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DIAGNOSIS OF PHARMACOVIGILANCE DIFFICULTIES BY HEALTH PROFESSIONALS IN COTE D'IVOIRE

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ABSTRACT

An opinion study about pharmacovigilance was carried out to identify the reasons of under-reporting. The target population was health professionals. A randomized representative sample of 500 health professionals was selected from the database of 4000 prescribers and pharmacists approved by the public health insurance. The topics under consideration were training, experience, obstacles and suggestion to improve pharmacovigilance in Cote d'Ivoire. We obtained 31.4% of responders. Physicians represented 93.6% followed by dentists (5.7%) and pharmacists (0.7%). Most of them came from urban zones (94.2%) and worked in public hospitals (97.1%). Only 11.2% of participants had a pharmacovigilance training. Twelve (8%) had reported adverse drug reactions to pharmaceutical facilities (66.7%), to Health Minister (16.7%) and to Clinical Pharmacology Department (16.7%). According to them, the spontaneous reporting problems identified were the lack of knowledge about pharmacovigilance organization (69.1%), ignorance of interest in reporting (21.9%) or lack of training (5%). In order to improve the reporting system, health professionals suggested having report forms and phone numbers in hospital. They also suggested the involvement of the heath district (75%) in monitoring adverse drug reactions system. So pharmacovigilance should hold a salient place in health care system of Cote d'Ivoire and must be closer to health professionals to enhance reporting.

Key words: Knowledge - Spontaneous reporting - Opinion - Adverse drug reaction –Pharmacovigilance.

INTRODUCTION

Spontaneous reporting in Cote d'Ivoire remains embryonic in spite of the decades of pharmacovigilance activities to stimulate it. In 1988, the National Committee of Pharmacovigilance was created without any application decree (Order N° 249 MSP/DSPH of November 18, 1988). Then in 2000, pharmacovigilance unit was created inside the regulatory organ of drug, the Pharmacy and Drug Department (PDD). However, the national system of pharmacovigilance, which remains a need for public health, is inoperative (no systematic monitoring, no standardized report and centralized collection, no signal detection). Thus the management of alert situations remains non-objective and hesitant [1]. The local databases of pharmacovigilance are available in the Clinical Pharmacology Department of the Medical school of University Felix Houphouet Boigny (U-FHB), which performed passive and active pharmacovigilance activities. In 1989, the first local study was carried out as topic of thesis of medicine on amino-4 quinolines-induced prurit. Since this time, several specific, punctual and fragmented studies had been undertaken: either on pharmacovigilance, or on vaccinovigilance, hemovigilance and biovigilance [2]. The conclusions of these studies did not lead to any national decision-making. Since 2007, a readjustment of the pharmacovigilance texts has been under development. To understand why this reporting hardly takes off, an opinion study about the pharmacovigilance was conducted at a training campaign.

MATERIALS AND METHODS

Study context

The system of pharmacovigilance in Cote d'Ivoire is under the supervision of PDD. The existing texts are twenty years old. Despite, no dynamic structure was able to collect and give alert for new and unexpected effects. A Ministerial decree created the Committee of

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Pharmacovigilance (NCP) within the PDD in November 1988. The Office of Pharmacovigilance, which constitutes the secretariat of this NCP, is in charge of coordinating the collection of the reports coming from the eight Regional committees, performing the investigations decided by the NCP, preparing information to be diffused to the health professionals and to the population. Unfortunately, no regional Committee of Pharmacovigilance exist apart from the Clinical Pharmacology Department of U-FHB, which is the reference centre of the NCP. The regional committee is in charge of organizing the pharmacovigilance activities on the regional level. In this situation, the adverse drug reaction monitoring is entirely done by the Clinical Pharmacology Department. It made specific studies of pharmacovigilance in the absence of a systematic reporting, centralizing and computerizing, collecting and diffusing useful validated informations. This Department has introduced health professionals to pharmacovigilance practice since 1989. It ensures periodic visit to corresponding physicians in the target services of the three University Hospital Centres of Abidjan and has a database of pharmacovigilance, which is used as national database. This database contains 1700 reports in 2006.

Population of the study

A randomized sample of 500 physicians representatives of the different levels of the national health pyramid was drawn from the database of 4000 prescribers and pharmacists approved by the *Mutuelle Generale des Fonctionnaires et agents de l'Etat de Côte d'Ivoire (MUGEF-CI)*. This General insurance was created in 1973 to cover expenditure of health care needs of the civil servants and government officials and their eligible parties by a system of mutual help and solidarity. This public health insurance concerned 150,000 civil servants and cover 500,000 eligible parties. Since 2002, MUGEF-CI, extended not only its services to health care, medicines, but also covered death risk and retirement. The rate of reimbursement passed from 60% in 1975 to 70% since November 1986. These selected prescribers and dispensers approved by this insurance receive each year, between September and November, three days of continuing training about public health issues in our contexts (tuberculosis, malaria, bacterial infection, HIV/AIDS) and on the good practices of prescription and dispensation.

