

## CURRENT ECONOMIC, SOCIAL ASPECTS OF HEALTH TECHNOLOGIES FOR PRETERM BIRTH AND REAL WORLD DATA OF DRUG PRESCRIPTIONS IN UKRAINE

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**Summary.** Improving the quality of life and health of pregnant women and their rational pharmacotherapy are the main objectives of WHO. Ukraine occupies 72 place in terms of motherhood in the world.

We have analyzed and compared the national and international reports, guidelines on requirements for treatment and prevention of preterm birth. We analyzed the real world data of the frequency of drug prescriptions using ABC / VEN analysis based on medical records about drug prescriptions for pregnant women, diagnosed according to ICD-10 - O47.0. We found that the most common in A group were drugs for 7 INN (14.58 % of total allocations) and the essential drugs was only sodium chloride, which indicated that not enough rational use of funds of patients.

We studied the evidence data about progesterone for effective treatment of PB. Therefore, that is important to optimize pharmaceutical care for pregnant women and rational use of medicines for effective pharmacotherapy of PB according to current health technologies.

**Key words:** pregnancy, preterm birth, health technology, real world data, drug prescriptions, progestin.

**Introduction.** According to the report «State of the World's Mothers 2014. Saving Mothers and Children in Humanitarian Crises» (was prepared by International Society «Save the Children») state Ukraine has 72 place (total – 178 states) in the world, depending on conditions of motherhood, such as rates of maternal health, educational, economic and political status of women and children). Other countries, such as Belarus has 26, Poland – 29, China – 61 place in this ranking [24].

Preterm birth (PB) is a serious medical, economical and social problem. This pathology is quite common among women in low-income countries, but in countries with high level, for example in the United States, that is also a significant problem. According to the WHO newsletter (2016) the rate of PB is over 60 % in Africa and South Asia [27, 28]. The global World Prematurity Network, which includes organizations from Europe, Africa, Australia, China, Latin America, Canada, United States, has the main task to improve care and quality of life of premature infants [25].

According to data of M. Delnold (2015) the prevalence of PB is 5–10 % in Europe [6]. In Ukraine, there is still no official data on PB. Last data was published in 2008, it showed the prevalence 12–46 % and morbidity – 4.0–4.5 % in 2014 [ 7, 13]. Pharmaceutical aspects of pregnant women in the hospital and using ABC VEN analysis were studied. Some aspects of pharmacoeconomic analysis «cost-effectiveness» for treatment of threatened abortion were elaborated in Ukraine [22].

**Research methods.** The aim of this article was to analyze the economical, social aspects of PB in the world

and Ukraine. Also, we studied the real world data on prescribing of drugs for the pregnant with threatened PB, and determined a financial cost for therapy, using ABC/ VEN-analysis and the effectiveness rates according to evidence data for progestogens for PB treatment. We used content-analysis for recommendations, ABC/ VEN analysis for drug prescriptions, systematic review of data.

**Results and discussion.** According to WHO Preterm Birth, defined as birth before 37 weeks of gestation, is the single most important determinant of adverse infant outcomes, in terms of survival and quality of life.. There are sub-categories of preterm birth, based on gestational age: extremely preterm (less 28 weeks), very preterm (28–32 weeks), moderate to late preterm (32–37 weeks) [26, 27]. Globally, it is the leading cause of perinatal and neonatal mortality and morbidity.

WHO published the new «Recommendations on interventions to improve preterm birth outcomes» in 2015. This guideline was developed using standard operating procedures which can improve the chances of survival and health outcomes for preterm infants. The recommendations include the evidence-based health technologies provided to the mother – for example steroid injections before birth, antibiotics when her water breaks before the onset of labour, and magnesium sulfate to prevent future neurological impairment of the child. As well as interventions for the newborn baby – for example thermal care (e.g. kangaroo mother care when babies are stable) , safe oxygen use, other treatments, and the Cochrane systematic reviews were used primarily.

