Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum

US Preventive Services Task Force Reaffirmation Recommendation Statement

US Preventive Services Task Force

IMPORTANCE In the United States, the rate of gonococcal ophthalmia neonatorum was an estimated 0.4 cases per 100,000 live births per year from 2013 to 2017. Gonococcal ophthalmia neonatorum can cause corneal scarring, ocular perforation, and blindness as early as 24 hours after birth. In the absence of ocular prophylaxis, transmission rates of gonococcal infection from mother to newborn are 30% to 50%.

OBJECTIVE To reaffirm the US Preventive Services Task Force (USPSTF) 2011 recommendation on ocular prophylaxis for gonococcal ophthalmia neonatorum.

EVIDENCE REVIEW The USPSTF commissioned a reaffirmation evidence update to identify new and substantial evidence sufficient enough to change its prior recommendation.

FINDINGS Using a reaffirmation process, the USPSTF found no new data that would change its previous conclusion that topical ocular prophylaxis is effective in preventing gonococcal ophthalmia neonatorum and related ocular conditions. The USPSTF found no new data that would change its previous conclusion that there is convincing evidence that topical ocular prophylaxis of all newborns is not associated with serious harms. Therefore, the USPSTF reaffirms its previous conclusion that there is convincing evidence that topical ocular prophylaxis for all newborns provides substantial benefit.

CONCLUSIONS AND RECOMMENDATION The USPSTF recommends prophylactic ocular topical medication for all newborns to prevent gonococcal ophthalmia neonatorum. (A recommendation)

Rationale

Importance
In the United States, the rate of gonococcal ophthalmia neonatorum was an estimated 0.4 cases per 100,000 live births per year from 2013 to 2017.1-4 Gonococcal ophthalmia neonatorum can cause corneal scarring, ocular perforation, and blindness as early as 24 hours after birth.5-7 In the absence of ocular prophylaxis, transmission rates of gonococcal infection from mother to newborn are 30% to 50%.8

Reaffirmation
In 2011, the USPSTF reviewed the evidence on prophylactic ocular topical medication for all newborns to prevent gonococcal ophthalmia neonatorum and issued an A recommendation.5 The USPSTF has decided to use a reaffirmation deliberation process to update this recommendation. The USPSTF uses the reaffirmation process for well-established, evidence-based standards of practice in current primary care practice for which only a very high level of evidence would justify a change in the grade of the recommendation.9 In its deliberation of the evidence, the USPSTF considers whether
the new evidence is of sufficient strength and quality to change its previous conclusions about the evidence.

**Benefits of Preventive Medication**
The USPSTF found convincing evidence that ocular prophylaxis of newborns with 0.5% erythromycin ophthalmic ointment can prevent gonococcal ophthalmia neonatorum.

**Harms of Preventive Medication**
The USPSTF found convincing evidence that ocular prophylaxis of newborns with 0.5% erythromycin ophthalmic ointment is not associated with serious harms.

**USPSTF Assessment**
Using a reaffirmation process, the USPSTF concludes with high certainty that the net benefit of topical ocular prophylaxis of all newborns to prevent gonococcal ophthalmia neonatorum is substantial.

**Clinical Considerations**

**Patient Population Under Consideration**
This recommendation applies to all newborns regardless of gestational age (Figure 2).
Preventive Medication
Erythromycin ophthalmic ointment is considered effective in preventing gonococcal ophthalmia neonatorum. Other medications, such as tetracycline ophthalmic ointment and silver nitrate, have been evaluated for the prevention of gonococcal ophthalmia neonatorum but are no longer available in the United States. Gentamicin was used during a period of erythromycin shortage, although its use was associated with ocular reactions (chemical conjunctivitis). Povidone-iodine has been proposed for prophylaxis, but there are limited data on its benefits and harms. Currently, erythromycin is the only drug approved by the US Food and Drug Administration for the prophylaxis of gonococcal ophthalmia neonatorum.

Additional Approaches to Prevention
The rates of gonococcal ophthalmia neonatorum are related to gonococcal infection rates in women of reproductive age. Accordingly, screening for and treatment of gonococcal infection in pregnant women is an important strategy for reducing the sexual transmission of gonorrhea and subsequent vertical transmission leading to gonococcal ophthalmia neonatorum. While screening and treatment programs have reduced the rates of gonorrhea in pregnant women, there are large disparities in access to prenatal care in the United States. Risk-based prophylaxis has also been proposed as an alternative strategy for preventing gonococcal ophthalmia neonatorum. Currently, there are no risk-based tools for screening pregnant women and no studies examining the use of risk-based vs universal prophylaxis. Therefore, ocular prophylaxis remains an important tool in the prevention of gonococcal ophthalmia neonatorum.

Useful Resources
The USPSTF recommends screening for gonorrhea in all sexually active women 24 years and younger and in older women at increased risk for infection, as well as pregnant women. The Centers for Disease Control and Prevention provides clinical guidance for ocular prophylaxis and treatment of gonococcal ophthalmia neonatorum.

Other Considerations
Research Needs and Gaps
The only available drug approved by the US Food and Drug Administration for the prevention of gonococcal ophthalmia neonatorum is 0.5% erythromycin ophthalmic ointment. It is currently unknown whether Neisseria gonorrhoeae has developed resistance to erythromycin ointment in the United States. However, given increased antimicrobial resistance noted in other countries, further research is needed to find safe and effective alternatives to erythromycin. Another area for research is whether risk-based prophylaxis of newborns, based on maternal risk factors, is as effective as universal prophylaxis.

