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COMPARISON OF THE EFFECTIVENESS OF THE APPLICATION OF VARIOUS SCHEMES FOR THE TREATMENT OF BRONCHIAL ASTHMA AND COPD IN A SUPRA-CLUSTER LEVEL OF CARE INSTITUTION

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Bronchial asthma and COPD are among the most common diseases with bronchoobstructive syndrome, however, the effectiveness of various treatment regimens using them is still debatable.

The aim of the study – studying the effectiveness of using different treatment regimens for the most common diseases with broncho-obstructive syndrome using the example of the pulmonology department of the tertiary care institution.

Materials and methods. A total of 203 medical histories and data from the medical information system MedAir were analyzed, followed by an evaluation of the effectiveness of applied treatment regimens using Farrell's technical efficiency index, cost-effectiveness analysis, and related factors.

Results. The analysis showed low adaptability of basic therapy regimens for patients with bronchial asthma (BA) and chronic obstructive pulmonary disease (COPD). Technical effectiveness of treatment was achieved in only 5.2% of patients (5 out of 97), while the majority received excessive (69%) or insufficient (28%) doses of drugs. Overall treatment effectiveness was higher in patients with BA (78%) compared to patients with COPD (62%). Among the three analyzed treatment regimens, the first was the most effective in terms of technical parameters (84%), the second – in terms of cost-effectiveness (76%), and the third achieved the highest indicators in terms of both criteria (88% technical effectiveness and 82% cost-effectiveness). However, conclusions regarding the third regimen are limited due to the small number of observations (12 patients). Factors affecting cost-effectiveness were gender, diagnosis, and year of observation. Women responded better to the first treatment regimen (82%), while the second regimen was more effective for employed men (71%). Patients with asthma showed a higher treatment efficacy (12% more compared to COPD). Although patient compliance was positively correlated with treatment outcomes, its effect was not statistically significant.

Keywords: bronchoobstructive syndrome, effectiveness, cost-effectiveness, chronic non-communicable diseases, healthcare organization.

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ПОРІВНЯННЯ ЕФЕКТИВНОСТІ ЗАСТОСУВАННЯ РІЗНИХ СХЕМ ДЛЯ ЛІКУВАННЯ БРОНХІАЛЬНОЇ АСТМИ ТА ХОЗЛ У ЗАКЛАДІ НАДКЛАСТЕРНОГО РІВНЯ ДОПОМОГИ

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Статтю присвячено вивченню ефективності застосування різних схем лікування для найбільш поширених захворювань із бронхообструктивним синдромом на прикладі пульмонологічного відділення Комунального некомерційного підприємства «Вінницька обласна клінічна лікарня ім. М. І. Пирогова Вінницької обласної Ради». Базуючись на аналізі ефективності внаслідок обсягу, основного лікування, використання ресурсів, індексу витрати – ефективність та факторів, які суттєво модифікували критерій витрати – ефективність, виявлено, що базова терапія була ефективнішою у пацієнтів із бронхіальною астмою порівняно з ХОЗЛ. Порівняння трьох схем лікування показало перевагу першої за технічною ефективністю та другої за критерієм витрати – ефективність, тоді як третя схема мала найвищі показники за обома критеріями, хоча висновки обмежені малою вибіркою. Вплив на ефективність мали стать, діагноз і рік спостереження.

Ключові слова: бронхообструктивний синдром, ефективність, витрати-ефективність, хронічні неінфекційні захворювання, організація охорони здоров’я.

Introduction. Bronchoobstructive diseases, including asthma (BA) and chronic obstructive pulmonary disease (COPD), are among the most common respiratory diseases. They have a significant impact on patients’ quality of life, healthcare costs and overall mortality. Bronchoobstructive syndrome is characterized by airway obstruction caused by inflammation, bronchospasm or structural changes. Asthma is defined as a chronic inflammatory disease of the airways, accompanied by airway hyperresponsiveness and the presence of recurrent symptoms such as dyspnea, cough and wheezing [5, 14]. Whereas COPD involves progressive and irreversible airflow limitation due to chronic inflammation and remodeling of the bronchial tree, often caused by smoking [1, 16].