Every year for nearly 15 million babies are born preterm (before 37 weeks), and this number is rising. Preterm birth complications are the leading cause of death among children under 5 years of age, responsible for nearly 1 million deaths due to complications of preterm birth in 2015. Globally, prematurity is the leading cause of death in children under 5 years. And in almost all countries with reliable data, preterm birth rates are increasing. Many survivors face a lifetime of disability, including learning disabilities and visual and hearing problems. Also 75 % of them could be saved with current, cost-effective health technologies.

Data indicated across 184 countries, the rate of preterm birth ranged from 5 % to 18 % of babies born. In low-income countries, 50 % of the babies born at or below 32 weeks (2 months early) die due to a lack of feasible, cost-effective health technologies, such as warmth, and basic care for infections and breathing difficulties. In high-income countries, almost all of these babies survive.

According to the data of British premature baby support charity Bliss, about one in eight babies, or 80000 a year, are born prematurely, of these, 17 000 need intensive care in UK. Among the children born very prematurely (22 to 27 weeks), they found that mortality rates among boys and girls were 5.3 and 9.7 times higher in early childhood. In late childhood boys were 7.0 times more likely to die than other children. The most surprising result was the high age in these boys and girls where increased mortality was registered [18].

Premature infants have an increased risk of dying in late childhood compared with healthy babies, they are significantly less likely to have children themselves. Mothers who were premature are more likely to give birth early as well. Several conditions can lead to premature delivery, including multiple pregnancy, gestational diabetes, pre-eclampsia or a stressful events, but about 30 % of premature births happen for no apparent reasons [5, 18, 19, 21, 23].

Since 2004 the International Working Group to study issues and prevention of PB, that is Preterm Birth International Collaborative (PREBIC) was established. In 2014 in Denmark the First European Congress «Spontaneous premature labor» and the second International symposium of PREBIC was held [19].

In May 2012 report "Born too soon. The global action report on preterm birth" was published. The authors were 45 international experts from 11 countries with support of 50 organizations. This document consists of 6 sections, four of which are devoted to using of good safe health technologies during pregnancy [11].

One of the latest protocols to improve treatment and prevention PB are the WHO Recommendation (WHO recommendations on interventions to improve preterm birth outcomes, 2015) [27], NICE, 2015 (Preterm labour and birth) [21]. In Ukraine there were approved the Orders of Ministry of Health dated 31.12.2004 № 676,

dated 03.11.2008 № 624, № 782 of 29.12.2005 on the requirements for health technologies during pregnancy and preterm birth [13 -15].

We compared the requirements for treatment of preterm birth in these recommendations and protocols, the results are given in Table 1:

Our task was to analyze 102 medical records of pregnant women which diagnosed with PB (ICD-10: - O47.0)/ These patients were hospitalized in the gynecology department of Lviv Regional Hospital in 2016, January–June. We founded that 62 pregnant women were the first-time birth, 40 were second-time, and the mean age was 27.3 years.

It was established that for PB treatment was prescribed 75 trade names of drugs, corresponding to 46 INN of drugs and 2 dietary supplements. Most frequently pregnant women were receiving these drugs top 10 in Figure 1.

In total, 689 prescriptions were made that on average was 6.75 drugs per pregnant, which indicated polypharmacy.

Using the ABC analysis, we evaluated the design prescriptions of drugs, distributing drugs into three groups depending on their consumption. Was determined that the value of drugs, the average retail cost of packaging on September 2016. The analysis of PB schemes revealed that the group included 7 drugs from A group for the INN (14.58 % of total prescriptions), which are the most costly drugs. In the group C is 11 and includes 30 names on drugs INN, whose share of prescriptions was 22.9 % and 62.5 %, respectively (Table. 1).

