Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum: U.S. Preventive Services Task Force Reaffirmation Recommendation Statement

SUMMARY OF RECOMMENDATION AND EVIDENCE

The USPSTF recommends prophylactic ocular topical medication for all newborns for the prevention of gonococcal ophthalmia neonatorum. **This is a grade A recommendation.**

RATIONALE

Importance

Gonococcal ophthalmia neonatorum develops in approximately 28% of infants born to women with gonorrheal disease in the United States. Identifying and treating the infection is important because gonococcal ophthalmia neonatorum can result in corneal scarring, ocular perforation, and blindness.

Recognition of Risk Status

The USPSTF recommends that all newborns receive prophylaxis; however, some newborns are at increased risk for gonococcal ophthalmia neonatorum. Newborns at increased risk include those with a maternal history of sexually transmitted infections, substance abuse, or no prenatal care.

Benefits of Risk Assessment and Preventive Medication

There is convincing evidence that blindness due to gonococcal ophthalmia neonatorum has become rare in the United States since the implementation of universal prophylaxis of newborns.

Harms of Risk Assessment and Preventive Medication

There is convincing evidence that universal prophylaxis of newborns is not associated with serious harms.

USPSTF Assessment

The USPSTF concludes that there is high certainty that the net benefit is substantial for topical ocular prophylaxis for all newborns for the prevention of gonococcal ophthalmia neonatorum.

CLINICAL CONSIDERATIONS

Patient Population Under Consideration

This recommendation applies to all newborns.

Preventive Medication

Prophylactic regimens using 1.0% tetracycline or 0.5% erythromycin ophthalmic ointment are considered equally effective in the prevention of gonococcal ophthalmia

neonatorum; however, the only drug approved by the U.S. Food and Drug Administration for this indication is 0.5% erythromycin ophthalmic ointment. Tetracycline ophthalmic ointment and silver nitrate are no longer available in the United States. A 2.5% solution of povidone-iodine may be useful in preventing ophthalmia neonatorum, but it has not been approved for use in the United States at this time.

Optimal Timing

Prophylaxis should be provided within 24 hours after birth.

OTHER CONSIDERATIONS

Research Needs/Gaps

The only drug approved by the U.S. Food and Drug Administration for the prevention of gonococcal ophthalmia neonatorum is 0.5% erythromycin ophthalmic ointment. Further research is needed to find safe and effective alternatives to erythromycin. Another area for research is the question of whether risk-based prophylaxis of newborns, based on maternal risk factors, could be as effective as universal prophylaxis.

DISCUSSION

In 2005, the USPSTF reviewed the evidence on providing ocular prophylaxis for newborns to prevent gonococcal ophthalmia neonatorum, and found no new evidence of harms associated with ocular prophylaxis (1). The benefits of ocular prophylaxis continue to be well established. In 2009, the USPSTF performed an update of the evidence, with a focus on new and substantial evidence on the benefits and harms of ocular prophylaxis. The USPSTF found no new substantial evidence on the benefits and harms of ocular prophylaxis in newborns, and therefore reaffirms its recommendation that all newborns receive ocular prophylaxis to prevent gonococcal ophthalmia neonatorum. The 2005 recommendation statement and supporting materials can be found at http://www.uspreventiveservicestaskforce.org/uspstf/uspsgono.htm.

Response to Public Comments

A draft of this reaffirmation was posted for public comment on the USPSTF Web site from August 16, 2010 to September 13, 2010. Nineteen comments were received from individuals or organizations. All comments were reviewed in the creation of this final document.

RECOMMENDATIONS OF OTHERS

The American Academy of Pediatrics, Centers for Disease Control and Prevention, World Health Organization, Canadian Task Force on Preventive Health Care, American Academy of Family Physicians, and Canadian Paediatric Society all recommend universal ocular prophylaxis of newborns for the prevention of gonococcal ophthalmia neonatorum (2–7).