Global analyses have shown that the prevalence of asthma varies from 1% to over 20% in different countries, depending on geographical region, income level and access to health care [5, 12]. In China, for example, asthma affects about 4.2% of the population, with a higher incidence in men than in women (4.7% versus 3.6%) [5]. In the United States, the prevalence of asthma is about 7.7%, with women at higher risk of developing the disease than men (10.4% versus 6.3%) [12]. COPD also remains a major public health problem, with a global prevalence of 10.3% among adults over 40 years of age [1]. In low-income regions, this figure is significantly higher due to the prevalence of risk factors such as tobacco smoking and air pollution [15].

The main risk factors for asthma include genetic predisposition, exposure to allergens, air pollution and passive smoking [14]. In turn, risk factors for COPD include active smoking (the main etiological factor), long-term inhalation of dust and chemicals, and frequent respiratory infections in childhood [13, 15]. Gender differences play an important role in the development of both diseases: men are more likely to suffer from COPD, while women have a higher risk of developing asthma [4, 13].

The scale of the problem is confirmed by mortality rates. According to WHO, COPD is the third leading cause of death in the world, accounting for more than 3 million deaths annually [1]. In comparison, asthma causes about 400,000 deaths per year, especially in low- and middle-income countries [5, 14]. Effective treatment of these diseases includes the use of inhaled corticosteroids, bronchodilators, and control of risk factors. However, access to treatment often remains limited, especially in vulnerable populations [5, 15].

Thus, asthma and COPD are the leading causes of morbidity and mortality in the world. Their treatment requires a comprehensive approach, taking into account the gender and age characteristics, as well as the socio-economic conditions of patients.

The aim of the study – to compare the effectiveness of different treatment regimens for bronchial asthma and COPD using the example of a tertiary care institution.

Materials and methods of research. To achieve the set goal, we performed an analysis of 203 disease histories and data from the medical information system MedAir of patients of the Pulmonology Department at the Communal nonprofit enterprise “Vinnytsya regional Clinical Hospital named after M.I. Pirogov Vinnytsia Regional Council”. We analyzed the recommendations of doctors after discharge and the date of the next deterioration of the patients' condition according to the medical information system. Treatment schemes were analyzed: 1. Symbicort turbohaler (manufactured by AstraZeneca AB, Sweden): Formoterol + Budesonide; 2. Seretide diskus (producer Glaxo Wellcome Production, France): Salmeterol + Fluticasone; 3. Beklazon-Eko (manufacturer Norton (Waterford) Limited, Ireland) – Beclomethasone.

Committee on Bioethics of National Pirogov Memorial Medical University, Vinnytsya (protocol № 7 from 08.11.2022) found that the studies do not contradict the basic bioethical standards of the Declaration of Helsinki, the Council of Europe Convention on Human Rights and Biomedicine (1977), the relevant WHO regulations and laws of Ukraine. Before starting the study, we obtained informed consent from the patients.

For statistical processing of the obtained results, we used the analytical system R, version 4.3.1 (2023-06-16) GNU GPL license v.(≥ 2) svn.rev 84548, using the “aarch64-apple-darwin20” platform, the “Benchmarking” library, “readxl”, “ggplot2”, “AER”, DEA analysis functions eff(), dea(), cost.opt(), dea.boot(), sdea(), slack(), statistical test functions ks. test(), qf(), tobit regression function tobit().

Efficacy was determined by volume to establish dosing inefficiencies. The optimal doses were determined as the ratio of E indices according to CRS (Constant Returns to Scale) to those according to VRS (Variable Returns to Scale). Optimality is achieved by the value of the ratio 1. Insufficient or excessive dosage is determined by comparing the VRS index with that according to DRS (Decreasing Returns to Scale), namely if VRS < DRS, we have insufficient dosage, and when VRS = DRS and the efficiency due to the volume is less than one we determine the excess dosage. and technical efficiency by distance to the frontier.

The study of the effectiveness of the main treatment (basic therapy) of BA and COPD was carried out on the basis of the technical efficiency of product production with constant resources, i.e. output efficiency according to the Farrell index

We also studied both the efficiency of resource use, i.e. input efficiency according to the inverse Farrell index E, and the technical efficiency of product production with unchanged resources, i.e. output efficiency according to the Farrell index (Farrell efficiency, F~1/E). The indicated indices were determined using DEA (Data Envelopment Analysis), namely the resource efficiency index, which is sought by their (x)

$$E^0 = E((x^0, y^0); T^*) = min\{E \in \Re_+ | (Ex^0, y^0) \in T^*\}$$

minimization:
and the Farrell index by maximizing the produced product (days to the next exacerbation):

$F^0=F((x^0,y^0);T^{\wedge *})=\max\{F\in R_+ |(x^0,Fy^0)\in T^*\}$

We determined the cost-effectiveness index, which has a scale from 0 (zero efficiency) to 1 (100% efficiency). The cost-effectiveness criterion takes into account not only the resources, the produced product, but also the prices of resources, that is, it adds a price component to the consideration, and therefore it is considered preferable. It is calculated as the ratio of optimal costs for a given frontier to those observed for the same manufactured product.

