AMERICAN ACADEMY OF OPHTHALMOLOGY®

JOINT CLINICAL STATEMENT

Use of Erythromycin in the Prevention of Neonatal Ophthalmia

A joint clinical statement of the American Association for Pediatric Ophthalmology and Strabismus and the American Academy of Ophthalmology

Background

Ophthalmia neonatorum (ON) is defined as conjunctivitis presenting in the first 4 weeks of life.[1] Frequently identified etiologies of ON include *Staphylococcus spp.* and *Serratia marcescens*.[2] Historically, however, the most visually significant etiology has been *Neisseria gonorrhoeae* because of its aggressive progression that can be associated with a high risk of corneal scarring, ocular proliferation, and rapid vision loss.[3] Colonization typically occurs during delivery, followed by a brief incubation period (typically less than 3 days but can extend up to 3 weeks).[4] Infection is generally bilateral and presents with marked eyelid edema and chemosis. Watery discharge appears early and rapidly progresses to mucopurulence. In severe cases, complications such as corneal ulceration, globe perforation, and panophthalmitis may develop.[5] *Chlamydia trachomatis* with milder symptoms accounts for up to 40% of ON cases.[6] Co-infection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* is common.[7]

In the United States, the prevalence of gonococcal ON has remained low in recent years, with estimates ranging from 1.1 to 1.6 cases per 100,000 live births during 2010-2015.[8] However, these estimates were based on data from the first year of life rather than the first month. Prevalence of neonatal infection depends on the prevalence of infection among pregnant women and whether pregnant women are screened and treated for gonorrhea during pregnancy.[9] A recent report found that the disease burden among women of reproductive age (15-39 years) has increased over the past decade, potentially elevating the risk of gonococcal ON.[10]

Primary prevention of gonococcal ON involves universal screening and treatment of pregnant women for *Neisseria gonorrhoeae* infection, along with ocular prophylaxis for neonates. Tetracycline ophthalmic ointment and silver nitrate were previously evaluated but they are no longer available in the United States. Currently, erythromycin is the only Food and Drug Administration-approved prophylactic agent. Gentamicin was used as an alternative during an erythromycin shortage; however, reports indicated it was associated with ocular adverse reactions.[11] The estimated cost of routine neonatal ocular prophylaxis with erythromycin is $1.94 per infant.[12] Historically, ocular prophylaxis with erythromycin has been favored due to its relatively low cost and mild adverse effects.[6]

In their 2019 recommendation statement, the United States Preventive Services Task Force recommended ocular prophylaxis with erythromycin ointment for all newborns within 24 hours after birth.[9] In 2021, the Centers for Disease Control and Prevention (CDC) also recommended universal prophylaxis by instilling erythromycin 0.5% ophthalmic ointment into both eyes of all newborns as soon as possible after birth, ideally in the delivery room and within 24 hours.[13] Recently, there has been discussion about the need for mandatory prophylaxis and targeting prophylaxis to high-risk cases. The 2024 policy statement of the American Academy of Pediatrics (AAP) reflected this shift and supports “ongoing re-evaluation of the medical necessity of legislative mandates in the United States for universal neonatal eye prophylaxis...” In their 2024 statement, AAP recommended that if gonorrhea infection is prevalent in the region and

prenatal treatment cannot be ensured, or where required by law, 0.5% erythromycin ointment should be instilled into the eyes of newborn infants to prevent sight-threatening gonococcal ON.

Recommendations

Recognizing the shifting discussions regarding the prophylactic use of erythromycin for the prevention of gonococcal ON, the American Academy of Ophthalmology recommends[1]:

- Adhere to CDC guidelines for prenatal screening of and treatment for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* to prevent intrapartum exposures.
- Any individuals who have not previously been screened should undergo screening for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* infection at the time of labor and delivery, with immediate treatment when indicated.
- Promote increased awareness of the signs, symptoms, diagnosis, and treatment of gonococcal ON among newborn care providers and parents through education initiatives.
- Continue universal neonatal topical prophylaxis with erythromycin in the following circumstances:
    - In regions where gonorrhea is prevalent and routine prenatal screening and treatment cannot be ensured
    - Where required by state law

These recommendations are aligned with the recent position taken by the AAP. [1] The Academy believes further research into the regional and socioeconomic and demographics of cost-effectiveness for universal versus targeted prophylaxis is needed to guide future recommendations and evolving best practices.

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Approved By:

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