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Comparative Perception of Pharmacovigilance by Physicians versus Paramedical Professions in Ivory Coast

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Abstract

Objective: To assess the perception of pharmacovigilance by healthcare professionals practicing at the University Teaching Hospital of Cocody (Ivory Coast) in 2017. **Methodology:** A descriptive and analytic cross-sectional survey has been conducted in 2017 at the University Teaching Hospital of Cocody. This survey involved a sample of healthcare professionals practicing in 17 services who are prescribing medications and gave their oral consent. **Results:** A response rate of 54.08% (106/196) among physicians versus 43.87% (86/196) for the nurses and 27.61% (21/76) for the mid-wives. 57.94% (62/107) of paramedics versus 94.33% (100/106) of physicians had already heard about pharmacovigilance, during their basic training (40.18% of paramedics versus 73.58% of doctors). However, the main obstacles to the practice of pharmacovigilance were it teaching hours considered insufficient (94.39% of paramedics versus 75.47% of physicians), the lack of knowledge on the location of the pharmacovigilance unit (80.37% of paramedics versus, 40% of physicians) and the reporting of the adverse drug reactions to a hierarchical supervisor (60.60% of paramedics versus 37.25% of physicians). A regular visit of pharmacovigilance monitors in the hospital services (34.57% of paramedics versus 29.24% of physicians) and the availability of reporting forms (30.84% of paramedics versus 27.35% of physicians) could improve the perception of pharmacovigilance by the healthcare professionals. **Conclusion:** Our investigational survey has highlighted some factors that may influence the perception of pharmacovigilance by the healthcare professionals in Ivory Coast.

Keywords

Perception, Pharmacovigilance, Healthcare Professionals, Hospital

1. Introduction

Pharmacovigilance is an essential element of drug safety. Although it is a well-established activity in developed countries, it remains non-functional in Ivory Coast despite the existence of regulatory Acts organizing the National Pharmacovigilance System [1] [2] [3] [4]. The drawback has been the reporting of a small number of adverse drug reactions (ADRs) and the lack of reassessment of the benefit-risk ratio of the drugs commercialized in Ivory Coast. In this context, the Clinical Pharmacology Department of the University Teaching Hospital (CHU) of Cocody-Abidjan has implemented a local pharmacovigilance system which collects, evaluates and prevents ADRs at the CHU of Cocody. To be effective, this pharmacovigilance system requires the voluntary declaration of adverse drug reaction (ADR), especially those that are serious and/or unexpected in hospital. In this perspective, the contribution of health actors and the public to voluntary reporting is necessary. Indeed, when a drug is marketed, its safety profile is poorly known in real life as the drug is used in different subsets of people (children, pregnant women…) or different indications or dosages. So, the spontaneous reporting of ADRs by healthcare professionals would assess the safety profile because it is a surveillance method based on the aggregation, at the level of a territory, of ADR cases subsequent to their marketing authorization. In Ivory Coast, few studies have shown that ADRs are poorly reported by healthcare professionals [5] and our study is the first to focus on the perception of pharmacovigilance at Cocody University Hospital Center (CHU). Also, to increase the number of adverse drug reactions (ADRs) notifications we were interested in the perception of the pharmacovigilance by the doctors, nurses and midwives of the CHU of Cocody. These healthcare professionals were targeted on the basis that: on one hand, they represented in 2017 the majority of healthcare personnel at the CHU of Cocody; on the other hand, because of their key role in prescribing, administering and monitoring the drugs.

Our main objective was to assess the perception of pharmacovigilance by the healthcare professionals practicing at the CHU of Cocody in 2017. The secondary objectives were to describe the professional characteristics of the targeted healthcare personnel, to determine their general knowledge on pharmacovigilance, to determine their expectations after reporting adverse drug reactions (ADRs) and to list the measures to be taken to stimulate such notifications.

2. Method

From March 15, 2017 to April 05, 2017, we conducted a descriptive and analytical cross-sectional survey in 17 services that prescribed medications (drugs) at the

CHU of Cocody. The included services were Ophthalmology, Pneumo-phtisiology, Digestive surgery, Urology, Stomatology, Otorhinolaryngology, Neurology, Rheumatology, Paediatric surgery, Traumatology, Gynecology, Hepato-gastroenterology, Intensive care, Paediatrics, X-ray (imaging) and a grouped-emergency services (Paediatric, Surgical, Gynecological and Medical).