Analysis of factors that significantly modified the cost-effectiveness criterion according to treatment schemes was carried out on the basis of tobit regression ("AER" library of the international analytical system R). The analysis was performed only for the first and second schemes that had a sufficient number of patients. The basic formulation of the model works is presented below, α is the vector of model coefficients presented in the article, ε are the residuals of the model with a standard normal distribution, i.e. $\varepsilon \sim N(0,\sigma^2)$. The estimate of the scaling parameter σ, or rather the logarithm of the estimate, is presented in the last line as the effect "Log(scale)".

$$E = \begin{cases} 0, & \text{if } az + \varepsilon \leq 0 \\ az + \varepsilon & \text{if } 0 < az + \varepsilon < 1 \\ 1 & \text{if } az + \varepsilon \geq 1 \end{cases}$$

The results of the research and their discussion

Analysis of the effectiveness of treatment by input efficiency showed that the frontier of effectiveness was formed by only 5 patients out of 97 included in the analysis, which is evidence that the regimens of basic therapy are inadequately adapted to patients. The distribution by centiles is given in Table 1. It can be seen that 50% of patients were characterized by an efficiency index of less than 0.2302, and in a quarter the index did not exceed 0.1250. Analysis of effectiveness due to volume. Only in 3 of 97 patients the doses turned out to be optimal. Optimal doses are defined as the ratio of E indices by CRS (Constant Returns to Scale) to those by VRS (Variable Returns to Scale). Optimality is achieved by the ratio of 1. Insufficiency or excess of dosage is determined by comparing the VRS index with that of DRS (Decreasing Returns to Scale), namely if VRS < DRS, we have insufficient dosage, and when VRS = DRS and efficiency due to volume less than one, we determine excess dosage. The result showed that of all patients with efficiency due to volume less than 1, namely 97 – 3 = 94 patients, 67 had excessive dosage, while in 27 doses were lower than optimal. Study of the effectiveness of the main treatment (basic therapy) of BA and COPD. It turned out that only 5 out of 53 patients with asthma formed the frontier of technical efficiency according to the Farrell index, i.e. had optimal prescriptions. At the same time, 4 out of 44 patients with COPD had optimal prescriptions, i.e. formed the frontier. The percentiles of the Farrell index distributions of patients with asthma and COPD are shown in Table 1.

Unlike the E index, the Farrell index has values greater than 1 proportional to lower effectiveness. From these distributions, we can conclude that the prescriptions for patients with asthma are more effective. Graphically, the cumulative distribution functions of the Farrell index values for patients with asthma and COPD are shown in Fig. 1.

A fairly tight fit of the two curves indicates the absence of significant differences, which were tested based on both the parametric Fisher's exact test (F) and the nonparametric Kolmogorov's difference of two cumulative distributions. The results of the two tests are given in Table 2. The value of the Kolmogorov test statistic D = 0.16381, p-value = 0.4765 indicates the absence of significant differences in the curves, as does the Fisher's parametric test with a test statistic of 0.79708, which is outside the 95% confidence interval of the F-distribution, namely 0.7413575–1.356138. This indicates that a significantly better effectiveness of basic therapy for patients with asthma has been established.

Comparative analysis of the effectiveness of treatment regimens based on basic therapy according to Farrell's criteria. We took into account both basic and concomitant therapy, that is, we considered treatment in a complex, although the scheme was determined by the basic therapy. Three such common schemes were found, with the corresponding number of patients 52, 19, and 5. Technical efficiency Output was studied using the Farrell criterion. Table 1 shows the centiles of the distributions of the Farrell index of patients under three treatment schemes. The advantage of the third scheme is obvious, but its advantage is compromised by the small number of observations, so the main conclusions are still based on the first and second schemes. The first scheme is clearly better, which has lower values of the Farrell index at all centiles of the distribution, which indi-

Table 1

Summary of data comparing the effectiveness of different treatment regimens for BA and COPD

