MODEL FOR PREDICTION AND PREVENTION OF ADVERSE PERINATAL OUTCOMES IN COVID-19 IN WOMEN

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МОДЕЛЬ ПРОГНОЗУВАННЯ І ПРОФІЛАКТИКИ НЕСПРИЯТЛИВИХ ПЕРИНАТАЛЬНИХ НАСЛІДКІВ ПРИ COVID-19 У ЖІНКИ

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Abstract. Relevance. *The task of developing a model for predicting and preventing adverse perinatal outcomes in women with COVID-19 is relevant, which should provide an effective clinical solution taking into account individual and regional characteristics, which will contribute to reducing maternal and perinatal morbidity and mortality.* **Purpose.** *To create a tool for early identification of pregnant women with a high risk of complications in case of COVID-19 to reduce maternal and perinatal mortality, prevent adverse perinatal complications (using the example of Ivano-Frankivsk region).* **Materials and methods.** *The creation of a model for predicting and preventing adverse perinatal outcomes in case of COVID-19 in women is based on research using the bibliosemantic research method, the method of structural-logical analysis, analytical, statistical and conceptual methods, clinical, anamnestic and laboratory-instrumental methods, and questionnaires.* **Results.** *The medical and social justification, principles of formation and expected results of the implementation of the model of prediction and prevention of adverse perinatal consequences of COVID-19 in women are presented. The development and implementation of such a model can be carried out in 5 stages over 3 years: preparatory and analytical (1–2 quarters of the 1st year); creation and testing of a digital model (3–4 quarters of the 1st year); pilot implementation in the region (1–2 quarters of the 2nd year); scaling and integration (3–4 quarters of the 2nd year); effectiveness assessment and continuous improvement (3rd year and beyond). Model components: screening stage (at the primary level); prediction stage (secondary level); response stage (tertiary level); information support and monitoring.* **Conclusions.** *The practical implementation of the developed model allows improving the quality of medical care for pregnant women during the pandemic, optimizing the use of healthcare system resources, reducing the incidence of complications and improving perinatal outcomes even in conditions of limited resources.*
Key words: *COVID-19, pregnancy, perinatal care, prediction, prevention, model.*

Резюме. Актуальність. *Актуальним є завдання розробки моделі прогнозування і профілактики несприятливих перинатальних наслідків у жінок із COVID-19, яка має забезпечити ефективне клінічне рішення з урахуванням індивідуальних та регіональних особливостей, що сприятиме зниженню материнської і перинатальної захворюваності та смертності. Мета. Створити інструмент для ранньої ідентифікації вагітних із високим ризиком ускладнень у разі COVID-19 для зниження материнської та перинатальної смертності, попередження несприятливих перинатальних ускладнень (на прикладі Івано-Франківської області). Матеріали та методи. Створення моделі прогнозування і профілактики несприятливих перинатальних наслідків при COVID-19 у жінки базується на проведених дослідженнях з використанням бібліосемантичного методу дослідження, метод структурно-логічного аналізу, аналітичний, статистичні та концептуальний методи, клінічні, анамнестичні та лабораторно-інструментальні методи, анкетування. Результати. Наведено медико-соціальне обґрунтування, принципи формування та очікувані результати впровадження моделі прогнозування і профілактики несприятливих перинатальних наслідків при COVID-19 у жінки. Розробка і впровадження такої моделі може здійснюватись у 5 етапів за 3 роки: підготовчо-аналітичний (1–2 квартал 1-го року); створення і тестування цифрової моделі (3–4 квартал 1-го року); пілотне впровадження в регіоні (1–2 квартал 2-го року); масштабування та інтеграція (3–4 квартал 2-го року); оцінка ефективності та постійне вдосконалення (3-й рік рік і далі). Компоненти моделі: етап скринінгу (на первинному рівні); етап прогнозування (вторинний рівень); етап реагування (третинний рівень); інформаційна підтримка та моніторинг. Висновки. Практичне впровадження розробленої моделі дозволяє покращити якість медичної допомоги вагітним у період пандемії, оптимізувати використання ресурсів системи охорони здоров'я, знизити частоту ускладнень та підвищити перинатальні результати навіть в умовах обмежених ресурсів.*
Ключові слова: *COVID-19, вагітність, перинатальний догляд, прогнозування, профілактика, модель.*

Introduction

The COVID-19 pandemic has become an unprecedented challenge for the global health system. Pregnant women are particularly vulnerable to the spread of the infection, as they have physiological changes in the immune, respiratory, and cardiovascular systems that reduce their ability to effectively resist viral diseases [1, 2]. SARS-CoV-2 has demonstrated the ability to provoke a wide range of obstet-

ric complications that negatively affect both the course of pregnancy and the condition of the fetus [3].

