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Scientific evidence on COVID-19 vaccination in pregnant women: a scoping review

Evidências científicas quanto à vacinação contra a covid-19 em grávidas: uma revisão de escopo

Evidencia científica sobre vacunación contra covid-19 en mujeres embarazadas: una revisión de alcance

ABSTRACT

Objective: To compile and analyze scientific evidence on COVID-19 vaccination in pregnant women, focusing on safety, benefits, and challenges to acceptance. **Method:** This is a scoping review based on the Arksey and O'Malley approach, with enhancements by Levac et al. Eligibility criteria included studies published between 2020 and 2025, in Portuguese, English, or Spanish, addressing COVID-19 vaccination in pregnant women, considering safety, efficacy, adverse effects, or recommendations. The search was conducted in scientific databases, with qualitative analysis and classification of levels of evidence according to the Agency for Healthcare Research and Quality (AHRQ). **Results:** The analysis showed that vaccination in pregnant women significantly reduces the risk of infection, hospitalization, and adverse maternal and neonatal outcomes. mRNA vaccines, such as Pfizer and Moderna, demonstrated efficacy and safety, offering protection for both mother and newborn, without an increase in adverse perinatal events. However, vaccine hesitancy and misinformation remain major barriers to acceptance. **Final remarks:** COVID-19 vaccination in pregnant women is safe and effective. Targeted communication strategies and the active inclusion of this group in immunization programs are essential to increase coverage and mitigate the impacts of the disease on this vulnerable population.
Descriptors: COVID-19 vaccines; Pregnant women; Safety; Clinical practice guidelines.

RESUMO

Objetivo: Compilar e analisar evidências científicas sobre a vacinação contra a covid-19 em gestantes, com foco na segurança, nos benefícios e nos desafios à aceitação. **Método:** Trata-se de uma revisão de escopo fundamentada na abordagem de Arksey e O'Malley, com aprimoramentos de Levac et al. Os critérios de elegibilidade foram estudos publicados entre 2020 e 2025, em português, inglês ou espanhol, que abordassem a vacinação contra a covid-19 em gestantes, considerando segurança, eficácia, efeitos adversos ou recomendações. A busca foi realizada em bases de dados científicas, com análise qualitativa e categorização dos níveis de evidência, segundo a Agency for Healthcare Research and Quality (AHRQ). **Resultados:** A análise revelou que a vacinação em gestantes reduz significativamente os riscos de infecção, internação e complicações maternas e neonatais. Vacinas de mRNA, como Pfizer e Moderna, demonstraram eficácia e segurança, proporcionando proteção para a mãe e o recém-nascido, sem aumento nos eventos adversos perinatais. No entanto, a hesitação vacinal e a desinformação ainda são barreiras à adesão. **Considerações finais:** A vacinação contra a covid-19 em gestantes é segura e eficaz. Estratégias de comunicação direcionadas e a inclusão ativa desse grupo nos programas de imunização são fundamentais para ampliar a cobertura e reduzir os impactos da doença nessa população vulnerável.
Descritores: Vacinas contra covid-19; Gestantes; Segurança; Guia de prática clínica.

RESUMEN

Objetivo: compilar y analizar evidencias científicas sobre la vacunación contra la covid-19 en mujeres embarazadas, con énfasis en la seguridad, los beneficios y los desafíos para su aceptación. **Método:** se trata de una revisión de alcance basada en el marco metodológico de Arksey y O'Malley, con mejoras propuestas por Levac et al. Los criterios de elegibilidad incluyeron estudios publicados entre 2020 y 2025, en portugués, inglés o español, que abordaran la vacunación contra la covid-19 en gestantes, considerando aspectos de seguridad, eficacia, efectos adversos o recomendaciones. La búsqueda se realizó en bases de datos científicas, con análisis cualitativo y categorización de los niveles de evidencia según la metodología de la Agency for Healthcare Research and Quality (AHRQ). **Resultados:** el análisis mostró que la vacunación en mujeres embarazadas reduce significativamente el riesgo de infección, hospitalización y complicaciones maternas y neonatales. Las vacunas de ARNm, como Pfizer y Moderna, demostraron eficacia y seguridad, brindando protección tanto a la madre como al recién nacido, sin aumento de eventos adversos perinatales. No obstante, la reticencia a la vacunación y la desinformación continúan siendo barreras importantes para su aceptación. **Conclusión:** la vacunación contra la covid-19 en gestantes es segura y eficaz. Estrategias de comunicación adecuadas y la inclusión activa de este grupo en los programas de inmunización son fundamentales para ampliar la cobertura y reducir los impactos de la enfermedad en esta población vulnerable.
Descriptores: Vacunas contra la covid-19; Gestantes; Seguridad; Guía de práctica clínica.