	Min	25%	50%	Mean	75%	Max
Input E	0.0208	0.125	0.2302	0.2982	0.3452	1
By volume	0.1806	0.8145	1	0.8463	1	1
BA Farrell	1	1.743	2.532	2.665	3.227	6.518
COPD Farrell	1	1.560	2.518	3.090	3.741	12.435
Scheme 1 Farrell	1	1.117	1.459	1.483	1.879	2
Scheme 2 Farrell	1	1.349	2	2.341	3.766	4
Scheme 3 Farrell	1	1	1	1.158	1.320	1.472
Scheme 1 CE	0.5	0.5	0.5	0.6610	0.8678	1
Scheme 2 CE	0.25	0.2772	0.5	0.5281	0.6596	1
Scheme 3 CE	0.7074	0.8018	1	0.9018	1	1

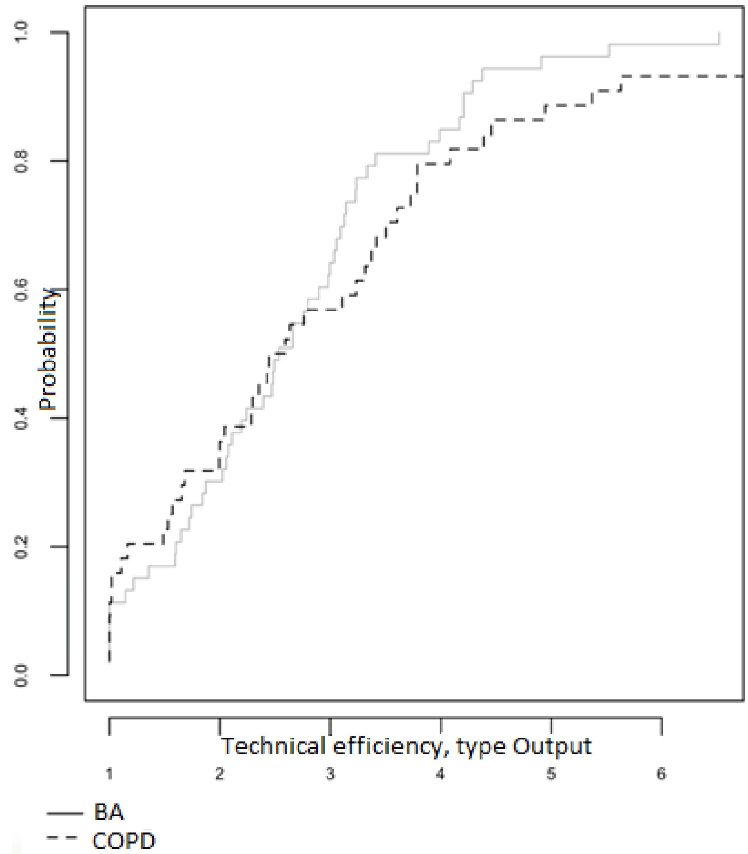

Fig. 1. Cumulative distributions of the technical efficiency of the treatment of BA and COPD

cates its regularly higher efficiency. The results of the application of the nonparametric Kolmogorov and parametric F tests are given in Table 2. There is a significant difference in efficiency between the first and second groups according to the Kolmogorov test (D = 0.42004, p-value = 0.009244), the p-level of reliability is high ($p < 0.01$), the Fisher criterion estimate is 0.3600035 and is outside the 95% confidence interval 0.6714396–1.500687. Scheme 2 also has a significantly lower Farell efficiency compared to scheme No. 3, namely the p-level of reliability of the Kolmogorov test corresponds to 0.03091 centile of the criterion distribution density (D = 0.68421, p-value = 0.03091). The reliability of the effectiveness is also evidenced by the Fisher exact test estimate of 8.463432, which is outside the confidence interval (0.4154131–3.264267). No significant differences in Farrel efficiency were found between the first and third treatment regimens (D = 0.48077, p-value = 0.1661).

