

## ОРГАНІЗАЦІЯ ТА ЕКОНОМІКА ФАРМАЦІЇ

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### THE EXPERT EVALUATION OF DRUGS AS A BASIC FACTOR FOR DEVELOPMENT OF THE SOCIOECONOMIC LISTS RECOMMENDED FOR TREATING ENTERITIS OF THE VIRAL ORIGIN IN CHILDREN

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*Key words: viral diarrhea; enteritis of the viral origin; expert evaluation; antidiarrheal drugs; socioeconomic lists of drugs; children*

*In the article the results of a comprehensive expert evaluation of drugs for treating viral diarrhea (VD) in children as an important stage in development of regulatory socioeconomic lists (SEL) are presented. In particular, the results of calculations of the expert competency are given. It has been found that among the respondents almost 15% of the experts has experience in the specialty for over 20 years, 50% – from 10 to 20 years of service indicating the high professional competence of the physicians surveyed. In addition, 92% of experts have higher or the first qualification category, which confirms the high professional level of the respondents. It has been determined that 76% of the samples of drugs evaluated by competent experts were recommended for inclusion in the recommended SEL for treating VD in children. The calculations allowed including 19 drugs corresponding to 5 pharmacological groups to the recommended SEL by trade names, as well as 3 drugs by INN. The results can be used in future to create the recommended insurance (primary and secondary) lists of drugs for VD pharmacotherapy in children taking into account the additional pharmacoeconomic studies; it remains the topical issue of the national healthcare system in the conditions of health insurance implementation.*

Viral diarrhea (gastroenteritis) is inflammation of the stomach and intestines caused by viruses, it is also known as the stomach flu. Viral gastroenteritis affects mainly children.

Diarrhoeal disease is the second leading cause of death in children under five years old, and is responsible for killing around 760 000 children every year [6]. The Integrated Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea (GAPPD) was developed by WHO/UNICEF in 2013 to decrease mortality from pneumonia to fewer than 3 children per 1000 live births, and from diarrhoea to less than 1 per 1000 by 2025.

In Ukraine medical standards for treating child diarrhea are used in medical practice. At the same time reforming and development of the current healthcare system require some improvement in organization of pharmaceutical providing of the population. Thus, the problem of improving the existing pharmaceutical care for children is especially vital. The expert (doctors) evaluation has an important role for assessing the effectiveness of medicines.

Taking into account the importance of the problem the expert evaluation of medicines for treating viral diarrhea (enteritis) in children was conducted, and the list of drugs for further studies in order to include them to

regulated lists for viral diarrhea treatment in children was proposed.

#### Materials and Methods

The questionnaire for children infectionists considered the peculiarities of treatment of viral diarrhea (VD) in children. It consisted of two parts: the first part – informative – contained the information about the respondent (specialty, experience, category, etc.), the second part – the content – included a table of 55 drugs assessed by such parameters as “efficiency”, “incidence of side effects”, “frequency of prescription”, “prospects of use” and “availability”. The list of drugs for evaluation by experts was formed on the basis of the analysis of protocols of medical care to children with acute intestinal infections, namely viral (secretory) diarrhea, and the results of marketing analysis of the domestic market of drugs for treating VD in children [5].

To provide the reliability of the information obtained as a result of the expert evaluation we sent 59 questionnaires to specialists of Vinnytsia, Zhytomyr, Mykolayiv, Kharkiv and Chernivtsi regions during 2014-2016.

#### Results and Discussion

Summarizing the information about the experts who participated in the study revealed general trends for their basic characteristics. Thus, almost 15% of the experts

Table 1

The summarized results of calculations of the level of competence of pediatric specialists when treating viral diarrhea

The number of questionnaires by the level of competence, %	Level of expert competence, Cc					Total, %
	Cc $\geq$ 0.81 – very high	Cc – 0.61-0.8 – high	Cc – 0.41-0.6 – sufficient	Cc – 0.21-0.4 – low	lc – 0.2-0.1 – very low	
	31	48	18	3	0	100

had experience in the specialty for over 20 years, 50% – from 10 to 20 years of service indicating the high professional competence of the physicians surveyed. In addition, 92% of experts had higher or the first qualification category confirming the high professional level of the respondents.