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INTRODUCTION

Since the beginning of the COVID-19 pandemic caused by the SARS-CoV-2 virus, the planet has experienced an unprecedented health crisis, unevenly affecting vulnerable populations such as pregnant women. Pregnancy is a physiological state characterized by changes in the immune, cardiovascular, and respiratory systems, which makes women more susceptible to viral infections and their potential complications[1].

In the early years of the pandemic, several studies showed that COVID-19 infection in pregnant women was linked to serious complications. Among the observed effects were increased hospitalizations, the need for ventilatory support, and admissions to Intensive Care Units. Furthermore, there was a rise in the rate of negative outcomes during childbirth. Some of these factors include premature birth and preeclampsia. These findings highlight the vulnerability of pregnant women to infection. Thus, prevention and adequate monitoring are essential for this group[2].

With the progress of large-scale vaccination and increased surveillance of adverse events, robust scientific evidence has emerged regarding the safety of COVID-19 vaccines during pregnancy. Recent studies have shown that vaccines using messenger RNA (mRNA), such as BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna), are safe for pregnant women, as these vaccines have not been linked to an increased risk of pregnancy complications. In addition, vaccination provides benefits to both the mother and the baby, underscoring its importance for this population[4].

Vaccinating pregnant women offers protection against severe forms of COVID-19 and brings considerable benefits to newborns. Studies show that receiving the vaccine during pregnancy helps IgG antibodies pass through the placenta. This mechanism gives the baby passive immunity, especially in the first months of life. During this period, children's immune systems are still developing and are more vulnerable to infections. The protection that a vaccinated mother provides is an effective prevention strategy. Thus, immunization during pregnancy is essential for the health of both the mother and child [5].

This indirect immunization approach is similar to that used in vaccination programs against influenza and pertussis during pregnancy. These initiatives aim to protect both the expectant mother and the newborn baby, especially in the first months of life. The transfer of antibodies from mother to child through the placenta is an effective way to ensure passive immunity for the newborn. Studies indicate that this tactic significantly reduces infant morbidity and mortality rates. Thus, vaccination during pregnancy is a recognized practice supported by scientific evidence[6].

Despite growing scientific evidence confirming the safety of the COVID-19 vaccine for pregnant women, uncertainty about immunization remains a major challenge. This is due to misleading advertising, fear of adverse effects, lack of clarity about the risks to the baby, and difficulties in accessing health services. These factors affect vaccine acceptance among some pregnant women, even when medical guidance is supportive. Addressing these challenges is vital to boost vaccine adherence and safeguard maternal and neonatal health[7].

Factors such as maternal age, educational background, ethnicity, previous

vaccination history, and the existence of concomitant diseases were recognized as elements that affect vaccination adherence in this group[7]. Moreover, the lack of consistency in government policies and ambiguity in communications from health authorities have created uncertainty among pregnant women and health professionals in different national contexts[8].

In this scenario, thoroughly and systematically recognizing the available evidence on COVID-19 immunization during pregnancy was essential. Conducting a scoping review allowed for the identification of knowledge gaps, an understanding of the most important findings related to vaccine safety, efficacy, and coverage, and provided support for clinical decisions and health policies. Therefore, this study aimed to compile existing scientific evidence on COVID-19 vaccination in pregnant women, focusing on the benefits, perceived risks, challenges to acceptance, and coping strategies.

METHOD

This scoping review followed the approach proposed by Arksey and O'Malley, refined by Levac et al., who underscored the importance of clearly defining the review objectives, maintaining continuous collaboration among researchers, and interpreting the results. This approach was particularly suitable for identifying new topics, including COVID-19 vaccination in pregnant women, providing a broad overview of current scientific research, and highlighting important gaps for future investigations[10,11].

The research question was formulated based on the acronym PCC (Population, Concept, and Context), as recommended for scoping reviews.

With the growth of scientific research since the beginning of the pandemic and the demand to understand the impacts of vaccination in this specific group, the scope review allows for the combination of different forms of evidence, providing support for clinical choices and public policies[12,13].

