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ANALYSIS OF PHARMACEUTICAL SUPPLY OF BREAST CANCER PATIENTS

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The aim: *to conduct a clinical and economic analysis of the state of pharmaceutical support for patients with breast cancer in women.*

Materials and methods. *During the research, data from the National List of Essential Medicines, the 14th State Formulary of Medicines, the Ukrainian clinical protocol, the clinical protocols of Great Britain and the United States of America for the treatment of breast cancer, and a depersonalized database of drug prescriptions were used. The research used such methods as clinical-economic, organizational-economic, mathematical-statistical, graphic, grouping and generalization.*

Research results. *It was established that 46 schemes of schemes for the treatment of breast cancer are presented in Ukrainian and international clinical protocols (Great Britain, USA). In all three protocols, there were 5 regimens for the treatment of breast cancer, such as CMF (Cyclophosphamide, Methotrexat, Fluorouracil), AC (Doxorubicin, Cyclophosphamide), DC (Docetaxel, Cyclophosphamide), TC (Trastuzumab, Capecitabin), EC (Epirubicin, Cyclophosphamide).*

Analysis of the pharmaceutical component in the protocols for individual drugs showed that they included 23 drugs according to the INN, which belong to the group of antineoplastic drugs. The Ukrainian clinical protocol includes 17 drugs, the British protocol – 14 drugs, and the American one – 15 drugs. The frequency analysis of antineoplastic drugs included in the Ukrainian clinical protocol revealed the TOP-3 in terms of drug prescription frequency: L01A A01 Cyclophosphamide (K_i=0.037), L01C D02 Docetaxel (K_i=0.029), L01D B01 Doxorubicin (K_i=0.026). The largest number of prescribed drugs are vital drugs – 61.96 %, the smallest share – essential drugs – 2.17 %, and the share of non-essential drugs is 35.87 %. The ABC analysis made it possible to determine the group of the most expensive drugs in the treatment of breast cancer – these are antineoplastic and immunomodulating agents. The total expenses for this group amounted to UAH 772,459.96, which according to the US dollar exchange rate of the National Bank of Ukraine at the end of August 2022 was USD 21,122.77. According to the analysis of the matrix of the integrated ABC-VEN-frequency analysis, it was established that the largest number of prescriptions belonged to the group of less expensive and vital drugs (B/V) – 7 drugs (48.73 % of the total amount. At the same time, the largest amount of expenses is observed in for the A/V group – UAH 772,459.96 (52.83 % of all costs directed to the pharmaceutical support of patients). The results of the structural analysis of the group of the most expensive drugs showed that the highest costs were characteristic of L01CD02 Docetaxel (UAH 1166,531.31; 39.81 % of the total cost in the group), and the lowest – for L01DB01 Doxorubicin – UAH 63,694.14 (5.46 %, respectively).

Conclusions*. According to the results of the conducted research, it was established that the largest costs fall on the group of essential drugs (1047735.07 UAH, 71.65 % of all costs). This determines the need for further pharmacoeconomic calculations of breast cancer treatment to optimize the costs of antineoplastic drugs.*

Keywords*: breast cancer, clinical and economic analysis, frequency analysis, ABC analysis, VEN analysis, pharmaceutical support, drug*

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1. Introduction

Today, one of the global problems in the world and in Ukraine is the scale of spread and constant increase in the number of new cases of breast cancer in women. According to the World Health Organization, more than 2.2 million cases of this disease were registered in 2020, which was the first among all types of cancer among women [1]. At the same time, more than 18,000 new cases and 7,000 deaths were registered in Ukraine [2]. According to scientists' forecasts, by 2040, the number of registered new cases of breast cancer in the world may increase by more than 3 million, and the number of deaths will increase by more than 1 million per year [3].

Unfortunately, the treatment of breast cancer is expensive and not every patient is able to take on the financial side of the process [4, 5]. As a result, economic costs and burden on the health care system are increasing, which requires rational use of limited financial resources. According to the prognostic data of the "Cancer Ukraine 2020" country profile of the cancer report from the World Health Organization, the level of oncology costs is expected to increase, so that by 2030 they will

increase to USD 4.00 per capita, which is twice as much as in 2022. For the European region as a whole, a similar situation regarding the economic burden is developing. Therefore, such a financial situation becomes a heavy burden for patients with various types of cancer [6, 7].

Since 2018, a medical reform has been underway in Ukraine, which is aimed at improving the financing of health care institutions and improving the quality of providing medical and pharmaceutical services to the population. According to the latest research, the funding of the healthcare industry in Ukraine is insufficient, which leads to problems with the physical and socio-economic accessibility of high-cost drugs and treatment methods for the population, including in the case of breast cancer [8, 9].

