

COMPARISON OF PHARMACISTS PROFESSIONAL ACTIVITY OF UKRAINIAN PHARMACY ON PROVISION OF INFORMATION ON ADVERSE REACTIONS OF PHARMACEUTICAL PRODUCTS

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Abstract

The aim of the research is the comparison of professional activity of pharmacists of pharmaceutical institution in Ukraine with different education level in relation to their responsibilities in detection and prevention of adverse reactions (AR) or lack of efficacy of pharmaceutical products (PP), set out in the regulatory documentation on this matter.

Materials and methods. The questionnaire was developed and used for pharmacists of pharmaceutical institution, taken training on cycles of postgraduate education during 2016–2018. 70 higher education pharmacists (HEPs) and 80 specialized secondary education pharmacists (SSEP) were inquired. The integrity was evaluated by Fisher's ratio test (F). For convenience of calculation the corresponding functions of MS Excel were used.

Results. The majority of SSEPs and HEPs of Ukrainian pharmaceutical institutions are aware of their duty to provide information on AR or lack of efficacy of pharmaceutical products to the Department of Post-authorization Supervision of the State Expert Center of the Ministry of Health of Ukraine and are aware of the regulatory legal documentation on this issue, however they are not active enough to take necessary action filling in the "Adverse drug reaction reporting form" and sending it to the national department. One of the reasons for the underactivity of pharmacy workers, irrespective of their level of education, is the low organization of this process in pharmacy institutions, in particular the absence of the "Adverse drug reaction reporting forms".

Conclusion. Higher education pharmacist are more self-acting in completing "Adverse drug reaction reporting forms" and are less likely to shift their responsibilities to the pharmacy manager. It is critical to resolve the issue on enhancement of efficiency of detecting AR and/or lack of efficacy of PP in pharmacy institutions of Ukraine is to improve the quality of organizational work of pharmacy managers.

Keywords: higher education pharmacist, specialized secondary education pharmacist, reports of adverse drug reaction.

DOI: 10.21303/2504-5679.2020.001417

1. Introduction

The sixties of the XX century are considered the beginning of the history of pharmacovigilance. It was during the XX World Health Assembly that a decision was made on the need to establish an international control system of adverse reactions (AR) to pharmaceutical products (PP) [1]. Existing drug monitoring programs are intended to prevent the occurrence of AR, as well as to study and minimize medical errors that may occur when taking PP. Adverse reactions on PP can be the result of resistance, drug interactions, counterfeiting or their inappropriate quality, poisoning, drug dependence, drug abuse, etc. [2]. The vast majority of patient security aspects are under the control of the pharmacovigilance system. Spontaneous reports are

the main sources of information about AR on drug products [3]. Spontaneous reports of AR or lack of efficacy of PP coming from pharmacy practitioners are extremely necessary for future creation of recommendations on safety of drugs [4]. According to WHO recommendations [5], a modern pharmacist, regardless of his or her level of education (higher or specialized secondary), should be able to advise patients and their representatives on problems of healthy lifestyle, as well as on the conditions for safe and effective usage of PP that help prevent AR [6].

The main document governing the procedure for collecting and providing information on cases of AR and/or lack of efficacy of drugs in Ukraine is the MoH Order of Ukraine No. 898 (December 27, 2006). According to this order, practitioners of the public health system (medical and pharmaceutical) are considered to be the official sources of information on adverse drug reactions [6]. Pharmacy practitioners (Higher Education Pharmacists (HEPs) and Specialized Secondary Education Pharmacists (SSEPs)) must extensively detect AR on drugs and provide the patient or his/her representative with relevant information on the potentially adverse effects of drugs and the causes of AR. They must consult patients on the importance and need to report the occurrence of AR and/or lack of efficacy in the application of drugs, as clearly indicated by the current "Protocol 1.2. of the pharmaceutical sales representative (pharmacist) when receiving information about cases of AR and/or lack of efficacy of PP" [7]. The duties of pharmacists also include advising a pharmacy shoppers when filling in the form "Adverse drug reaction reporting form to provide patients and/or their representative with information on AR and/or lack of efficacy of PP in its medical application" ("Adverse drug reaction reporting form") about the case of AR and/or lack of efficacy of PP and inform about the addressee of this information [6].

Workers of pharmacy institutions of Ukraine (both HEPs and SSEPs) take a direct part in the care of patients and their representatives. Their direct responsibilities include the ability to advise patients on all aspects of the use and safety of drugs. However, the real professional activity of the workers of Ukrainian pharmaceutical industry on these issues has not been sufficiently illustrated in the literature [8–10], and the effectiveness of carrying out their professional duties depending on the level of education in the scientific literature has not been shown to date.