Applying the PRISMA-ScR guidelines ensures methodological rigor and enhances transparency throughout the review process[14]. In addition, recent studies show significant benefits of vaccination in pregnant women in preventing adverse outcomes, highlighting the importance of carefully gathering and analyzing this evidence[13,15].

The review question, formulated based on the Population, Concept, and Context (PCC) mnemonic, can be elaborated as follows: Population (P): Pregnant women; Concept (C): COVID-19 vaccination; Context (C): Scientific evidence available in the literature on efficacy, safety, adherence, and/or outcomes related to vaccination in pregnant women. Therefore, the review question was structured as follows: What scientific evidence is available in the literature on COVID-19 vaccination in pregnant women, considering aspects such as efficacy, safety, adherence, and maternal-fetal impacts?

The eligibility criteria covered studies conducted between 2020 and 2025, available in Portuguese, English, or Spanish, that specifically addressed COVID-19 vaccination in pregnant women. Original articles, systematic reviews, scoping reviews, observational studies, clinical trials, and clinical guidelines addressing safety, efficacy, adverse effects, or recommendations related to vaccination of this population group were considered. Editorials,

comments, letters to the editor, abstracts that did not provide full access to the text, and studies that did not specifically focus on pregnant women or were not related to the COVID-19 vaccine were excluded.

Besides searching databases, manual searches were also conducted in reference lists of included studies, as recommended by PRISMA-ScR.

This scope review was conducted through systematic searches of recognized scientific databases, such as the National Library of Medicine, National Institutes of Health (PubMed/MEDLINE), SciVerse Scopus (Scopus), Embase (Elsevier), Cochrane Library, and Google Scholar. The investigation included publications from 2020 to 2025, using both controlled terms and free terms related to COVID-19 immunization in pregnant women, as well as Boolean operators.

To ensure adequate sensitivity and specificity, the search strategy included additional synonyms connected by the Boolean operators AND and OR. The complete strategy used for the PubMed database is presented below: ("COVID-19 Vaccines"[MeSH Terms] OR "COVID-19 vaccination" OR "Vacinas contra COVID-19" OR "Vacunación contra COVID-19") AND ("Pregnant Women" [MeSH Terms] OR "gestantes" OR "mujeres embarazadas") AND ("safety" OR "segurança" OR "seguridad" OR "clinical practice guidelines" OR "guia de prática clínica" OR "guías de práctica clínica"). Filters were applied for the period from 2020 to 2025 for the Portuguese, English, and Spanish languages. In the Embase database, Emtree controlled terms were used instead of MeSH terms.

The studies were selected in two stages. In the first stage, the title and abstract were screened to exclude studies that did not meet the established inclusion criteria. In the second stage, the full texts of the selected articles were reviewed to ensure they met the predefined inclusion criteria. Data screening and extraction were performed independently and duplicated by two researchers, with disagreements resolved by consensus.

Data collection was performed using an organized form, taking into account the following elements: authors and year of publication, study category, characteristics of the pregnant population (age, pregnancy trimester, health conditions), type of COVID-19 vaccine administered, main results related to safety, efficacy, and side effects, as well as guidelines and advice on vaccination of pregnant women.

Data analysis was qualitative in nature, involving the collection of data obtained on safety, efficacy, and guidelines related to vaccination. The information was organized according to the different types of vaccines administered, the efficacy detected, and the adverse effects mentioned, to systematically organize and examine the data collected.

The results were presented through tables and descriptive narratives. The qualitative analysis concentrated on safety and effectiveness. The summary of vaccination guidelines was based on documents from health organizations such as the World Health Organization and the Centers for Disease Control and Prevention. In addition to classifying the level of evidence, a critical evaluation of the evidence sources was conducted, taking into account the methodological quality of the studies analyzed.

To classify the evidence levels, the system proposed by the Agency for Healthcare Research and Quality (AHRQ)

was adopted, which organizes scientific evidence into seven levels: 1. Systematic reviews or meta-analyses of controlled clinical studies. 2. Well-structured randomized controlled clinical trials. 3. Controlled clinical trials without randomization. 4. Well-defined cohort or case-control studies. 5. Systematic reviews of qualitative and descriptive research. 6. Descriptive or qualitative studies. 7. Opinion of experts or authorities on the subject. This classification provides a standardized assessment of the strength of the evidence presented in the review[16].

The studies were independently reviewed by two researchers to ensure impartiality and accuracy of the findings. Both researchers used pre-established criteria to select and analyze the articles, discussing any discrepancies that might arise during the process. This approach aimed to increase confidence in the conclusions and minimize any bias in the information analysis. The collaboration between the researchers allowed for a more robust and detailed evaluation of the studies that were considered in the review.

