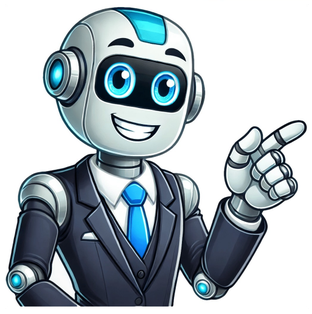
I'm not a robot



Last updated April 11, 2025 This Practice Advisory was developed by the American College of Obstetricians and Gynecologists with the assistance of Hyagriv N. Simhan, MD, MS; Allison Bryant, MD, MPH; Manisha Gandhi, MD; and Mark Turrentine, MD. This Practice Advisory serves as an update to Practice Bulletin No. 234, Prediction and Prevention of Spontaneous Preterm Birth, originally published in 2021 1 . This Practice Advisory is provided to address the April 6, 2023, decision by the U.S. Food and Drug Administration (FDA) to withdraw approval of Makena and its generics (17-alpha hydroxyprogesterone caproate [17-OHPC]) 2 . Additionally, this Practice Advisory serves to update the current evidence and recommendations for the use of progestogen for the prevention of recurrent preterm birth. This Practice Advisory has been updated to remove a link to the accompanying FAQs, which have been withdrawn, and to incorporate information about compounding. The American College of Obstetricians and Gynecologists (ACOG) guidance regarding the use of progestogen for the prevention of preterm birth is included in ACOG Practice Bulletin No. 234, "Prediction and Prevention of Spontaneous Preterm Birth" 1 . Updated recommendations are: Vaginal progesterone may be considered as a treatment option for patients with a history of preterm birth, singleton gestation, and a shortened cervix. However, vaginal progesterone has not been proven effective in the absence of a shortened cervix and should not be considered as an alternative to 17-OHPC. Intramuscular 17-OHPC is not recommended for the primary prevention of preterm birth in patients with a history of spontaneous preterm birth. Dependent upon cervical length measurement, prior pregnancy history, and past treatment, a discussion of the range of interventions available to prevent a recurrent preterm birth should occur and a collaborative action plan should be developed. With regard to the use of prophylactic 17-OHPC specifically for the prevention of recurrent preterm birth, the FDA's assessment of the current body of evidence concluded that there were not sufficient data to indicate that this was an effective treatment in the broad population it was originally approved for—all pregnant people with a prior spontaneous preterm birth between 20 and 37 weeks of gestation. Whether this intervention would be useful in a subset of people requires future study. The FDA does not seem to base its decision on safety concerns. Although compounding remains an option, the FDA's decision to withdraw approval of Makena will significantly impact access to and availability of 17-OHPC for the prevention of preterm birth. Compounded drugs, including those containing hydroxyprogesterone caproate, do not undergo FDA premarket review for safety, effectiveness, or quality. Regulatory concerns in some states or potential limited coverage by medical insurance carriers may result in limited access to compounded medications in some regions of the country. Another important update to the evidence pertains to the use of vaginal progesterone for prevention of recurrent preterm birth in asymptomatic people. The results of a meta-analysis and an additional recently published study evaluating vaginal progesterone to prevent recurrent preterm birth found that vaginal progesterone was not associated with a reduction in recurrent preterm birth 3 4 . As a result, ACOG's guidance is updated via this Practice Advisory to recommend that in the setting of a singleton pregnancy with a history of prior spontaneous preterm birth, and in the absence of a shortened cervix, vaginal progesterone should not be offered as a prevention option. The table from the Practice Bulletin is updated and is included in this Practice Advisory Table 1. In summary, at this time, the body of evidence is equivocal regarding the effectiveness of 17-OHPC, and the referenced FDA action will limit access to 17-OHPC for patients. Furthermore, the body of evidence does not indicate that vaginal progesterone is effective for the prevention of recurrent preterm birth in singleton pregnancies with a prior preterm birth between 20 and 37 weeks of gestation in the absence of a shortened cervix 3 4 . As described in Practice Bulletin No. 234, patients with a singleton pregnancy and prior spontaneous preterm birth should be assessed with serial endovaginal ultrasound cervical length measurement 1 . Dependent upon cervical length measurement, prior pregnancy history, and past treatment, a discussion of the range of interventions available to prevent a recurrent preterm birth should occur and a collaborative action plan should be developed Table 1. Preterm birth remains a significant public health issue and more evidence for effective