

СОЦІАЛЬНА МЕДИЦИНА І ФАРМАЦІЯ: ІСТОРІЯ, СУЧАСНІСТЬ ТА ПЕРСПЕКТИВИ РОЗВИТКУ

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ANALYSIS OF THE PROBLEMS OF THE RATIONAL USE OF ANTIBACTERIAL DRUGS IN UKRAINE

Aim. To analyze the current situation with the antibacterial drugs turnover, as well as to develop effective ways to solve the problem of growing resistance of bacteria to antibiotics, including determination of the active role of a pharmacist in this process.

Materials and methods. The analysis of the current situation in the domestic system of pharmaceutical supply of the population was carried out on the basis of a survey of pharmaceutical specialists directly involved in the process of dispensing antibacterial drugs from pharmacies in the outpatient setting. In accordance with the aim of the study a questionnaire was developed for interviewing pharmaceutical specialists. The questionnaire included the aim and objectives of the survey. During the survey, the confidential terms of use of the information received were notified. The required size of the respondent sample was calculated taking into account the expected reliability of the results obtained. The questionnaire proposed included closed questions that provided data on the state of the problem of the rational dispensing of antibacterial drugs, as well as open-ended questions revealing the individual attitude of the respondents to the problems of the rational drug consumption from the pharmacotherapeutic group indicated. The questions contained in the questionnaire were divided into two groups: the basic ones allowing us to obtain the necessary information from the respondent and the control ones indirectly confirming the accuracy of answers to basic questions and allowing exclusion of unclear answers.

Results. The article presents the results of a survey of pharmaceutical specialists on the problem of the rational supply and consumption of antibacterial drugs and the assessment of their role in organization of an effective prescription model for this group of drugs in Ukraine. It has been determined that a significant majority of respondents consider it necessary to sell antibacterial drugs strictly by prescriptions (90.42 %), but, in practice, approximately the same number of respondents (90.73 %) still dispenses antibacterial drugs without a prescription: "Sometimes" (67.73 %) or "Always" (23.0 %). Respondents consider as important measure to implement a set of measures to disseminate knowledge about the rationality of using antibiotics (84.98 %) through the pharmacy network. At the same time, a large majority of respondents (90.10 %) transfer responsibility for the proper consumption of antibacterial drugs onto doctors. According to the opinion of the respondents (42.49 %), the development of an appropriate target program with the involvement of pharmacists and doctors should be the main direction of implementing the strategy of the rational use of antibacterial drugs in Ukraine. Among the factors contributing to the unsystematic use of antibacterial drugs, the leading position by the number of respondents were such answer options as "Thoughtless self-medication of the population" (79.23 %), "Violation of prescription dispensing" (62.62 %) and "Availability of antibiotics in the pharmacy" (47.92 %).

Conclusions. According to the results of the study it has been found that the complexity and controversial nature of the problem of the rational consumption of antibacterial drugs in Ukraine requires a comprehensive solution involving all subjects of the pharmaceutical supply system of the population.

Key words: antibacterial drugs; resistance; pharmaceutical employees; rational use of antibiotics; dispensing of antibiotics by prescription; consumption of antibiotics.

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АНАЛІЗ ПРОБЛЕМ РАЦІОНАЛЬНОГО ВИКОРИСТАННЯ АНТИБАКТЕРІАЛЬНИХ ПРЕПАРАТІВ В УКРАЇНІ

Мета: проведення аналізу поточної ситуації з обігом антибактеріальних препаратів, а також розробка ефективних напрямків щодо вирішення проблеми зростаючої резистентності бактерій до антибіотиків, зокрема і визначення активної ролі провізора в цьому процесі.

Матеріали та методи: аналіз здійснювався на основі анкетування фармацевтичних фахівців, які безпосередньо беруть участь у процесі відпуску з аптек антибактеріальних лікарських препаратів населенню в амбулаторних умовах. Відповідно до поставленої мети дослідження була розроблена анкета для проведення опитування фахівців фармації, яких інформували про конфіденційність використання наданої інформації. Необхідний розмір вибірки респондентів розраховувався з урахуванням очікуваної достовірності отриманих результатів. Анкета містила питання закритого типу, які дозволили отримати дані про стан проблеми раціонального відпуску антибактеріальних препаратів, а також відкриті питання, що розкривають індивідуальне ставлення опитуваних до проблем раціонального споживання лікарських засобів вказаної фармакотерапевтичної групи. Питання умовно були розділені на дві групи: основні, що дозволяють отримати необхідну інформацію від респондента, і контрольні, які непрямим чином підтверджують достовірність відповідей на основні питання і дозволяють виключити недостатньо чіткі відповіді.