This review protocol was previously registered on the Zenodo platform, under the DOI registration number: https://doi.org/10.5281/zenodo.15733835.

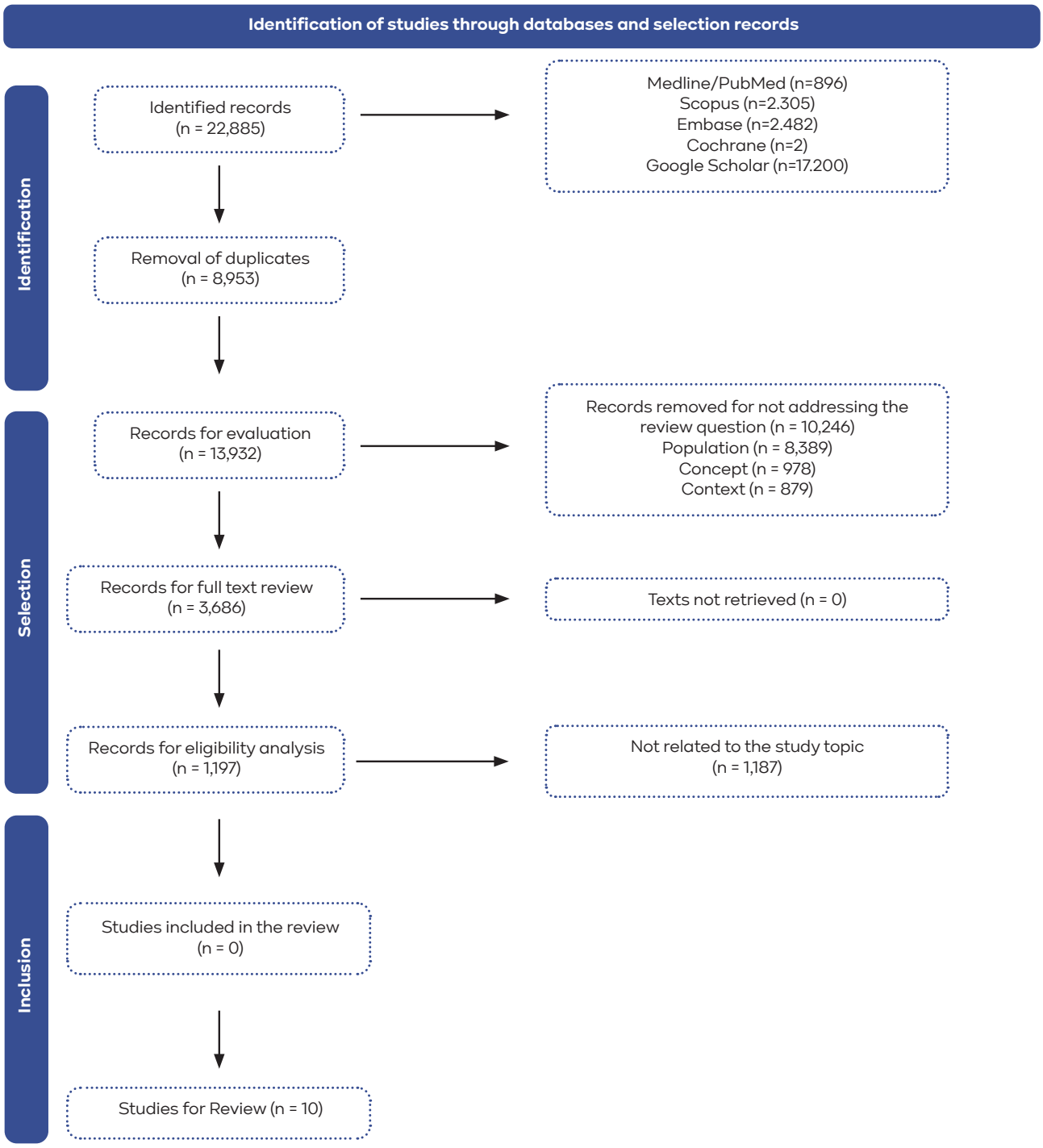
This study was not submitted to the Research Ethics Committee, as it is a literature review, following the ethical and legal principles defined by Resolution No. 466/2012 of the National Health Council (NHC). The review was limited to the analysis of previously published research, without obtaining primary data from individuals. Therefore, no additional ethical validation was necessary. The study followed the ethical precepts of research, which include integrity and transparency of procedures.