To implement population access to effective medical and pharmaceutical care in Ukraine, the "Program of Medical Guarantees – 2023" was introduced, which provides for the allocation of budget funds to reimburse the cost of 42 packages of medical services [10]. One of the packages, number 13, is intended for chemotherapeutic treatment and support of adults and children with oncological diseases in outpatient and inpatient settings. It defines the scope of providing medical services for patients, the cost of which is paid by the state under the signed contract of the medical institution with the National Health Service of Ukraine. Such services include specialist consultations, laboratory, instrumental and cytological studies, pharmaceutical support [11, 12]. Therefore, for the rational use of financial resources of health care, full financial support by the state of these packages of services for the population, and the inclusion of the latest drugs in clinical protocols, it is necessary to determine the amount of money spent on the treatment of breast cancer in outpatient and inpatient settings. This has determined the necessity of conducting our research.

The aim of the study is to conduct a clinical and economic analysis of the state of pharmaceutical support for the treatment of breast cancer in women.

2. Research planning (methodology)

A plan was developed for the study, consisting of the following stages:

I – analysis of domestic and foreign scientific literary sources for the last 10 years on the research issues, as well as clinical protocols, regulatory documents and guidelines for the treatment of breast cancer. The analysis of the pharmaceutical component of clinical protocols in Ukraine was carried out according to the data of the National List of Essential Medicines (Resolution of the Cabinet of Ministers of Ukraine dated 25.03.2009 No. 333) [13], "Unified clinical protocol of primary, secondary (specialized), tertiary (highly specialized) medical care. Breast cancer", approved by the order of the Ministry of Health (MOH) of Ukraine dated 30.06.2015 No. 396 (hereinafter referred to as Clinical Protocol) [14] and the 14th edition of the State Formulary of Medicines (order of the Ministry of Health of Ukraine dated 13.06.2022 No. 1011) [15].

II – formulation of the goal, outline of the subject and objects of the research. Selection of research methods in accordance with the set goal, defined subject and objects;

III – analysis of the depersonalized statistical database of drug prescriptions for patients with breast cancer who were treated in one of the health care institutions during 2019–2020, using clinical and economic analysis and mathematical and statistical methods;

IV – analysis of the pharmaceutical component of clinical protocols for the treatment of breast cancer in Great Britain and the United States of America (USA) [16, 17];

V – systematization and generalization of the obtained data, determination of limitations of research and their promising directions of implementation, construction of graphs and tables, formulation of conclusions. Writing an article.

3. Materials and methods

To conduct a retrospective analysis of drug prescriptions for patients, a depersonalized database of prescriptions for patients with breast cancer who were treated in a health care facility was used. The specified institution provides specialized medical care in accordance with the contract concluded with the National Health Service of Ukraine under the Program of Medical Guarantees. 3,121 prescriptions for patients with breast cancer were selected and analyzed using a random sampling method.

To compare schemes and drugs for the treatment of breast cancer abroad, the data of "Clinical guidelines for the management of breast cancer" (Great Britain) [16] and "NCCN Guidelines Version 4.2023. Breast Cancer. NCCN Evidence BlocksTM" (USA) [17].

To analyze costs for the treatment of breast cancer, various methods of health technology assessment (HTA) are used, which allow to determine the clinical and economic advantages of using the latest disease treatment schemes, methods and programs not only on the example of a specific institution and the health care system as a whole. One of the methods used in HTA is a clinical and economic analysis, which makes it possible to estimate the costs of those drugs prescribed by doctors in the inpatient department of a certain health care institution [18, 19].

The work used methods of clinical and economic analysis, namely integrated frequency, and ABC-/VEN-analysis.

Frequency analysis provides ranking of selected pharmaceuticals and their pharmacotherapeutic groups by frequency of use in medicinal purposes. The calculation of the coefficient of frequency of appointments (K_i) was carried out according to the formula [20]:

$$Ki = \frac{N}{n},$$

where N – the number of prescriptions of medicinal products by international non-proprietary name (INN);

n is the total number of drug prescriptions for patients.

In the future, VEN-analysis was performed, which allows to evaluate the actual consumption of drugs to assess the compliance of pharmacotherapy with current national standards and clinical treatment protocols. To

conduct the VEN analysis, we used a formal approach, which involves the use of regulatory documents by comparing the availability of drugs in the National List of Basic Drugs, since according to it, state price regulation is carried out on the domestic pharmaceutical market and the assortment of state purchases of drugs is formed, in the 14th release of the State Formulary of Medicines of Ukraine and the Clinical Protocol for the treatment of breast cancer. After comparing the data, all drugs prescribed to patients are divided into three categories: "V" (Vital), "E" (Essential) and "N" (Non-essential), which ultimately allows analyzing the structure of funds, which were aimed at the pharmaceutical support of patients with breast cancer in accordance with the medical and social significance of the drugs used. In the case of presence of drug in the three specified documents, it receives the index "V", if it is present only in the State Formulary and Clinical Protocol – "E", and if it is absent in both documents or in only one of them – "N".