Результати. У статті представлені результати анкетування фармацевтичних працівників щодо проблеми раціонального відпуску та споживання антибактеріальних лікарських препаратів (АБЛП) і дана оцінка їх ролі в організації ефективної моделі рецептурного відпуску цієї групи препаратів в Україні. Установлено, що значна більшість респондентів вважає за необхідне відпуск АБЛП суворо за рецептами (90,42 %), а на практиці приблизно така сама кількість опитаних (90,73 %) все-таки відпускає АБЛП без рецепта: «іноді» (67,73 %) або «завжди» (23,0 %). Респонденти вважають доцільною реалізацію через аптечну мережу комплексу заходів щодо поширення знань про раціональність використання антибіотиків (84,98 %) і, при цьому переважна більшість респондентів (90,10 %) переносить відповідальність за належне їх споживання на лікарів. Основним напрямком реалізації стратегії раціонального використання АБЛП в Україні, на думку респондентів (42,49 %), має стати розробка відповідної цільової програми із залученням провізорів (фармацевтів) і лікарів. Серед чинників, що сприяють безсистемному застосуванню АБЛП, домінуючі позиції за кількістю опитаних зайняли такі варіанти відповідей, як «Бездумне самолікування населення» (79,23 %), «Порушення рецептурного відпуску» (62,62 %) і «Доступність антибіотиків в аптеці» (47,92 %).

Висновки. За результатами дослідження встановлено, що складність і суперечливий характер проблеми раціонального споживання АБЛП в Україні потребують комплексного вирішення із залученням усіх суб'єктів системи фармацевтичного забезпечення населення.

Ключові слова: антибактеріальні лікарські препарати; резистентність; фармацевтичні працівники; раціональне використання антибіотиків; рецептурний відпуск антибіотиків; споживання антибіотиків.

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АНАЛИЗ ПРОБЛЕМ РАЦИОНАЛЬНОГО ИСПОЛЬЗОВАНИЯ АНТИБАКТЕРИАЛЬНЫХ ПРЕПАРАТОВ В УКРАИНЕ

Цель: проведение анализа текущей ситуации с оборотом антибактериальных препаратов, а также разработка эффективных направлений по решению проблемы растущей резистентности бактерий к антибиотикам, в том числе определения активной роли провизора в этом процессе.

Материалы и методы: анализ осуществлялся на основе анкетирования фармацевтических специалистов, непосредственно участвующих в процессе отпуска из аптек антибактериальных препаратов населению в амбулаторных условиях. В соответствии с поставленной целью исследования была разработана анкета для проведения опроса фармацевтических специалистов, которых уведомили о конфиденциальности использования полученной информации. Необходимый размер выборки респондентов рассчитывался с учетом ожидаемой достоверности полученных результатов. Анкета содержала вопросы закрытого типа, которые позволили получить данные о состоянии проблемы рационального отпуска антибактериальных препаратов, а также открытые вопросы, раскрывающие индивидуальное отношение опрашиваемых к проблемам рационального потребления лекарственных средств из указанной фармакотерапевтической группы. Вопросы условно были разделены на две группы: основные, позволяющие получить необходимую информацию от респондента, и контрольные, косвенным образом подтверждающие достоверность ответов на основные вопросы и позволяющие исключить нечеткие ответы.

Результаты. В статье представлены результаты анкетирования фармацевтических работников по проблеме рационального отпуска и потребления антибактериальных препаратов (АБП) и дана оценка их роли в организации эффективной модели рецептурного отпуска этой группы препаратов в Украине. Установлено, что значительное большинство респондентов считает необходимым отпуск АБП строго по рецептам (90,42 %), а на практике примерно такое же количество опрошенных (90,73 %) все же отпускает АБП без рецепта: «иногда» (67,73 %) или «всегда» (23,0 %). Респонденты считают целесообразной реализацию через аптечную сеть комплекса мероприятий по распространению знаний о рациональности использования антибиотиков (84,98 %), при этом преобладающее большинство респондентов (90,10 %) переносит ответственность по надлежащему их потреблению на врачей. Основным направлением реализации стратегии рационального использования АБП в Украине, по мнению респондентов (42,49 %), должна стать разработка соответствующей целевой программы с привлечением провизоров (фармацевтов) и врачей. Среди факторов, способствующих бессистемному применению АБП, доминирующие позиции по количеству опрошенных заняли такие варианты ответов, как «Бездумное самолечение населения» (79,23 %), «Нарушение рецептурного отпуска» (62,62 %) и «Доступность антибиотиков в аптеке» (47,92 %).