RESULTS

The search revealed a total of 22,885 sources in the selected databases, of which 8,953 were eliminated due to duplication in the digital repositories. After analyzing the titles and abstracts of the 13,932 selected articles, 10,246 were removed because they were not directly related to the main theme of this study, resulting in the analysis of 3,686 full articles, of which 1,197 were reviewed for eligibility, and 1,187 were excluded because they were not directly related to the study topic, lacked specific information on pregnant women, or were types of publications not considered eligible, such as editorials and letters to the editor.

Therefore, ten studies that were deemed important for the objectives of this research were included. The reasons for exclusions at each stage are described in the PRISMA-ScR flow diagram shown in Figure 1, providing clarity and enabling the process to be repeated.

Figure 1 - Flowchart of the process of identification, screening, eligibility assessment, and inclusion of studies developed based on the PRISMA 2025 recommendation



Source: Adapted from PRISMA-ScR[17]

The information obtained from each source of evidence included the title, the authors, the year of publication, the country of origin, the study objectives, the methodology used, the type of research conducted, the population studied, the vaccine under analysis, the main findings regarding safety, efficacy, and adverse events, the recommendations and conclusions, and the level of evidence, as defined by the Agency for Healthcare Research and Quality.

A thorough analysis of the evidence sources was conducted, taking into ac-

count the quality of the methods used, the consistency of the results obtained, and the possibility of bias, which complements the categorization of the evidence level and strengthens the reliability of the conclusions presented.

Table 1 presents detailed characteristics and data extracted from each included study, allowing for a systematic and critical analysis of the scientific evidence collected.

Table 1 - Description of studies included in the scope review, according to title, authors, year of publication, level of evidence, objectives, methodology, and studies' conclusions, Rio Branco, Brazil, 2025

N	TITLE	AUTHORS/YEAR	OBJECTIVES	METHODOLOGY/LEVEL	CONCLUSION
1[18]	COVID-19 vaccination in pregnancy: the benefits outweigh the risks	Chavan M, Qureshi H, Karnati S, Kollikonda S, 2021.	To evaluate the effects of COVID-19 vaccination received during pregnancy on SARS-CoV-2 infection, COVID-19-related hospitalization, COVID-19-related admission to the Intensive Care Unit (ICU), and maternal-fetal complications.	Systematic review with meta-analysis/Level 1.	Although there are still no clinical trial data to verify the safety of using the COVID-19 vaccine during pregnancy, the precedent of previous immunization efforts and the current pandemic provide strong support for vaccination. SARS-CoV-2 infection increases the likelihood of poor maternal and neonatal outcomes, which can be prevented by vaccination.
2[19]	Efficacy and clinical outcomes of mRNA COVID-19 vaccine in pregnancy: a systematic review and meta-analysis	Santimano AJ, Al-Zoubi RM, Al-Qudimat AR, Al-Darwish MB, Ojha LK, Rejeb MA, Hamad Y, Elrashid MA, Ruxshan NM, El Omri A, Bawadi H, Al-Asmakh MA, Yassin A, Aboumarzouk OM, Zarour A, Al-Ansari AA, 2024.	To provide healthcare professionals and non-professionals with a comprehensive and up-to-date overview of the information currently available on the vaccines available for pregnant women.	Systematic review with meta-analysis/Level 1.	It is clearly demonstrated that the administration of mRNA vaccines in pregnant women significantly reduces the risk of SARS-CoV-2 infection and mitigates pregnancy-related complications for both the mother and the newborn. Research focused on studying the effects of mRNA in pregnant women should take into account many of the factors highlighted in the review.
3[20]	COVID-19 vaccination during pregnancy: a systematic review and meta-analysis	Shafiee A, Kohandel Gargari O, Teymouri Athar MM, Fathi H, Ghaemi M, Mozhgani SH, 2023.	To evaluate current evidence on vaccination safety and its possible effect on pregnancy and neonatal outcomes.	Systematic review with meta-analysis/Level 1.	In this systematic review and meta-analysis, no clear differences were observed when comparing pregnant women who were vaccinated with those who did not receive the