2.1. Study Population

Our survey targeted the doctors, the nurses and the midwives who were working in those selected services and were prescribing medications (drugs) during 2017. We sampled the healthcare personnel from the administrative list of the CHU of Cocody. Thus, all the doctors, nurses and midwives assigned to selected services and present during the study period, regardless of their age, sex, nationality, hospital degree, year of professional experience, who gave oral consent were included in the study. On the other hand, the targeted healthcare professionals absent (with the exception of those on night shifts) or unassigned to the selected services at the time of the survey or who did not give consent nor complete the survey form were not included in the study.

2.2. Study Process

Firstly, we developed a standardized and anonymized questionnaire in the Department of Clinical Pharmacology from information of the literature reviews. The said questionnaire, after presentation and explanation to our healthcare professionals, was administered by the resident physician of the Clinical Pharmacology Department. In some cases, when the healthcare professionals were not available (lack of time, heavy workload, night shifts, etc.), the questionnaire was given to them for self-administration and then collected the following day by the resident physician of Clinical Pharmacology Department. The questionnaire was previously tested in the Medical and Gynecological emergency services of the CHU of Cocody in order to improve it. The questionnaire was based on bibliographic data which were adapted to our conditions of practice of medicine, nursing or midwifery. The improved questionnaire included, in the vast majority of cases, open-ended (closed) questions grouped into 5 broad variables, namely:

- The healthcare professionals characteristics (profession, name of the specific hospital services, professional title and year of professional experience);
- General knowledge on pharmacovigilance (level of knowledge, source of information, pharmacovigilance teaching hours in pre-doctoral training, existence and location of a pharmacovigilance unit at the CHU of Cocody, importance given to pharmacovigilance in practice);
- Reporting of adverse drug reactions (existence of ADRs in the hospital services, types of adverse reactions reported, reporting methods, motivation, reasons for non-reporting);
- The expectations of healthcare professionals after reporting an ADR;
- The Measures to boost the reporting of the ADRs.

2.3. Statistical Analysis

The collected data were entered on the EPI info7.4 software and processed by the statistical programme S.P.S.S. 17.0 (Statistical Package for the Social Sciences version 17.0). A Pearson Chi-square test was used to compare the results obtained with a significance level of less than 5%.

2.4. Ethical Considerations

In our study, we respected the anonymity of healthcare professionals and no activity of them was disturbed during working hours. In addition, we obtained the oral consent of all the targeted heads of departments (HODs) and a written authorization from the Director of the Medical and Scientific Department of the University Teaching Hospital of Cocody. Finally, no healthcare professional completed the questionnaire under coercion.

3. Results

3.1. Professional Characteristics

Of the 468 healthcare professionals surveyed (196 doctors, 196 nurses and 76 midwives), the response rate was 54.08% (106/196) among physicians versus 43.87% (86/196) for the nurses and 27.61% (21/76) for the midwives (Chi2 = 15.813, ddl = 2, $p < 0.001$, Table 1). These healthcare professionals are working mainly in the medical and surgical services (Table 1) and had a professional experience ranging from 1 to 10 years in most cases (Table 2).

3.2. General Knowledge on Pharmacovigilance

In our study, 94.33% (100/106) of physicians versus 57.94% (62/107) of paramedics (*i.e.* nurses and midwives) had significantly (Chi2 = 38.73, ddl = 1, $p < 0.001$) already heard about pharmacovigilance (Table 2), mainly during their basic training (73.58% of physicians versus 40.18% of paramedics; Chi2 = 24.206), ddl = 1, $p < 0.001$) with the pharmacovigilance teaching hours deemed sufficient by only 24.52% (26/106) of physicians versus 5.60% (6/107) of paramedics (Chi2 = 14.932, ddl = 1; $p < 0.001$). In addition, 48.11% (51/106) of physicians versus 16.63% (21/107) of paramedics were aware of the existence of the pharmacovigilance unit (Chi2 = 19.312, ddl = 1, $p < 0.001$). This unit was correctly identified and located to the Clinical Pharmacology Department by 90.19% of physicians versus 47.61% of paramedics. In addition, 54.71% (58/106) of the physicians versus 48.59% (52/107) of the paramedics considered pharmacovigilance very important in their daily practices ((Khi2 = 0.798, ddl = 1, $p < 0.30$) as shown in Table 2.