The aim of the research is the comparison of professional activity of pharmacists of pharmaceutical institution of Ukraine with different education level in relation to their responsibilities in detection and prevention of AR or lack of efficacy of PP, set out in the regulatory documentation on this matter.

2. Materials and methods

The questionnaire was developed and used for pharmacists of pharmaceutical institution, taken training on cycles of postgraduate education at the Clinical Pharmacology Department of the Institute of Pharmacy Professionals Qualification Improvement (IPHPQI) of National University of Pharmacy (Kharkiv) during 2016–2018. Five questions of the questionnaire were aimed at revealing the awareness of practitioners about their responsibility to provide information to the Department of Post-authorisation Supervision of the State Expert Center of the Ministry of Health of Ukraine about the AR and/or lack of efficacy of drugs, as well as the ability to fill in "Adverse drug reaction reporting form" [6]. As a result of the study, 70 HEPs and 80 SSEPs were questioned. The integrity was evaluated by Fisher's ratio test (F). For convenience of calculation the corresponding functions of MS Excel were used.

3. Results

On the first question: «Do you know about the responsibility of the pharmacist to provide information to the Post-authorisation Supervision Department of the "State Expert Center of the Ministry of Health of Ukraine" about the AR/lack of efficacy of drugs obtained from pharmacy shoppers?», out of 80 SSEPs, 66 (82.5 %) respondents gave positive answer on awareness of their responsibilities and 14 (17.5 %) responded negatively (**Fig. 1, a**). Therefore, among HEPs, 48 (69 %) respondents answered "yes" and 22 (31 %) answered "no" (**Fig. 1, b**). The comparison of both groups of pharmacy workers is confirmed by the fact that the vast majority of them are well aware of their responsibilities in this area, but SSEPs are more aware ($p < 0.01$; $F = 2.950$).

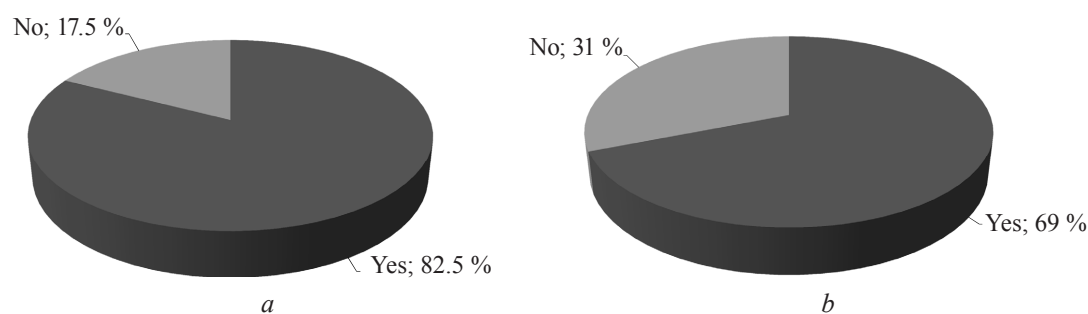


Fig. 1. Distribution of respondents regarding the answer to the question: «Do you know about the responsibility of the pharmacist to provide information to the PaSD of the SEC of MOH about the AR/lack of efficacy of drugs obtained from pharmacy shoppers?»: *a* – SSEPs; *b* – HEPs

When analyzing the answer to the second poll question: «Specify the correct regulatory framework that determines the duty of the pharmaceutical sales representative (pharmacist) to provide information about the AR/lack of efficacy of drugs obtained from pharmacy shoppers in the PaSD of the SEC of the Ministry of Health» it was found that the correct answer was given by 60 (75 %) SSEPs (**Fig. 2, a**). According to these data, 20 (25 %) surveyed SSEPs do not know the relevant regulatory framework.

Among HEPs, 52 (74 %) respondents from this group answered the second question correctly, 16 (23 %) answered incorrectly, 2 (3 %) did not answer this question (**Fig. 2, b**). There are no significant differences on this question between the HEPs group and the SSEPs group ($p>0.05$; $F=0.760$). This indicates approximately the same level of knowledge of the respondents from both groups on this issue.