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N	TÍTULO	AUTORES/ANO	OBJETIVOS	METODOLOGIA/NÍVEL	CONCLUSÃO
					COVID-19 vaccine. Based on the low certainty of the evidence, vaccination during pregnancy was associated with a favorable Apgar score in newborns and fewer premature births.
4[21]	COVID-19 Vaccines during pregnancy and breastfeeding: a systematic review	Novillo B, Martínez-Varea A, 2022.	To provide an update on COVID-19 vaccines during pregnancy and breastfeeding.	Systematic review/ Level 1.	COVID-19 vaccines are not only suggested but strongly recommended for pregnant and breastfeeding women to protect mothers and newborns.
5[22]	Safety and effectiveness of COVID-19 vaccines during pregnancy: a living systematic review and meta-analysis	Ciapponi A, Berrueta M, Argento FJ, Ballivian J, Bardach A, Brizuela ME, Castellana N, Comandé D, Gottlieb S, Kampmann B, Mazzoni A, Parker EPK, Sambade JM, Stegelmann K, Xiong X, Stergachis A, Buekens P. 2024	This study evaluated the safety and efficacy of COVID-19 vaccines administered to pregnant women and shared this evidence through an interactive online website.	Systematic review with meta-analysis/Level 1..	This dynamic systematic review highlights the importance of continuously monitoring vaccine safety and efficacy, particularly in high-risk populations for the impact of COVID-19, such as pregnant women, during the introduction of new vaccines.
6[23]	Effectiveness and safety of COVID-19 vaccine in pregnant women: a systematic review with meta-analysis	Tormen M, Taliento C, Salvioli S, Piccolotti I, Scutiero G, Cappadona R, Greco P, 2023.	To evaluate the effects of COVID-19 vaccination received during pregnancy on SARS-CoV-2 infection, COVID-19-related hospitalization, COVID-19-related admission to the Intensive Care Unit (ICU), and maternal-fetal complications.	Systematic review with meta-analysis/Level 1.	COVID-19 vaccination administered during pregnancy appears to reduce SARS-CoV-2 infection and COVID-19-related hospitalization, with no significant effects on maternal-fetal complications.
7[24]	Effects of COVID-19 vaccination during pregnancy on SARS-CoV-2 infection and maternal and neonatal outcomes: a systematic review and meta-analysis	Rahmati M, Yon DK, Lee SW, Butler L, Koyanagi A, Jacob L, Shin JI, Smith L, 2023.	To address associations between COVID-19 vaccination during pregnancy and maternal and neonatal outcomes.	Systematic review with meta-analysis/Level 1.	COVID-19 vaccination during pregnancy is safe and highly effective in preventing maternal SARS-CoV-2 infection during pregnancy, without increasing the risk of adverse maternal and neonatal outcomes,

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N	TÍTULO	AUTORES/ANO	OBJETIVOS	METODOLOGIA/NÍVEL	CONCLUSÃO
					and is associated with a reduction in stillbirths, preterm births, and neonatal ICU admissions.
8[25]	Systematic review and meta-analysis of the effectiveness and perinatal outcomes of COVID-19 vaccination in pregnancy	Prasad S, Kalafat E, Blakeway H, Townsend R, O'Brien P, Morris E, Draycott T, Thangaratinam S, Le Doare K, Ladhani S, von Dadelszen P, Magee LA, Heath P, Khalil A, 2022.	Systematic review and meta-analysis of published data on the effects of COVID-19 vaccination on pregnancy and the effectiveness of the vaccine in pregnancy.	Systematic review with meta-analysis/Level 1	mRNA vaccination against COVID-19 during pregnancy appears to be safe and is associated with a decrease in stillbirths.
9[26]	Peripartum outcomes associated with COVID-19 vaccination during pregnancy: a systematic review and meta-analysis	Watanabe A, Yasuhara J, Iwagami M, Miyamoto Y, Yamada Y, Suzuki Y, Takagi H, Kuno T, 2022.	To evaluate the association between COVID-19 vaccination during pregnancy and peripartum outcomes.	Systematic review with meta-analysis/Level 1.	COVID-19 vaccination during pregnancy was not associated with an increased risk of peripartum outcomes, but rather with a reduced risk of NICU admission, IFD, and maternal SARS-CoV-2 infection. Therefore, COVID-19 vaccination should be encouraged for pregnant women.
10[27]	COVID-19 vaccination during pregnancy and adverse perinatal outcomes: a systematic review and meta-analysis	Wang J, Deng Y, Wang W, 2024.	To estimate the associations between vaccination against coronavirus disease 2019 (COVID-19) during pregnancy and the risks of adverse perinatal outcomes.	Systematic review with meta-analysis/Level 1.	This meta-analysis demonstrated that any type and dose of COVID-19 vaccination during any trimester of pregnancy did not increase the risk of adverse perinatal outcomes.

Source: Prepared by the authors, 2025.
*LOE – Level of Evidence

The ten articles included were published between 2021 and 2024, with the final sample consisting exclusively of international publications. In terms of countries of origin, the United States (30%), the United Kingdom (20%), Canada (10%), Spain (10%), Qatar (10%), Iran (10%), and China (10%) stand out, demonstrating the wide geographical distribution of the research.

In relation to the year in which they were published, most of the studies appeared during the peak of scientific interest in COVID-19: 30% occurred in 2021, 40% in 2022, 20% in 2023, and 10% in 2024. All studies are systematic reviews with meta-a-

nalysis and are considered level 1 evidence.

Overall, the research provided up-to-date and robust data on COVID-19 immunization in pregnant women, providing clear information based on scientific evidence, expert opinions, and clinical practice guidelines. These results were compiled and structured into tables and descriptions to facilitate understanding and analysis, in accordance with the review questions and objectives.

The evidence reinforces the importance of vaccination in reducing infections, hospitalizations, and maternal-fetal complications, in addition to identifying significant barriers to vaccine uptake, which contributes to informing public policies and clinical strategies focused on maternal and child health.

DISCUSSION

COVID-19 vaccination in pregnant women has been the subject of intense scientific analysis since the beginning of the pandemic. Initially, the lack of specific clinical trials involving pregnant women led to uncertainty about the safety and efficacy of vaccines for this group. Evidence from observational studies and systematic reviews has built a strong knowledge base that supports public policies and clinical recommendations. This debate, supported by recent scientific research, addresses the main aspects of the available evidence: efficacy, mother safety, perinatal outcomes, and challenges to vaccination acceptance.

Vaccine effectiveness in pregnant women

Current literature clearly shows that COVID-19 vaccination in pregnant women significantly reduces the risk of SARS-CoV-2 infection, as well as hospitalizations, ICU admissions, and death. The meta-analysis conducted by Prasad et al.(25), one of the most comprehensive studies, found that vaccinated pregnant women had a 90% reduction in the risk of developing symptomatic and severe infections, as well as a lower risk of obstetric complications associated with COVID-19. Rahmati et al. [24] also observed a decrease in the rate of cesarean sections and premature births among vaccinated women.

Furthermore, Santimano et al.[19] emphasize that messenger RNA (mRNA)-based vaccines, such as those developed by Pfizer-BioNTech and Moderna, generate robust and protective immune responses comparable to those observed in non-pregnant women. The immune system's response has been studied in various population groups, with Ma et al.[23] demonstrating the vaccines' effectiveness in real-world investigations, even in communities with low vaccination rates and high social vulnerability.

This evidence underscores the vital role of vaccination in safeguarding pregnant women against severe forms of the disease, while also contributing to mitigating the impact on healthcare systems.

Maternal protection: adverse reactions and obstetric events

Ensuring vaccine safety during pregnancy is a major concern for both patients and healthcare professionals; however, a systematic review of the evidence suggests a positive safety profile. In research conducted by Shafiee et al.[20], no statistically significant increase in the incidence of spontaneous abortion, fetal abnormalities, intrauterine growth restriction, or pre-

eclampsia was observed among women who received the vaccine.

Watanabe et al.[26] also corroborate this conclusion by denying a link between vaccination and increased risk of premature birth, premature rupture of membranes, or postpartum hemorrhage. Most of the side effects described in the studies were mild or moderate, including myalgia, headache, fatigue, and pain at the injection site. These symptoms were transient and self-limiting.

The real-time assessment by Ciapponi et al.[22] emphasizes that safety remains consistent despite ongoing surveillance and the addition of new research over time. The consistency of information across different countries and population groups also provides greater external reliability to the findings obtained.

Perinatal and neonatal outcomes

Vaccination while pregnant not only protects the mother, but also offers benefits to the fetus and baby. According to Prasad et al.[25] and Wang et al.[27], a reduction in the incidence of stillbirths, premature births, and admissions to neonatal ICUs was observed among immunized women. One of the recommended tactics is the transfer of IgG antibodies through the placenta, which may offer a form of passive protection to the newborn.