The ABC analysis method (Pareto analysis) was used to assess the structure of costs aimed at providing pharmaceutical support to patients with breast cancer, which allows determining the groups of the most expensive pharmaceuticals. During the ABC analysis, all prescribed drugs are divided into three groups in order of decreasing costs for them, namely "A" – the most expensive drugs, which account for 80 % of costs; "B" is less expensive (15 % of expenses) and "C" is the least expensive (5 % of expenses). Purchase prices were used to determine the cost of drugs for the course of treatment prescribed to patients with breast cancer.-

The work uses a graphic method for visual display of results and structuring of information using tables. During the study, all calculations were performed using the statistical analysis package Statistica (version 12.0, StatSoft, Tulsa, USA). A p-value<0.05 is statistically significant.

4. Research results

At the first stage of the study, a frequency analysis was carried out, with the help of which the total and average number of appointments, the total number of prescribed drugs, and their distribution by ATC classification groups were determined.

It was established that on average, the patients of the analyzed sample spent 9 bed-days in the hospital. During this time, a total of 3,121 appointments were made for them.

According to the results of the analysis of the depersonalized database of the health care institution regarding the prescriptions for patients with breast cancer, 92 drugs according to the INN, belonging to 9 pharmacotherapeutic groups, were identified. In the Table 1 presents the results of the distribution of drugs by pharmacotherapeutic groups according to the frequency of prescriptions. It was established that the drugs of group B were most often prescribed – drugs affecting the blood system and hematopoiesis, namely 1010 (or 32.4 % of the total number of prescriptions), and the smallest number of prescriptions was observed for group N – drugs affecting the nervous system – 23 (0.7 %).

Table 1

Results of the frequency analysis of drug prescriptions of pharmacotherapeutic groups according to the 1st level of the ATC classification system

Name of ATC group	Number of prescriptions	Coefficient of prescriptions (K_i)	%
A – alimentary tract and metabolism	538	0.172	17.2
B – blood and blood forming organs	1010	0.324	32.4
C – cardiovascular system	254	0.081	8.1
H – systemic hormonal preparations, excl. sex hormones and insulins	431	0.138	13.8
J – antiinfectives for systemic use	87	0.028	2.8
L – antineoplastic and immunomodulating agents	520	0.167	16.7
M – musculo-skeletal system	227	0.073	7.3
N – nervous system	23	0.007	0.7
R – respiratory system	31	0.010	1.0
Total	3121	–	100

The structure of prescriptions according to the INN, which belongs to the pharmacotherapeutic group B – agents affecting the blood system and hematopoiesis, is shown in Fig. 1. It was established that among the specified group of drugs, drugs of subgroup B05 were most often prescribed – blood substitutes and perfusion solutions (43.75 %).

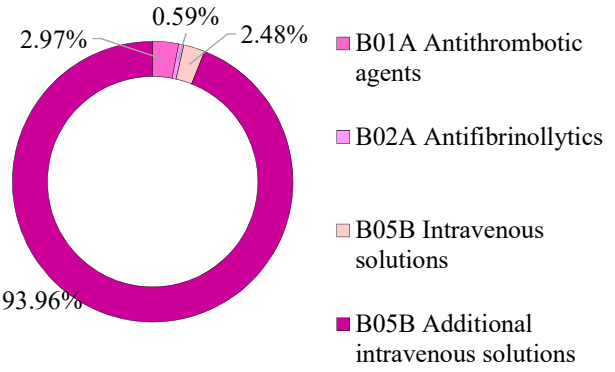

Fig. 1 Structure of drug prescriptions according to the INN of drugs affecting the blood system and hematopoiesis

Further, during the study, the TOP-10 drugs according to the INN, which were most often used in patients with breast cancer, were determined (Table 2).

At the next stage of the research, the pharmaceutical component of the Clinical Protocol and the international clinical protocol for the treatment of breast cancer of countries such as Great Britain and the United States was analyzed [16, 18, 19]. A total of 46 regimens were selected, which included antineoplastic drugs for the treatment of various types of breast cancer. The Clinical Protocols present 29 treatment schemes, the Great Britain protocols – 10 schemes and the USA – 24 schemes. In all three specified treatment protocols, there was complete agreement only with 5 schemes: CMF (Cyclophosphamide, Methotrexat,

Fluorouracil), AC (Doxorubicin, Cyclophosphamid), DC (Docetaxel, Cyclophosphamid), TC (Trastuzumab, Capecitabin), EC (Epirubicin, Cyclophosphamide). There is also overlap between the Clinical Protocol and the US protocol for 4 regimens, such as TAC (Doxorubicin, Cyclophosphamid, Docetaxel), CAP (Capecitabin), TR (Trastuzumab, Paclitaxel) and Trastuzumab emtansine. At the same time, the Clinical Protocol of Ukraine and Great Britain coincided with only 3 treatment schemes: DCap (Docetaxel, Capecitabine), GP (Gemcitabine, Paclitaxel) and FEC (Fluorouracil, Epirubicin, Cyclophosphamide). It is worth noting that in the domestic Clinical Protocol, treatment regimens are not divided by type of breast cancer, for example, HER2–, HER2+ (human epidermal growth factor receptor 2), etc., unlike the two international protocols that were analyzed.