Comparative analysis of treatment regimens based on basic therapy according to cost-effectiveness (CE) criteria. Comparative analysis of treatment regimens based on basic therapy according to cost-effectiveness criteria cannot be conducted for patients with asthma and COPD, since different regimens are used for each group of nosologies. However, this can be done according to treatment regimens. We also took into account both basic and concomitant therapy, and the regimen was determined by the main therapy. Accordingly, the regimens included 52, 19, and 5 patients. It should be recalled that the cost-effectiveness index has a scale from 0 (zero efficiency) to 1 (100% efficiency). The cost-effectiveness criterion takes into account not only resources, the product produced, but also the prices of resources, i.e. adds a price component to the consideration, and is therefore considered preferable. It is calculated as the ratio of optimal costs for a given frontier to those observed for the same product produced. As in the case of Farrell's technical efficiency, the cost-effectiveness index gives preference to the third treatment regimen (Table 1), where 3 out of 5 patients had an index value exceeding 0.999. For the first regimen, this number was 8 out of 52, for the second 3 out of 19. These differences are regular across all centiles, i.e. relate to the distributions as a whole. Statistical tests indicate that the second treatment regimen is significantly worse in terms of cost-effectiveness. Thus, the significantly lower cost-effectiveness of the second regimen compared to the first regimen was confirmed by the Kolmogorov test with statistics D = 0.47368, p-value = 0.002027 and Fisher's criterion 0.7183119. No significant differences in the distributions of the cost-effectiveness index of the first and third treatment regimens were found. The third regimen turned out to be significantly more effective than the first (D = 0.67308, p-value = 0.01492) and the second (D = 0.73684, p-value = 0.01515), the same conclusions were reached by Fisher's tests (Table 2).

Allocative efficiency of treatment regimens based on basic therapy. It turned out that all regimens have optimal allocative efficiency, that is, the best combination of the sizes of the main and accompanying therapy. Moreover, no slack was observed for any patient, i.e. there were no discrepancies in the amounts (disproportions) of the prescriptions of the main and accompanying therapies. That is,

Table 2

Data from the analysis of the effectiveness of prescribing different regimens to patients with BA and COPD

	Kolmogorov's test	F - test	95% CI
BA - COPD, Farrel	D = 0.16381, p-value = 0.4765	0.79708	0.6714396–1.500687
Scheme 1 vs 2, Farrel	D = 0.42004, p-value = 0.009244	0.3600035	0.6073806–1.759054
Scheme 1 vs 3, Farrel	D = 0.48077, p-value = 0.1661	3.046865	0.4599551–3.149015
Scheme 2 vs 3, Farrel	D = 0.68421, p-value = 0.03091	8.463432	0.4154131–3.264267
Scheme 1 vs 2, CE	D = 0.47368, p-value = 0.002027	0.7183119	0.6073806–1.759054
Scheme 1 vs 3, CE	D = 0.67308, p-value = 0.01492	3.452706	0.4599551–3.149015
Scheme 2 vs 3, CE	D = 0.73684, p-value = 0.01515	4.806694	0.4154131–3.264267

in most cases, both the main and accompanying therapies were used in excess amounts, as established above, but the excess was proportional.

Analysis of factors that significantly modified the cost-effectiveness criterion by treatment regimens. We determined the factors that significantly modified the cost-effectiveness criterion by treatment regimens, since the influence of factors may be different. These factors were: patient age and gender, place of residence (village; city), employment, length of hospital stay, diagnosis (BA; COPD), year of observation, compliance. Of all the criteria, we chose cost-effectiveness as multi-dimensional and, therefore, the most informative. The results of the tobit regression are given for the first and second treatment regimens, respectively, in Tables 3 and 4.

From Table 3 it is clear that the included factors with a significant impact are gender, diagnosis, and year of observation. From the negative value of the regression coefficient it follows that the cost-effectiveness of the first scheme deteriorated over the years from 2019 to 2024. The coefficient was significantly better in women. The first scheme was significantly more effective in the treatment of BA. The presence of compliance increased the effectiveness, but not significantly.

Analysis of the impact of factors on the cost-effectiveness of the second treatment regimen by Tobit regression shows

Table 3

Analysis of the impact of factors on the cost-effectiveness of the first treatment regimen using tobit regression

Effect	**Coefficient**	**Error**	**z**	**p**
Constant	0.8235	0.1869	4.4067	1.05E-05
Age	–0.0006	0.0030	–0.1852	0.8531
Sex	–0.1818	0.0545	–3.3343	0.0009
Living in the village	0.0318	0.0483	0.6577	0.5108
Employment	0.0046	0.0198	0.2337	0.8152
Duration of inpatient treatment	–0.0077	0.0098	–0.7844	0.4328
Diagnosis	0.1348	0.0593	2.2715	0.0231
Year	–0.0604	0.0233	–2.5948	0.0095
Compliance	0.0650	0.0537	1.2095	0.2265
Log(scale)	–1.8008	0.0981	–18.3642	2.54E-75

