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Perception of Pharmacovigilance by Nurses and Midwives of the Cocody University Teaching Hospital in Abidjan

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Abstract

Objective: To assess the perception on pharmacovigilance by the nurses and midwives at the University Teaching Hospital (CHU) of Cocody in 2017. Methodology: Descriptive and analytic cross-sectional study conducted in 17 services of the University Teaching Hospital (CHU) of Cocody using an anonymized and standardized questionnaire. Results: The response rate was 39.33% for the 86 nurses and 21 midwives with at least 10 years of professional experience (50.6%). 57.94% of the respondents (n =62) have already heard about pharmacovigilance during their basic training (40.18%, n = 43). However, only 19.63% (21/107) of the respondents knew about the existence of a pharmacovigilance unit which they wrongly located to the pharmacy (11/21) of the CHU of Cocody. 40.18% of respondents (n = 43) had previously experienced an adverse drug reaction that was reported (76.74%, n = 33) to a hierarchical supervisor (60.60%, n = 20). The causes of non-reporting were either the frequent occurence (4/10) or the benign nature (2/10) of the adverse drug reaction. Specific actions to be taken (37.38%, n = 40) and a feedback (28.97%, n = 31) were the respondents' main expectations for the stimulation of the reporting system. They also wanted the pharmacovigilance monitors to regularly visit their services (34.57%, n = 37) and to provide them with the reporting forms (30.84%, n = 33). Conclusion: Our study has allowed us to highlight the lack of knowledge of the pharmacovigilance and to identify certain factors that could improve the perception of the pharmacovigilance by the nurses and the midwives in Ivory Coast.

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Keywords

Perception, Pharmacovigilance, Nurses, Midwives, Hospital

1. Introduction

According to WHO, pharmacovigilance is defined as the science and activities related to the detection, evaluation, understanding and prevention of the risk of adverse effects and any other problems related to the use of the drug [1]. Although it is a well-established activity in industrialized countries, it encounters difficulties in sub-Saharan Africa in its implementation. In Côte d'Ivoire, a West African country, the absence of a National Pharmacovigilance Center (NPVC) hampers the setting up of a national system of pharmacovigilance [2] [3]. In this context, the Clinical Pharmacology Department of the University Teaching Hospital (CHU) of Cocody records and evaluates the reports of the adverse drug reactions (ADRs).

However, these reportings are conducted exclusively by doctors at the CHU of Cocody. Hence, the need to understand the perception of the pharmacovigilance by the nurses and the midwives who are the paramedical personnel in Côte d'Ivoire.

Our study was the first to focus on the perception of the pharmacovigilance by the nurses and midwives practicing at the CHU of Cocody. It was justified, on one hand by the fact that nurses and midwives have regulatory obligation like any other healthcare professionals to report ADR in Côte d'Ivoire [2]. On the hand, by the fact that in 2017, nurses and midwives accounted for the majority of health care workers in the Ivorian health system [4]. The overall objective of our study was to assess the perception on pharmacovigilance by the nurses and midwives practicing at the University Teaching Hospital (CHU) of Cocody in 2017. The specific objectives were to describe the professional characteristics of the nurses and the midwives, to determine their general knowledge on pharmacovigilance, to determine their expectations (following an ADR report) and lastly, to identify the measures to stimulate their spontaneous notification.

2. Method

From March 15, 2017 to April 05, 2017, we conducted a descriptive and analytical cross-sectional survey at the University Teaching Hospital (CHU) of Cocody in all drugs prescribing services (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 nurses and midwives practicing in 2017 in any of the

hospital services where drugs were prescribed. From this source population, we selected from the administrative list of the paramedical staff at the CHU of Cocody a sample based on the oral consent and the physical presence. Indeed, periodic visits by one of physicians of pharmacology department according to an appointment calendars allowed, after the explanation of the questionnaire, to recruit the participants in their workplace. Thus, all nurses and midwives present during the study period regardless of their age, gender, nationality, year of professional experience as long as they have agreed to participate in the survey were included in the study. On the contrary, the nurses and the midwives employed in the selected services but absent (with the exception of those on night shifts) at the time of the survey or who did not give their consent or who did not complete the survey form were not included in the study.

