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**Pharmacoeconomic Approaches to Forecasting of the Budget Impact and Compensation for Rotavirus Enteritis in Children in Ukraine**

In the conditions of the growth of morbidity and mortality rates from enteritis of the viral origin in children, in particular rotavirus enteritis (RE), a special attention is paid to optimization of the cost for pharmacotherapy, and forecasting of possible expenses for the treatment and preventive vaccination of RE in children.

**Aim.** To conduct the "budget impact" analysis of pharmacotherapy and preventive vaccination of RE in children in Ukraine in 2017-2018 and predict the amount of compensation for drugs by two of the approaches to the management of the disease for 2018.

**Materials and methods.** The method of the "budget impact" pharmacoeconomic analysis, graphical, analytical and methods of mathematical modeling, Statistica 6 software were used.

**Results.** The impact on the budget due to the introduction of vaccination among children requires more costs than pharmacotherapy, namely the ratio of costs in the first year – 1:30, in the second year – 1:10. The predicted volume of vaccination compensation in Ukraine is 772,952,274 UAH (711 UAH per a child), compensation for the cost of drugs for the treatment of RE – 3560,853 UAH. (281.49 UAH per a patient).

**Conclusions.** It has been found that there is a significant economic burden of vaccination on the budget; however, this method has the benefits delayed in time. The predicted total volume of compensation (reimbursement) of vaccination is significantly higher than the volume of compensation of the RE pharmacotherapy. However, the cost of vaccination per capita exceeded by 2.5 times compared to the treatment.

**Key words:** viral acute intestinal infections; rotavirus enteritis; children; "budget impact analysis"; cost compensation; vaccine prophylaxis
The state of health of the child population is one of the most important indicators of social and economic development of any country in the world. The peculiarity of the pharmaceutical providing of children in Ukraine is the classification of this category to the privileged, i.e. the cost of therapy, in whole or in part, should be reimbursed by the state. In accordance with the approved Concept of the healthcare financing reform the introduction of obligatory social health insurance (HI) is one of the effective mechanisms for implementation of constitutional guarantees of the state, and it will give an opportunity to improve the pharmaceutical providing of the population, including children [1]. Thus, scientific developments and recommendations regarding the practical principles for obligatory social HI in Ukraine are of particular importance.

For example, modeling of the budget impact (BIA), in particular by the “budget impact” analysis (BIA) and forecasting of the amount of compensation of the basic health technologies (HT) may be used by the most socially significant nosologies, which enterites of the viral origin belong to, among them rotavirus enteritis (RE) has the largest proportion. Thereby, the aim of the work was to conduct BIA of pharmacotherapy and preventive vaccination of RE in children in Ukraine in 2017-2018 and predict the amount of compensation for drugs by two of the approaches to the management of the disease.

Materials and methods

The method of the “budget impact” pharmaco-economic analysis, graphical, analytical and methods of mathematical modeling, Statistica 6 software were used to obtain and analyze the data. The study was based on a static model of BIA, in which the use of two approaches to quality disease (RE) management was compared: preventive vaccination and the basic pharmacotherapy approved by the relevant protocols for the treatment of acute intestinal infections in children in Ukraine [2-5]. The analysis included direct and indirect costs of treatment (costs for payment of days of disability by the sick leave of the patient’s parents and the production losses of the society due to their absence in the workplace (the loss of GDP of the country), as well as prediction of the number of probable patients in future periods [6].

The calculations of the impact on the budget were made taking into account the following conditions:

- 100 % of patients up to 5 years old (60 months), patients with viral enteritis were received the basic therapy (rehydration and auxiliary).
- Healthy children up to 2 years old (24 months) were vaccinated by the antirotavirus vaccine (Rota-rix, “GSK”) taking into account the course of vaccination – 2 doses at intervals of 4 weeks [7].

The data of the State Statistics Service were used to predict the number of healthy children from 0 to 2 years for vaccination and the number of children with RE for the period from 2012 to 2017 according to the country regions [8]. The prognosis of indicators for different administrative-territorial units of the country in 2018 was carried out using the method of mathematical modeling, namely by constructing a polynomial model for each region of the country, except for the Donetsk and Mykolaiv regions. For a series of data in the Donetsk region a linear trend was used, while for a series of data in the Mykolaiv region a step-line trend was applied [9].

In calculations the average purchase price (the Morion database: May, 2016) of the monovalent vaccine “Rotarix”, oral suspension, 1.5 ml/dose in appl. (tube) No.1 (GlaxoSmithKline Biologicals S.A., Belgium) was used. Calculations of the cost of pharmacotherapy were carried out in our previous studies using pharmaco-economic approaches [10-12]. The algorithm for forecasting of the amount of compensation for the cost of drugs according to the administrative-territorial regions of the country is given in Fig.

Results and discussion

The methods of conducting BIA for the treatment and preventive vaccination of viral acute intestinal infections (AII) on the example of RE in children in 2017-2018 and the data obtained are presented in
According to our calculations, the number of children to be vaccinated in 2018 will be only 35% of the initial (predicted by 2017) child population. Under all these conditions the ratio of the total costs for the treatment of viral AII and antirotavirus vaccine in the second year – 2018 – the use will be 1:10 indicating the importance and economic, timed-out benefits of vaccination.

