1. Introduction

According to the assessment of the Ministry of Health of Ukraine, as a result of Russia’s war against our country, the number of patients who will need psychological support will be about 15 million people, of which 3–4 million are patients who will be prescribed drug treatment [1].

In this regard, the National Program of Mental Health and Psychosocial Support was launched in Ukraine, the main goal of which is to help citizens overcome stress and survive the consequences of traumatic events. WHO and international partners also participate in the implementation of this program. The main task of the Program is not only to increase the number of participants, to expand the list of pharmacological groups of drugs, but above all to ensure the availability of drugs and psychological help for patients [2].

Currently, the Program enables patients with chronic diseases to receive medication during outpatient...
treatment for the following nosologies: cardiovascular diseases, heart attack and stroke prevention, diabetes (type 1 and 2), bronchial asthma, mental and behavioural disorders, epilepsy. In 2023, INN was added for the treatment of patients with Parkinson’s disease and COPD (chronic obstructive pulmonary disease) [3, 4].

At the same time, during the period of martial law in the country, changes were made to the normative legal acts, which allows doctors to write paper prescriptions for drugs that are included in the Program [5]. As for patients with mental and behavioural disorders, primary care physicians have been given the opportunity to issue repeat prescriptions for this category of patients, which has had a positive effect on the availability of appropriate outpatient treatment for patients with mental disorders [6], but there remains a sufficient number of issues that require analysis and study at the national level.

The implementation of the National Program of Mental Health and Psychosocial Support and the Government Program will make it possible to increase the availability of basic vital drugs for patients in outpatient treatment. If necessary, citizens will be able to get medicine at their place of stay, having a declaration with their family doctor, or conclude a new declaration with a new doctor. However, the effectiveness of the implementation of these programs requires monitoring – constant tracking of its results, first of all according to the opinion of the participants – doctors, pharmacists and patients.

The analysis of official sources of information showed that the issues of generic replacement [7] and patient co-payment [8, 9] are relevant both in Ukraine and in many countries of the world – China [10, 11], Ethiopia [12], the USA [13, 14] and others [15–18], and require more detailed research during the survey of Program participants.

The organization and conduct of a questionnaire survey of Program participants is one of the most effective tools for influencing the implementation process, as it is based on the principles of feedback, efficiency, and objectivity in making management decisions to ensure the availability of medicines, which determines the relevance of this study.

Therefore, the aim of the study was to conduct a questionnaire survey of doctors and pharmacists to determine the current state and the main problems that arise in the process of providing pharmaceutical care, while special attention was paid to the issue of availability of drugs for patients with mental and behavioural disorders in the implementation of the Program.

2. Research planning (methodology)

To conduct the research and achieve the goal, the following stages were completed:

– analysis of scientific publications related to conducting a questionnaire survey of doctors and pharmacists in Ukraine and other countries regarding the issues of generic substitution of drugs, registration of drugs under INN and co-payment of patients for drugs; analysis of treatment protocols and statistical data on the prevalence of mental disorders among the population, as well as the issue of providing patients with drugs in outpatient treatment in Ukraine and the world (stage I – preparatory);

– development of 2 questionnaires for conducting a questionnaire survey of doctors and pharmacists of pharmacy institutions, substantiating the required number of respondents by region and conducting the selection of respondents in accordance with participation in government programs (stage II – methodological);

– preparation of official letters to institutions, approval of letters for each group of respondents, organization of survey and preliminary analysis for each group of respondents (III stage – organizational);

– statistical processing of the received answers, determination of statistical indicators characterizing the agreement of respondents’ opinions on each group separately (IV stage – statistical);

– critical evaluation of the obtained results within each group of respondents, as well as a comparative analysis of the opinions of doctors and pharmacists of pharmacies, identification of common opinions and disagreements among doctors and pharmacists (V stage – analytical);

– registration of the obtained results, determination of prospects for further research and public presentation of materials (VI stage – summarizing).

As a result, the research design includes 6 stages, reflecting the peculiarities of conducting questionnaire surveys in the medical and pharmaceutical sphere regarding the participants of government programs in health care.