Выводы. По результатам исследования установлено, что сложность и противоречивый характер проблемы рационального потребления АБП в Украине требуют комплексного решения с привлечением всех субъектов системы фармацевтического обеспечения населения.

Ключевые слова: антибактериальные лекарственные препараты; резистентность; фармацевтические работники; рациональное использование антибиотиков; рецептурный отпуск антибиотиков; потребление антибиотиков.

Statement of the problem. Antibacterial drugs (ABD) play an important role in the fight against infectious diseases. The dynamically growing global consumption of antibiotics is alarming since being often excessive and incorrect it is all, to a greater extent, characterized by resistance from microorganisms. The World Health Organization (WHO) published a report on the Global Antimicrobial Resistance Surveillance System (GLASS). It says that resistance to ABD is noted throughout the world. The growth of microbial resistance to antibiotics is a global challenge to global public health. According to the GLASS, in 2016-2017, doctors found resistance to antibiotics among more than 500,000 patients from 22 countries with suspected bacterial infection [1].

Antimicrobial resistance (AMR) is one of the greatest threats facing humanity. According to the WHO, antibiotic immunity annually kills at least 700 thousand people. By 2050, while maintaining the growth rate at the existing level, this figure is expected to increase to 10 million people. Obviously, this situation could be changed by providing more rational use of modern ABD. This task was formulated by the WHO in the report entitled "The role of a pharmacist in encouraging prudent use of antibiotic medicines and averting antimicrobial resistance – a review of current policies and experiences in Europe. 2014"; it emphasized the role of a pharmacist as the main regulator of dispensing drugs from pharmacies [2]. Pharmacists work to protect and promote the health, safety and well-being of patients and the public, making them more resilient to infections. The pharmacists' unique position in healthcare systems makes them the most accessible healthcare professional. Through a process of triage, pharmacists evaluate whether or not they can offer a solution via treatment of minor ailment symptoms. Furthermore, when antibiotics are not needed, pharmacists can reassure patients and correct any misunderstandings. When antibiotics are needed, pharmacists, ideally supported by available diagnostic tools, supply antibiotics in specific

legally defined cases, or refer to a physician or a specialist.

In the realities of the development of the Ukrainian healthcare system and pharmaceutical provision of the population the situation is even more complicated since the problems faced by foreign doctors are supplemented by the lack of funding for healthcare, the low solvency of the population, the prevalence of unsubstantiated self-medication and the specificity of domestic legislation. For comparison, we note that in most countries of the European Union (EU), Japan and the USA, ABD cannot be bought without a prescription since antibiotics are included in the category "Prescription-only-medicine". At the same time, in practice, antibiotics in Ukraine can be purchased at pharmacies without a prescription (at the buyer's request or by direct recommendation of a pharmacist). It should be noted that this situation is characteristic, according to the WHO, for 18 countries more, mainly for the states of the former USSR [2].

The growing AMR poses a real threat to the health and lives of many citizens. Despite the fact that in 2018, the Ministry of Health (MoH) of Ukraine once again updated and officially approved the new list of over-the-counter drugs (order of the Ministry of Health dated 04/02/2018, "On Approval of the List of Medicines Permitted for Use in Ukraine, Dispensed Without Prescriptions from the Pharmacies and their Structural Divisions"), in fact, non-listed ABD can be freely purchased from pharmacies. This is due to the direct dependence of the profitability of pharmacies on sales, which, in turn, leads to the irrational use of ABD. The lack of public knowledge about the side effects of antibiotics, which leads to an increase in compliance violation, also contributes to this fact. All this leads to the fact that under these conditions an increase of the AMR becomes an even more significant public health problem.

Analysis of recent research and publications. Modern problems of the rational use of antibacterial drugs and violations of prescription dispensing as an important component

of the healthcare system have recently received much attention in research on the diverse approaches of the pharmaceutical and medical sectors of the healthcare system. The works of such domestic scientists as I. G. Bereznyakov, I. A. Zupanets, A. A. Kotvitskaya, A. S. Nemchenko [5-9] were devoted to solving of these problems.