2.2. Study Process

In a first step, we developed based on the literature reviews [5] [6] [7] [8], a standardized and anonymized questionnaire containing in the majority of cases open-ended (closed) questions. The questionnaire was designed on the classical model for assessing attitudes, knowledge and practice. It was, after validation at the Clinical Pharmacology Department, pre-tested in the Medical and Gynecological emergency services for improvement. Thereafter, the registrar of the Clinical Pharmacology Department made several rounds in the selected services to interview the nurses and midwives who were previously informed about the objectives of the study for the completion of the questionnaire. In some cases (lack of time, heavy workload, absence due to night shift, etc.), the questionnaires were given to the nurses and midwives for self-administration and then collected the following day. The perception of pharmacovigilance was evaluated from 13 questions grouped in 5 broad variables. It was:

- The professional characteristics (profession, name of the specific hospital service, and seniority in the position).
- General knowledge on pharmacovigilance (source of information, pharmacovigilance teaching hours in the basic 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 service, types of adverse reactions reported, reporting methods, reasons for non-reporting).
- The expectations of nurses and midwives after reporting an ADR.
- Measures to improve the rate of reporting of ADR by the nurses and midwives.

2.3. Statistical Analysis

The data was analyzed using the EPI info7.4 software for the capturing of the information and the S.P.S.S. program. 17.0 (Statistical Package for the Social Sciences version 17.0) for statistical analysis. A Pearson Chi-square test was used to compare the results with a significance level of 5%.

2.4. Ethical Considerations

When collecting the data, we respected the anonymity of the nurses and midwives and ensured that their activities were not disrupted during working hours. Moreover, we obtained the oral agreement of the Head of the services and the Unit Care Supervisors (UCS) of the selected services. In addition, a written authorization from the Director of the Medical and Scientific Department of the University Teaching Hospital of Cocody was obtained before the beginning of the study. Finally, no healthcare provider completed the questionnaire under coercion.

3. Results

3.1. Professional Characteristics of Nurses and Midwives

Of the 272 paramedics (196 nurses and 76 midwives) surveyed, only 39.33% (86 nurses and 21 midwives) voluntarily answered the questions (**Table 1**). They mainly worked in the service of internal Medicine (58.46%) and Surgery (52.11%) and had in the majority of cases (50.6%) a professional experience of less than 10 years (**Table 2**). The other primary information such as age, sex, specialty and place of residence were incorrectly entered on the questionnaire and could not be showed in a table.

3.2. General Knowledge on Pharmacovigilance by Nurses and Midwives

In our study, 57.94% (62/107) of paramedics (52 nurses and 10 midwives) had already heard of pharmacovigilance (Table 2), mainly during their basic training (43/107). However, only 5.60% (6/107) of these respondents were satisfied with the volume of hours allocated to the pharmacovigilance module (Table 2). In addition, 19.63% (21/107) of respondents were aware of the existence of a pharmacovigilance unit (Table 2) that they had pointed to be inside the pharmacy (11/21) of the University Teaching Hospital of Cocody or at the Clinical Pharmacology

Table 1. Distribution of nurses and midwives by services.

	Nurses (n = 196)		Midwives $(n = 76)$		
-	Responses	Percentages	Responses	Percentages	Percentages
Medicine**	36/60	60%	02/05	40%	58.46%
Surgery***	33/64	51.56%	04/07	57.14%	52.11%
Gynecology	00/00	00%	12/36	33.33%	33.33%
Pediatric	06/17	35.29%	02/27	0.07%	18.18%
Emergency service*	11/55	20%	01/01	100%	2.42%
Total	86	43.87%	21	27.61%	39.33%

^{*}Emergency service: Emergencies of Medicine, Surgery, Gynecology and Pediatrics; **Medicine: Pneumophtisiology, intensive care unit, Rheumatology, Gastroenterology, Neurology; ***Surgery: Traumatology, Digestive Surgery, Urology, Ophthalmology, Oto-Rhino-Laryngology, Stomatology, Pediatric Surgery.

Table 2. General knowledge on pharmacovigilance by paramedicals (nurses and midwives).