According to the results of forecasting of the total amount of compensation of vaccination against acute intestinal infections in children in 2017-2018 (on the example of rotavirus enteritis)

**Table**

<table>
<thead>
<tr>
<th>No.</th>
<th>Stages</th>
<th>Health technology 1: “Treatment”</th>
<th>Health technology 2: “Preventive vaccination”</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Determination of the number of HT consumers in 2017</td>
<td>The predicted number of patients with viral AII up to 5 years (60 months): 12 245 persons</td>
<td>The predicted number of healthy children up to 2 years (24 months) for a single vaccination: 1 087 134 persons</td>
</tr>
<tr>
<td>2</td>
<td>Calculation of direct costs, UAH</td>
<td>Rehydration therapy: 707 038,45 Enterosorbent therapy: 453 065 Probiotic therapy: 1 303 773</td>
<td>The vaccine cost (purchasing) (Rotaryx) × 2 doses × the number of consumers:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total: 2 463 876,45</td>
<td>Total: 820 699 199</td>
</tr>
<tr>
<td>3</td>
<td>Calculation of indirect costs, UAH</td>
<td>Costs for the totality of patients: 25 036 127,00</td>
<td>absent</td>
</tr>
<tr>
<td>4</td>
<td>Calculation of the net impact on the budget, UAH (stage 2 + stage 3)</td>
<td>27 500 003,45</td>
<td>820 699 199</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The ratio of costs for HT 1 and HT 2 in the first year of use is 1:30</td>
<td></td>
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<tr>
<td>5</td>
<td>Forecasting of the impact of viral AII on the budget in 2018 under conditions of the HT 2 use in 2017, UAH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1</td>
<td>Determination of the number of HT consumers in 2018</td>
<td>The predicted number of patients with viral AII up to 5 taking into account the vaccine efficacy (89.5 %): 1 286 persons</td>
<td>Only healthy children up to 12 months need vaccination: 371 822 persons</td>
</tr>
<tr>
<td>5.2</td>
<td>Calculation of the net impact on the budget 2018, UAH</td>
<td>2 888 117,96</td>
<td>280 695 795,8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The ratio of costs for HT 1 and HT 2 in the second year of use is 1:10</td>
<td></td>
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</tbody>
</table>
RE in Ukraine the amount of 772,952,274 thousand UAH (29102,118 thousand USD) was determined, it was 711 UAH (26.77 USD) per one child under the age of 2 years. Among the regions of the country, there were three leaders in terms of compensation for the cost of the vaccine – the Vinnytsia, Dnipropetrovsk regions and the city of Kyiv. The lowest indicators of compensation of the cost of drugs were observed in the Kirovograd, Luhansk, Chernihiv regions.

The estimated amount of compensation of the cost of drugs for the RE treatment in children was 3560,853 thousand UAH or 134,068 thousand USD. The amount of compensation per one child patient with RE was 281,49 UAH or 10.60 USD. The highest proportion (%) of the predicted compensation was for drugs of saccharomyces boulardii (A07FA02) – 42.24%, and the lowest one for drugs of the sodium chloride group (B05XA03) – 0.60%.

According to the predicted amount of compensation for drugs the leaders among the regions were the Lviv, Dnipropetrovsk, and Khmelnytsky regions, while the lowest indicators were typical for the Donetsk, Kirovograd, Poltava regions.

CONCLUSIONS
1. The method for conducting the pharmaco-economic analysis by the method of BIA for the treatment and preventive vaccination of enteritis of viral etiology in children has been developed and tested.
2. It has been determined that the ratio of total costs for the RE treatment and the costs of vaccination in 2017 will be 1:30, in 2018 – 1:10, it indicates a significant annual reduction in the cost of the RE pharmacotherapy in children under the condition of vaccination against rotavirus.
3. On the basis of the complex studies it has been proven that the estimated amount of compensation of the cost of vaccination in Ukraine is 772,952,274 thousand UAH (29102,118 thousand USD), it is 711 (26.77 USD) per one child up to 2 years.
4. It has been found that the predicted amount of compensation for the cost of drugs for the RE treatment in children is 3560,853 thousand UAH or 134,068 thousand USD. The amount of compensation is 281,49 UAH or 10,60 USD per one child patient.
5. It has been shown that the highest proportion (%) in the predicted compensation is observed in the adjuvant therapy (63.47 %), in the rehydration therapy this indicator is 20.35%, in the antibiotic therapy – 16.18 %.
6. The structural analysis of the predicted reimbursement according to the regions of the country has shown that the leaders in terms of the predicted amount of compensation for drug therapy of RE are the Lviv, Dnipropetrovsk, Khmelnytsky regions, and the lowest indicators are characteristic for the Donetsk, Kirovograd, Poltava regions.

Consequently, it has been found that coverage of the child population by vaccination against rotavirus infection requires significantly higher costs compared to the pharmacotherapy for child patients in Ukraine, their volume is significantly decreased in subsequent periods by reducing RE morbidity and the number of healthy children to be immunized. It has been substantiated that the introduction of the procedure for compensation of costs for pharmaceutical care providing at the regional level will enable to use the budget funds effectively and individual approaches to treatment of certain groups of patients and categories of the population.

Conflict of Interests: authors have no conflict of interests to declare.

References
3. WHO vaccine–preventable diseases : monitoring system. 2016 global summary. – Available at : http://apps.who.int/immunization_monitoring/globalsummary/
7. Державна служба статистики України [Електронний ресурс]. – Режим доступу : www.ukrstat.gov.ua