Table 2

TOP-10 drugs by frequency of prescription according to INN

No.	ATC	INN	The absolute number of prescriptions	Share in the general structure of prescriptions, %
1	B05X A03	Sodium Chloride	944	29.93
2	A04A A01	Ondansetron	399	12.65
3	H02A B02	Dexamethason	394	12.49
4	L01A A01	Cyclophosphamid	115	3.65
5	C01E B15	Trimetazidin	111	3.52
6	L01C D02	Docetaxel	91	2.86
7	L01D B01	Doxorubicin	80	2.54
8	M05B A08	Zoledronic acid	77	2.44
9	M01A B15	Ketorolac	75	2.38
10	L01X C03	Trastuzumab	68	2.16

In the future, the pharmaceutical component of three clinical protocols was analyzed for individual drugs according to the INN (a total of 23 drugs according to the INN). The Clinical Protocol included 17 drugs, the British protocol – 14 drugs, and the American protocol – 15 drugs. In all three documents, there was a complete match of only 9 drugs according to the INN. These are drugs such as L01A A01 Cyclophosphamide, L01B A01 Methotrexat, L01B C02 Fluorouracil, L01B C06 Capecitabine, L01C D01 Paclitaxel, L01C D02 Docetaxel, L01D B01 Doxorubicin, L01D B03 Epirubicin and L01F D01 Trastuzumab.

The results of the study are shown in Table 3. In the domestic Clinical Protocol, there is a coincidence for 11 drugs, both in the protocol of Great Britain and in the protocol of the USA.

In the future, a frequency analysis of the group of antineoplastic drugs used for the treatment of breast cancer in Ukraine was carried out. According to the results of the analysis, presented in Table 4, it was found that the number of prescriptions of anticancer drugs by doctors to patients was only 14.25 % of the total number of prescriptions. In general, there were no appointments in the health care institution for 4 of the 17 drugs presented in the Clinical Protocol. It is also worth noting that 3 more antineoplastic drugs were found among the prescriptions of doctors, which are not included in any of the analyzed clinical protocols: L02A E03 Goserelin (K_i=0.01), L02 E04 Triptorelin (K_i=0.01) and L02B G04 Letrozol (K_i=0.05). These drugs belong to group L02A – drugs used for hormone therapy. In addition, in two cases, Ukrainian doctors prescribed one drug from the protocol of Great Britain L01D C03 – Mitomycin.

Table 3

The results of the analysis of the pharmaceutical component in relation to individual drugs according to the INN in three clinical protocols

No.	ATC	INN	Ukraine	Great Britain	USA
1	L01A A01	Cyclophosphamid	+	+	+
2	L01B A01	Methotrexat	+	+	+
3	L01B C02	Fluorouracil	+	+	+
4	L01B C05	Gemcitabin	+	+	–
5	L01B C06	Capecitabin	+	+	+
6	L01C A04	Vinorelbin	+	+	–
7	L01C D01	Paclitaxel	+	+	+
8	L01C D02	Docetaxel	+	+	+
9	L01D B01	Doxorubicin	+	+	+
10	L01D B03	Epirubicin	+	+	+
11	L01D B07	Mitoxantron	–	+	–
12	L01D C03	Mitomycin	–	+	–
13	L01E G02	Everolimus	+	–	–
14	L01E H01	Lapatinib	+	–	–
15	L01E H02	Neratinib	–	–	+
16	L01F D01	Trastuzumab	+	+	+
17	L01F D02	Pertuzumab	+	–	+
18	L01F D03	Trastuzumab emtansine	+	–	+
19	L01F F02	Pembrolizumab	–	–	+
20	L01F G01	Bevacizumab	+	–	–
21	L01X A02	Carboplatin	–	+	+
22	L01X K01	Olaparib	–	–	+
23	L02B G06	Exemestan	+	–	–

The next stage of the research was conducting a VEN analysis, the results of which indicate that the largest number of prescribed drugs are Vital drugs – 57 (61.96 % of the total), the smallest share – Essential drugs – 2 (2.17 %), and the share of non–essential drugs is 35.87 % (33). The group of essential drugs includes 8 pharmacotherapeutic groups. The most numerous of them is group L – antineoplastic and immunomodulating agents. According to the second level of the ATC classification system, it is represented by groups: L01 – antineoplastic drugs (13 drugs, 22.80 % of the total number in the group) and L02 – drugs used for hormonal therapy (4 drugs, 7.01 %). At the third level of the ATC classification, there are drugs of groups L01A – alkylating compounds (1 drug, 1.75 % of the total amount per group), L01B – antimetabolites (4 drugs, 7.01 %), L01C – alkaloids of plant origin and other drugs of natural origin (3 drugs, 5.26 %), L01D – cytotoxic antibiotics and related drugs (3 drugs, 5.26 %), L01X – other antineoplastic agents (2 drugs, 3.51 %), L02A – hormones and related substances (2 drugs, 3.51 %) and L02B – hormone antagonists and analogues (2 drugs, 3.51 %). Only one antineoplastic drug L01X C03 – Trastuzumab was included in the group of important drugs, and 2 drugs L01D C03 – Mitomycin and

L01F D02 – Pertuzumab were included in the group of unimportant drugs.