3.3. Reporting of Adverse Effects

In our survey, 68.86% (73/106) of the responding physicians versus 59.81% (64/107) of the paramedics indicated to have come across an adverse event (Chi2 = 1.903, ddl = 1, $p < 0.10$), mostly ADRs (Table 3). These events were reported

Table 1. Distribution of health professionals by services.

	Nurses (n = 196)		Midwives (n = 76)		Physicians (n = 196)	
Services	Responses	Percentages	Responses	Percentages	Responses	Percentages
Medicine**	36/60	60%	02/05	40%	44/68	64.7%
Surgery***	33/64	51.56%	04/07	57.14%	38/38	100%
Gynecology	00/00	00%	12/36	33,33%	12/20	60%
Paediatric	06/17	35.29%	02/27	0.07%	09/45	20%
Emergency service*	11/55	20%	01/01	100%	3/25	12%
Total	86	43.87%	21	27.61%	106	54.08%

*Emergency service: Emergencies of Medicine, Surgery, Gynecology and Paediatrics; **Medicine: Pneumophtisiology, intensive care unit, Rheumatology, Gastroenterology, Neurology; ***Surgery: Traumatology, Digestive Surgery, Urology, Ophthalmology, OtoRhino Laryngology, Stomatology, Paediatric Surgery.

by 69.9% (51/73) of physicians versus 76.74% (33/43) of paramedics (Chi2 = 0.641, ddl = 1, $p < 0.30$), mainly to an hierarchical supervisor (37.25% of physicians versus 60.60% of paramedics). The main causes of non-reporting by physicians and paramedics were the already known factor, the frequent occurrence or the benign nature of adverse events (Table 3).

3.4. Expectations and Measures to Stimulate Spontaneous Notification

After a report of the adverse drug reactions, a feedback (Table IV) was expected by 41.50% (44/106) of physicians versus 28.97% (31/107) of paramedics (Chi2 = 3.669; ddl = 1, $p < 0.05$). Also, the second expectation of the physicians (n = 32, 30.18%) represented by a specific code of conduct was the main expectation for the paramedics (n = 40, 37.38%) (Chi2 = 1.232, ddl = 1; $p < 0.20$). Nonetheless, the healthcare professionals surveyed recommended essentially a regular visit by the pharmacovigilance monitors in the prescribing services (29.24% of physicians versus 31.57% of the nurses and midwives) in order to stimulate the reporting of adverse drug reactions (Chi2 = 0.697, ddl = 1, $p < 0.30$). The availability of reporting forms was secondarily reported in 27.35% (29/106) of physicians versus 30.84% (33/107) of the nurses and midwives (Chi2 = 0.312, ddl = 1, $p < 0.50$) as shown in Table 4.

4. Discussion

Our survey was conducted among 106 doctors, 86 nurses and 21 midwives practicing at the CHU of Cocody in 2017. It was the first Ivorian study which described the perception of pharmacovigilance at the CHU of Cocody. It had some limitations mainly related to the availability of the healthcare professionals and the method of data collection (self-administered questionnaire or administered by the registrar of the Clinical Pharmacology Department). Apart from these limitations, the information gathered had made it possible to analyze the data

Table 2. General knowledge on pharmacovigilance.

Modalities	Paramedical staff (%)	Physicians (%)	P values
Already heard about pharmacovigilance			
Yes	62 (57.94)	100 (94.33)	<0.001
No	45 (42.06)	6 (5.66)	
Total	107	106	
Source of information			
Initial formation	43 (40.18)	78 (73.58)	<0.001
Colleague	11 (10.28)	8 (7.54)	
Media	4 (3.73)	10 (9.43)	
Physician	2 (1.86)	00	
Book	1 (0.93)	00	
Training workshop	1 (0.93)	4 (3.77)	
No answers	45 (42.05)	6 (5.66)	
Total	107	106	
Schedule volume of pharmacovigilance			
Enough	6 (5.60)	26 (24.5)	<0.001
Not enough	101 (94.3)	80 (75.4)	
Total	107	106	
Existence of a pharmacovigilance unit at Cocody Teaching Hospital			
Yes	21 (19.63)	51 (48.11)	<0.001
No	86 (80.37)	37 (34.90)	
No answers	00	18 (16.98)	
Total	107	106	
Importance of pharmacovigilance			
Not important	4 (3.73)	00	<0.30
Little important	12 (11.21)	6 (5.66)	
Important	23 (21.49)	42 (39.62)	
Very important	52 (48.59)	58 (54.71)	
No answers	16 (14.95)	00	
Total	107	106	
Seniority in the profession			
0 - 5 years	31 (28.97)	42 (39.62)	
6 - 10 years	23 (21.49)	27 (25.47)	
11 - 15 years	17 (15.88)	13 (12.26)	
>15 years	36 (33.64)	24 (22.64)	
Total	107	106	

Table 3. Reports of adverse events.