This article presents only a part of the results of a complex questionnaire survey of doctors and pharmacists, which related to the problems of prescriptions according to the INN, generic substitution of drugs and patient co-payment, as these questions provide an opportunity to assess the availability of pharmaceutical care for patients with mental and behavioural disorders and reflect really a picture.

3. Materials and methods

The number of Program participants is growing every year, as evidenced by open data on the website of the National Health Service of Ukraine [19]. The issue of assessing the implementation of the Program remains important, in particular the issues of drug prescriptions according to the INN, generic substitution of drugs and patient co-payment, as these questions provide an opportunity to assess the availability of pharmaceutical care for patients with mental and behavioural disorders.

The results of the analysis of publications related to the question of conducting a questionnaire survey among doctors and pharmacists, regarding the assessment of the problems of generic substitution and patient co-payment [7–18] and practical experience on the subject under study made it possible to develop 2 questionnaires, which included data on respondents, as well as 21 questions, relating to the structure of prescription and dispensing of drugs under government programs. Respondents were offered from 1 to 18 answer options, were given the opportunity to choose several options, and in each question had the opportunity to provide their own answer option.
In the period from 14.06 to 30.06.2022, the authors conducted a questionnaire survey of two groups of respondents to determine the main problems that arise in the participants of the government program on reimbursement of drugs, namely:

- doctors of 11 specialties from more than 100 regional, local and district health care institutions from 22 regions of Ukraine, who provide primary and specialized medical care to patients with mental and behavioural disorders – a total of 134 respondents, in particular – 59 % psychiatrists, of which 60 % have more than 10 years of work experience in their specialty, which indicates their high qualification level;
- pharmacists of pharmacy establishments from 21 regions of Ukraine, different forms of ownership – 336 respondents, pharmacists, of whom 43 % have more than 10 years of work experience, which confirms a sufficiently high professional level.

The selection of medical and pharmacy institutions, as well as specialists, was carried out based on their purposeful selection, considering such basic criteria as: territorial placement of institutions by regions of the country and the level of their active participation in the Program for outpatient treatment of patients with mental and behavioural disorders.

The survey of specialists was conducted at the initiative of leading national institutions in the field of health care, electronically by filling out a Google form and did not include personal data about survey participants. This approach made it possible to ensure professional expertise, reliability, and objectivity of the survey results.

To assess the consistency of the responses of all respondents – doctors and pharmacists – to the questions of the questionnaire, calculations of the concordance coefficient were carried out using the Statistica 6.1 software package. The conducted statistical calculations indicate a high consistency of the opinions of the respondents in each group:
- for doctors – $W=0.72$;
- for pharmacists – $W=0.71$.
Here $W$ is the calculated concordance coefficient.

4. Research results

Based on the results of the questionnaire survey, we highlighted the most important questions, which were proposed to both groups of respondents, and which provide an opportunity to investigate the issue of drug availability for patients, users of the government program. Thus, to the question regarding the generic substitution of pharmaceuticals by pharmacists, in the absence of a drug prescribed by a doctor – only 27.6 % of doctors consider it possible, while 67.9 % of pharmacy workers confirmed the implementation of generic substitution in the absence of a pharmaceutical prescribed by a doctor (Fig. 1).

Regarding negative answers, doctors consider the following statement to be the most critical: generic substitution must be agreed with a specialist, as it is necessary to consider the patient’s episodic exceptions and side effects that may occur while taking the drug. Pharmacists claim that they often explain to the patient the difference between the prescribed drug and a generic substitute, and the patient makes the decision himself. Also, it is recommended to contact a doctor with this question, but if the patient asks to recommend a drug, then the pharmacist carries out the replacement and discharge.

76.1 % of doctors and 80.6 % of pharmacists answered yes in response to the question of whether regulatory regulation of generic drug substitution is needed, which can significantly improve access and affordability of treatment for patients. At the same time, both categories of respondents note that generics must be of high quality and meet GMP standards.

Analyzing the impact of the expansion of the Program to provide drugs for patients with mental and behavioural disorders and increase the physical and price availability of drugs, most experts consider this a positive solution, while there remains a certain list of problems that need to be worked out and considered in further changes (Fig. 2).

The issue of expanding the list of INNs remains the most relevant for this category of patients, since patients must buy some or even all drugs prescribed by a doctor at their own expense, which leads to excessive monthly out-of-pocket expenses, since most patients take these drugs constantly during life.

In our opinion, the issue of prescribing drugs by INN or trade name remains important, because today doctors under the Program can prescribe drugs only by INN, and pharmacists must offer a list of available drugs and the patient can receive drugs free of charge or with a surcharge. According to the results of the survey, 76.9 % of doctors and 65.8 % of pharmacists confirmed the expediency of prescribing drugs according to the INN, but some doctors (22.4 %) continue to prescribe drugs under the trade names of drugs.

In accordance with the research methodology, we proposed a list of separate questions for each group of respondents, which, in our opinion, are important and were investigated during the survey. Thus, in response to the
question regarding the introduction of electronic cards for patients under the Program, whether it simplified the doctor’s work with patients and made it possible to work more efficiently: 59.7 % answered that these changes are positive, while 40.3 % believe that that spend much more time filling out forms in the system. Among the main problems that cause a negative attitude towards electronic document management are technical problems with the operation of the system, lack of mobile communication for patients (it is necessary to print out a paper version of the prescription), some doctors keep both electronic and paper cards, which usually has a negative effect on patient appointment time.

Regarding the prescription of drugs for patients with mental and behavioural disorders, 73.1 % of doctors gave a positive answer that they use the Program and prescribe drugs to patients, while 26.9 % answered that there are not enough INNs in the list of the program to prescribe to patients.

During the survey, doctors were asked to choose the INNs that are most often prescribed to patients for the treatment of depressive disorders according to the Unified Clinical Protocol of primary, secondary (specialized) and tertiary (highly specialized) medical care “Depression” [20] (it was possible to choose several answer options), (Fig. 3).

As can be seen from Fig. 3, most respondents chose Escitalopram and Paroxetine, while only 2 INN Fluoxetine and Amitriptyline are included in the Program, which cannot fully satisfy the needs of both the prescribing doctor and the patient to receive the medicine free of charge or with a surcharge.

To date, the reimbursement program has enabled primary care physicians to prescribe for patients with mental and behavioural disorders, with 74.6 % of physicians agreeing that a psychiatrist should be the one to prescribe, citing the need to assess the stability of the patient’s condition, if necessary, correct pharmacotherapy.

In response to the questions for pharmacists regarding the problems that most often arise when working with the Program: 37.5 % of respondents chose the option – the lack of a sufficient number of drugs on the balance in the pharmacy, 47.3 % – problems of the technical nature of the pharmacy, and 21.3 % – the patient has problems with receiving the electronic prescription and confirmation code. Therefore, the lack of drug residues is a significant problem of pharmacies today.

Another important issue is the patient’s co-payment for drugs. In response to the question regarding the patient’s choice, 74.4 % of pharmacists confirmed that the patient chooses a free drug under the Program whenever possible, and 11.9 % that a drug with a surcharge is chosen. As for co-payments: patients try to choose drugs with a minimal co-payment or drugs that they have been taking for a long time, so they are ready to pay extra for the drug.

![Fig. 2. Results of the survey on the question “Do you think that increasing access and affordability for patients with mental and behavioural disorders of prescription of drugs under the INN under the reimbursement program “Affordable Medicines”?”](image_url)

![Fig. 3. Results of the survey on the question “Which of the listed drugs according to the INN from the clinical protocol of primary, secondary (specialized) and tertiary (highly specialized) medical care “Depression” do you prescribe most often when treating a patient diagnosed with a depressive disorder?”](image_url)
5. Discussion of research results

The reimbursement program is an effective mechanism for providing patients with pharmacotherapy in outpatient treatment both in Ukraine and in the European region in general [21]. However, the effectiveness of the state policy regarding generic replacement and patient co-payment requires constant study and analysis of the problem, because some generic drugs and generic drug replacement must be agreed upon by all participants of government programs and be effective for the patient [22]. It was thanks to conducting a questionnaire that a practical vision of the problem of generic substitution of drugs was established, which requires further research for the purpose of regulatory regulation in the country.

Thus, about 80 % of pharmacists and doctors support the legislative regulation of generic drug replacement, while 27.6 % of doctors support the implementation of generic drug replacement in a pharmacy, and 67.9 % of pharmacists support the possibility of doing so. Among the main problems remain episodic exceptions for each patient and the possibility of adverse reactions, which can be caused by the replacement of one or another drug. At the same time, the very mechanism of prescribing drugs according to the program is exclusively under the INN, and pharmacy employees recommend those drugs that are available free of charge or with a surcharge. Both groups of respondents confirmed compliance with such a prescribing mechanism, the percentage of positive responses was more than 65 %, while 22.4 % of doctors continue to prescribe drugs under the brand name.

In general, 67.9 % of doctors and 41.7 % of pharmacists support the expansion of the government Program for the treatment of patients with mental and behavioural disorders, which increases the access and availability of patients to treatment, but the percentage of responses about the limited list of INN and, as a result, the need to buy drugs entirely at one’s own expense, remains quite substantial. The assessment of doctors regarding the transition to electronic treatment plans and electronic prescriptions is quite heterogeneous, so 40.9 % of specialists say that it takes much more time, as there are technical problems with the program itself or the patient’s lack of mobile communication.

As a result of changes in legal acts, primary care physicians were given the opportunity to re-issue electronic prescriptions for patients with mental and behavioural disorders, which should improve access to treatment, while 74.6 % of the surveyed experts believe that it is the doctor who should re-issue prescription, as it will help to assess the patient’s condition and correct pharmacotherapy depending on the dynamics.

The main problems faced by pharmacists are technical issues (47.3 %), the lack of a sufficient number of drugs remaining in the pharmacy (37.5 %), and the patient’s problems with receiving an electronic prescription from a doctor (21.3 %). In our opinion, the issue of a sufficient number of drugs and the availability of free drugs in the stock of pharmacies is quite important and requires additional analysis and study in further research.

As for the issue of patient co-payment, 74.4 % of pharmacists confirmed that patients choose a drug that is free of charge under the Program and does not require additional payment.

At the final stage, we compared the obtained results with the studies of other scientists, which specifically concerns the conduct of a questionnaire among doctors and pharmacists and their relationship to the issues of generic drug replacement and patient co-payment. Thus, in the publication [11, 12], Chinese scientists present the results of a survey regarding generic substitution, while 67.6 % of doctors and 71 % of pharmacists support the policy of generic substitution and 78 % of doctors prescribe generic drugs in medical institutions in China. These data are quite close to the research results.

In the publication [13], according to scientists from Ethiopia, most doctors, 70.6 %, on the contrary, indicate a sufficiently low level of prescription of generic drugs, while 91 % of doctors and 87.2 % of pharmacists agreed with the need to approve the instruction on prescribing a patient and generic replacement of drugs in the pharmacy, which is also confirmed by our research.

The authors of the publication [14, 15] raised the issue of communication between a doctor and a pharmacist in the USA, which specifically concerns the problem of patient co-payment for drugs in a pharmacy. It was found that doctors lack information about the cost of drugs for the patient, and as a result, the patient does not know the cost of his treatment until he buys the drug at the pharmacy. It is the pharmacist’s role that is decisive in the matter of pharmaceutical assistance to the patient: how to get medicine with minimal costs. In our study, it was also established that 74.4 % of pharmacy pharmacists indicated the priorities of patients regarding the free receipt of drugs for the treatment of mental and behavioural disorders.

The role of the pharmacist in providing patients with medicines is highlighted in the World Bank report on the main problems that arise in the process of providing care to patients with mental and behavioural disorders in Ukraine [23]. It is pharmacists, in most cases, who assess the situation and identify the disease, and recommend that the patient consult a primary care doctor or a specialist doctor, provide information on pharmacotherapy. According to the official report on the results of implementation, most patients buy drugs at their own expense, especially patients who want to receive more modern drugs or want to replace original drugs with generics. As a result, patients’ out-of-pocket costs for the treatment of mental disorders may exceed even the state’s costs for all psychiatric care in one year.

Study limitations. The survey of doctors and pharmacists was not conducted in all regions of the country due to the martial law, nor was the survey of all Program participants: primary care physicians, holders of registration cards, and patients.

Prospects for further research. An important issue in the expansion of the Program is a real assessment of the main problems among doctors and pharmacists that arise in the process of providing pharmaceutical care.
to patients. Among the most important priority tasks related to the further development of the reimbursement program is the regulation of regulatory and legal issues of generic drug replacement in pharmacies and the expansion of the list of INNs, which will increase access and availability of treatment for patients with mental and behavioral disorders.

Prospects for further research include conducting questionnaire surveys of all other participants of the Program (patients, primary care physicians, owners of drug registration certificates).

6. Conclusions

According to the results of a survey of doctors and pharmacists, participants of the Reimbursement Program, which was conducted in the period from 14.06 to 30.06, 2022, the main problems with the regulatory and legal regulation of generic drug replacement in pharmacies were identified, which more than 80% of the surveyed respondents pay attention to and the impact of co-payment the patient’s choice of drug – 74.4% of pharmacists confirmed the patient’s choice in favour of a free drug for treatment. The limited list of INNs included in the Program also has a significant impact on access and availability of treatment for patients in outpatient settings and forces them to purchase drugs at their own expense.

The main problems that arise in the process of implementing the Reimbursement Program remain technical issues for both groups of respondents, maintaining electronic and paper treatment plans for patients, which takes much more time of doctors – specialists, and limited drug stocks in pharmacies – all this definitely affects the quality of providing pharmaceutical assistance to patients. It is also advisable to expand similar studies regarding the survey of all participants of the Program in the future.

Comparing the obtained results with foreign surveys of doctors and pharmacists regarding generic drug replacement and patient co-payment, it is possible to conclude that they are largely similar and identical.

Conflict of interests

The authors declare that they have no conflict of interest in relation to this study, including financial, personal, authorship, or any other, that could affect the study and its results presented in this article.

Funding

The study was performed without financial support.

Data availability

The manuscript has no associated data.

References


5. Pro zatverdzhennia Zmin do deiakyh normatyvno-pravovykh aktiv Ministerstva okhorony zdorovia Ukrainy shchodo za-zabezpechennia funktsionuvannia sfery okhorony zdorovia u period voiennoho stanu (2022). Nakaz Ministerstva okhorony zdorovia Ukrainy No. 727. 03.05.2022. Available at: https://zakon.rada.gov.ua/laws/show/z0504-22#Text


7. Statystyka podanykh deklaratsii pro vybr likaria pervynnoi medychnoi dopomohy. Available at: https://edata.e-health.gov.ua-e-data/dashboard/declar-stats


10. WHO guideline on country pharmaceutical pricing policies (2020). WHO, 70. Available at: https://www.who.int/publications/i/item/9789240011878


Received date 05.01.2023
Accepted date 27.05.2023
Published date 30.06.2023

Alla Nemchenko*, Head on Department, Department of Organization and Economics of Pharmacy, National University of Pharmacy, Pushkinska str., 53, Kharkiv, Ukraine, 61002

Anna Lyadenko, Postgraduate Student, Department of Organization and Economics of Pharmacy, National University of Pharmacy, Pushkinska str., 53, Kharkiv, Ukraine, 61002, Lead Specialist, Department of Work With Reimbursement Agreements, National Health Service of Ukraine, Bandery ave., 19, Kyiv, Ukraine, 04073

Olesia Nemchenko, Manager of Pharmacy, Limited Liability Company “Panacea” in Kharkiv, Danilevskoho str., 16/57, Kharkiv, Ukraine, 61058

Serhii Lebed, Head of State Service, State Service for Medicines and Drug Control in the Rivne region, 16 Lypnia str., 38, Rivne, Ukraine, 33028

*Corresponding author: Alla Nemchenko, e-mail: asnemchenko@ukr.net