interventions is urgently needed. The American College of Obstetricians and Gynecologists will continue to monitor the evidence as it evolves and advocate for prevention strategies for preterm birth that are effective and accessible to all patients. Access the Society for Maternal-Fetal Medicine statement. Please contact with any questions. Prediction and prevention of spontaneous preterm birth. ACOG Practice Bulletin No. 234. American College of Obstetricians and Gynecologists. Obstet Gynecol 2021;138:e65-90. doi: 10.1097/AOG.0000000000004479 Article Locations: . U.S. Food and Drug Administration. FDA Commissioner and Chief Scientist announce decision to withdraw approval of Makena. FDA; 2023. Accessed April 6, 2023. Available at: Article Locations: Conde-Agudelo A, Romero R. Vaginal progesterone does not prevent recurrent preterm birth in women with a singleton gestation, a history of spontaneous preterm birth, and a midtrimester cervical length >25 mm. Am J Obstet Gynecol 2022;227:923-6. doi: 10.1016/j.ajog.2022.07.054 Article Locations: Nelson DB, Lafferty A, Venkatraman C, McDonald JG, Eckert KM, McIntire DD, et al. Association of vaginal progesterone treatment with prevention of recurrent preterm birth. JAMA Netw Open 2022;5:e2237600. doi: 10.1001/jamanetworkopen.2022.37600 Article Locations: The American College of Obstetricians and Gynecologists recognizes and supports the gender diversity of all patients who seek obstetric and gynecologic care. In original portions of this document, authors seek to use gender-inclusive language or gender-neutral language. When describing research findings, this document uses gender terminology reported by investigators. To review ACOG's policy on inclusive language, see . A Practice Advisory is a brief, focused statement issued to communicate a change in ACOG guidance or information on an emergent clinical issue (eg, clinical study, scientific report, draft regulation). A Practice Advisory constitutes ACOG clinical guidance and is issued only online for Fellows but may also be used by patients and the media. Practice Advisories are reviewed periodically for reaffirmation, revision, withdrawal or incorporation into other ACOG guidelines. This information is designed as an educational resource to aid clinicians in providing obstetric and gynecologic care, and use of this information is voluntary. This information should not be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. It is not intended to substitute for the independent professional judgment of the treating clinician. Variations in practice may be warranted when, in the reasonable judgment of the treating clinician, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology. The American College of Obstetricians and Gynecologists reviews its publications regularly; however, its publications may not reflect the most recent evidence. Any updates to this document can be found on www.acog.org/clinical. While ACOG makes every effort to present accurate and reliable information, this publication is provided "as is" without any warranty of accuracy, reliability, or otherwise, either express or implied. ACOG does not guarantee, warrant, or endorse the products or services of any firm, organization, or person. Neither ACOG nor its officers, directors, members, employees, or agents will be liable for any loss, damage, or claim with respect to any liabilities, including direct, special, indirect, or consequential damages, incurred in connection with this publication or reliance on the information presented. Publications of the American College of Obstetrician and Gynecologists are protected by copyright and all rights are reserved. The College's publications may not be reproduced in any form or by any means without written permission from the copyright owner. The American College of Obstetricians and Gynecologists (ACOG) is the nation's leading group of physicians providing evidence-based obstetric and gynecologic care. As a private, voluntary, nonprofit membership organization of more than 60,000 members, ACOG strongly advocates for equitable, exceptional, and respectful care for all women and people in need of obstetric and gynecologic care; maintains the highest standards of clinical practice and continuing education of its members; promotes patient education; and increases awareness among its members and the public of the changing issues facing patients and their families and communities. www.acog.org This guideline covers the care of women with a singleton pregnancy at increased risk of, or with symptoms and signs of, preterm labour (before 37 weeks), and women with a singleton pregnancy having a planned preterm birth. It aims to reduce the risks of preterm birth for the baby and describes treatments to prevent or delay early labour and birth. For information