The analysis showed that among the drugs of group A were selected such subgroups LS: G03 – "Hormones of sexual glands and the preparations, used for the pathology of the sexual sphere", B05 – "Blood substitutes and perfusion solutions", A11 – "Vitamin", A03 – "Drugs used in functional gastrointestinal disorders", G02 – "Other gynecological medicines", N07– "Other drugs acting on the nervous system». The largest share are sub V05 – a 26 appointments with B05X B and 68 appointments of B05X A, as well as preparations subgroup G03 and A11 – 89 appointments and 70 respectively.

The highest cost was in group of progestogen drugs, and that were 10 trade names, of which 5 were in dosage forms for vaginal use, two dosage forms were in injectable and oral forms. Prescriptions of drugs of national producers amounted to 20 % of all prescriptions.

Next task was to analyze the evidence based pharmacy data on the effectiveness of progestogens. Because these drugs are prescribed most often for private drug therapy according to the analysis of medical records lists. We searched the evidence data in PubMed. We founded the evidence of effectiveness for vaginal progesterone for use in women with singleton pregnancy and a short cervix [14, 17]. Internal use of 17 $\alpha$ -hydroxyprogesterone kapronat appropriate for

**Table 1. Analysis of the requirements for prescribing for preterm birth**

Document, year	Group and/or drug	Level of recommendation
<b>Corticosteroids</b>		
WHO, 2015	For women, which have a risk of PB from 24 to 34 weeks and other requirements	Strong
	For women which PB will be inevitable within 7 days of treatment, including in the first 24 hours	Strong
	For women with premature rupture of amniotic membranes and the lack of signs of infection	Strong
	Not recommended for women with a planned cesarean section at a late stage of prematurity (34–36 + 6 weeks)	Middle
	It's recommended for women with hypertensive disorders during pregnancy, with up - and gestational diabetes who are at risk of PB	Strong
	The first drug is Dexamethasone or Betamethasone, 24mg individual doses i/m.	Strong
NICE, 2015	It's recommended for women with high risk or premature rupture of membranes in the period 23–26+6weeks; 24–25 +6 weeks; 26–33+6weeks; 34-35+6 weeks vaginal. Repeated courses are only in some cases (the interval since the end of last year, gestational age, birth opportunity for 48 hours).	Not specified
Orders of Ministry of Health of Ukraine	The use of Dexamethasone and Betamethasone is prescribed with doses and course of treatment	Evidence level A
	Not recommended for repeated courses	Not specified
	When there is a current manifestation of severe infection not used	Not specified
<b>Tocolytics</b>		
WHO, 2015	Not recommended for women with a risk of fatal PB; to improve the outcomes in newborns	Middle
NICE, 2015	Nifedipine is recommended for women at risk in the period 24-25 weeks, 26–33 weeks vaginal. When contraindicated, then use the Oxytocin receptor antagonists, is not recommended beta-mimetics	Not specified
Orders of Ministry of Health of Ukraine	-	-
<b>Magnesium sulfate</b>		
WHO, 2015	It's recommended for women who are at risk of inevitable PB to 32 weeks of pregnancy; to prevent cerebral palsy in children	Strong
NICE, 2015	It's recommended for infants and for women who are at risk or PB possibility of them within 24 hours. in the period 24–29+6weeks.vaginal, 30-33+6 weeks, the scheme and doses are for pharmacotherapy	Not specified
Orders of Ministry of Health of Ukraine	It's indicated that no PB prevents and increased postnatal mortality	Not specified
<b>Progesteron</b>		
WHO, 2015	-	-
NICE, 2015	For women, which were a history of spontaneous PB or between 16-34 weeks, and 16–24 weeks vaginal. it was shown that cervical length less than 25 mm., as well as for women without a history of PB and with a short cervix	Not specified
Orders of Ministry of Health of Ukraine	-	-

women with a singleton pregnancy in history were PP [8]. Effective pharmacotherapy for the presence of a pregnant woman bleeding in the first trimester [9]. Dydrogesterone has more advantages compared with vaginal progesterone in women who became pregnant via IVF [10], and also reduces the risk of miscarriage in women with suspected potential. Article 2016 shows that the effectiveness of progesterone (30 mg) is for the prevention of severe preeclampsia pregnant women at high risk [14, 25]. Not recommended for primary