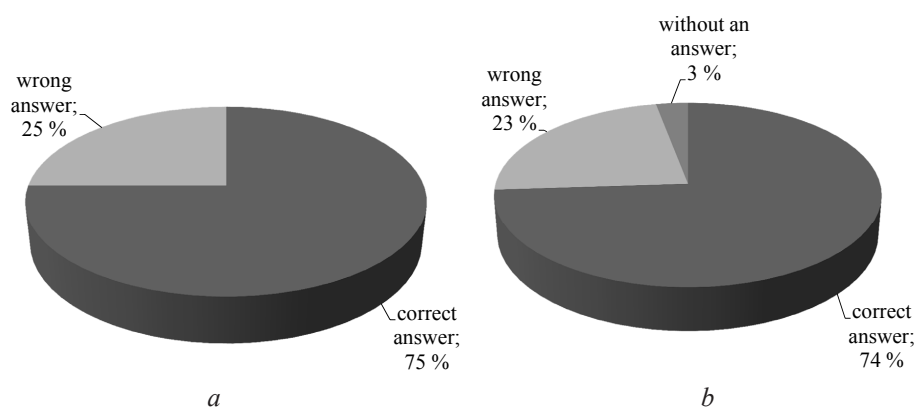


Fig. 2. Distribution of respondents regarding the answer to the question: “Specify the correct regulatory framework that determines the duty of the pharmaceutical sales representative (pharmacist) to provide information about the AR/lack of efficacy of drugs obtained from pharmacy shoppers in the PaSD of the SEC of the Ministry of Health”: *a* – SSEPs; *b* – HEPs

Analysis of the third poll questionnaire: “Are there the forms of “Adverse drug reaction reporting form” in your pharmacy” – the answer “yes” was given only by 22 (27.5 %) SSEPs, and “no” by 58 (72.5 %) (**Fig. 3, a**). Among the respondents of the HEPs group, 26 (37 %) answered “yes” and 44 (63 %) respectively “no” (**Fig. 3, b**). The obtained data indicate the shortcomings concerning the organizational work of the management of a number of pharmacy institutions. Differences on this question are significant in the HEPs and SSEPs groups ($p<0.01$; $F=2.291$).

The pharmacy institutions in which HEPs work, are better equipped with the necessary forms, possibly due to their more demanding attitude to this issue. However, this situation, to a greater extent, characterizes only the effectiveness of organizational work, not the professional qualities of a pharmacy worker. Probably, the level of education can contribute to greater awareness and requirements of employees to the pharmacy management on organizational issues.

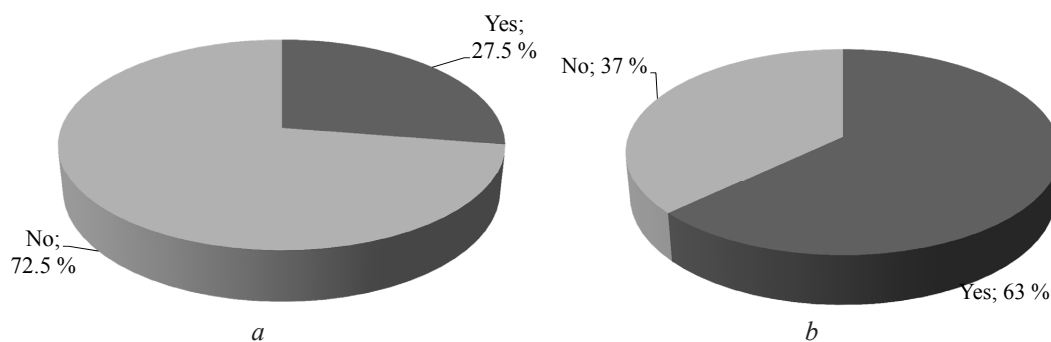


Fig. 3. Distribution of respondents regarding the answer to the question: «Are there the forms of “Adverse drug reaction reporting form” in your pharmacy”? *a* – SSEPs; *b* – HEPs

To the fourth question: “How can you send an “Adverse drug reaction reporting form” to the PaSD of the SEC of the Ministry of Health?” 20 (25 %) of the SSEPs respondents could not give a correct answer (**Fig. 4, a**), and among HEPs 26 (37 %) of all respondents in this group could not answer correctly (**Fig. 4, b**). This indicates the insufficient information awareness of the regulatory framework and a lack of skills in this activity, which contributes to a decrease in data entry on AR/lack of efficacy of drugs to the PaSD of the SEC of MOH. Differences on this question in the SSEPs and HEPs groups are significant ($p < 0.01$; $F = 2.698$) and the greater number of negative responses in the HEPs group may indicate that it is the duty to send “Adverse drug reaction reporting form” to the pharmacy establishments where the HEPs and SSEPs work together, relying on the latter. It also indicates the lack of efficacy of organizational work in pharmaceutical institutions.

