

2. Zeybek B, Hill A, Menderes G, Borahay MA, Azodi M, Kilic GS. Robot-assisted abdominal cerclage during pregnancy. *JLS* 2016;20: e2016.00072.
3. Neveu M-E, Fernandez H, Defieux X, Senat M-V, Houllier M, Capmas P. Fertility and pregnancy outcomes after transvaginal cervico-isthmic cerclage. *Eur J Obstet Gynecol Reprod Biol* 2017;218: 21–6.
4. Shin S-J, Chung H, Kwon S-H, Cha S-D, Lee H-J, Kim A-R, et al. The feasibility of a modified method of laparoscopic transabdominal

cervicoisthmic cerclage during pregnancy. *J Laparoendosc Adv Surg Tech A* 2015;25:651–6.

5. Moawad GN, Tyan P, Bracke T, Abi Khalil ED, Vargas V, Gimovsky A, et al. Systematic review of transabdominal cerclage placed via laparoscopy for the prevention of preterm birth. *J Minim Invasive Gynecol* 2018;25:277–86.

© 2018 Elsevier Inc. All rights reserved. <https://doi.org/10.1016/j.ajog.2018.10.030>

Progesterone for preterm birth prevention: the importance of informed consent



TO THE EDITORS: I would like to congratulate Nelson et al¹ for their excellent study on 17-alpha hydroxyprogesterone caproate (17OHP-C) and for their many replies to the follow-up letters. I would like to also recognize the letter writers for enhancing the discussion.

However, one critical element that seems to be missing from the debate is that ultimately it is up to the pregnant woman herself to decide what medications she will use or be given. Physicians can recommend 17OHP-C (or not), but the patient makes the ultimate call. Truly informed consent requires a full discussion of risks, benefits, and alternatives. For 17OHP-C, the risks are injection site reactions, likely increased rates of gestational diabetes,^{1,2} and possibly increased rates of miscarriage and stillbirth.³

These risks are detailed on the Makena label. Another risk is the unknown long-term effects of being exposed to a synthetic progestin throughout fetal development. The benefit is that 17OHP-C might help to prevent recurrent preterm delivery, although this has been shown in only 1 study,⁴ about which there are serious concerns.

The alternative is some combination of watchful waiting/serial cervical ultrasound/cerclage and/or vaginal progesterone. In my personal experience, most patients who receive full counseling on this issue decline 17OHP-C. However, some do opt to be given it. The key here is that the patient receives full and accurate counseling so that she can actually provide proper informed consent. I am curious to know how Nelson et al would summarize their patient counseling in this area. ■

Adam C. Urato, MD
Chief, Maternal-Fetal Medicine
MetroWest Medical Center
115 Lincoln Street
Framingham, MA 01702
Beth Israel Deaconess Medical Center
Saint Elizabeth's Medical Center
Boston, MA
aurato@bidmc.harvard.edu

The author reports no conflict of interest.

REFERENCES

1. Nelson DB, McIntire DD, McDonald J, et al. 17-Alpha hydroxyprogesterone caproate did not reduce the rate of recurrent preterm birth in a prospective cohort study. *Am J Obstet Gynecol* 2017;216: 600.e1–9.
2. Rebarber A, Istwan NB, Russo-Stieglitz K, et al. Increased incidence of gestational diabetes in women receiving prophylactic 17 α -hydroxyprogesterone caproate for prevention of recurrent preterm delivery. *Diabetes Care* 2007;30:2277–80.
3. Food and Drug Administration. Center for Drug Evaluation and Research. Application number: 21945Orig1s000. Medical Review, page 48. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/021945Orig1s000MedR.pdf. Accessed Sept. 24, 2018.
4. Meis PJ, Klebanoff M, Thom E, et al. Prevention of recurrent preterm delivery by 17 alpha-hydroxyprogesterone caproate. *N Engl J Med* 2003;348:2379–85.

© 2018 Elsevier Inc. All rights reserved. <https://doi.org/10.1016/j.ajog.2018.12.012>

REPLY



We thank Dr Urato for his interest in our report¹ published in the *Journal* in June 2017 as well as his recent letter on patient consent for obstetric interventions. We have and continue to fully support a patient's unchallengeable right to decline any obstetric intervention including 17-alpha hydroxyprogesterone caproate (17OHP-C) for prevention of preterm birth.

The Society for Maternal-Fetal Medicine (SMFM) and the American College of Obstetricians and Gynecologists have both endorsed the use of 17OHP-C for the prevention of preterm birth in singleton pregnancies.^{2,3} Most recently, in January 2017, the SMFM Publications Committee once again emphasized 17OHP-C be used for the prevention of recurrent preterm birth. Indeed, the SMFM noted that there continued to be an underutilization of 17OHP-C in the United States despite this recommendation.⁴

We were intrigued by Dr Urato's statement, "In my personal experience, most patients who receive full counseling ...