Systematic Review of Progestogens for Prevention of Preterm Birth

Full-text Review Form

First Author, Year: _____

REFID #: _____ Abstractor Initials:

__ __ __

Primary Inclusion/Exclusion Criteria		
	YES	**NO**
1. Original research (exclude editorials, commentaries, letters to editor, reviews, etc)		
2. Eligible study size of 20 pregnant females and/or infants Record N if < 20 relevant subjects enrolled: ____		
3. Does study apply to SER topic? (If No, select at least one of the following reasons): a. ___ Treatment for infertility/luteal phase defect b. ___ Treatment for recurrent miscarriage c. ___ Does not involve treatment with a progestogen d. ___ Basic science, anatomy or physiology only e. ___ Imaging/diagnostic study only f. ___ PTB prevention intervention without progestogens g. ___ Other _____		
4. Does study answer one of the following key questions? (check the box(es) next to the question(s) the study applies to)		

KQ1. In pregnant women who are at risk for preterm birth (<37 weeks EGA), does progestogen treatment compared with placebo, usual care or other interventions improve maternal or fetal/neonatal health outcomes, including but not limited to:

- Complications during pregnancy (e.g., chorioamnionitis, antenatal hospitalizations, and intrauterine growth restriction)
- Mode of birth and complications during birth (e.g., cesarean birth and surgical complications)
- Prematurity
- Postpartum and neonatal complications (e.g., maternal postpartum hemorrhage and IVH)
- Longer term outcomes (e.g., neurodevelopmental delay and future reproductive outcomes)

KQ2. What is the nature and frequency of maternal and child adverse effects of progestogen treatment, including but not limited to:

- Complications during pregnancy (e.g., allergic reactions or development of gestational diabetes)
- Mode of birth and complications during birth (e.g., unanticipated maternal harms)
- Postpartum and neonatal complications (e.g., infections and sepsis)
- Longer term outcomes

KQ3. How do the effectiveness, adverse effects and safety of progestogen treatment differ based on the maternal risk factors for PTB such as: severity of prior PTB, degree of cervical shortening, order of multiple gestations, fetal fibronectin status, preterm premature rupture of membranes, threatened PTB, and socioeconomic predictors of prematurity including race/ethnicity?

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	YES	**NO**
4 (continued). Does study answer one of the following key questions? (check the box(es) next to the question(s) the study applies to)		
KQ4. How do the effectiveness, acceptability, adherence, adverse effects and safety of progestogen treatment differ based on the formulation, dose, frequency of administration and gestational age (GA) at initiation or discontinuation of therapy with the progestogen? KQ5. How do the effectiveness, adverse effects and safety of progestogen treatment differ based on co-interventions used to prevent PTB and its consequences, including antibiotics, corticosteroids, tocolysis, and surgical interventions such as cervical cerclage? KQ6. What is the effect of health systems and provider factors including provider knowledge and attitudes, provider specialty, cost of drug, availability of drug in formularies, and Medicaid and private payer coverage on the utilization of progestogens for eligible at risk women?		
5. Did you answer yes to all 4 questions above? If YES, hand search references and record relevant reference numbers here:		

EXCLUDE IF AN ITEM IN A GRAY BOX IS SELECTED

If EXCLUDED, retain for:

_____**BACKGROUND/DISCUSSION**

_____**REVIEW OF REFERENCES**

_____**Other**_____

COMMENTS: