

Factors related to the knowledge of nursing professionals about pharmacovigilance

Fatores relacionados ao conhecimento de profissionais de enfermagem sobre farmacovigilância

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ABSTRACT

Objective: to verify the factors related to the knowledge of nursing professionals about pharmacovigilance. **Methods:** cross-sectional study, carried out with 271 nursing professionals, with university and school level, through convenience sampling. A questionnaire, consisting of two parts, was used: one about the sociodemographic and professional profile, and the other about knowledge in pharmacovigilance and the practice of reporting adverse events related to medications. The data were analyzed in a descriptive and inferential manner, through comparison and correlation tests, considering a significance level of 5%. **Results:** the knowledge score showed statistical differences in relation to professional training, function performed in the institution and the age of the professionals, while the practice of notifications did not obtain significantly statistical differences. **Conclusion:** the factors related to the knowledge in pharmacovigilance of nursing professionals were professional training, the role played in the institution and the age of the professionals.

Descriptors: Pharmaceutical Preparations; Drug Utilization; Pharmacovigilance; Patient Safety; Nurse Practitioners.

RESUMO

Objetivo: verificar os fatores relacionados ao conhecimento de profissionais de enfermagem sobre farmacovigilância. **Métodos:** estudo transversal, realizado com 271 profissionais de enfermagem, de nível superior e médio, por meio da amostragem por conveniência. Utilizou-se de questionário, formado por duas partes: uma acerca do perfil sociodemográfico e profissional, e outra sobre o conhecimento em farmacovigilância e a prática de notificação de eventos adversos relacionados a medicamentos. Os dados foram analisados de maneira descritiva e inferencial, por intermédio de testes de comparação e correlação, considerando nível de significância de 5%. **Resultados:** o escore de conhecimento apresentou diferenças estatísticas em relação à formação profissional, função exercida na instituição e idade dos profissionais, enquanto a prática de notificações não obteve diferenças significativamente estatísticas. **Conclusão:** os fatores relacionados ao conhecimento em farmacovigilância de profissionais de enfermagem foram a formação profissional, a função exercida na instituição e a idade dos profissionais.

Descritores: Preparações Farmacêuticas; Uso de Medicamentos; Farmacovigilância; Segurança do Paciente; Profissionais de Enfermagem.

Introduction

Pharmacovigilance can be defined as the science that has actions related to the investigation, identification, analysis and prevention of adverse effects or any incidents related to the use of medicines, also encompassing deviations in the quality of medicines, therapeutic ineffectiveness, medication errors, the use of erroneous medication, without registered indication, abuse, intoxications and drug interactions⁽¹⁾.

The National Patient Safety Program highlights that the surveillance of health products is a specific initiative in the field of patient safety⁽²⁾. In this way, patient safety is shown as one of the practical pillars of hospital pharmacovigilance actions, when considering notifications of technical complaints and adverse events, a propelling factor in improving the quality of medicines and health products in general⁽³⁾.

At the forefront of carrying out these actions, there is the Brazilian Network of Sentinel Hospitals, implemented with the aim of facilitating the obtaining of information by the National Health Surveillance Agency, regarding technical complaints, adverse reactions and injuries regarding the use of health products⁽⁴⁾.

By virtue of working directly with the preparation and administration of medications, in order to enable the skillful perception of technical complaints and adverse reactions, and to be responsible for most of the notifications of irregularities that involve them, nursing professionals are the ones who most participate in pharmacovigilance activities⁽⁵⁻⁶⁾.

Despite the contribution of these professionals in hospital pharmacovigilance and, consequently, in the implementation of patient safety measures, two central factors contribute to minimal or insufficient participation of these in the actions inherent to this activity: fragile knowledge about the aspects involving pharmacovigilance and notifications adverse events, and little specific scientific production about the performance of Nursing in these activities⁽⁶⁻⁷⁾.

The reduced practical performance of nursing professionals in pharmacovigilance may be associated with the underreporting scenario, usually exemplified by professionals due to characteristics such as lack of records, unpreparedness to perform, work overload, apprehension in face of the possibility of punishment and lack of standardization in filling in⁽⁸⁾. In addition to these factors, the possibility that the fragile practice of surveillance and monitoring the use of medications is related to the occurrence of adverse events, associated with health care, and increases the costs of hospital stay, hospitalization time and morbidity and mortality^(1-2,6,8).

Thus, studies claim that the knowledge of nursing professionals in relation to adverse events involving the use of medications is limited, given the urgency of implementing the culture of patient safety in health institutions⁽⁹⁻¹⁰⁾. In addition to the restricted knowledge about adverse events, nursing professionals also demonstrate limited perceptions about aspects inherent to pharmacovigilance and the practice of reporting adverse reactions to medications⁽⁶⁾.

Since knowledge permeates the practice of nursing professionals, in the face of pharmacotherapy, and in view of the co-responsibility of professionals, from the need for effective implementation of safety measures for the consumption of drugs, this study aimed to verify the factors related to knowledge of nursing professionals on pharmacovigilance.

Methods

Cross-sectional study carried out in a public teaching hospital in the State of Paraíba, Brazil. All nursing professionals from the institution, with university and school education, were included in sectors that dealt directly with the process of preparation and administration of medications, totaling 303 individuals.

Professionals who partially responded to the instrument, who used technological and/or human resources to seek clarification on the topic, refused to

participate and were away or on leave of any nature were not included. Thus, the convenience sample was delimited, composed of 271 professionals.

Data collection was carried out from September 2018 to February 2019. The instrument for data collection was a questionnaire, formed by two parts: one referring to the socio-demographic and professional profile of the participants, composed of 13 questions, and the other related to knowledge and practice in hospital pharmacovigilance. The latter was composed of 17 questions, of these, ten addressed knowledge about hospital pharmacovigilance and seven, professional practice.

The instruments were applied individually, under the direct supervision of the researcher and in the professionals' work sectors, at previously agreed times and dates. The average time to complete the questionnaire was 15 minutes.

Despite not having been submitted to validation processes, the final version of the questionnaire was built from previous research on the theme, the institution's particularities, presented during the application of a pilot instrument with 18 professionals, and based on documents from the World Health Organization, Pan American Health Organization and the Health Department, such as the document Good Pharmacovigilance Practices for the Americas⁽¹¹⁾.

The data obtained were grouped in a spreadsheet, in the Microsoft Office Excel 2016 program, and imported into the Statistical Package for the Social Sciences software, version 20 for Windows. The analysis of the characterization of the socio-demographic and professional profile of the participants took place using descriptive statistics, with measures of mean, standard deviation and minimum and maximum for quantitative variables, and measures of absolute and relative frequency for categorical data.

The exposure variables of the study were the sociodemographic and professional profile, and the practice of notifications, while the outcome variable was the knowledge of nursing professionals about

pharmacovigilance. The sociodemographic and professional variables included sex, age, professional training, function performed at the institution, training institution, participation in discussions on pharmacovigilance at the training and work institution, workload at the institution, total work period, number of bonds employment, training time and experience in the institution.

The issues related to the notification of adverse reactions to medications and technical complaints, in turn, had three to four alternatives of choice that portrayed the professionals' practice in the notification process.

The questions related to knowledge in pharmacovigilance had four choice alternatives, of which only one was correct, and for the purposes of analysis, the incorrect alternatives received code 0 and the correct alternative was coded as 1. Subsequently, a score was constructed from the sum of the ten questions that measure knowledge, resulting in scores ranging from zero to ten.

The knowledge score in pharmacovigilance encompassed questions about definitions, purposes and areas of action of adverse reactions to drugs, technical complaints, notifications of adverse events involving drugs, sentinel hospitals and the performance of nursing professionals.

Subsequently, the score was subjected to the Kolmogorov-Smirnov test and the analysis of histograms, to verify the normality of the data. Based on the result of asymmetric distribution, comparisons between quantitative and categorical variables were made using the *Mann-Whitney and Kruskal-Wallis U tests*, used in situations where categorical variables make up, respectively, two groups of variables and more than two groups of variables. The median and quartiles 25 and 75 were used as a measure of central tendency.

The correlation between quantitative variables was performed using the Spearman Correlation test, considering the values: 0 - no correlation; 0 to 0.30 -

weak correlation; 0.30 to 0.70 - moderate correlation; >0.70 - strong correlation. In all tests, a significance level of 5% was considered.

The research followed the ethical principles governed by Resolution No. 466/2012, of the National Health Council, so that the project was assessed and approved by the Research Ethics Committee of the teaching hospital in the study setting, being approved according to opinion No. 2,690.131/18 and Presentation Certificate for Ethical Appreciation No. 89624718.8.0000.5182.

Results

Most participants were female (87.8%), with a mean age of 39.9 ± 8.3 years, with a minimum age of 24 and a maximum age of 65 years. The training time was concentrated in the intervals from 6 to 10 years (33.2%) and greater than 15 years (32.5%), with an average of 13.2 ± 8.8 years. The length of experience at the institution ranged from seven days to 33 years, with an average of 8.2 ± 8.4 years, although most professionals had been working for less than a year (42.1%).

Despite the fact that most of them have a university degree in Nursing (63.1%), they mostly worked as nursing assistants or technicians (66.1%). A little more than half of the participants claimed to have completed the course at a public educational institution (51.3%). Most had only one job (60.9%), with a weekly workload of 30 to 40 hours at the institution (72.0%). Of the professionals who declared they had more than one job, most worked over 40 hours a week (61.3%). Just over half of the professionals had access to information on pharmacovigilance at the training institution (50.6%), despite not having it at the work institution (50.2%).

The comparison between the knowledge score in pharmacovigilance and the sociodemographic and professional characteristics are shown in Table 1. There were statistically significant differences in the knowledge of the professionals, according to the training and the role performed in the institution.

Table 1 – Comparison between the median knowledge score in pharmacovigilance and the sociodemographic and professional characteristics. Campina Grande, PB, Brazil, 2019 (n=271)

Variables	f (%)	Pharmacovigilance knowledge score	
		Median (Q ₂₅ -Q ₇₅)	p-value
Gender			0.935*
Female	238 (87.8)	7.5 (6.0-8.0)	
Male	33 (12.2)	7.0 (6.0-9.0)	
Professional qualification			<0.001*
Nursing Assistant/Technician	100 (36.9)	7.0 (5.0-8.0)	
Nurse	171 (63.1)	8.0 (7.0-9.0)	
Role played at the institution			<0.001*
Nursing Assistant /Technician	179 (66.1)	7.0 (6.0-8.0)	
Nurse	92 (33.9)	8.0 (7.0-9.0)	
Training institution			0.381*
Public	139 (51.3)	7.0 (6.0-9.0)	
Private	132 (48.7)	8.0 (6.0-8.0)	
Participation in discussions on pharmacovigilance at the training institution			0.495 [†]
Yes	137 (50.6)	7.0 (6.0-8.0)	
No	83 (30.6)	8.0 (6.0-9.0)	
Do not remember	51 (18.8)	8.0 (6.0-9.0)	
Participation in discussions on pharmacovigilance at the institution where you work			0.373 [†]
Yes	100 (36.9)	7.0 (6.0-9.0)	
No	136 (50.2)	8.0 (7.0-8.0)	
Do not remember	35 (12.9)	8.0 (5.0-8.0)	

*Mann-Whitney U test; [†] Kruskal-Wallis test

Table 2 shows the values of the correlation between the pharmacovigilance knowledge score and age, time since graduation and time at the institution. The relationship between the score and age showed statistical significance and a weak negative correlation, indicating, however, that the lower the age of the professionals, the higher the knowledge score in pharmacovigilance.

Table 2 – Correlation between the knowledge score in pharmacovigilance and the sociodemographic and professional characteristics. Campina Grande, PB, Brazil, 2019 (n=271)

Correlation	Pharmacovigilance knowledge score
	ρ (p value)*
Age	-0.150 (0.013)
Training time	-0.100 (0.099)
Time in the institution	-0.027 (0.659)

*Spearman’s Correlation Test (ρ - Correlation coefficient)

The comparison between the score of knowledge in pharmacovigilance and the practice of reporting adverse events is shown in Table 3. There were no statistically significant differences in the knowledge of professionals, according to the reporting practices they adopted.

Table 3 – Comparison between the median knowledge score in pharmacovigilance and the practice of reporting adverse events. Campina Grande, PB, Brazil, 2019 (n=271)

Variables	f (%)	Pharmacovigilance knowledge score	
		Median (Q ₂₅ -Q ₇₅)	p-value*
Made any notification			0.393
Yes	130 (48.0)	7.5 (6.0-9.0)	
No	117 (43.2)	8.0 (6.0-8.0)	
Does not remember	24 (8.9)	7.0 (5.5-8.0)	
How you make notifications			0.059
Records in the medical record	116 (42.8)	7.0 (6.0-8.0)	
Register in specific form	54 (19.9)	8.0 (7.0-9.0)	
Search sector that supports	25 (9.2)	7.0 (6.0-8.0)	
Never notified	76 (28.0)	8.0 (6.0-8.0)	
Difficulties to notify			0.315
Has no difficulties	194 (71.6)	7.0 (6.0-9.0)	
Does not know how to notify	59 (21.8)	7.0 (6.0-8.0)	
Does not know how to identify adverse reactions to medications and/ or technical complaints	1 (0.4)	4.0 (4.0-4.0)	
Does not know how to proceed in the face of adverse reactions to drugs and / or technical complaints	17 (6.3)	8.0 (7.0-8.0)	

*Kruskal-Wallis test

Discussion

The limitations of the research involved the use of a cross-sectional design, so as not to allow the study of the relationship between cause and effect, and convenience sampling, which may result in selection bias. However, in order to reduce the possibility of this occurrence, all professionals from the investigated institution were included.

The results of this study contribute to highlight the need to reformulate the institutional models of approach to patient safety, based on factors that influence the knowledge and practice of nursing professionals, such as the level of education and age, as well as to strengthen strategies for continuing and permanent education, and fostering the inclusion of this theme in the curricula of higher and technical training in Nursing.

Although knowledge and professional skills are seen as methods that make it possible to meet the individual needs of users and improve clinical quality and care outcomes⁽⁹⁻¹⁰⁾, the results of this study showed statistically significant differences between age, level of training and the role exercised in the institution, in relation to the knowledge scores in pharmacovigilance.

A similar result was observed in previous studies that found that the group that most makes mistakes during health care and obtains the lowest knowledge scores in research on adverse reactions to drugs and pharmacovigilance is composed of technicians and nursing assistants^(6,12).

The findings of this study can be explained, firstly, due to the lack of previous contact with actions and discussions on pharmacovigilance, since the majority of mid-level professionals stated that they did not remember or had had any contact with the topic at the health institution where they acted. In addition, it is noteworthy that these professionals have limited attributions, due to the competencies assigned to the category, assuming, therefore, a different perception of higher education professionals, with regard to the

professional, organizational and pharmacological factors that constitute the barrier to the safe use of medicines, acting only punctually and allocating most activities to nurses⁽¹²⁾.

Despite having obtained a weak correlation, the result that the lower the professional's age, the higher the score of knowledge in pharmacovigilance, can be explained due to the fact that aging can affect professional development strategies, as a result, for example, less likely to participate in continuous improvement activities from the age of 50. Corroborating this scenario, young professionals form the basis of the health systems workforce and the implementation of new health care programs, keeping older professionals away from updating and innovation initiatives⁽¹³⁻¹⁴⁾.

In addition, the process of functional decline that occurs from the age of 45 stands out and interferes with work activities, due to the loss of enthusiasm and/or chronological progress⁽¹⁵⁻¹⁶⁾, which may justify the result presented by older professionals, since 25.0% of the participants in this research were aged 45 years or older. The recent insertion of the theme in the teaching curricula of technical and undergraduate courses is also emphasized.

As shown in other studies, the practice of notifications in pharmacovigilance faces some barriers that compromise its effectiveness, such as: having a spontaneous, voluntary and passive surveillance character, fostering the underreporting scenario; be seen as an activity restricted only to situations that cause harm to the patient, due to the fear that the occurrence is associated with possible errors by the professional; be perceived by professionals as an additional task compared to other tasks; absence of governmental and institutional stimulus initiatives; and lack of standardization in filling in the instruments made available by health institutions, although the use of electronic forms only is encouraged^(3,8,17).

The weakness of the notification practice and, consequently, of the process of monitoring products in post-marketing, through regulatory agencies, corroborates the results of this study, in order to result

in a loss in the feeding of the information systems that characterize the occurrences of adverse events and would enable the adoption of coping strategies, such as the collection of medications⁽¹⁸⁾.

From the results of this study, it is estimated that most professionals do not understand the existence of databases, such as the Notification System for Adverse Events and Technical Complaints Related to Health Products, linked to sentinel hospitals⁽¹⁷⁾. Thus, although the hospital in the research setting is part of the Brazilian Network of Sentinel Hospitals, most of the participants indicated that they did not know what a sentinel hospital is or that they were unaware that the institution was thus accredited.

Although this aforementioned network was launched as a strategy to obtain quality information on adverse events for health products in general, to promote and disseminate monitoring and surveillance systems, as well as to improve risk management in health services and to cooperate with the formation of people⁽⁴⁾, part of the research participants stated that they did not know how to report, how to identify adverse reactions to medications and/or technical complaints or how to proceed in the event of occurrences. Of those who indicated they had some difficulty, most justify it because they never received instructions about this practice or stated that it was not routine at the institution.

Educational strategies have shown effective results in terms of increasing the number of notifications, the best levels of knowledge of professionals and the adoption of good practices in pharmacovigilance^(5,19-20).

In this way, the application of methods of continuing education and continuous training that involve the sectors of management of the health services, the administrative coordinators of the categories and the professionals stands out, since the success of a pharmacovigilance program depends on the level of information from professionals, as well as their interest in joining the program^(5,19-20).

In order to consolidate the culture of patient

safety and medication monitoring and surveillance systems, considering the fact that the research institution is a teaching hospital and is part of the Brazilian Network of Sentinel Hospitals, the implementation of support programs continuous professional development should aim at training students and improving the clinical practice of service professionals.

Conclusion

The factors that were related to the knowledge of nursing professionals about pharmacovigilance were professional training, the role exercised in the institution and age, in order to point out that higher education professionals in Nursing had better knowledge about the theme, when compared to the technical level, as well as younger professionals. It was found that although the practice of reporting adverse reactions to drugs and technical complaints is not widely disseminated among professionals, it was not a factor related to knowledge in pharmacovigilance.

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Collaborations

Macêdo GGC, Figueirêdo DSTO, Andrade LL and Carvalho MAP contributed to the conception and design or analysis and interpretation of data, writing of the article, relevant critical review of the intellectual content and final approval of the version to be published.

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