An important step to obtain reliable research results of the expert evaluation of drugs is calculation of the competence of each expert. The competence coefficient (Cc) allows determining the ability to attract experts to assess a drug and, as a result, to confirm the adequacy of the therapy prescribed.

The five levels of competence for ranging of specialists treating VD in children were proposed. The results obtained from the calculations of experts' Cc are given in Tab. 1.

It was found that there were no experts in the group of experts with a very low competence, and the group with a low competence includes only 3% of the totality of respondents. It can be considered as a satisfactory phenomenon. The groups of experts with a sufficient, high and very high level of professional competence consisted of 18%, 48% and 31% of the sample, respectively. Thus, the structure of the sample showed a high level of awareness among the respondents and contributed to reliability of the results of the study.

Further a comprehensive assessment of drugs for treating VD in children included only opinions of experts with a sufficient, high and very high level of professional competence (97% of the respondents).

The drugs proposed to experts should be evaluated by the parameters specified using the four point grading scale. Thus, each drug included in the analysis received the weighted mean score of experts according to the parameters studied. Further, the multivariate mean value ( $\bar{p}_i$ ) was used for each medicine by four parameters. Taking into account the small range of the values obtained (0.43-1.33) it was difficult to identify drugs that could be recommended for inclusion to the recommended socioeconomic lists (SEL). Consequently, the results of calculations of  $\bar{p}_i$  concerning the levels of opportunities for including drugs to SEL medicines were ranked into three groups:  $h_1$  (high level),  $h_2$  (intermediate level),  $h_3$  (relatively low level). Ranking was carried out by the method of equal intervals, step  $h$  corresponded to 0.3.

It was determined that the drugs with  $\bar{h}_i$  value varied from 1.33 to 1.03 were referred to the first group ( $h_1$ ) in terms of the possibilities of including the drug to the recommended SEL, and  $\bar{p}_i$  values in the range of 1.02-0.72 – to the second group ( $h_2$ ). Therefore, 14 drugs (corresponding to 10 drugs by INN) were referred by the experts

to the group of drugs with the high level of the possibilities of inclusion to the recommended SEL, 27 drugs (or 5 drugs by INN) were referred by the experts to the group of drugs with the intermediate level. It was determined that 76% of the samples of drugs evaluated by competent experts were recommended for inclusion in the recommended SEL for treating VD in children.

It should be noted that the experts were asked to name and evaluate medicines of antibiotics and other groups often used by them when treating viral diarrhea in children except those that were proposed in the questionnaire. Thus, among 10 drugs by INN specified by different doctors the medicines of 9 INN received the multivariate mean value being higher than 0.72, i.e. could be considered as those that should be included to the local regulated lists. Among these drugs there are 8 of cephalosporin antibiotics drugs: ceftazidime (= 1.27), ceftriaxone (1.27), cefepime (1.21), cefotaxime (1.08), cefoperazone (0.92), cefixime (0, 81), trimethoprim/sulfamethoxazole (0.81), cefoperazone/sulbactam (0.77) and one antimicrobial antidiarrheal agent – nifuroxazide (1.31).

The next stage of our study was to create the socioeconomic list of medicines recommended for VD treatment in children. To create a socioeconomic list of drugs recommended for the treatment of enteritis of the viral origin (viral diarrhea, VD) in children the following data were used: the results of analysis of the State Formulary List of drugs (VII issue, order No. 183 dated 03/31/15) and the existing standards of medical care for the group of patients under research; the results of the expert evaluation of this group of drugs conducted, namely drugs ranking to group  $h_1$  or  $h_2$  were included to the recommended list; the results of a retrospective analysis of the domestic market of drugs for treating VD in children, namely data on the actual presence of drugs at the wholesale market (proposals of distributors) were used. The results of the assessment of VD pharmacotherapy in children were also applied using frequency analysis (by the frequency of physicians' prescriptions), ABC-cost analysis for each drug and VEN-analysis [1-4, 7]. Thus, by the results of frequency analysis of physicians' prescriptions for VD in children nifuroxazide was included to the recommended SEL. However, being a leader by the frequency of prescriptions, it is recommended only for the treatment of pathogens of invasive diarrhea in the treatment protocols of VD (secretory diarrhea) in children.