Scientific observations indicate an increase in the frequency of preterm birth, preeclampsia, fetoplacental insufficiency, intrauterine growth retardation, and even perinatal mortality in pregnant women with COVID-19 [4; 5]. It has been established that the severe course of the disease, especially in the third trimester, significantly increases the risk of adverse outcomes, in particular due to systemic hypoxia, endothelial dysfunction, and cytokine storm [6].

The issue of predicting such complications is attracting serious attention. The presence of clinical and laboratory predictors – such as increased levels of C-reactive protein, D-dimer, ferritin, and decreased lymphocyte counts – allows the creation of risk assessment algorithms and models for early intervention [7]. In some cases, women require hospitalization in the intensive care unit, which complicates the possibilities of traditional perinatal care [8].

There is a growing need to create prediction models that would allow taking into account the multifactorial nature of COVID-19 in pregnant women. Such models should combine clinical, epidemiological, social, and biochemical indicators to assess the individual risk of adverse pregnancy outcomes [9]. At the same time, the prevention system should include both general epidemic measures (vaccination, contact monitoring) and modern clinical recommendations for the management of infected pregnant women in accordance with the guidelines of WHO, FIGO, and ACOG [10; 11].

Against the background of limited resources of the medical system in Ukraine, it is important to adapt these international approaches to the realities of the national model of perinatal care. Data from domestic researchers confirm the increase in the frequency of hypoxic-ischemic fetal lesions, obstetric hemorrhages and preterm births in women with confirmed COVID-19 [12]. However, in Ukraine there are currently no universal prognostic tools that cover the full range of clinical data, diagnostic features and preventive options.

Therefore, the task of developing a model for predicting and preventing adverse perinatal outcomes in women with COVID-19 is urgent. Such a model should provide an effective clinical solution taking into account individual and regional characteristics, which will contribute to the reduction of maternal and perinatal morbidity and mortality [13].

Purpose

To create a tool for early identification of pregnant women at high risk of complications in case of COVID-19 to reduce maternal and perinatal mortality, prevent adverse perinatal complications (using the example of Ivano-Frankivsk region).

Materials and methods

The medical and social justification for the need to create a model for predicting and preventing adverse perinatal outcomes in women with COVID-19 is based on previously conducted studies [14-17].

To identify problematic issues in the provision of perinatal medical care during the COVID-19 pandemic and approaches to solving them, the research materials used were international recommendations, the legislative framework of Ukraine on the provision of perinatal care during the COVID-19 pandemic, and the bibliosemantic research method and the method of structural-logical analysis were used.

A comparative analysis of the effectiveness of perinatal care at the state and regional levels (Ivano-Frankivsk region) for 2017–2021 was conducted, which includes, in particular, 2 years of the COVID-19 pandemic and previous years for the analysis of dynamic trends using statistical data from the Ministry of Health of Ukraine.

The assessment of the volume of perinatal care during the COVID-19 pandemic in the context of a separate region was carried out based on data from the Electronic Integrated Disease Surveillance System (ELISSZ) and data from the Ivano-Frankivsk Regional Perinatal Center (OPC). Data from the State Committee for Statistics of Ukraine and statistical documents of the Ministry of Health of Ukraine were used. Bibliosemantic, analytical, statistical and conceptual methods were used. The study period was 2020–2023.

A retrospective and clinical study to determine the risk factors for perinatal complications was carried out on the basis of obstetric and gynecological hospitals of the Ivano-Frankivsk region from April 2020 to December 2022. The study included 341 patients with laboratory-confirmed COVID-19 during pregnancy (the main group) and 50 pregnant women who did not have COVID-19 during pregnancy. The frequency of the most adverse perinatal outcomes (antenatal and neonatal mortality, preeclampsia, fetal distress and/or growth retardation, premature birth, neonatal asphyxia, congenital pneumonia) was 27.3%. A comprehensive study to identify risk factors for adverse perinatal outcomes included 200 women hospitalized with COVID-19 during pregnancy: subgroup O1 – 50 women with adverse perinatal outcomes, subgroup O2 – 150 patients with a relatively favorable course of the gestational period). Research methods: clinical and anamnestic analysis (study of age, gestational age, obstetric history, concomitant pathology, features of the course of COVID-19; laboratory and instrumental methods (complete blood count with formula, ESR); biochemical markers (CRP, D-dimer, procalcitonin, interleukin-6, vitamin D, von Willebrand factor); CT/lung radiography; fetal ultrasound, Dopplerometry, CTG; assessment of perinatal outcomes (type of delivery; presence of perinatal complications, mortality).

