61(3): 246-55.

39. Rajan TV (2003) The Gell–Coombs classification of hypersensitivity reactions: a re-interpretation. Trends Immunol 24(7): 376-9.

40. (2002) Comment élaborer et mettre en oeuvre une politique pharmaceutique nationale - Deuxième édition. 2nd ed. Cameroon P 104.

41. Hauben M, Zhou X (2003) Quantitative Methods in Pharmacovigilance. Drug Saf 26(3): 159-86.

42. Hugman B (2006) The Erice Declaration: The Critical Role of Communication in Drug Safety. Essential Medicines and Health Products Information Portal. 29(2).

43. Collet J, MacDonald N, Cashman N, Pless R (2000) Monitoring signals for vaccine safety: the assessment of individual adverse event reports by an expert advisory committee. Advisory Committee on Causality Assessment. Bull World Health Organ 78(2): 178-85.

44. Pugatch M, Torstensson DD, Laufer M (2015) The Evolution of Pharmacovigilance. Oxon Pugatch Consillium P 42.

45. Sangeleer M, (2012) Be (pharmaco)vigilant! Important changes in the PV-legislation Belgian Association of Pharmaceutical Physicians.

46. Toklu HZ, Uysal MK (2008) The knowledge and attitude of the Turkish community pharmacists toward pharmacovigilance in the Kadikoy district of Istanbul. Pharm World Sci 30(5): 556-62.

47. Gupta SK, Nayak RP, Shivaranjani R, Vidyarthi SK (2015) 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. 6(1): 45-52.

48. Fouda AM (2018) Communique de presse no:D13-95. Yaoundé: Ministère de la Sante Publique, Direction de la Pharmacie du Medicament et Laboratoires.