Identification of aspects of the problem unsolved previously. The analysis of sources of special literature, as well as other periodicals, made it possible to determine that no comprehensive studies on studying the issue were conducted.

Objective statement of the article. The aim of this study was to analyze the current situation with the ABD turnover, as well as to develop effective ways to solve the problem of growing AMR, including determination of the active role of the pharmacist in this process. In connection with the growing uncontrolled consumption of antibiotics by the population, it is now necessary to develop effective scientific and practical measures to solve this problem; this can only be done on the basis of a full and comprehensive analysis of the current situation. The study used data based on the survey of pharmacists.

Presentation of the main material of the research. According to the results of the survey the assessment of the homogeneity of the totality of the respondents surveyed, as well as the degree of consistency of expert answers on the questionnaire, was made. We mathematically proved that the sample of respondents presented was homogeneous; therefore, the survey results were assessed by the total population of the experts interviewed. In addition, the assessment of the consistency of the answers of the respondents on questions with the option of multiplicity of answers was made. For this purpose, the Pearson correlation coefficient (τ_{kj}) was used. In this case, the sample was vector $\vec{x}_j = (x_{j1}, \dots, x_{ji}, \dots, x_{jm})^1$ where j was the sample number (the group of respondents); i ($i = 1, m$) – the number of answer options for the questionnaire; x_{ji} – the number of respondents in the group of specialists who noted i as the answer. The calculated coefficient (τ_{kj}) was within the range of $-1 \leq \tau_{kj} \leq 1$. The Student's criterion was the criterion of significance of Pearson's correlation coefficient (t_{cr}).

According to the results of the statistical processing of the survey data, we concluded that the experts had consistency of opinion on the issues proposed in the questionnaire. Preparation and processing of the questionnaire data was carried out using the Microsoft Office Excel 2010. After the preliminary preparation the data was imported into the Statistica 6.0 application statistical analysis program (software license V.7. English – V.6 Russia K 892818).

The survey with the use of these questionnaires was conducted at the premises of the NUPh (Kharkiv, Ukraine) from 01/12/2017 to 03/31/2018 among the students of the correspondence department (313 people) representing 19 regions of Ukraine (including pharmaceutical specialists of Kharkiv). A diagram of the distribution of the share (%) of respondents in the regions of Ukraine is given in Fig. 1. The number of respondents from each region was chosen in proportion to the number of pharmacies in this area.

The results of the survey of pharmaceutical specialists will be discussed further in more detail. 283 Specialists, who were 90.42 % of the total number of the respondents interviewed, expressed a positive opinion to the question of the questionnaire: "Do you think antibiotics have to be dispensed from pharmacies only by prescriptions of doctors?". In practice, there was a slightly different situation. As we see from the data of Fig. 2, the overwhelming majority of the interviewed specialists "Sometimes" (67.73 % of the respondents) or "Always" (23.0 %) dispense ABD for pharmacy visitors without a doctor's prescription, and it is a direct violation of the current legislation on the sale of drugs by prescriptions of doctors in Ukraine.

According to the results of the survey only about 10.0 % of specialists (29 respondents, 9.27 %) "Never" dispense antibiotics without a doctor's prescription (Fig. 2). As shown, 90.42 % of specialists are sure that antibiotics should be strictly sold by prescriptions, while in practical activity approximately the same number of respondents (90.73 %) still "Sometimes" (67.73 %) or "Always" (23.0 %) dispenses ABD without a prescription. Moreover, even the fact that, according to the results of the survey, almost two thirds of pharmaceutical specialists