Administration of questionnaire

These selected physicians and pharmacists were invited by mail to a pharmacovigilance training. Before the beginning of this training, we performed a self-questionnaire of 12 questions about pharmacovigilance spread over 4 topics (training, experience in reporting, obstacles of reporting and suggestion to improve pharmacovigilance and sociodemographic data). This study was carried out for 18 days (between September 16th and December 2nd, 2006). Six groups were trained during this period.

RESULTS

Sociodemographic characteristics

We obtained 31.4% of respondents (157 participants). Table 1 shows the socio-demographic characteristics of the participants of this study. Physicians represented 93.6% followed by dentists (5.7%) and pharmacists (0.7%). They lived mostly in urban zones (94.2%) and they worked in public health hospitals (97.1%). Private structures represented 2.9%. The mean age with standard deviation was 41± 7.6 years old (ranging: 30 to 62 years). 42.4% of the participants were between 35 and 40 years old. Male predominance (90.4%) was noted with a sex ratio of 9.4. The mean experience year was 9.6± 7.6 (ranging: 1 to 34 years). Also, 67.6% had professional experience less than 10 years.

Training and experience

Only 11.2% of the participants said they had pharmacovigilance training. 44.1% of participants reported having followed this training less than 5 years before. They learned through these trainings the importance of good practices of prescription and security use, monitoring efficacy of drugs. They were also informed on drug safety. 12 professionals (8%) had reported adverse effects to pharmaceutical facilities (66.7%), to the Health Minister (16.7%) and to the Clinical Pharmacology Department (16.7%). These cases reported were transmitted orally (57.1%), by phone (28.6%), by letter (7.1%), by report form (7.1%) or by medical reports (7.1%). No case was reported by email.

Problems and suggestions

The notification problems according to them were due to the lack of knowledge about reporting system (69.1%), ignorance of the interest of notification (21.9%) or lack of training (5%). We noted that 1.4% of physicians had no opinion about spontaneous reporting. Furthermore, 2.1% of them were not available (lack of time) or didn't find necessary reporting Adverse Drug Reactions (ADR). More than fifty percent of the professionals (58.6%) had localised properly Clinical Pharmacology Department of the U-FHB and 6.4%, the pharmacovigilance unit of PDD. No professional knew that ADR reporting was compulsory in Cote d'Ivoire.

The health professionals suggested (n=83) that to improve the reporting system, report forms (75/83), phone or free phone number (60/83) should be available. They needed the involvement of the health district in the reporting system (60/83). They also suggested that pharmacovigilance organization, legislative rules or laws must be communicated and spread (80/83). In addition, they hoped (n=93) to receive responses to their questions. They also hoped that their report should be taken into account (90/93) for decision-making (80/93) or for carrying out some studies, expertise or researches (78/93). They needed help about drug information (efficacy, safety, effectiveness…) (87/93). Furthermore, they wanted to be

trained (93/93) and their awareness heightened (87/93). They wished to be informed about publications, or reglementary disposition on drug and other aspects of drugs as well.

COMMENTS

This opinion study showed that, the issue of pharmacovigilance in Cote d'Ivoire was organizational, structural and statutory on the one hand and on the other hand related to all the actors of this field.

At the structural and law level, pharmacovigilance is inoperative and not structured like in other African countries. Legal texts are not completed or not very explicit. Indeed, the decree of 1988 modified in 2000, creates a division of pharmacovigilance in PDD without any regional sections like in France. It doesn't give any precision about the organization and the operating mode of its network. The non-existence in hospitals of any person in charge of pharmacovigilance explains the anarchic transmitting of ADRs reports. The professional's salient reporting to the pharmaceutical industries is justified by their frequent contacts with pharmaceutical sale representatives who care about the safety of their products. They are proactive all the time in promoting their products.

So to improve the reporting system, professionals suggested that they should have easier available report forms and phones. Also, the health district should be involved. Indeed, the districts can be used as the essential link in the collection of the ADRs reported. The health district is the functional unit of our medical health pyramid. It can constitute the first step towards regional reporting systems. This will allow to make an exhaustive collection and permit proper decisions making at the national level. Also, the mobilization at the local level of drug committees of health care facilities could accelerate the implementation of the national system of Pharmacovigilance. Such system reduces under-reporting issues and necessarily leads to consensus decision. The responsibility of the health authorities is also involved. The failure of the organization of the sector is related to the lack of coherent statutory text, and a policy of sensitization and incentive for the professionals to get more involved [3]. So the design of complementary law text could encourage involve health professionals.