Table 4

Results of the frequency analysis of prescriptions of antineoplastic drugs available in the Clinical Protocol from the total number of prescriptions

No.	ATC	INN	Number of prescriptions	Coefficient of prescriptions (K_i)	%
1	L01A A01	Cyclophosphamid	115	0.037	3.68
2	L01B A01	Methotrexat	10	0.003	0.32
3	L01B C02	Fluorouracil	9	0.003	0.29
4	L01B C05	Gemcitabin	11	0.004	0.35
5	L01B C06	Capecitabin	5	0.002	0.16
6	L01C A04	Vinorelbin	12	0.004	0.38
7	L01C D01	Paclitaxel	24	0.008	0.77
8	L01C D02	Docetaxel	91	0.029	2.92
9	L01D B01	Doxorubicin	80	0.026	2.56
10	L01D B03	Epirubicin	43	0.014	1.38
11	L01E G02	Everolimus	–	–	–
12	L01E H01	Lapatinib	–	–	–
13	L01F D01	Trastuzumab	39	0.012	1.25
14	L01F D02	Pertuzumab	4	0.001	0.13
15	L01F D03	Trastuzumab emtansine	–	–	–
16	L01F G01	Bevacizumab	–	–	–
17	L02B G06	Exemestan	2	0.001	0.06
Total			445	–	14.25

At the last stage of the study, an integrated ABC/VEN analysis of drugs prescribed for the treatment of breast cancer was carried out. The following data were obtained during ABC analysis. Group "A" included 7 drugs according to the INN (7.60 % of the total number of drugs), group "B" – 7 drugs (7.60 %), and group "C" – 78 drugs (84.80 %). In group A, the drugs belong to 2 pharmacotherapeutic groups: L – antineoplastic and immunomodulatory drugs (6 drugs, 85.71 % of the drugs in the group) and M – drugs affecting the musculoskeletal system (1 drug, 14.29 %). Drugs of group B are represented by 3 pharmacotherapeutic groups according to the first level of the ATC classification: A – drugs that affect the digestive system and metabolism (1 drug, 14.29 % of the number in the group), B – drugs that affect the blood system and hematopoiesis (1 drug, 14.29 %) and L – antineoplastic and immunomodulating agents (5 drugs, 71.43 %). At the second level of the ATC classification, the distribution of drugs was obtained according to 4 groups: A04 – antiemetics and drugs that eliminate nausea (1 drug, 14.29 %), B05 – blood substitutes and perfusion solutions (1 drug, 14.29 %). L01 – antineoplastic agents (4 drugs, 57.13 %) and L02 – drugs used for hormonal therapy (1 drug, 14.29 %). According to the third level of distribution, the analyzed drugs belong to 7 pharmacotherapeutic groups, each of which is represented by only one drug (14.29 %): A04A – antiemetics and anti-nausea drugs, B05X – additional solutions for intravenous administration, L01A – alkylating compounds, L01B – antimetabolites, L01C – alkaloids of plant origin and other drugs of natural origin, L01X – other antineoplastic agents and L02A – hormones and related substances. The results of the distribution of drugs by INN in group "A" by the amount of expenses are presented in Fig. 2.

The results of the distribution showed that the highest level of drug costs in group A is characteristic of L01CD02 Docetaxel (1166531.31 UAH; 39.81 % of the total cost in the group), and the lowest is for L01DB01 Doxorubicin – UAH 63694.14 (5.46 %, respectively).

Based on the result of the matrix analysis of the integrated ABC-VEN-frequency analysis, it was established that the largest number of prescriptions falls simultaneously on the group of less expensive and vital drugs, the B/V group – 7 drugs (48.73 % of the total number) (Table 5). At the same time, the largest number of expenses is observed in the A/V group – UAH 772,459.96 (52.83 % of all expenses).