Two cephalosporin antibiotics were also included to the recommended list, they both received the highest scores of experts – ceftazidime ( $\bar{p}_i = 1.27$ ) and ceftriaxone ( $\bar{p}_i = 1.27$ ). The inclusion of these drugs in the list formed will allow considering the possibility of their use

Table 2

The summarized results of the study concerning creation of socioeconomic lists of drugs for treating VD in children

ATC-code	Name of the pharmacotherapeutical group	The number of trade names of the drugs under research
A07B	Antidiarrheal agents: Medicines used to treat infectious and inflammatory diseases. Intestinal adsorbents	4
A07CA	Medicines of electrolytes with carbohydrates. Oral rehydration salt formulations	2
A07F	Antidiarrheal microorganisms	2
B05BB	Solutions for the intravenous administration. Solutions affecting the electrolyte balance	6
B05XA	Blood substitutes and perfusion solutions. Electrolyte solutions	5
A07AX03	Antimicrobials used to treat intestinal infections. Nifuroxazide	–
J01D D	Third-generation cephalosporins: ceftazidime, ceftriaxone	–

in preparation of the major socioeconomic lists for providing pharmaceutical care when treating diarrhea of the viral origin in children.

In the case of several drugs with similar active ingredients/substances only one drug with the highest expert evaluation (the multivariate mean value) was included to the recommended SEL. At the same time the priority was given to domestic drug manufacturers. For example, drugs of diosmectite (ATC code – A07VS05) were both included because, in fact, doctors prescribed diosmectite of the French production and experts also preferred the French drug. The summarized results of the study concerning creation of socioeconomic lists of drugs for treating VD in children are presented in Tab. 2.

Obviously, the recommended organizational and economic list compiled by the results of the research conducted needs additional pharmaco-economic studies that will give an economic assessment of availability of VD pharmacotherapy for children. The list created can be used further in implementing the health insurance in the national healthcare system, in particular for formation of insurance and other regulatory lists for treating VD in children.

Therefore, this study allowed compiling SEL for treating VD in children formed according to the recommendations of experts and taking into account the state of the actual VD pharmacotherapy in children, as well as the results of the analysis of the domestic wholesale market of drugs.

#### CONCLUSIONS

1. Viral diarrhea (gastroenteritis) is a disease with high indexes of morbidity and mortality among children

under five years old. The Integrated Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea (GAPPD) was developed by WHO/UNICEF in 2013. It indicates the special attention of the international society to the problem.

2. The analysis of the assessment of the expert competence conducted has shown that almost 15% of the experts has experience in the specialty for over 20 years, 50% – from 10 to 20 years of service, and 92% of experts have higher or the first qualification category.

3. The calculations conducted have indicated that the groups of experts with a sufficient, high and very high level of professional competence consist of 18%, 48% and 31% of the sample, respectively; at the same time there are no experts in the group of experts with a very low competence, and the group with a low competence includes only 3% of the totality.

4. The results of the study conducted have shown that 76% of the drugs evaluated by competent experts are recommended for further study to include to SEL for treating VD in children.

5. The calculations have allowed to find that 19 drugs corresponding to 5 pharmacological groups to the recommended SEL by trade names, as well as 3 drugs by INN can be recommended for further study in order to be included to SEL for treating viral diarrhea in children.

Thus, the results obtained can be used to create the recommended insurance (primary and secondary) lists of drugs for VD pharmacotherapy in children taking into account the additional pharmaco-economic studies; it remains the topical issue of the national healthcare system in the conditions of health insurance implementation.