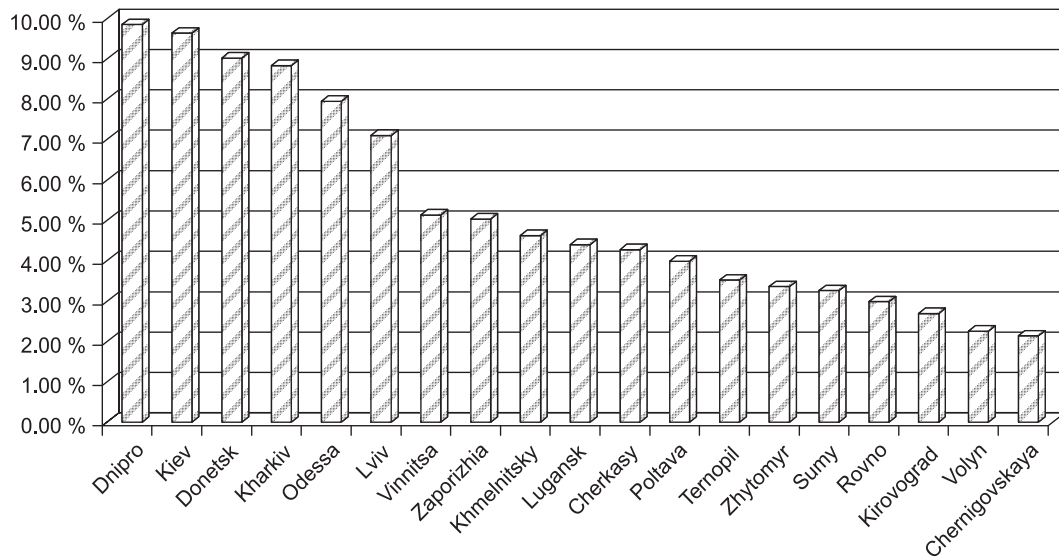


Fig. 1. The distribution of the share (%) of respondents in the regions of Ukraine

(194 respondents, 61.98 %) sometimes receive information about non-compliance with antibiotics dosing rules does not stop them from such actions, and 37 respondents (11.92 %) indicate that they receive such information constantly. This controversial situation with ABD dispensing is typical for Ukrainian realities, in which pharmaceutical employees work. It is logical that in such a situation the majority of respondents (282 respondents, 90.10 %) reacted negatively to the use of repeated prescriptions for the purchase of antibiotics.

The answers to the next block of questions defining possible ways to increase the improvement of prescription dispensing and the rational use of ABD were informative enough to assess the attitude of specialists to the problem of unreasonable and improper use of antibiotics.

It has been found out that the majority of respondents (266, 84.98 %) consider it expedient to implement a set of measures to disseminate knowledge about the rationality of using antibiotics through the pharmacy network. The relevance of organizing such events is also confirmed by the fact that at present, according to the results of the survey, only a little more than half of pharmacists (174 respondents, 55.59 %) "Always" provide information about antibiotics and the peculiarities of their administration by patients. Another 126 respondents do this (40.26 %) "Sometimes". Thus, a significant number of patients are left without the necessary information to

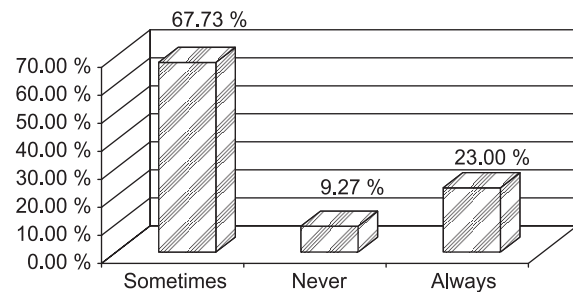


Fig. 2. Analysis of the structure of the respondents' answers regarding the frequency of pharmacy sales of antibiotic without a prescription

maintain their health and a high level of the quality of life.

The understanding of the depth and complexity of the problem of the rational dispensing of ABD from the respondents interviewed is indicative. Most experts agree on the need to gain and deepen knowledge and skills in this area. The absolute majority (299 respondents, 95.53 %) believe that it is advisable to train pharmacists in issues related to the rational use of antibiotics. Therefore, the understanding and adoption of possible ways to implement the strategy of the rational use of ABD in practical medicine and pharmacy by specialists are relevant. Of three proposed answers to the question "In which direction should the strategy of the rational use of antibiotics be implemented?" the respondents chose almost equally among the response options (Fig. 3).