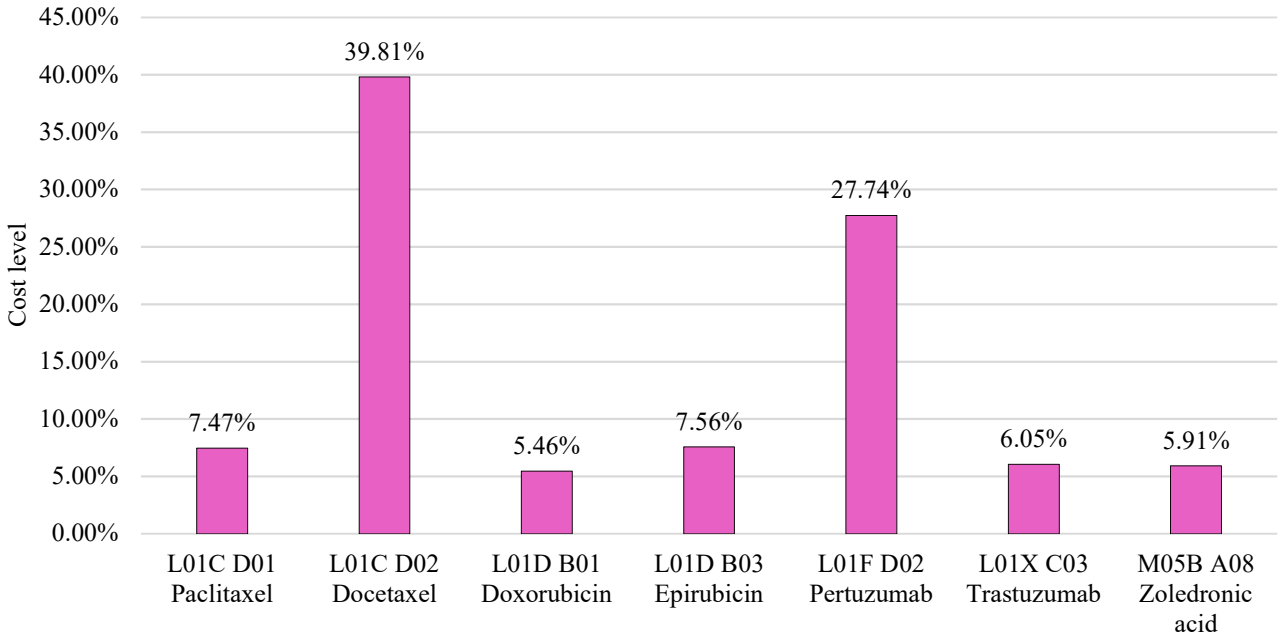

Fig. 2. Distribution of the costs of the most expensive drugs under the INN by group "A"

Table 5

Matrix of integrated ABC-VEN-frequency analysis of pharmaceutical support for patients with breast cancer

Group	V				E				N			
	Number of prescriptions (specific weight, %)	Number of drugs	Consumption		Number of prescriptions (specific weight, %)	Number of drugs	Consumption		Number of prescriptions (specific weight, %)	Number of drugs	Consumption	
			UAH	%			UAH	%			UAH	%
A	315/10.09	5	772459.96	52.83	39/1.25	1	70527.60	4.82	4/0.13	1	323543.75	22.13
B	1521/48.73	7	227270.52	15.54	–	–	–	–	–	–	–	–
C	763/24.46	45	48004.59	3.28	2/0.06	1	3010.77	0.21	477/15.28	32	17456.77	1.19
Total	2599/83.28	57	1047735.07	71.65	39/1.31	2	73538.37	5.03	481/15.00	33	341000.52	23.32

5. Discussion of research results

Systematizing the results of the conducted research, the following can be asserted. The pharmaceutical component of the Clinical Protocol for the treatment of breast cancer in Ukraine contains 29 schemes, for comparison in the USA – 24 schemes, and in Great Britain – 10. The Clinical Protocol of Ukraine presents 13 drugs out of 19 drugs that could be found in foreign treatment protocols. The largest number of drugs are represented in the USA protocol (15 drugs), including the newest antineoplastic drugs for the treatment of breast cancer, such as L01EH02 Neratinib and L01XK01 Olaparib [21, 22]. Taking into account the appearance on the international pharmaceutical market of new drugs specifically for the treatment of breast cancer [23, 24], it is worth conducting additional research on the HTA of the latest drugs for the treatment of breast cancer in the future with the aim of revising the pharmaceutical component of the Clinical Protocol and making changes to the composition of the National List of Basic Drugs in accordance with modern trends in the treatment of breast cancer and the composition of clinical protocols of countries that have certain successes in the treatment of various types of breast cancer. The above-mentioned data make it possible to assert the conduct of VEN and, in the future, an integrated ABC/VEN-analysis using a survey of oncologists of the appropriate profile regarding the causes of such a situation in clinical practice.

The ABC analysis made it possible to determine the group of the most expensive drugs for the treatment of breast cancer. Considering the price characteristics of anticancer drugs, the presence of these drugs in group A looks logical and expected. The total expenses for this group amounted to UAH 772,459.96, which at the US dollar exchange rate of the National Bank of Ukraine (USD 1.00=UAH 36.57) at the end of August 2022 amounted to USD 21,122.77. According to the data of the Pension Fund of Ukraine, as of August 29, 2022, the average salary was UAH 13,957.63 [25], so expenses for category "A" amounted to approximately 84 average salaries in Ukraine. Although the high cost of antineoplastic drugs is obvious, this does not negate the fact that in the conditions of the economic crisis and low solvency of the population, allocating funds for expensive drugs can become problematic. Therefore, a partial solution to this issue should be early diagnosis and prevention of this disease in women, which requires fewer financial costs from the state. The example of other countries that successfully conduct programs to increase medical literacy on cancer among the population can be a good opportunity for the adoption of such experience by pharmaceutical specialists in Ukrainian pharmacies [26].