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#### **ЕКСПЕРТНА ОЦІНКА ЛІКАРСЬКИХ ЗАСОБІВ ЯК ВАЖЛИВА СКЛАДОВА У ПРОЦЕСІ РОЗРОБКИ РЕКОМЕНДОВАНИХ СОЦІАЛЬНО-ЕКОНОМІЧНИХ ПЕРЕЛІКІВ ДЛЯ ЛІКУВАННЯ ЕНТЕРИТІВ ВІРУСНОГО ПОХОДЖЕННЯ У ДІТЕЙ**

**М.В.Балинська**

**Ключові слова:** вірусна діарея; ентерити вірусного походження; експертна оцінка; антидіарейні лікарські засоби; соціально-економічні переліки лікарських засобів; діти

Представлені результати комплексної експертної оцінки ЛП для лікування вірусних діарей (ВД) у дітей як одного з важливих етапів у розробці системи регулюючих соціально-економічних переліків (СЕП). Зокрема, наведені результати розрахунків показників компетентності дитячих інфекціоністів та встановлено, що серед загальної сукупності опитаних респондентів майже 15% експертів мали стаж роботи за спеціальністю понад 20 років, 50% – від 10 до 20 років стажу, що свідчить про високу досвідченість опитаних лікарів. Окрім того, 92% експертів мали вищу або першу кваліфікаційну категорію, що підтверджує високий професійний рівень респондентів. Встановлено, що 76% вибірки ЛП, які оцінювалися компетентними експертами, були запропановані до включення у рекомендований для подальшого вивчення СЕП для лікування ВД у дітей. За результатами розрахунків щодо обґрунтування рекомендованого СЕП ЛП для лікування ВД у дітей встановлена можливість включення в останній 19 ЛП за торговельними назвами, що відповідають п'ятьом фармакотерапевтичним групам та додатково ЛП за трьома INN. Представлені результати можуть бути використані в подальшому для створення рекомендованих страхових (основного та додаткового) переліків ЛП для фармакоterapiї ВД у дітей за умови додаткових фармако-економічних досліджень, що залишається актуальним питанням вітчизняної системи охорони здоров'я в умовах впровадження медичного страхування.

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#### **ЕКСПЕРТНАЯ ОЦЕНКА ЛЕКАРСТВЕННЫХ СРЕДСТВ КАК ВАЖНАЯ СОСТАВЛЯЮЩАЯ В ПРОЦЕССЕ РАЗРАБОТКИ РЕКОМЕНДОВАННЫХ СОЦИАЛЬНО-ЭКОНОМИЧЕСКИХ ПЕРЕЧНЕЙ ДЛЯ ЛЕЧЕНИЯ ЭНТЕРИТА ВИРУСНОГО ПРОИСХОЖДЕНИЯ У ДЕТЕЙ**

**М.В.Балинская**

**Ключевые слова:** вирусная диарея; энтериты вирусного происхождения; экспертная оценка; антидиарейные лекарственные средства; социально-экономические перечни лекарственных средств; дети

Представлены результаты комплексной экспертной оценки ЛП для лечения вирусных диарей (ВД) у детей, как одного из важных этапов в разработке системы регулирующих социально-экономических перечней (СЭП). В частности, приведены результаты расчетов показателей компетентности детских инфекционистов и установлено, что среди общей совокупности опрошенных респондентов почти 15% экспертов имели стаж работы по специальности более 20 лет, 50% – от 10 до 20 лет стажа, что свидетельствует о высоком профессионализме опрошенных врачей. Кроме того, 92% экспертов имели высшую или первую квалификационную категорию, что подтверждает высокий профессиональный уровень респондентов. Установлено, что 76% выборки ЛП, которые оценивались компетентными экспертами, были рекомендованы для дальнейшего изучения относительно включения в СЭП для лечения ВД у детей. По результатам расчетов по обоснованию рекомендованного СЭП ЛП для лечения ВД у детей установлена возможность включения в последний 19 ЛП по торговым названиям, соответствующим пяти фармакотерапевтическим группам и дополнительно ЛП по трем INN. Представленные результаты могут быть использованы в дальнейшем для создания рекомендованных страховых (основного и дополнительного) перечней ЛП для фармакоterapiи ВД у детей с учетом дополнительных фармако-экономических исследований, что остается актуальным вопросом отечественной системы здравоохранения в условиях внедрения медицинского страхования.