Novillo and Martínez-Varea[21] pointed out that, in addition to the protection transmitted through the placenta, targeted antibodies were also identified in breast milk after immunization with mRNA vaccines, which may provide extra protection in the first months of life, a crucial phase of immune fragility.

The favorable impact on newborn outcomes provides a double benefit: apart from safeguarding maternal health, vaccination has the potential to significantly reduce the risk of infections and complications for the baby, which is especially relevant in regions where COVID-19 is widely prevalent and neonatal intensive care resources are limited.

Barriers to immunization and vaccine hesitancy

Despite scientific evidence supporting vaccination, vaccine hesitancy remains one of the main barriers to immunization among pregnant women. Factors such as misinformation, fear of adverse effects on the baby, and confusing messages on social media contribute to increased vaccine rejection. The study by Chavan et al.[18] emphasizes that the benefits of vaccination far outweigh the potential risks and that hesitancy is more influenced by individual views than by scientific evidence.

Furthermore, Ma et al.[23] have shown that accurate guidance from health professionals is one of the most important factors in vaccination uptake. In this context, doctors, nurses, and community health workers must receive adequate training so they can act as transmitters of evidence-based information.

Government vaccination initiatives need to consider the concerns of pregnant women, as well as cultural, religious, and social aspects. Clear communication, attention to people's needs, and the humanization of services are effective strategies for increasing confidence in vaccines.

Perspectives and suggestions for the future

Research data from multicenter stu-

dies and systematic reviews show that COVID-19 vaccination is safe and effective in pregnant women. The available evidence supports the need to include pregnant women in all immunization programs, both nationally and internationally.

However, there are still major shortcomings. Most of the studies analyzed focus on developed countries, and it is essential to expand research in low- and middle-income countries. Moreover, future research must consider specific groups, such as women with associated health conditions, pregnant adolescents, and pregnant women facing situations of social vulnerability.

The implementation of active surveillance systems and the continuous promotion of updated reviews, such as that conducted by Ciapponi et al.[22], are essential for keeping guidelines up to date and ensuring safe vaccination practices. In addition, it is essential to strengthen health education to combat misinformation and increase vaccination rates among pregnant women.

Some limitations of this scoping review process should be noted. Despite the application of rigorous criteria for eligibility and methodological quality, there is a possibility that significant studies may have been left out, either because they were beyond the search range, because they were not fully accessible, or because they were published in languages that were not considered in the screening process. Additionally, as with any scoping review, no detailed methodological quality analysis was carried out, which restricts the strength of causal conclusions and the direct use of results in clinical practice. However, the strategy used enabled a comprehensive mapping of the main evidence on the subject and provided valuable information for professional practice and public policy formulation.

It is important to acknowledge the limitations posed by the rapid generation of scientific knowledge on the subject. Although continuous reviews, such as that conducted by Ciapponi et al., strive to address this difficulty, there is still the possibility that new and relevant studies published after the databases' finalization in the reviews analyzed may be left out.

Even with such limitations, the revised dataset is robust enough to affirm, with a high degree of confidence, the safety and efficacy of COVID-19 vaccination during pregnancy and the benefits it provides for both mother and baby.

FINAL REMARKS

This scope analysis shows, based on a broad and robust scientific research base, that COVID-19 vaccination during pregnancy is safe, effective, and associated with beneficial outcomes for mothers and their babies. The data evaluated suggest that vaccinated pregnant women are less likely to contract SARS-CoV-2, as well as reductions in hospitalizations, severe forms of the disease, and deaths. In addition, there is a significant reduction in perinatal complications, such as premature births and neonatal hospitalizations, as well as the transfer of passive immunity to the fetus and newborn.

The lack of evidence linking vaccines to teratogenic effects, miscarriages, or serious obstetric complications reinforces confidence in the safety of vaccines for this group. These conclusions are supported by systematic reviews, meta-analyses, and observational studies using population data, conducted in diverse social and

geographic contexts.

Nevertheless, hesitancy regarding vaccines among pregnant women remains a challenge to be overcome, requiring improved health communication approaches, professional training, and the ongoing struggle against misinformation. Proactive action by health professionals is essential to increase adherence and credibility in vaccination campaigns.

Considering the above, it can be concluded that COVID-19 vaccination in pregnant women is highly recommended as a vital strategy for the safety of both mothers and newborns and should be included in evidence-based public health guidelines. Furthermore, continuous evaluation of the vaccines' effects and new research covering pregnant women in more fragile conditions are recommended to ensure equity in access and protection offered by immunizations.

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