Study limitations. The research was conducted based on one health care institution during a relatively short period of time. This does not make it possible to establish a complete picture of the pharmaceutical provision of medicines for breast cancer patients throughout Ukraine. Therefore, to form the necessary statistical base regarding the analysis of the organization of pharmaceutical support for women with breast cancer, it is necessary to conduct further research in different regions of the country. In addition, in the data selection study, there was no distribution of appointments according to the stages of breast cancer development depending on complications and the therapy performed, as well as the distribution of patients according to the primary or repeated case of breast cancer, the appointment of chemotherapy for the first time or after relapse. We believe that such a generalization can be used at the preliminary stage of research into the state of pharmaceutical support for breast cancer patients.

The obtained data indicate that drugs under the INN for medicinal purposes are mostly included in the main document for public procurement – the National List of Essential Medicines. Since our research uses a formal approach, and the composition of the above-mentioned documents has certain clarifications, the obtained results have limitations. In the future, it is necessary to conduct a clinical and economic analysis using an expert approach, which involves the involvement of doctors by specialty profile as experts in the survey.

These studies are carried out as part of the implementation of the concept of introducing HTA into the sphere of health care of Ukraine, which will allow in the future to find ways of rational use of limited health care resources directed to the treatment of cancer patients, including breast cancer [27, 28].

Prospects for further research. A promising direction of the research may be a clinical and economic analysis considering the expert opinion of specialists and a comparison of the results with the current study, as well

as a pharmacoeconomic evaluation of the rationality of the use of antitumor drugs in the treatment of patients with breast cancer using different methods.

6. Conclusions

According to the results of the conducted research, it was established that the largest costs fall on the group of essential drugs (1047735.07 UAH, 71.65 % of all costs). This determines the need for further pharmacoeconomic calculations of breast cancer treatment to optimize the costs of antineoplastic drugs.

Conflict of interests

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

Financing

The study was conducted without financial support.

Data availability

Data will be provided upon reasonable request.

References

1. International Agency for Research on Cancer. World Health Organization. Available at: https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf

2. International Agency for Research on Cancer. World Health Organization. Available at: https://gco.iarc.fr/today/data/factsheets/populations/804-ukraine-fact-sheets.pdf

3. Arnold, M., Morgan, E., Rumgay, H., Mafra, A., Singh, D., Laversanne, M. et al. (2022). Current and future burden of breast cancer: Global statistics for 2020 and 2040. The Breast, 66, 15–23. doi: https://doi.org/10.1016/j.breast.2022.08.010

4. Semin, J. N., Palm, D., Smith, L. M., Ruttle, S. (2020). Understanding breast cancer survivors' financial burden and distress after financial assistance. Supportive Care in Cancer, 28 (9), 4241–4248. doi: https://doi.org/10.1007/s00520-019-05271-5

5. Greenup, R. A., Rushing, C., Fish, L., Campbell, B. M., Tolnitch, L., Hyslop, T. et al. (2019). Financial Costs and Burden Related to Decisions for Breast Cancer Surgery. Journal of Oncology Practice, 15 (8), e666–e676. doi: https://doi.org/10.1200/jop.18.00796

6. Cancer Ukraine 2020 country profile. World Health Organization. Available at: https://cdn.who.int/media/docs/default-source/country-profiles/cancer/ukr-2020.pdf?sfvrsn=5d341f5f_2&download=true

7. European Region profile. World Health Organization. Available at: https://cdn.who.int/media/docs/default-source/ncds/ncd-surveillance/cancer-profiles-2020/euro-cancer-profile-2020.pdf?sfvrsn=6fbcb00e_3

8. Pikhotska, O., Khomiakova, I. (2021). Financing of the healthcare system in the context of its reformation. Derzhavne upravlinnya: udoskonalennya ta rozvytok, 12. doi: https://doi.org/10.32702/2307-2156-2021.12.33

9. Krynychko, L., Motailo, O. (2021). New approaches to financing the health care system. Public Administration Aspects, 9 (2), 86–100. doi: https://doi.org/10.15421/152122

10. Deiaki pytannia realizatsii prohramy derzhavnykh harantii medychnoho obsluhovuvannia naselennia u 2022 rotsi (2021). Postanova Kabinetu Ministriv Ukrainy No. 1440. 29.12.2021. Available at: https://zakon.rada.gov.ua/laws/show/1440-2021-%D0%BF#Text

11. Vymohy do «Prohramy medychnykh harantii – 2023». Available at: https://contracting.nszu.gov.ua/kontraktuvannya/kontraktuvannya-2023/vimogi-pmg-2023

12. Pro dohovory pro medychne obsluhovuvannia naselennia za prohramoiu medychnykh harantii (2018). Postanova Kabinetu Ministriv Ukrainy No. 410. 25.04.2018. Available at: https://zakon.rada.gov.ua/laws/show/410-2018-%D0%BF#Text