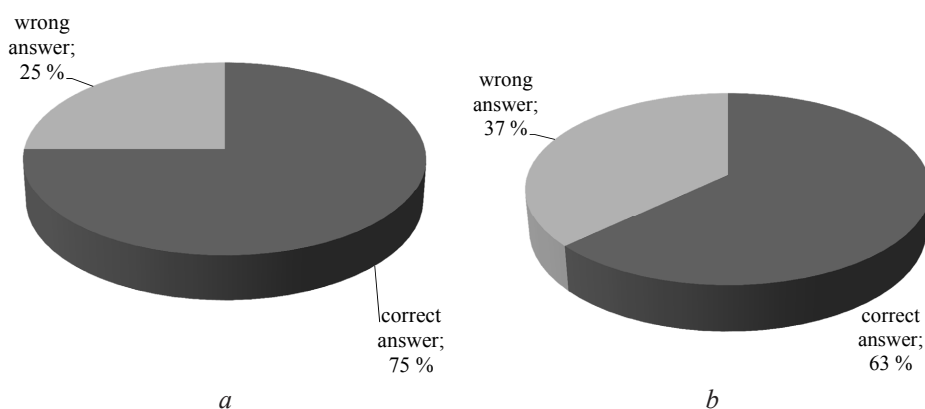


Fig. 4. Distribution of respondents regarding the answer to the question: “How can you send an “Adverse drug reaction reporting form” to the PaSD of the SEC of the Ministry of Health”?
a – SSEPs; *b* – HEPs

When analyzing the answer to the question: “What were your actions when pharmacy visitors reported about AR/lack of efficacy of PP?” it was found that only 10 (12.5 %) of the interviewed SSEPs and 10 (14.3 %) of HEPs ($p > 0.05$; $F = 0.765$) held a consultation on prevention of AR; 28 (35 %) respondents from SSEPs group and 20 (28.6 %) from HEPs group ($p > 0.05$; $F = 0.358$) referred to a doctor for consultation; 2 (2.5 %) respondents from SSEPs group did not respond to the information about AR/lack of efficacy of PP, there were none in the HEPs group ($p < 0.05$; $F = 2.172$); 30 (37.5 %) respondents from SSEP group and ($p < 0.01$; $\varphi = 2.898$) from HEPs group informed the head of the pharmacy institution: 8 (10 %) SSEPs and 20 (28.6 %) HEPs ($p < 0.01$; $F = 4.058$) completed “Adverse drug reaction reporting form” about AR/lack of efficacy of PP (**Fig. 5**).

Thus, the majority of interviewed SSEPs and HEPs responded to patients’ complaints about adverse drug reactions, consulted them themselves, or referred them to a doctor. Therefore, there were 20 (28.6 %) respondents from the HEPs group who completed the “Adverse drug reaction reporting form” independently, and only 8 (10 %) from the SSEPs group (significant differences),

indicating greater autonomy in the activities of the HEPs on this question. Significantly, the majority ($p < 0.01$) of the SSEPs group, 30 (37.5 %) transferred their responsibilities to the manager. Respondents from the HEPs group were most active in solving problems such as completing the Adverse drug reaction reporting form and completing a number of issues on their own without transferring their responsibilities to the pharmacy manager.

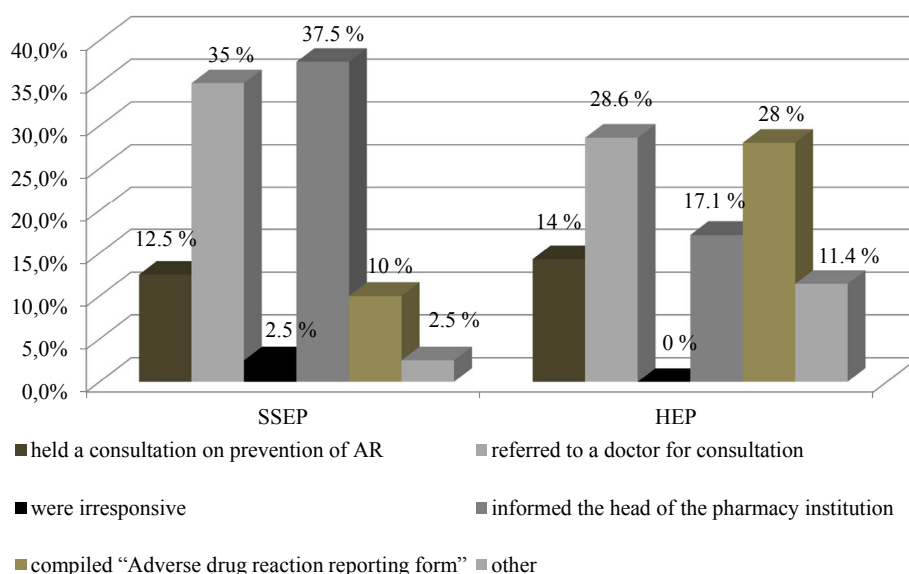


Fig. 5. Distribution of respondents regarding the answer to the question: "If you wrote a report on AR/lack of efficacy of PP, how would you do it?"