Statistical analysis: calculation of the odds ratio (OR) with a 95% confidence interval, coefficient of variation in the analysis of expert assessment. Development of a mathematical prediction model: based on the expert assessment of the identified clinical and laboratory risk factors, a model for stratifying pregnant women by risk level was built.

Socio-medical methods: content analysis of medical records (341 patients with laboratory-confirmed COVID-19 during pregnancy) and 50 pregnant women who did not have COVID-19 during pregnancy; sociological questionnaire (120 patients who were pregnant at the time of the pandemic and 70 doctors who provided perinatal care during this period were interviewed); expert assessment method

(30 doctors assessed the effectiveness of the proposed model at a sufficient level).

Results

The medical and social justification for the need to create a model for predicting and preventing adverse perinatal outcomes in women with COVID-19 is as follows. Medical justification: SARS-CoV-2 negatively affects the endothelium, immune system, and coagulation system, which complicates the course of even physiological pregnancy, and therefore a model is needed that allows: to identify pregnant women with a high risk of adverse outcomes in the early stages; to predict the dynamics of the course of pregnancy in the presence of infection; to prevent complications through individualized observation, hospitalization, and preventive interventions Social justification: the consequences of COVID-19 in pregnant women have a significant impact on the demographic situation (increased perinatal mortality and worsening fertility rates); family well-being (increased psycho-emotional stress, risks of losing a child); the economy of the region (costs for neonatal resuscitation, intensive care, hospitalization).

The principles of forming a model for predicting and preventing adverse perinatal outcomes in women with COVID-19 are as follows.
• Use of bioethical and evidence-based approaches.
• Combining clinical data, laboratory and instrumental research results, vaccination history and comorbidities.
• Use of digital solutions (AI algorithms, programs, mobile applications) for prediction.
• Providing a personalized management route for pregnant women with COVID-19 or at high risk of infection.

The development and implementation of such a model can be carried out in 5 stages (Fig. 1) over 3 years:
1. Preparatory and analytical (1st–2nd quarter of the 1st year)
2. Creation and testing of a digital model (3rd–4th quarter of the 1st year)
3. Pilot implementation in the region (1st–2nd quarter of the 2nd year)

STAGE 1 — Preparatory and analytical	**Objective: To create a basis for the implementation of a prediction system** • Conduct a regional analysis of cases of complicated pregnancy with COVID-19 for 2020–2024. • Formation of a multidisciplinary expert group (obstetricians, infectious disease specialists, epidemiologists, IT specialists). • Identification of clinical and laboratory risk predictors. • Analysis of the existing IT infrastructure (eHealth, medical information systems). • Preparation of algorithms and protocols based on the evidence base (WHO, ACOG, Ministry of Health of Ukraine guidelines).
STAGE 22 — Creation of a digital model	**Objective: To develop an electronic risk prediction and assessment tool** • Creation of a regional software module with an interface for doctors. • Implementation of an individual risk assessment scale. • Internal testing of the model in several pilot health facilities. • Development of a mobile application or integration with existing eHealth applications. • Creation of instructions and training materials.
STAGE 3 — Pilot implementation	**Objective: To verify the effectiveness of the model in practice** • Implementation of the model in 3–5 obstetric institutions of different levels. • Conducting training courses for staff (doctors, nurses, social workers). • Monitoring the sensitivity, specificity and predictive accuracy of the model. • Analysis of the impact of the model on routing, complication rates, and prevention effectiveness.
STAGE 4 — Scaling and integration	**Goal: Implement the model in all health care facilities in the region** • Inclusion of the model in the regional standard for providing medical care to pregnant women. • Expansion of access to the software tool to all obstetric institutions in Ivano-Frankivsk region. • Formation of automated clinical decisions for risk groups (hospitalization plan, appointment of prophylaxis, consultations). • Regular clinical and administrative audit of results.
STAGE 5 — Performance evaluation and improvement	**Objective: Ensure the model is sustainable and adaptable to changes** • Collect data on perinatal outcomes: preterm birth rates, hypoxia, mortality. • Update the model based on new scientific data (including post-COVID conditions). • Conduct external peer review (e.g., WHO, international medical funds). • Publish results in scientific journals and present at medical forums.