Modalities	Paramedical staff (%)	Physicians (%)	P values
	Have you ever experienced an adverse event?		
Yes	43 (40.18)	73 (68.86)	<0.001
No	64 (59.81)	33 (31.13)	
Total	107	106	
	Adverse event related to		
Drug	32 (74.41)	65 (89.04)	<0.02
Equipment	6 (13.95)	6 (8.21)	
Reagent	3 (6.97)	0	
Labile blood product	2 (4.65)	2 (2.73)	
Total	43	73	
	Was an adverse event declared?		
Yes	33 (76.74)	51 (69.86)	<0.30
No	10 (23.25)	22 (30.13)	
Total	43	73	
	If yes, did you report it?		
To a superior	20 (60.60)	19 (37.25)	<0.02
To the staff meeting	6 (18.18)	9 (17.64)	
In the patient's file	5 (15.15)	8 (15.68)	
To a colleague	1 (3.03)	00	
To the drugstore	1 (3.03)	2 (3.92)	
A the service of Pharmacology	00	10 (19.60)	
At the National Transfusion Center	00	1 (1.96)	
To pharmaceutical companies	00	2 (3.92)	
Total	33	51	
	If no, reasons for non-declaration		
Fréquent event	4 (44.44)	6 (27.27)	
Benign event	2 (22.22)	3 (13.63)	
Known event	1 (11.11)	10 (45.45)	
Not important event	1 (11.11)	1 (4.54)	
Lack of time	00	2 (9.09)	
No reason	1 (11.11)	00	
Total	09	22	

Table 4. Expectations after reporting an adverse event and steps to be taken to stimulate reporting.

Variables	Paramedical staff	Physicians
Expectations after reporting		
Feedback	31 (28.97)	44 (41.50)
A withdrawal from marketing	13 (12.14)	4 (3.77)
A health alert	15 (14.01)	15 (14.15)
Precise management	40 (37.38)	32 (30.18)
A modification of the instructions	8 (7.47)	10 (9.43)
Unspecified	00	1 (0.94)
Total	107	106
Measures to stimulate reportings		
Creation of a website	11 (10.28)	19 (17.92)
Availability of declaration forms	33 (30.84)	29 (27.35)
Regulars visits of the animators in the services	37 (34.57)	31 (29.24)
Feedback with precise management	26 (24.29)	26 (24.52)
Newsletter to prescribers	00	1 (0.94)
Total	107	106

relating to the socio-professional characteristics, the general knowledge on pharmacovigilance, the reporting of the ADRs and lastly, the expectations and measures to stimulate the spontaneous notification.

4.1. Socio-Professional Characteristics

In our survey, the physician's response rate (54.08%) was significantly different from that of nurses (43.87%) and of the midwives (27.61%) ($p < 0.001$). This rate (54.08%) was higher than that of the 2006 Ivorian survey (31.4%) conducted on a random sample of 500 practitioners extracted from the database of the approved drug prescribers of the "Mutuelle Générale des Fonctionnaires de Côte d'Ivoire (MUGEF-CI)" [5]. In contrast, the response rate of the targeted healthcare professionals in our study was lower than that reported in the literature [6]-[13]. This could be explained by the methodological differences and by the level, variables according to countries, and healthcare professional's awareness on pharmacovigilance. Moreover, in our work the physicians response was neither influenced by the service in which they work ($p = 0.593$) nor their seniority in the profession ($p = 0.309$); which was not the case for the nurses and midwives regarding their working service ($p < 0.001$) and years of experience ($p < 0.01$).