Thus, the introduction of the practice of the rational use of antibacterial drugs was

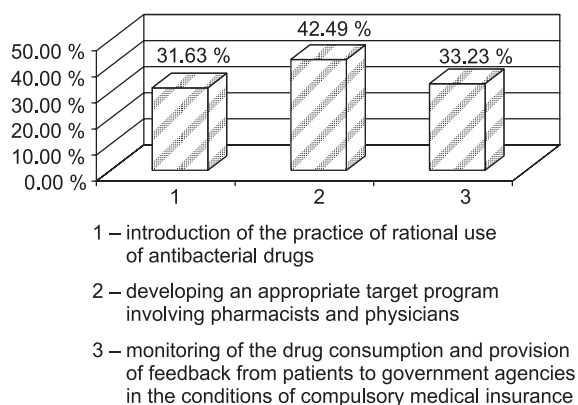


Fig. 3. The results of the respondents survey regarding the direction of the implementation of strategies for the rational use of antibiotics

supported by 99 respondents (31.63 %), the monitoring of the drug consumption and provision of feedback from patients to government agencies in the conditions of compulsory medical insurance were supported by 104 respondents (33.23 %). A slightly larger number (133 respondents, 42.49 %) noted the answer to supporting the idea of developing an appropriate target program involving pharmacists and physicians.

As the results of the survey show, a significant number of the pharmaceutical specialists surveyed (260 respondents, 83.07 %) has already been acquainted with the guidelines and standards of the Good Pharmaceutical Practice (GPP). At the same time, an even larger number of respondents (275, 87.86 %) expect that the mandatory implementation of the GPP standard will lead to an increase in the quality of pharmaceutical services.

With an explicit understanding of the complexity of solving the problem under discussion and readiness to engage in its solution, the majority of pharmaceutical specialists (282 respondents, 90.10 %) believe that the responsibility for the proper consumption of antibiotics should be transferred onto doctors (Fig. 4). It is noteworthy that 118 respondents (37.70 %) consider that pharmacists should simultaneously solve this problem with medical specialists. Significantly less respondents rely on the effectiveness of the efforts of regulatory authorities (58 respondents, 18.53 %), professional organizations (30 respondents, 9.58 %) and patient associations (12 respondents, 3.83 %).

To a certain extent, this is explained by the increased unsystematic consumption of the ABD by the population. In general, the results of the answers to this question (Fig. 5) clearly show how complex is the problem of the rational consumption of ABD in Ukraine.

The analysis of the survey results allowed identification of three main factors contributing to the unsystematic use of ABD. Thus, the option “Insensitive self-medication of the population” (248 respondents, 79.23 %) was the undisputed leader in the number of the answers noted. The “Violation of prescription dispensing” was at the second position (196 respondents, 62.62 %). The rest options proposed, such as “Availability of antibiotics in the pharmacy” (150 respondents, 47.92 %) and “Irrational prescribing of antibiotics by doctors” (144 respondents, 46.01 %) also scored sufficiently.

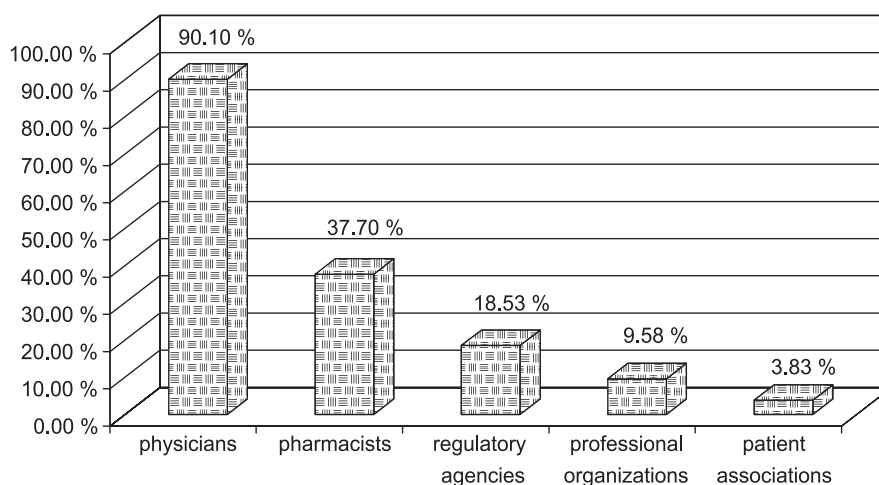


Fig. 4. The distribution of the respondents' opinion regarding the responsibility for solving problems of the proper use of antibiotics