4. Discussion

Reporting ARs PP by health care providers is an important component of postmarketing drug surveillance. Pharmacists contribute to the drug safety by preventing, identifying, documenting and reporting of ARs PP [5, 12]. The role of pharmacist in the department of pharmacovigilance varies with different countries but, professionally their responsibility remains the same irrespective of the jurisdiction [5, 13–15].

Pharmacists are in a unique position to detect and report ARs PP because of their specialized training in pharmaceuticals and widespread use of computers [15]. However, the potential contribution of pharmacists to drug safety through ARs PP reporting is hampered by underreporting, which is a major problem [15, 16]. Health care providers in many countries face several obstacles when reporting ARs PP to pharmacovigilance centers, including inadequate knowledge of ARs and ARs PP reporting, concerns about malpractice litigation, lack of motivation, lack of time, high workload, lack of economic incentive, complacency, indifference, ignorance of ARs PP reporting requirements, and negative attitudes among others [15, 17–20].

Our research is relevant because the real professional activity of the workers of Ukrainian pharmaceutical institutions on these issues has not been sufficiently illustrated in the literature [8–10], and the effectiveness of carrying out their professional duties depending on the level of education in the scientific literature has not been shown to date.

The conducted questionnaire survey made it possible to conclude that the majority of the surveyed HEPs and SSEPs of pharmacy institutions are aware of information about their duties to provide information to the PaSD of the SEC of the Ministry of Health about the AR/lack of efficacy of drugs and know the regulatory framework regulating the procedure of provision of these communications. The presence of many respondents who are not sufficiently active in performance of their duties in this regard in both the HEPs and the SSEPs groups can be largely attributed to the low level of organization of this process in pharmacy institutions.

The results are consistent with data from researchers from other countries, who found that there is a lack of support from employers to provide reports on the ARs of pharmacists. Similarly,

Green E. C. [21] reported that encouragement from managers and departments will improve reporting. However, due to commercial pressure in pharmacy practice and large volumes of prescriptions, the ARs PP report cannot give priority to employers and managers. Therefore, employers and managers should be sensitive to the importance of pharmacovigilance and encouraged to support pharmacists in their efforts to report ARs PP.

It was found that educational level can increase the awareness and demand of pharmacists to their managers on organizational issues. HEPs are more self-acting in completing “Adverse drug reaction reporting form” and are less likely to shift their responsibilities to the pharmacy manager.

Study limitations. The following study limitations should be considered in interpreting the results. First, the sample size was insufficient (representatives of pharmacy institutes were from most (but not all) regions of the country). Second, all respondents were participants of the educational process at the department, which could affect their answers.

Prospects for further research. More research using larger samples should be conducted to confirm this study’s findings. Future research should quantify the extent to which factors influence pharmacist ARs PP reporting activity. Further, future studies should identify interventions to address the barriers and thereby improve ARs PP reporting by pharmacists.

5. Conclusions

1. The majority of HEPs and SSEPs in pharmacy institutions of Ukraine are aware of their responsibility to inform about AR/lack of efficacy of PP to the Department of Post-authorization Supervision of the “State Expert Center of the Ministry of Health of Ukraine” and are aware of information on regulatory documentation on this matter, however, they are not sufficiently active to perform necessary actions to complete the “Adverse drug reaction reporting form” and send it to the national department. One of the reasons for the lack of activity of pharmacy workers, irrespective of their level of education, is the low organization in pharmacy institutions, in particular the absence of the “Adverse drug reaction reporting forms”.

2. Educational level can increase the awareness and demand of pharmacists to their managers on organizational issues.

3. Higher education pharmacists are more self-acting in completing “Adverse drug reaction reporting form” and are less likely to shift their responsibilities to the pharmacy manager.

4. In order to decide the issue of improvement of efficiency on detecting AR/lack of efficacy of PP in Ukrainian pharmacy, in particular, reducing the dangerous effects of medicines and improving the quality of medical care to the population of Ukraine, it is very important not only to provide the ongoing education of pharmacists, but also to improve the organizational work of pharmacy managers.

Conflicts of interest

The authors declare that they have no conflicts of interest.

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Received date 24.06.2020

Accepted date 10.09.2020

Published date 30.09.2020

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