4.2. General Knowledge of Pharmacovigilance

In our study, most paramedics (n = 62; 57.94%) and physicians (n = 100; 94.33%) had previously heard about pharmacovigilance ($p < 0.001$) primarily through

their basic training (**Table 2**). Indeed, this training was the main source of information in 40.18% of the paramedics versus 73.58% of the physicians ($p < 0.001$). However, the volume of teaching hours of the pharmacovigilance module during the basic training was considered sufficient only by 5.60% (6/107) the paramedics versus 24.5% (26/106) of the physicians ($p < 0.001$). And so, any increase in the teaching hours of pharmacovigilance would be desirable in the basic training of healthcare professionals in Côte d'Ivoire. Similarly, a need for continuing education in pharmacovigilance was suggested in our survey because only 19.63% (21/107) of the paramedics versus 48.11% (51/106) of the physicians knew of the existence of a pharmacovigilance unit at the CHU of Cocody ($p < 0.001$). The lack of knowledge of this unit (especially by 80.37% of the paramedics) was an obsticle to the reporting of the adverse drug reactions and therefore a factor in favor of a poor perception on pharmacovigilance. Our situation was comparable to that described in a Saudi study [7], as well as in an Indian study [8]. In Saudi Arabia, 12.1% of doctors did not know the term "pharmacovigilance" and 62.2% of healthcare professionals did not know of the existence of a national pharmacovigilance center [7]. Similarly, in an Indian study [8], 77% of doctors had already heard about pharmacovigilance but only 6.6% could located the national pharmacovigilance center. An awareness of the practice of pharmacovigilance and continuous training could correct these results. In our study, apart from this lack of knowledge and the low teaching hours of pharmacovigilance, other factors of under-reporting of adverse drug reactions were highlighted.

4.3. Reporting of Adverse Drug Reactions

These included the non-compliance with the regulatory reporting procedures [1] [4] and the already known factor (déjà-vu) or the frequent occurence of the adverse drug reactions. In our study, the paramedical personnel (n = 43, 40.18%) and the physicians (n = 73, 68.86%) who had previously come across an adverse event, mainly linked to a drug (**Table 3**), for the most part, reported the events to a hierarchical supervisor (60.60% of the paramedics versus 37.25% of the physicians, $p < 0.02$). This was not in line with the Ivorian regulatory Act which oblige all healthcare professional to report an adverse reaction that could be due to a drug or health product to the National Pharmacovigilance Center [1] [4]. Since the latter only exists by the ministerial decree creating it [4], all adverse drug reactions occurring at the CHU of Cocody should have been reported to the Clinical Pharmacology Department. In addition, the main reason for non-reporting among the paramedics (n = 9) and the physicians (n = 22) was the frequent occurrence (4/9) or the already known (déjà-vu) factor (10/22) of the adverse drug reactions respectively. This was also not justified because all adverse drug reactions should be reported, especially those that are unexpected or serious [1]. These results were comparable to those found in several studies [6]-[13].

4.4. Expectations and Measures to Stimulate the Reporting Process

In our survey (Table 4), the expectations following a report of an adverse drug reaction by the paramedics (n = 107) and or the physicians (n = 106) were primarily a feedback and a specific code of conduct (actions) (66, 33% of the paramedics versus 71.69% of the physicians). These two main expectations, if they were systematically addressed through a personalized newsletter sent to the healthcare professionals would increase the reporting of the adverse drug reactions at the CHU of Cocody. Apart from the feedback, the healthcare professionals in our study recommended essentially a regular visit of pharmacovigilance monitors in hospital services (34.57% of the paramedical versus 29.24% of the physicians, $p < 0.30$) and the availability of the reporting forms (30.84% of the paramedics versus 27.35% of the physicians, $p < 0.50$). These measures were comparable to those reported in other studies [6]-[13] and reflected the involvement of healthcare professionals to improve the reporting of the adverse drug reactions at the CHU of Cocody.

5. Conclusion

Our investigation survey has revealed some factors that could explain the under-reporting of the adverse drug reactions. The main obstacles to the practice of pharmacovigilance were it teaching hours considered insufficient, the lack of knowledge on the location of the pharmacovigilance unit and the reporting of the adverse drug reactions to a hierarchical supervisor. A regular visit of pharmacovigilance monitors in the hospital services and the availability of reporting forms could improve the perception of pharmacovigilance by the healthcare professionals. In addition, a multicenter study with a larger staff size would refine the factors influencing the perception of pharmacovigilance by health professionals.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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