Discussion
Burden of Disease
Ophthalmia neonatorum is conjunctivitis occurring in infants during the first month of life. Gonococcal ophthalmia neonatorum occurs when gonococcal infection is transmitted to newborns during delivery by women infected with N gonorrhoeae. The rates of gonococcal conjunctivitis in infants are directly related to the rates of gonorrhea among women of reproductive age. In the United States, adolescents and young adult women have the highest rates of gonorrhea, with rates peaking at age 19 years (872.2 cases per 100 000 women); among women aged 20 to 24 years, there were 648.8 cases per 100 000 women in 2017. Estimated rates of gonorrhea among pregnant women in the US primary care
setting are not available. Although gonococcal infection rates have declined since national screening programs were implemented in the 1970s, reported gonorrhea cases have increased recently, from 105.3 cases to 171.9 cases per 100,000 population from 2013 to 2017, respectively. An estimated 6.2% of births in the United States occur among women receiving little to no prenatal care, although rates as high as 20% have been documented in certain populations based on location and race/ethnicity. 

Data based on infant age (younger than 1 year) and specimen source (conjunctiva or eye) indicate there were an estimated 42 infections (±0.4 cases) per 100,000 live births per year from 2013 to 2017. However, limitations in reporting suggest this is an underestimate. Using a broader definition that includes cases with unknown, other, or missing specimen sources, the prevalence of gonococcal ophthalmia neonatorum during that period could possibly be higher.

Untreated gonococcal ophthalmia neonatorum can result in severe and lasting conditions, including corneal scarring, ocular perforation, and blindness. There are no contemporary estimates of blindness related to gonococcal ophthalmia neonatorum in the United States. Historical estimates from 19th-century Europe show that gonococcal ophthalmia neonatorum was a major cause of childhood blindness, resulting in corneal damage in 20% of infected infants and blindness in 3%. An observational study from Nairobi, Kenya, in the 1980s reported that 16% of a series of 64 infants with gonococcal ophthalmia neonatorum had corneal involvement.

Scope of Review
To reaffirm its 2011 recommendation on ocular prophylaxis for gonococcal ophthalmia neonatorum, the USPSTF commissioned a targeted evidence review. The aim of this review was to identify substantial new evidence that was sufficient to change the prior recommendation.

Benefits of Preventive Medication
Previous USPSTF reviews found convincing evidence that topical ocular prophylaxis can prevent gonococcal ophthalmia neonatorum. The USPSTF found no new data that would change its previous conclusion that topical ocular prophylaxis is effective in preventing gonococcal ophthalmia neonatorum and related ocular conditions.

Potential Harms of Preventive Medication
The USPSTF found no new data that would change its previous conclusion that there is convincing evidence that topical ocular prophylaxis of all newborns is not associated with serious harms. Possible harms include the potential for antimicrobial resistance to treatment medication.

Estimate of Magnitude of Net Benefit
The USPSTF considered the evidence using a reaffirmation process and found that topical ocular prophylaxis is effective in preventing gonococcal ophthalmia neonatorum and related ocular conditions, with small associated harms and substantial benefit. Therefore, the USPSTF reaffirms its previous conclusion that there is convincing evidence that topical ocular prophylaxis for all newborns provides substantial benefit.

Response to Public Comment
A draft version of this recommendation statement was posted for public comment on the USPSTF website from September 11 to October 9, 2018. Several comments questioned the continued need for universal prophylaxis given the relative low rate of disease. The USPSTF reaffirmed its recommendation based on several factors, including the rapid course and serious adverse effects of infection, increasing rates of gonococcal infection, and the large number of persons who do not receive screening for gonococcal infection during pregnancy in the United States. Comments also supported risk-based prophylaxis as an alternative strategy for prevention. However, there are no tools for assessing the risk of infection in newborns and no studies examining the use of risk-based universal prophylaxis. The USPSTF revised the recommendation to clarify this point. In addition, a number of comments promoted the use of iodine solutions (povidone-iodine) as an alternative to erythromycin ophthalmic ointment. The evidence review found limited studies on the use of iodine solutions and notes that they are not approved for use in the United States as ocular prophylaxis for gonococcal ophthalmia neonatorum. The USPSTF added language to address this concern.

Reaffirmation of Previous USPSTF Recommendation
This recommendation is a reaffirmation of the USPSTF 2011 recommendation statement. In 1996 and 2005, the USPSTF reviewed the evidence on ocular prophylaxis for gonococcal ophthalmia neonatorum and found that the benefits of screening substantially outweigh the harms. For the current recommendation, the USPSTF commissioned a targeted review to look for substantial new evidence on the benefits and harms of ocular prophylaxis and determined that the net benefit of ocular prophylaxis continues to be well established. The USPSTF found no new substantial evidence that could change its recommendation and therefore reaffirms its recommendation to provide prophylactic ocular topical medication for all newborns to prevent gonococcal ophthalmia neonatorum.

Recommendations of Others
The Centers for Disease Control and Prevention, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, and the World Health Organization all recommend universal topical ocular prophylaxis to prevent gonococcal ophthalmia neonatorum. The Canadian Pediatric Society recommends against universal prophylaxis. Several European countries, including Denmark, Norway, Sweden, and the United Kingdom, no longer require universal prophylaxis, instead opting for a prevention strategy of increased screening and treatment of pregnant women. In 2017, the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists recommended screening all pregnant women at risk for gonorrhea or who live in a high-prevalence area at the first prenatal visit; women with gonococcal infection should be retested in 3 to 6 months, preferably in the third trimester. In addition, if the result of the first test is negative but the woman is at high risk for gonorrhea, retesting at the beginning of the third trimester is recommended.
USPSTF Recommendation: Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum

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**Disclaimer:** Recommendations made by the USPSTF are independent of the US government. They should not be construed as an official position of AHRQ or the US Department of Health and Human Services.

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**REFERENCES**