prevention private use 17 $\alpha$ -hydroxyprogesterone kapronat and vaginal progesterone forms in multiple pregnancies, and 17 $\alpha$ -hydroxyprogesterone kapronat – women with multiple pregnancies with a short cervix. [8] Also, supplementation of progesterone in the first 12 weeks of pregnancy is not an effective way to prevent recurrent miscarriages [18]. However, research on the effectiveness of the pregnant women are held, also studied the impact on perinatal mortality, as final conclusions are difficult to make.

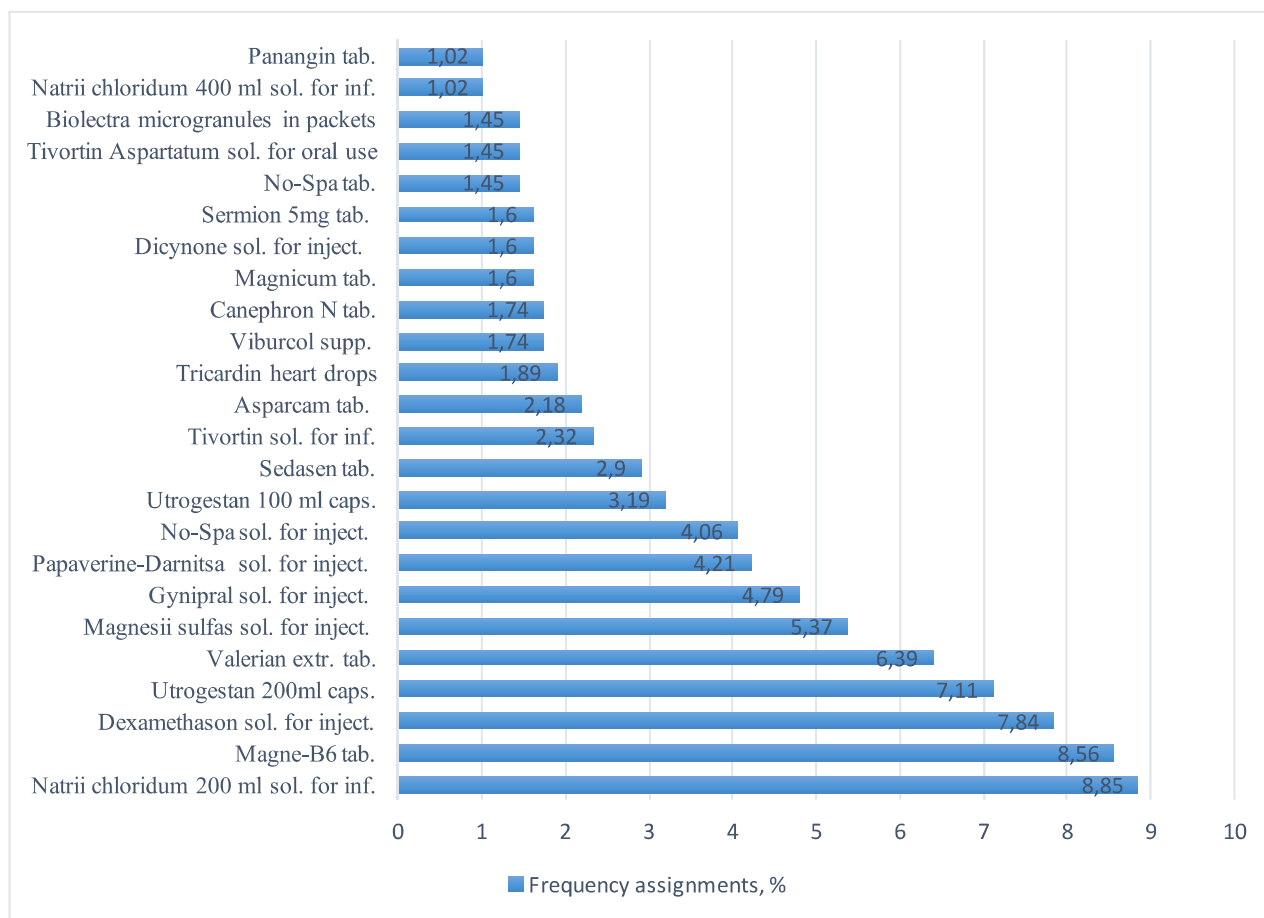


Figure 1. Frequency analysis of drug prescriptions for preterm birth (part)

For efficient and effective use of funds held by us VEN-analysis of consumption of medicines. This analysis divides drugs into three categories depending on their importance for the treatment of certain diseases: V – vital, E – necessary, N – minor, the importance of taking such drugs is questionable. The distribution of drugs to the appropriate category we conducted using a formal approach; if the drug was in the State logbook drug release 8 [5] and the National List of Essential medicines [6], then attributed to the drug group V. When the drug was only one of these lists, then – in group E, in the absence of drugs in these documents – group N (tabl.2).

It was established, that according to a retrospective analysis of medical records the drug costs at the lowest

purchase prices were 75354.25 UAH, the cost per one patient was 740 UAH in average.

The VEN analysis showed that 12 drugs on INN were formed a Vital group, but the group of A / V entered only one drug, it's a sodium chloride. The largest number in the group C were 9 drugs, though some of them, such as magnesium sulfate, nifedipine, there are in these documents as a preparations for tocolytic therapy. The share of essential drugs is 43.8 % (21 drugs on INN, and the non-essential are 31.3 % (15 drugs on INN).

The next step was to analyze a data regarding evidence-based pharmacy on drug as progestogens. This group is often prescribing for pharmacotherapy PB according to our analysis of medical records. We used the results of the latest evidence-based data that is presented in

Table 2. ABC – analysis of the consumption of drugs at risk of preterm birth

Group ABC	Number of drugs on INN	Consumption, UAH	The share of expenditure (%)
A	7	60751.44	80.62
B	11	10749,5	14.27
C	30	3853.31	5.11
Total	48	75354.25	100.00

searching network PubMed. Evidence-based data about progesterone for vaginal application for women with singleton pregnancy and a short cervix are presented [2, 9]. Intravenous using of 17 $\alpha$ -hydroxyprogesterone capronate is appropriate for women with a singleton pregnancy in PB history [1]. Effective implementation of pharmacotherapy for the presence of a pregnant woman bleeding in the first trimester [9]. Dydrogesterone has more advantages compared with vaginal progesterone in women who became pregnant via IVF [26], and also reduces the risk of miscarriage in women with suspected potential. In 2016 was published the results that showed the effectiveness (30 mg) for the prevention of severe preeclampsia pregnant women at high risk [12, 17].

Now it not recommended for primary prevention use of 17 $\alpha$ -hydroxyprogesterone capronate and vaginal progesterone forms in multiple pregnancies, and 17 $\alpha$ -hydroxyprogesterone capronate for women with multiple pregnancies with a short cervix [8] Also, supplementation of progesterone in the first 12 weeks of pregnancy is not found an effective method of prevention of repeat abortions isn't known [18]

However, research on the effectiveness of even being pregnant and also studied the impact on perinatal mortality, so definitive conclusions difficult to do. For effective use we made VEN analysis. It makes it possible to distribute the drugs into 3 categories depending on their importance for the treatment of this disease: V – vital, E – essential, N – non-essential, the importance of these drugs are questionable. The distribution of drugs to the appropriate category performed using a formal approach based on the presence of drugs at the same time in the State Formulary 8 edition [14], the National List of Essential medicines [10], while the drug belonged to the group V. When the drug was only one of the above document then was in the group E, in the absence of drug in these documents was in group N (Table 3).