on related topics, including twin and triplet pregnancy, see our women's and reproductive health summary page. November 2024: There is a problem with the supply of cassettes used for fetal fibronectin testing. We will review our guidance on diagnosing preterm labour in women with intact membranes and use our topic prioritisation process to decide whether to update it. For more information, see the NHS England letter on the discontinuation of Hologic fetal fibronectin testing. Last reviewed: 1 May 2023 We have reviewed our guidelines portfolio to identify topics that we think will add the most value to the health and care system and have agreed the updates recommended in this surveillance report will not proceed as planned. Next review: This guideline will be reviewed if there is new evidence that is likely to change the recommendations. How we prioritise updating our guidance Decisions about updating our guidance are made by NICE's prioritisation board. For more information on the principles and process see NICE-wide topic prioritisation: the manual. For information about individual topics, including any decisions affecting this guideline, see the summary table of prioritisation board decisions. In this guideline, we use the terms 'woman' or 'mother' throughout. These should be taken to include people who do not identify as women but are pregnant or have given birth. Recommendations This guideline includes new and updated recommendations on: repeat doses of maternal corticosteroids It also includes recommendations on: Who is it for? Healthcare professionals who care for women at increased risk of or with symptoms and signs of preterm labour and women having a planned preterm birth Commissioners and providers of maternity services Women at increased risk of or with symptoms and signs of preterm labour and women having a planned preterm birth, and their families and carers Guideline development process How we develop NICE guidelinesThe recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian. All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme. Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties. Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible. Link to RCOG home Management of Monochorionic Twin Pregnancy (No. 51) Detection of spontaneous preterm birth by maternal urinary volatile organic compound analysis: A prospective cohort study. Ronde E, Frerichs NM, Brantenaar S, El Manouni El Hassani S, Wicaksono AN, Covington JA, De Boer NKH, De Meij TG, Hankemeier T, Reiss IKM, Schoenmakers S. Ronde E, et al. Front Pediatr. 2022 Dec 12;10:1063248. doi: 10.3389/fped.2022.1063248. eCollection 2022. Front Pediatr. 2022. PMID: 36578660 Free PMC article. ABSTRACT: Preterm birth is the leading cause of neonatal mortality and the most common reason for antenatal hospitalization 1 2 3 4. In the United States, approximately 12% of all live births occur before term, and preterm labor preceded approximately 50% of these preterm births 5 6. Although the causes of preterm labor are not well understood, the burden of preterm births is clear—preterm births account for approximately 70% of neonatal deaths and 36% of infant deaths as well as 25–50% of cases of long-term neurologic impairment in children 7 8 9. A 2006 report from the Institute of Medicine estimated the annual cost of preterm birth in the United States to be $26.2 billion or more than $51,000 per premature infant 10. However, identifying women who will give birth preterm is an inexact process. The purpose of this document is to present the various methods proposed to manage preterm labor and to review the evidence for the roles of these methods in clinical practice. Identification and management of risk factors for preterm labor are not addressed in this document. This content is only available to members and subscribers. Log In Nonmembers: Subscribe now to access exclusive ACOG Clinical content, including: ACOG Clinical is designed for easy and convenient access to the latest clinical guidance for patient care. Developed with members', physicians', and women's health care professionals' needs in mind, user-friendly features include: Easy, advanced search function to find the most relevant guidance Enhanced document presentation Advanced features and functionality You'll find clinical content written and peer reviewed by experts and valuable information that spans guidance on the diagnosis and management of the full spectrum of obstetric and gynecological conditions and clinical management issues. Note for Life Fellows: Annual membership dues are waived but there is a discounted annual subscription fee of $95 for access to publications such as the Green Journal, Practice Bulletins, and Committee Opinions. Individual subscriptions include print and online access. Subscribe today. Subscribe