Modalities	Number of Paramedical staff	Percentages
	Already heard about pharmacovigilance	
Yes	62	57.94%
No	45	42.06%
Total	107	100%
	Source of information	
Initial formation	43	40.18%
Colleague	11	10.28%
Media	4	3.73%
Physician	2	1.86%
Book	1	0.93%
Training workshop	1	0.93%
No answers	45	42.05%
Total	107	100%
	Volume of hours to pharmacovigilance	
Enough	6	5.60%
Not enough	101	94.3%
Total	107	100%
E	xistence of a pharmacovigilance unit at Cocod	y teaching hospital
Yes	21	19.63%
No	86	80.37%
Total	107	100%
	Importance of pharmacovigilance	
Not important	4	3.73%
Little important	12	11.21%
Important	23	21.49%
Very important	52	48.59%
No answers	16	14.95%
Total	107	100%
	Seniority in the profession	
0-5 years	31	28.97%
6-10 years	23	21.49%
11-15 years	17	15.88%
>15 years	36	33.64%
Total	107	100%

Department (10/21). Furthermore, the paramedics (75/107) found pharmacovigilance important (21.49%) or very important (48.59%) in their daily practice (**Table 2**).

3.3. Reporting of Adverse Events by Nurses and Midwives

In our survey, 40.18% (43/107) of the paramedics had already come across an adverse event (**Table 3**), mainly an adverse drug reactions (32/43). They reported these events in 76.74% (33/43) of the cases to a hierarchical supervisor

Table 3. Reports of adverse event by nurses and midwives.

Modalities	Number of Paramedical staff	Percentages (%)
	Have you ever experienced an adve	erse event?
Yes	43	40.18
No	64	59.81
Total	107	100
	Adverse event related to	
Drug	32	74.41
Equipment	6	13.95
Reagent	3	6.97
Labile blood product	2	4.65
Total	43	100
	Was an adverse event declared?	
Yes	33	76.74
No	10	23.25
Total	43 100	
	If yes, did you report it?	
To a superior	20	60.60
To the staff meeting	6	18.18
In the patient's file	5	15.15
To a colleague	1	3.03
To the drugstore	1	3.03
A the service of Pharmacology	00	00
At the National Transfusion Center	00	00
To pharmaceutical companies	00	00
Total	33	100
	If no, reasons for non-declaration	1
Fréquent event	4	44.44
Bénin event	2	22.22
Known event	1	11.11
Not important event	1	11.11
Lack of time	00	00
No reason	1	11.11
Total	09	100

(20/33). The main causes of non-reporting of adverse drug reactions (**Table 3**) were related to their frequent occurrence (4/10) or their benign nature (2/10).

3.4. Expectations and Measures to Stimulate Spontaneous Notification

Specific instructions such a code of conduct (37.38%) and a feedback after reporting (28.97%) were the main expectations of our respondents (**Table 4**). They also wanted a regular visit of the pharmacovigilance monitors in their services (34.57%) and the provision of the reporting forms to stimulate a spontaneous reporting of adverse drug reactions (**Table 4**).

4. Discussion

The spontaneous notification is based solely on the will of the healthcare professionals, despite its mandatory nature in many countries, particularly in Côte d'Ivoire [1] [2]. It is, therefore, associated with the perception on pharmacovigilance by the same professionals. Our study had some limitations mainly related to how the data were collected (self-administered questionnaire or administered by the registrar of pharmacology) and the availability of paramedical personnel. However, it allowed us to collect 107 responses (39.33%) out of 272 total administered questionnaires. This response rate, lower than what is reported in the literature [5]-[10] highlights the difficulties encountered during the data collection.

Table 4. Expectations and steps to be taken to stimulate reporting by nurses and midwives.

Variables	Number of Paramedical staff	Percentages (%)
Expectations after reporting		
Feedback	31	28.97
A withdrawal from marketing	13	12.14
A health alert	15	14.01
Precise management	40	37.38
A modification of the instructions	8	7.47
Unspecified	00	00
Total	107	100
Measures to stimulate reportings		
Creation of a website	11 (10.28)	10.28
Availability of declaration forms	33 (30.84)	30.84
Regulars visits of the animators in the services	37 (34.57)	34.57
Feedback with precise management	26 (24.29)	24.29
Newsletter to prescribers	00	00
Total	107	100

4.1. Socio-Professional Characteristics of the Nurses and Midwives

In our study, the response rate of the paramedics varied significantly according to the profession (nursing or midwifery) ($\text{Chi}^2 = 6.058$, ddl = 1, P < 0.02) and the service in which they are working ($\text{Chi}^2 = 18.634$, ddl = 4, P < 0.001). This could explain the various level of their knowledge on pharmacovigilance. In addition, most of our paramedics (54/107) had a professional seniority of less than 10 years. This was not reported in several studies [5] [6] [7] [8] [9] in which the majority of nurses interviewed had more than 11 years of working experience.