Table 4

Analysis of the impact of factors on the cost-effectiveness of the second treatment regimen using tobit regression

Effect	**Coefficient**	**Error**	**z**	**p**
Constant	1.5276	0.6606	2.3125	0.0208
Age	0.0059	0.0042	1.4252	0.1541
Sex	0.4309	0.1708	2.5224	0.0117
Living in the village	–0.0877	0.1153	0.7607	0.4469
Employment	–0.1024	0.0320	3.2033	0.0014
Duration of inpatient treatment	–0.0547	0.0350	1.5659	0.1174
Diagnosis	–0.2749	0.1725	1.5939	0.1110
Year	–0.0857	0.0657	1.3052	0.1918
Compliance	0.0753	0.2088	0.3607	0.7183
Log(scale)	–1.5739	0.1622	9.7019	2.95E-22

that gender and employment had a significant impact, namely the cost-effectiveness of the second treatment regimen was better for men $\alpha = 0.4309$, $p = 0.0117$, as well as for the employed population. All other factors considered did not have a significant impact on the cost-effectiveness of the second treatment regimen. Again, the presence of compliance increased the effectiveness, but not significantly.

The treatment of asthma and COPD is associated with significant financial costs for both healthcare systems and patients. The economic burden of these diseases includes direct medical costs (drugs, hospitalization, outpatient care) and indirect costs (reduced work productivity, disability, etc.) [3, 16].

Comprehensive treatment of obesity-associated asthma is effective in both early and late-onset asthma. It was found that patients in both groups improved respiratory function, reduced inflammation, and improved asthma symptom control after treatment, while the effectiveness of interventions was somewhat lower in patients with late onset [7].

A study conducted in Italy showed that the average annual cost per patient with COPD was €2,549, with 56% of this cost attributable to hospitalization, 28% to drug therapy, and only 16% to outpatient visits [3]. Similarly, the results of the COSYCONET study in Germany showed that the direct costs of COPD were significantly higher in patients with comorbidities such as cardiovascular diseases or diabetes, ranging from €2,000 to €5,000 per year, depending on the severity of the disease [16].

For asthma, a study in the United States estimated the economic burden of the disease at $81.9 billion annually, of which $50.3 billion was direct medical costs and $29 billion was indirect costs related to lost productivity due to missed work or school [10]. In the UK, the cost of treating severe refractory asthma was £29,000 per patient per year, 10 times higher than the cost of treating patients with mild asthma [11]. Cost-effectiveness studies have highlighted that early use of modern treatment regimens, including inhaled corticosteroids and bronchodilators, reduces the cost of hospitalization and treatment of complications. For example, a self-management program for patients with COPD in the UK has been shown to be cost-effective, saving around £25 per patient per year through reduced exacerbations and hospitalizations [6]. In turn, a study conducted in Italy confirmed that optimizing medication use through individual pharmacist consultations for patients with asthma reduces overall costs by 16% [8]. In addition, demographic factors such as age and gender also affect costs. In the USA, women had higher costs for hospitalization for asthma than men ($3,497 vs. $3,108), which is associated with more frequent complications [17].

The combined use of hypoxic training and breathing exercises with positive end-expiratory pressure on lung ventilation function and gas exchange in elderly patients with chronic obstructive pulmonary disease improves external respiration and pulmonary gas exchange efficiency and reduces the cost of treatment [2].

Projected trends indicate that by 2030 the number of patients with COPD in England and Scotland could increase by 33%, which would increase overall costs to over £2.5 billion annually [9].

Conclusions. Analysis of the effectiveness of treatment of BA and COPD indicates a general non-adaptation of basic therapy regimens to the needs of patients. Only 5 out of 97 patients reached the frontier of technical effectiveness, and most of them encountered excessive (67 patients) or insufficient dosing (27 patients). The effectiveness of basic therapy was higher in patients with BA compared to COPD.

Comparison of the three treatment regimens indicates the superiority of the first regimen in terms of technical effectiveness (Farrell index) and the second in terms of cost-effectiveness. However, the third regimen had the highest indicators in both criteria, although its conclusions are limited by the small number of observations.

Analysis of the influence of factors revealed that gender, diagnosis and year of observation had a significant impact on cost-effectiveness. In women and patients with BA, the effectiveness of the first regimen was significantly better. The second regimen demonstrated higher effectiveness for employed men. Despite the positive impact of compliance, its role was not statistically significant.

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