

U.S. Preventive Services Task Force

Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum: Recommendation Statement

Summary of Recommendation and Evidence

The USPSTF recommends prophylactic ocular topical medication for all newborns to prevent gonococcal ophthalmia neonatorum (*Table 1*). **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,⁹ 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.

As published by the USPSTF.

This summary is one in a series excerpted from the Recommendation Statements released by the USPSTF. These statements address preventive health services for use in primary care clinical settings, including screening tests, counseling, and preventive medications.

The complete version of this statement, including supporting scientific evidence, evidence tables, grading system, members of the USPSTF at the time this recommendation was finalized, and references, is available on the USPSTF website at <https://www.uspreventiveservicestaskforce.org/>.

This series is coordinated by Kenny Lin, MD, MPH, Deputy Editor.

A collection of USPSTF recommendation statements published in *AFP* is available at <https://www.aafp.org/afp/uspstf>.

TABLE 1

Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum: Clinical Summary of the USPSTF Recommendation

Population	Newborns
Recommendation	Provide prophylactic ocular topical medication to prevent gonococcal ophthalmia neonatorum. Grade: A
Preventive medication	Erythromycin ophthalmic ointment is the only drug approved by the U.S. Food and Drug Administration for the prophylaxis of gonococcal ophthalmia neonatorum. Ocular prophylaxis of newborns is mandated in most states and is considered standard neonatal care.
Other relevant USPSTF recommendations	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.

Note: For a summary of the evidence systematically reviewed in making this recommendation, the full recommendation statement, and supporting documents, go to <https://www.uspreventiveservicestaskforce.org/>.

USPSTF = U.S. Preventive Services Task Force.

PREVENTIVE MEDICATION

Erythromycin ophthalmic ointment is considered effective in preventing gonococcal ophthalmia neonatorum.¹⁰ 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.³ Gentamicin was used during a period of erythromycin shortage, although its use was associated with ocular reactions (chemical conjunctivitis).¹¹ Povidone-iodine has been proposed for prophylaxis, but there are limited data on its benefits and harms.³ Currently, erythromycin is the only drug approved by the U.S. Food and Drug Administration for the prophylaxis of gonococcal ophthalmia neonatorum.¹¹ Ocular prophylaxis of newborns is mandated in most states⁶ and is considered standard neonatal care.¹¹

ADDITIONAL APPROACHES TO PREVENTION

The rates of gonococcal ophthalmia neonatorum are related to gonococcal infection rates in women of reproductive age.³ 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.^{1,12} 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.¹³ The Centers for Disease Control and Prevention provides clinical guidance for ocular prophylaxis and treatment of gonococcal ophthalmia neonatorum.¹⁰

This recommendation statement was first published in *JAMA*. 2019;321(4):394-398.

The "Other Considerations," "Discussion," "Reaffirmation of Previous USPSTF Recommendation," and "Recommendations of Others" sections of this recommendation statement are available at <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/ocular-prophylaxis-for-gonococcal-ophthalmia-neonatorum-preventive-medication1>.

The USPSTF recommendations are independent of the U.S. government. They do not represent the

views of the Agency for Healthcare Research and Quality, the U.S. Department of Health and Human Services, or the U.S. Public Health Service.

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