The issues involving actors are numerous. The pharmacovigilance system depends on health professionals. So to improve reporting, it must get close enough to them. In spite of their long years of medical experience (nine years), our health professionals are very little sensitized and trained on reporting. They were unaware of the principles and the concepts of pharmacovigilance. More than fifty (66%) of professionals were unable to locate the PDD and the Clinical Pharmacology Department, which took part in their initial medical course. May be that situation was due to a lapse of memory of the health professionals. As for the course of the initial training in medicine, the time devoted to pharmacogilance is four hours in the third year and two hours at the end of the medical courses (sixth year or bioclinic and therapeutic synthesis). In pharmacy and odontology this training is not done. Only 11.2% of the sample (approximately 2% of the health professionals in Cote d'Ivoire) had received training in pharmacovigilance in October 2005 at the time of a vast campaign of sensitization on pharmacovigilance initiated by our department and the PDD. This campaign concerned the regulation, missions, great concepts, tools and procedures of filling and reporting in pharmacovigilance. With these meetings of sensitization, professionals showed a real motivation, an interest and a curiosity for this new activity. The identified reasons of the under-notification related to experts agree with those of literature [2, 4-6]: firstly ignorance of the compulsory character of the reporting, then difficulties of diagnosis of the adverse drug reactions, fears and prejudice of doctors. Certain professionals fear sanctions or prosecution even if they report ADRs; finally the lack of motivation of the medical staff is real. They consider that it is an additional work, which must be paid. Actually, most of the time, the health authority is ignorant the public health interest to have a structured autonomous system of pharmacovigilance. In addition, Pharmaceutical sales representatives, often conduct campaigns of misinformation about the harmless character of their products. Their outcome is mainly commercial. They should have pharmacovigilant and public health behaviour. Health professionals wish to have a feedback to their questions and their report taken into account. To improve the notification, several solutions were proposed such as easy access to reporting forms; strengthen the network of pharmacovigilance correspondents; set up the policy of reporting ADRs by patients [4,7-8]. This approach is necessary to ensure the safe use of self-medication drugs and generic medicines. The World Health Organization (WHO) encourages this behaviour [9]. Therefore, constituting a mixed consultation team (doctor, trainee, nurse, student) could enhance reporting quality. A statistical analysis showed that nurses declared more cases of probable relationship (I3) and fewer case of doubtful relationship (I1) [10].

However this behaviour remained an important activity ignored by health professionals in their daily medical practice in Cote d'Ivoire. So we must necessarily be patient so that they acquire the reporting reflex. Educating, sensitizing and motivating must correct the inadequacy in our patients' care. For this reason, we recommend to PDD: - a) to work out a good practices of pharmacovigilance guideline and to ensure its large diffusion to all the health professionals and to patients, - b) to follow up and validate the legislative texts. The National Pharmacovigilance Centre have to be effective in order to be close to both health authorities and all actors of the field by appointing local reporters correspondents. This reference reporter will be the link between the health facilities and the NPC. He / She will be in charge of the

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collection of the report forms of his / her centre and to send them to the NPC toward health district. This responsibility would give an additional source of motivation; - c) It will be useful to send the report form to the prescribers, beforehand, at regular interval, - d) to provide communication materials as email address, a fax or a telephone for transmitting report cases, - e) to stimulate reporting by regularly organizing training seminars on pharmacovigilance and good practices of prescription and dispensation with all the actors of the health system (service or unit heads, doctors, pharmacists, unit care supervisors, nurses, midwives, nurse-assistances and students), - f) to work out monthly or quarterly free bulletin of information on drug, - g) to integrate the pharmacovigilance in the training courses by involving students in adverse effect report and providing help.

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Table 1. Socio-demographic profile of the prescribers and dispensers

Variables	n = 157	%
Profession		
- Physicians	131	93,6
- Dentists	8	5,7
- Pharmacists	1	0,7
- No data	17	10,8
Localization		
- Urban	129	94,2
- Rural	8	5,8
- No data	20	12,7
Type of office		
- Public	133	97,1
- Private	3	2,2
- Organization	1	0,7
- No data	20	12,7
Professional experience (years)		
- < 5	40	30,1
- [5-10[	50	37,5
- [10-15[	10	7,5
- [15-20[	12	9
- > 20	21	15,8
- No data	24	15,3
Age (years)		
- [30-35[	14	10,6
- [35-40[	56	42,4
- [40-45[	28	21,2
- [45-50[	11	8,3
- [50-55[	16	12,1
- > 55	7	5,3
- No data	25	15,9
Gender		
- Male	142	90,4
- Female	15	9,6

CONCLUSION

This study showed that our health professionals have long professional experience but a poorer knowledge about the usefulness of pharmacovigilance. The reasons of this lethargy are organizational, structural and statutory on the one hand and on the other hand related to the demotivation of all the actors of this field. Monitoring adverse drug reactions system must get in touch with health professionals, professional organization and patients for hence spontaneous reporting and should hold an important place in the health system of Cote d'Ivoire. We also think that, it could be a good idea to create an institute of Clinical Pharmacology to help the reporting grow.

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CONFLICT OF INTEREST:

The authors declare that they have no conflict of interest.

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