The proportion of essential drugs was 43.75 % (21 drugs on INN), and the non-essentials were 31.25 % (15 drugs on INN), such as Probiz Femina and Yodofol belonged to the group C / N. So these prescriptions are need to correct for optimization of efficacy and safety of PB.

**Table 3.** Results of ABC / VEN analysis of drug prescribing for pregnant women with threatened PB (part of study)

ATC Code	INN or common name of drug	Cost		ABC/VEN
		UAH	%	
G03D A04	Progesterone	32953.84	43.73	A/E
B05X B01	Arginine hydrochloride	9625.32	12.77	A/E
A11E C	Magne-B6	7681.12	10.19	A/N
B05X A03	Natrii chloridi	3146.55	4.18	A/V
A03A D02	Drotaverine	2837.47	3.77	A/E
G02C A05	Hexoprenaline	2612.61	3.47	A/E
N07XX10	Cytoflavin	1894.53	2.51	A/N
C 04A E 02	Nicergoline	1716.25	2.28	B/E
G01A C05	Dequalinii chloride	1327.81	1.76	B/E
R05X	Viburcol	1316.1	1.75	B/N
H02A B02	Dexamethasone	1156.68	1.53	B/V
A03A D01	Papaverine	920.05	1.22	B/E
G04BX50**	Canephron N	855.08	1.13	B/N
A12CC10.	Magnesium oxide	776.23	1.03	B/N
	Other 4 drugs	2681.30	3.56	B/V 3-B/E
C05C A03	Diosmin	559.02	0.74	C/N
J01F A07	Josamycin	428.16	0.57	C/E
A05AX10**	Cynara scolymus*	356.18	0.47	C/N
A12CC55**	Magnesium aspartate + Potassium aspartate	322.6	0.43	C/E
B05X A05	Magnesium sulfate	255.71	0.34	C/V
J01D D08	Cefiximum	211.64	0.28	C/V
G01AX10**	Chlorhexidine	201.15	0.27	C/V
	Other 23 drugs	1518.85	2.03	6 - C/V 9 - C/E 8 - C/N

### Conclusions.

1. Preterm birth is a huge economical, medical and social problem in the world, especially in low income countries. It was established that current Ukrainian clinical protocols include the treatment and prevention of PB have a need for a good revision because the WHO, NICE published a new evidence-based recommendations for health technologies of PB in 2015.

2. We determined that treatment for PB threat appointed 75 trade names of drugs, including 46 for INN

and 2 supplements. The average number of prescriptions for a pregnant woman shown polypharmacy. The cost of drug therapy is for one patient average 740 UAH.

3. Using ABC / VEN analysis showed that the group A included 7 drugs for the INN, the group B and C included 11 and 30 drugs, respectively.

4. Progestines have a good evidence data, but it need to determine the less expensive scheme/ drugs for the treatment and prevention of PB using pharmacoeconomic analysis results in Ukraine.

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## **СУЧАСНІ ЕКОНОМІЧНІ, СОЦІАЛЬНІ АСПЕКТИ ТЕХНОЛОГІЙ ОХОРОНИ ЗДОРОВ'Я ТА АНАЛІЗ РЕАЛЬНИХ ДАНИХ ПРИЗНАЧЕНЬ ЛІКІВ ДЛЯ ФАРМАКОТЕРАПІЇ ПЕРЕДЧАСНИХ ПОЛОГІВ**

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**Резюме:** поліпшення якості життя, здоров'я вагітних жінок та лікування передчасних пологів є основними цілями директив ВООЗ. Україна займає 72 місце в рейтингу за рівнем забезпечення материнства в світі.

Нами вивчені у порівняльному плані рекомендації ВООЗ, 2015 міжнародні рекомендації, накази МОЗ України щодо лікування передчасних пологів (ПП) та виявлено певні відмінності, що вимагає оновлення вітчизняних протоколів.

Ми проаналізували реальні дані частоти призначень лікарських засобів при ПР з використанням АВС/VEN-аналізу на основі 102 історій хвороб вагітних жінок з діагнозом відповідно до МКХ-10 - О47.0. Встановлено, що для лікування загрози ПП призначалися 75 торгових назв (46 МНН лікарських засобів та 2 БАД). Сумарно було 689 призначень ліків, що в середньому складає 6,75 препарата на одну вагітну жінку, що свідчить про поліпрагмазію. Виявлено, що в групі А найбільш часто призначаються препарати 7 МНН (14,58 % від загального обсягу) і основним лікарським засобом є натрію хлорид, що свідчить про недостатньо раціональне використання фінансових коштів пацієнтів.

Встановлено, що сумарно витрати на призначені ЛЗ при ПР становили 75354,3 грн, а витрати на фармакотерапію 1 пацієнтки були в середньому 740,2 грн.

Нами проаналізовані доказові дані про призначення прогестеронів для лікування ПР. Встановлено, що найбільш ефективним для лікування ПР за даними доказової фармації є прогестерон у лікарській формі для вагінального прийому для жінок з короткою шийкою матки, а дигістростерон – при застосуванні допоміжних репродуктивних технологій

Доцільною є оптимізація фармацевтичної допомоги вагітним при ПР за даними доказової фармації та призначення економічно ефективної фармакотерапії для раціоналізації витрат пацієнтів.

**Ключові слова:** вагітність, передчасні пологи, оцінка технологій охорони здоров'я, аналіз реальних даних, призначення ліків, прогестини.

## **СОВРЕМЕННЫЕ ЭКОНОМИЧЕСКИЕ, СОЦИАЛЬНЫЕ АСПЕКТЫ ТЕХНОЛОГИЙ ЗДРАВООХРАНЕНИЯ И АНАЛИЗ РЕАЛЬНЫХ ДАННЫХ ПОТРЕБЛЕНИЯ ЛЕКАРСТВ ПРИ ФАРМАКОТЕРАПИИ ПРЕЖДЕВРЕМЕННЫХ РОДОВ**

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**Резюме:** улучшение качества жизни и здоровья беременных женщин и их рациональной фармакотерапии являются основными целями ВОЗ. Украина занимает 72 место в рейтинге уровня обеспечения материнства в мире.

Мы проанализировали и сравнили национальные и международные рекомендации, руководящие принципы, касающиеся требований к лечению и профилактике преждевременных родов (ПР). Мы проанализировали реальные данные частоты назначений лекарственных средств с использованием АВС / VEN-анализа на основе историй болезней о назначении лекарств для беременных женщин, диагностированных в соответствии с МКБ-10 - О47.0.

Установлено, что для лечения ПР назначалось 75 торговых наименований (46 МНН лекарственных средств и 2 БАД). Суммарно было 689 назначений лекарств, что составляет в среднем 6,75 препарата на одну беременную

женщину и свидетельствует о полипрагмазии. Установлено, что в группе А наиболее назначаемыми были препараты по 7 МНН (14,58 % от общего объема) и основным лекарственным средством является по потреблению натрия хлорид, что свидетельствует о недостаточно рациональном использовании финансовых средств пациентов.

Установлено, что суммарно расходы на назначенные лекарства при ПР составили 5354,3 грн, а расходы на фармакотерапию 1 пациентки были в среднем 740,2 грн.

Нами проанализированы доказательные данные о назначении прогестерона для лечения ПР. Установлено, что наиболее эффективным в лечении ПР по данным доказательной фармации является прогестерон в лекарственной форме для вагинального приема для женщин с короткой шейкой матки, а дигистростерон – при применении вспомогательных репродуктивных технологий. Необходимым является оптимизация фармацевтической помощи беременным при ПР по данным доказательной фармации и назначения экономически эффективной фармакотерапии для рационализации расходов пациенток.

**Ключевые слова:** беременность, преждевременные роды, оценка технологий здравоохранения, анализ реальных данных, назначение лекарств, прогестины.

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