13. Deiaki pytannia derzhavnoho rehuliuvannia tsin na likarski zasoby i vyroby medychnoho pryznachennia (2009). Postanova KMU No. 333. 25.03.2009. Available at: https://zakon.rada.gov.ua/laws/show/333-2009-%D0%BF#n15

14. Pro zatverdzhennia ta vprovadzhennia medyko-tekhnolohichnykh dokumentiv zi standartyzatsii medychnoi dopomohy pry raku molochnoi zalozy (2015). Nakaz MOZ Ukrainy No. 396. 30.06.2015. Available at: https://www.dec.gov.ua/wp-content/uploads/2019/11/2015_396_ykpmd_rmz.pdf

15. Pro zatverdzhennia chotyrnadtsiatoho vypusku Derzhavnoho formuliara likarskykh zasobiv ta zabezpechennia yoho dostupnosti (2022). Nakaz MOZ Ukrainy No. 1011. 13.06.2022. Available at: https://moz.gov.ua/uploads/ckeditor/документи/dn_1011_13.06.2022_dod.pdf

16. Clinical Guidelines for the Management of Breast Cancer. Available at: https://www.england.nhs.uk/mids-east/wp-content/uploads/sites/7/2018/02/guidelines-for-the-management-of-breast-cancer-v1.pdf

17. NCCN Clinical Practice Guidelines in Oncology. Breast Cancer (2023). NCCN Evidence BlocksTM. Version 4. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast_blocks.pdf

18. Zaliska, O. M., Stasiv, Kh.-O. J. (2019). Scientific methodology and practical use of managed entry agreements for innovative medicines in system of health technology assessment in Ukraine. Farmatsevtychnyi Zhurnal, 4, 32–40. doi: https://doi.org/10.32352/0367-3057.4.19.04

19. Nemchenko, A. S., Nazarkina, V. M., Kosiachenko, K. L., Babenko, M. M. (2023). Problems of forming a professional environment in the health technology assessment system in Ukraine. Health & Education, 2, 28–36. doi: https://doi.org/10.32782/health-2023.2.5

20. Fang, J.-Q. (Ed.) (2017). Handbook of Medical Statistics. Sun Yat-Sen University, 852.

21. Harding, J. J., Piha-Paul, S. A., Shah, R. H., Murphy, J. J., Cleary, J. M., Shapiro, G. I. et al. (2023). Antitumour activity of neratinib in patients with HER2-mutant advanced biliary tract cancers. Nature Communications, 14 (1). doi: https://doi.org/10.1038/s41467-023-36399-y

22. Senkus, E., Delaloge, S., Domchek, S. M., Conte, P., Im, S., Xu, B. et al. (2023). Olaparib efficacy in patients with germline BRCA mutated, HER2 negative metastatic breast cancer: Subgroup analyses from the phase III OlympiAD trial. International Journal of Cancer, 153 (4), 803–814. doi: https://doi.org/10.1002/ijc.34525

23. Smyth, L. M., Tamura, K., Oliveira, M., Ciruelos, E. M., Mayer, I. A., Sablin, M.-P. et al. (2020). Capivasertib, an AKT Kinase Inhibitor, as Monotherapy or in Combination with Fulvestrant in Patients withAKT1E17K-Mutant, ER-Positive Metastatic Breast Cancer. Clinical Cancer Research, 26 (15), 3947–3957. doi: https://doi.org/10.1158/1078-0432.ccr-19-3953

24. Saesen, R., Lacombe, D., Huys, I. (2021). Design, organisation and impact of treatment optimisation studies in breast, lung and colorectal cancer: The experience of the European Organisation for Research and Treatment of Cancer. European Journal of Cancer, 151, 221–232. doi: https://doi.org/10.1016/j.ejca.2021.04.012

25. Pokaznyk serednoi zarobitnoi platy za 2022 rik v Ukraini (2023). Available at: https://www.pfu.gov.ua/2152284-pokaznyk-serednoyi-zarobitnoyi-platy-za-2022-rik/

26. Visscher, B. B., Vervloet, M., te Paske, R., van Dijk, L., Heerdink, E. R., Rademakers, J. (2021). Implementation of an animated medication information tool in community pharmacies, with a special focus on patients with limited health literacy. International Journal of Pharmacy Practice, 29 (6), 566–572. doi: https://doi.org/10.1093/ijpp/riab038

27. Solà-Morales, O., Volmer, T., Mantovani, L. (2019). Perspectives to mitigate payer uncertainty in health technology assessment of novel oncology drugs. Journal of Market Access & Health Policy, 7 (1), 1562861. doi: https://doi.org/10.1080/20016689.2018.1562861

28. Jönsson, B., Hampson, G., Michaels, J., Towse, A., von der Schulenburg, J.-M. G., Wong, O. (2018). Advanced therapy medicinal products and health technology assessment principles and practices for value-based and sustainable healthcare. The European Journal of Health Economics, 20 (3), 427–438. doi: https://doi.org/10.1007/s10198-018-1007-x

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