4.2. Knowledge of the Pharmacovigilance by the Nurses and Midwives

In our survey, 57.94% (62/107) of paramedics had already heard of the term pharmacovigilance mainly during their basic training (**Table 2**). However, the pharmacovigilance teaching hours considered insufficient and reported by 94.39% (101/107) of the paramedics reflects the need for a continuous training. There was no significantly different relationship between having previously heard about pharmacovigilance and nurse or midwife status (p = 0.14) and hospital service (p = 0.124). On the other hand, there was a significant difference between having previously heard about pharmacovigilance and professional experience (p = 0.028). This professional experience was not statistically related to declaring pharmacovigilance as an important activity (p = 0.61).

Apart from that, 80.37% (86/107) of the paramedics in our study were unaware of the existence of the pharmacovigilance unit and wrongly located it at the pharmacy (11/21). This could be a barrier to reporting of the adverse drug reactions at the CHU of Cocody. Our results were comparable to those of a Saudi study [10] in which 62.5% of healthcare professionals said they did not know the term "pharmacovigilance". Furthermore, in two (2) Italian and Portuguese studies [6] [7], the nurses did not know the existence of the national pharmacovigilance system in 50% and 58.1% of cases respectively.

4.3. Declaration of the Nurses and Midwives

In our work, the ignorance of the reporting procedures was another factor that could negatively influence the perception on pharmacovigilance. In fact, the majority of the 33 respondent paramedics (n = 20, 60.60%) had reported the adverse drug reactions to their hierarchical supervisor and none of these events were reported to the pharmacovigilance unit. This did not comply with the Regulatory Act that creates the national pharmacovigilance system in Côte d'Ivoire [2]. Under these conditions, a special emphasis should be made on the procedural aspects of the Act if the desire is to increase the number of adverse drug reactions reporting at the CHU of Cocody. Furthermore, in our survey, 4 out of 10 respondent paramedics did not report the adverse drug reactions because of their frequent occurrence (Table 3). This was not justified because all adverse drug reactions should have been reported, especially those that are unexpected

or serious [2]. In an Italian study [6], the poor knowledge of the pharmacovigilance system, the fear of conflicts with doctors and the fear of legal reprisals were the main reasons for the under-reporting of the adverse drug reactions by nurses.

4.4. Expectations of the Nurses and Midwives and Actions to Be Taken

In our study, paramedics mainly expected a precise code of conduct and a feedback on a reported event (Table 4). In addition, to stimulate a spontaneous notification, most of the respondent paramedics had suggested a regular visit of the pharmacovigilance monitors in their different services (34.57%, n = 37) and the provision of the reporting forms (30.84%; n = 33) as shown in **Table 4**. These expectations and measures expressed by the paramedics show their interest to see the pharmacovigilance been practiced at the CHU of Cocody. This interest should be taken into account in the organization of awareness and continuous training in the practice of pharmacovigilance in Côte d'Ivoire (Ivory Coast). In fact, regular visits by pharmacovigilance monitors to hospital services could help staff paramedic to detect adverse drug reactions, to identify and resolve problems encountered by nurses and midwives in process of declaration of adverse drugs reaction and develop a special relationship with them. This attitude, coupled with the disponibility of the declaration forms, could positively influence the perception of pharmacovigilance by paramedical staff. Overwise, Feedback with precise management is an important device in pharmacovigilance. This feedback, which also mentions the responsibility or not of the suspected drug (s), should be included in the patient file and thus testify to the occurrence of the adverse drugs reaction.

5. Conclusion

Our study allowed us to identify factors that may influence the perception of the pharmacovigilance by the nurses and midwives. The main barrier to reporting of the adverse drug reactions at the CHU of Cocody were an insufficient hourly volume in pharmacovigilance at initial training, the ignorance of the existence of the pharmacovigilance unit and the lack of knowledge of reporting procedures. This could be improved with a continuous training of these paramedical personnel, regular contact with the pharmacovigilance monitors and a specific code of conduct to be followed in case of any occurrence of adverse drug reactions.

Conflicts of Interest

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

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