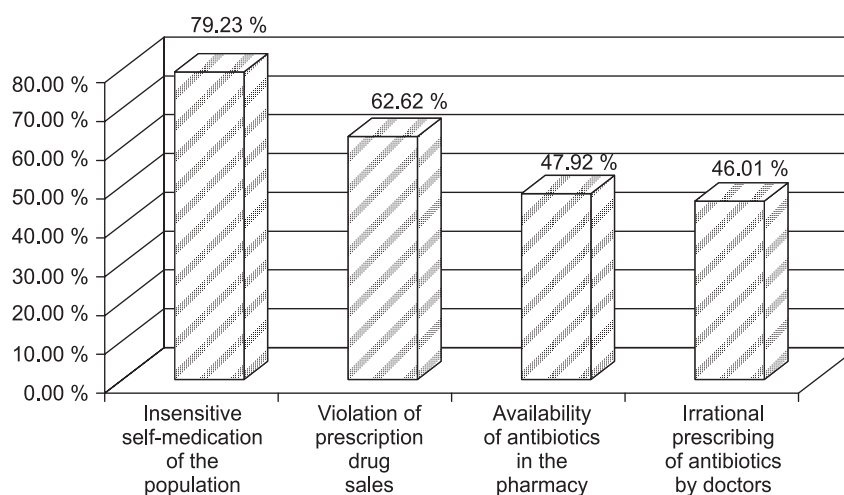


Fig. 5. The distribution of the respondents' opinion regarding the main factors that contribute to unsystematic consumption of ABD by the population

Systematizing the results of the research conducted we can confidently assert that the problem of the rational use of ABD in Ukraine needs to be considered in the context of solving a whole range of problems directly related to reforming the system of pharmaceutical support for the population in the direction of increasing the availability of pharmaceutical care provided to the population and the implementation of standards and regulations. Action to confront and help overcome the problem must be taken now. Policies already exist or are being formulated at national and regional levels.

Conclusions

1. Analysis of the results of the survey of pharmaceutical specialists on the problem of the rational supply and consumption of ABD in Ukraine has shown that pharmacists, on the one hand, are sufficiently informed about the current situation, understand its complexity, and are ready to take part in solving the problems. It has been found that 90.42 % of specialists believe that antibiotics should be dispensed strictly by prescriptions. At the same time, in practical activity approximately the same number of respondents (90.73 %) still dispenses ABD without a prescription "Sometimes" (67.73 %) or "Always" (23.0 %).

2. The absolute majority of respondents speak negatively about the fact of using repeated prescriptions for purchasing antibiotics (90.10 %), consider it expedient to implement a complex of measures to disseminate knowledge about the rational use of antibiotics

through the pharmacy network and deepen knowledge and skills in this area (299 respondents, 95.53 %, respectively).

3. It is quite controversial that 55.59 % of the respondents "Always" provide the information about antibiotics and the peculiarities of their use to patients, and 40.26 % of the respondents do this "Sometimes."

4. The majority of respondents (42.49 %) support the idea of developing an appropriate target program with the involvement of pharmacists and doctors as the main direction of implementing the strategy of the rational use of ABD in Ukraine.

5. A large majority of pharmaceutical specialists (90.10 %) believe that the task associated with the proper consumption of antibiotics should be the primary responsibility of doctors. At the same time, 118 respondents (37.70 %) believe that pharmacists should simultaneously solve this problem together with medical professionals.

6. Among the factors contributing to the unsystematic use of antibacterial drugs, the leading position by the number of respondents were such answer options as "Thoughtless self-medication of the population" (79.23 %), "Violation of prescription dispensing" (62.62 %) and "Availability of antibiotics in the pharmacy" (47.92 %)

7. According to the results of the questionnaire survey of pharmacists it can be concluded that the problem of the rational consumption of ABD is complex and controversial, and therefore requires a comprehensive solution.

The stricter requirements and control over the turnover of ABD will not be able to provide an effective solution of this problem.

Prospects for further research. Proper regulation of the problem of the rational use of antibacterial drugs in Ukraine is impossible without the mandatory implementation of the principles and standards of Good Pharmacy Practice, in which pharmaceutical professionals are urged to properly advise patients when dispensing antibiotics [3]. This position is fully consistent with the FIP (International Pharmaceutical Federation) for 2016 and is consistent with the materials of the reference

book "Fighting antimicrobial resistance. The contribution of pharmacists. 2015" [4].

In our opinion, the important recommendations for the national healthcare systems of individual countries (including Ukraine) are:

- a ban on the sale of antibiotics without a prescription;
- intensification of control on the export, import, use and sale of antimicrobials;
- the active dissemination of information on the rational use of antibiotics among the public.

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