REFERENCES

1. U.S. Preventive Services Task Force. Screening for gonorrhea: recommendation statement. Ann Fam Med. 2005;3:263–267.
2. American Academy of Pediatrics. Antimicrobial prophylaxis. In: Pickering LK, Baker CJ, Kimberlin DW, Long SS (eds). Red Book: 2009 Report of the Committee on Infectious Diseases. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009. p 828.
3. Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2006. MMWR. 2006;55(11):1–100.
4. World Health Organization. Guidelines for the Management of Sexually Transmitted Infections. Geneva: World Health Organization; 2003. Accessed at http://whqlibdoc.who.int/publications/2003/9241546263.pdf on 7 April 2011.
5. Goldbloom RB. Prophylaxis for gonococcal and chlamydial ophthalmia neonatorum. In: Canadian Task Force on the Periodic Health Examination. Canadian Guide to Clinical Preventive Care. Ottawa: Health Canada; 1994. pp168–175.
6. American Academy of Family Practice. Gonococcal Infection in Neonates, Ocular Topical Medication. Leawood, KS: American Academy of Family Practice; 2010. Accessed at http://www.aafp.org/online/en/home/clinical/exam/f-j.html on 7 April 2011.
7. Canadian Paediatric Society. Recommendations for the Prevention of Neonatal Ophthalmia. Paediatr Child Health. 2002;7:480–483.

TABLE 1. What the USPSTF Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer/provide this service only if there are other considerations in support of offering/providing the service to an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the “Clinical Considerations” section of USPSTF Recommendation Statement. If offered, patients should understand the uncertainty about the balance of benefits and harms.

TABLE 2. USPSTF Levels of Certainty Regarding Net Benefit

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: the number, size, or quality of individual studies; inconsistency of findings across individual studies; limited generalizability of findings to routine primary care practice; or lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: the limited number or size of studies; important flaws in study design or methods; inconsistency of findings across individual studies; gaps in the chain of evidence; findings not generalizable to routine primary care practice; or a lack of information on important health outcomes. More information may allow an estimation of effects on health outcomes.

Definition: The U.S. Preventive Services Task Force defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Appendix: U.S. Preventive Services Task Force

Members of the U.S. Preventive Services Task Force* at the time this recommendation was finalized are Virginia A. Moyer, MD, MPH, *Chair* (Baylor College of Medicine, Houston, Texas); Michael L. LeFevre, MD, MSPH, *Co-Vice Chair* (University of Missouri School of Medicine, Columbia, Missouri); Albert L. Siu, MD, MSPH, *Co-Vice Chair* (Mount Sinai School of Medicine, New York, New York); Kirsten Bibbins-Domingo, PhD, MD (University of California, San Francisco, California); Susan Curry, PhD (University of Iowa College of Public Health, Iowa City, Iowa); Glenn Flores, MD (University of Texas Southwestern, Dallas, Texas); Adelita Gonzales Cantu, RN, PhD (University of Texas Health Science Center, San Antonio, Texas); David Grossman, MD, MPH (Group Health Cooperative, Seattle, Washington); George Isham, MD, MS (HealthPartners Inc., Minneapolis, Minnesota); Rosanne M. Leipzig, MD, PhD (Mount Sinai School of Medicine, New York, New York); Joy A. Melnikow, MD, MPH (University of California Davis Medical Center, Sacramento, California); Bernadette Melnyk, PhD, RN (Arizona State University College of Nursing and Healthcare Innovation, Phoenix, Arizona); Wanda Nicholson, MD, MPH (University of North Carolina School of Medicine, Chapel Hill, North Carolina); Carolina Reyes, MD (University of Southern California, Los Angeles, California); J. Sanford Schwartz, MD (University of Pennsylvania Medical School and the Wharton School, Philadelphia, Pennsylvania); and Timothy Wilt, MD, MPH (University of Minnesota Department of Medicine and Minneapolis Veteran Affairs Medical Center, Minneapolis, Minnesota).

*For a list of current Task Force members, go to http://www.uspreventiveservicestaskforce.org/members.htm.