Fig. 1. Stages of development and implementation of a model for predicting and preventing adverse perinatal outcomes of COVID-19 in the mother (schematic representation)

4. Scaling and integration (3rd–4th quarter of the 2nd year)

5. Performance assessment and continuous improvement (3rd year and beyond)

Model components (Fig. 2):

I. Screening stage (at the primary level)

Goal: Early identification of pregnant women at risk.

Parameters:
• Gestational age
• Presence of COVID-19/suspicion (anamnesis, PCR/Ag test)
• Comorbidity (diabetes, obesity, hypertension)
• Vaccination status
• SpO2 saturation (<95%)
• Temperature > 37.8°C and
• additional course of the disease and pregnancy in dynamics.

Tool: Development of a risk assessment scale, moderate and high risk - hospitalization in a level II–III institution.

II. Prediction stage (secondary level)

Goal: Predict adverse outcomes.

Methodology:
• Retrospective analysis of cases of complications among pregnant women with COVID-19 in 2020–2023 in the region.
• Application of mathematical methods to build a prediction scale:
• Modeling of defined perinatal risks:
preterm birth,
antenatal fetal death,
hypoxia/asphyxia of the newborn,
cesarean section for urgent indications.

Platform: Specialized software integrated into the existing one (based on the regional health department or perinatology department).

III. Response stage (tertiary level)

Goal: Determining the patient's route and preventing complications.

Measures:
• Routing of high-risk pregnant women to level III institutions (Ivano-Frankivsk Regional Perinatal Center).
• Prescribing preventive drugs (anticoagulants, oxygen therapy).
• Active fetal monitoring (CTG, ultrasound, Doppler).
• Early involvement of a multidisciplinary team (obstetrician-gynecologist, infectious disease specialist, neonatologist, and, if necessary, other specialists).

Information support and monitoring
• Electronic registry of pregnant women with COVID-19 (based on regional medical information systems)
• Analytical panel with indicators (number of cases, mortality, premature births, SpO2 level, etc.)
• Quarterly audit of results to assess the effectiveness of the model

Expected effects of implementing prediction of adverse perinatal outcomes in women with COVID-19:
• Reduction in the rate of preterm birth by ≥20%.
• Reduction in the number of cases of intrauterine fetal death by ≥30%.
• Improvement in the dynamics of perinatal mortality indicators.
• Rational use of perinatal service resources.

Conclusions

1. SARS-CoV-2 infection during pregnancy significantly increases the risk of adverse perinatal outcomes, such as preterm birth, placental insufficiency, fetal hypoxia, preeclampsia, and perinatal mortality. The risk is particularly high in severe COVID-19 in the third trimester.

2. The most informative clinical and laboratory predictors of complications are: lymphopenia, increased levels of C-reactive protein, D-dimer, procalcitonin, and the presence of comorbidities (obesity, hypertension, diabetes mellitus).

3. The developed prediction model is based on a multifactorial analysis of clinical and socio-demographic indicators and allows stratification of pregnant women by risk level. This contributes to the individualization of pregnancy management and increased effectiveness of preventive measures.

4. Prevention of adverse outcomes should include not only timely COVID-19 diagnosis and treatment, but also constant monitoring of the condition of the mother and fetus, interdisciplinary management of patients, and ensuring vaccination in accordance with the guidelines of the Ministry of Health, WHO, and FIGO.

5. The practical implementation of the developed model allows improving the quality of medical care for pregnant women during the pandemic, optimizing the use of healthcare system resources, reducing the incidence of complications, and improving perinatal outcomes even in conditions of limited resources.

The authors declare that there is no conflict of interest.

Level	Institution	Tasks
I	outpatient clinic / women's consultation	Screening, referral, low risk
II	City / district maternity	Moderate risk management
III	Regional perinatal center	High risk, neonatal resuscitation
Methodological	Department of Health of Ivano-Frankivsk Regional State Administration Coordination	Coordination, statistics
Consultative	IFNMU (Department of Obstetrics / Epidemiology)	Scientific support

Fig. 2. Organizational structure of the implementation of the model for predicting and preventing adverse perinatal outcomes in women with COVID-19

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