Perinatal Services BC Guideline: Prevention and Management of Ophthalmia Neonatorum Caused by Chlamydia trachomatis and Neisseria gonorrhoeae

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While every attempt has been made to ensure that the information contained herein is clinically accurate and current, Perinatal Services BC acknowledges that many issues remain controversial, and therefore may be subject to practice interpretation. © Perinatal Services BC, 2018

Highlights of this Guideline

In July 2018 the government of British Columbia repealed section 17 of the Health Act Communicable Disease Regulation that mandated universal newborn baby eye prophylaxis.

Perinatal Services BC (PSBC) recommends the following:

- All women should be offered screening for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* at the first prenatal visit.^{1,2}
- Additional screening is recommended in each trimester for women with ongoing risk factors.^{1,2}
- Universal eye prophylaxis of all newborns to prevent Ophthalmia Neonatorum, caused by *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, until there is a safe alternative to erythromycin, such as rapid screening for women who have not been screened during pregnancy or with ongoing risk factors at the time of delivery for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. The only agent approved in Canada for newborn eye prophylaxis is erythromycin.³
- Monitor all newborns for signs and symptoms of Ophthalmia Neonatorum. It is imperative for both health care providers and parents to recognize the signs and symptoms of Ophthalmia Neonatorum and to respond appropriately.^{2,4,5,6}
- If infection is suspected collect conjunctival specimen and test for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.
- Cefotaxime is the recommended treatment for infants at risk for, or diagnosed with, Ophthalmia Neonatorum caused by *Neisseria gonorrhoeae*. Due to adverse reactions associated with ceftriaxone in the neonatal population, cefotaxime is the preferred antimicrobial.^{7,8}
- Consider a single dose of intramuscular cefotaxime prior to discharge if the infant is at risk for exposure to *Neisseria gonorrhoeae* and there is any concern that the mother or caregiver may not recognize the signs of Ophthalmia Neonatorum, and/or respond appropriately.^{2,6}
- Asymptomatic infants born to mothers with untreated *Neisseria gonorrhoeae* infection at the time of birth should receive a single dose of cefotaxime 100 mg/kg IV/IM.²
- Infants born to mothers with untreated *Neisseria gonorrhoeae* at the time of birth that are unwell require:
 - A full septic work-up (urine, blood and CSF specimens) for routine septic workup as well as gram stain and gonorrhea culture
 - Empiric antibiotics of ampicillin and cefotaxime
 - Consult with a pediatric infectious diseases specialist^{2,5}
 - Consult with an ophthalmologist
 - Referral to higher level of care if indicated
- Treat infants that test positive for *Chlamydia trachomatis* with oral or intravenous erythromycin.^{4,6,9,10}

Executive Summary

Ophthalmia Neonatorum (ON) is defined as acute conjunctivitis of any cause during the neonatal period and presents with conjunctival erythema, edema of the eyelids and ocular discharge. Causes of ON can be chemical, viral or bacterial. This guideline focuses on Ophthalmia Neonatorum caused by *Chlamydia trachomatis* and *Neisseria gonorrhoeae* and discusses best evidence-based practice to prevent, diagnose, and manage ON caused by these two pathogens.

This document is intended for use by physicians, midwives, nurse practitioners, acute care and public health nurses who provide health care to newborns in British Columbia. It incorporates recommendations and evidence-based information from a variety of trusted sources including provincial, national and international guidelines. Experts and stakeholders across BC were consulted during the development of this document.

A parent information brochure (Appendix A) has been developed to provide parents and/or caregivers with information about the signs and symptoms of Ophthalmia Neonatorum and when to bring the newborn for consultation with a health care provider. Primary care providers are responsible for providing this resource to patients, which can be downloaded and printed from Perinatal Services BC's website: www.perinatalservicesbc.ca/health-professionals/guidelines-standards/newborn.

The Highlights of this Guideline (on page 2) is a quick reference guide and is intended to serve as a high-level overview of information and action items that are considered relevant in the prevention and management of Ophthalmia Neonatorum caused by *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

This document is provided for guidance and is not meant to replace clinical judgment.

Overview

Chlamydia trachomatis is the most commonly reported sexually transmitted infection in Canada¹¹, and the most common pathogen causing Ophthalmia Neonatorum. Approximately 23 per cent¹² of infants born to women with active and untreated *Chlamydia trachomatis* infections typically present with mild to moderate conjunctivitis. Fifty per cent of these infants will also develop a nasopharyngeal infection and 10 to 20 per cent of these infants may develop a concomitant pneumonia.¹³ Complications from Ophthalmia Neonatorum caused by *Neisseria gonorrhoeae* are more severe and can lead to corneal scarring, ocular perforation and blindness. Skin wounds, such as scalp lesions due to fetal scalp electrodes, may become infected and disseminated infection can also occur.^{4,14} Two to 40 per cent of infants born to women with active and untreated *Neisseria gonorrhoeae* infection, and who did not receive eye prophylaxis, may develop Ophthalmia Neonatorum.^{14,15,16}

Neonatal eye prophylaxis was introduced by Credé in 1881 at a time when the maternal infection rates were high and there was no effective treatment for gonococcal Ophthalmia Neonatorum. Credé found that routine prophylaxis with topical 2% silver nitrate led to a dramatic reduction in the incidence of blindness caused by gonococcal Ophthalmia Neonatorum.¹¹ The discovery of antibiotics, prenatal screening and treatment of maternal sexually transmitted infections has had a dramatic effect on the prevention of Ophthalmia Neonatorum caused by *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.¹⁷ As of January 2000, gonococcal Ophthalmia Neonatorum was removed from national surveillance in Canada due to its low incidence. Several western countries abandoned prophylaxis in the 1960s in favor of monitoring, swabbing suspicious discharges and treating with appropriate solutions as required.¹⁷ Eye prophylaxis is mandatory in the USA¹⁸; however, the US Preventative Task Force is currently reviewing the effectiveness of different eye prophylaxis agents to prevent Ophthalmia Neonatorum and blindness, as well as the potential harms related to eye prophylaxis.¹⁹ The American Academy of Pediatrics is currently advocating for the revision of mandated eye prophylaxis, and improvement of antenatal screening to prevent Ophthalmia Neonatorum.⁴

In July 2018 the government of British Columbia repealed section 17 of the Health Act Communicable Disease Regulation that mandated universal newborn eye prophylaxis. Currently there are no other legislatively mandated communicable disease prophylaxis or treatment measures, even for immunization programs that do protect and improve public health. Mandating babies' eye prophylaxis infringes on the autonomy of the parent as surrogate decision maker and does not necessarily protect or improve public health.¹⁷

In Canada, newborn eye prophylaxis remains to be mandated in all provinces/territories except for New Brunswick, Newfoundland, Saskatchewan, Yukon and British Columbia. Although New Brunswick, Newfoundland and Saskatchewan do not mandate newborn eye prophylaxis it is still recommended and part of their policy.

Prevalence of Chlamydia trachomatis and Neisseria gonorrhoeae in BC

Since 2003 a steady increase in the prevalence of both *Chlamydia trachomatis* and *Neisseria gonorrhoeae* have been noted in the BC population, echoing the national trend. This can be attributed to a true rise in disease, improved screening and uptake of testing, and an increase in the sensitivity of diagnostic testing.^{10,11,20,21} The increase in the reported prevalence of *Neisseria gonorrhoeae* can also be attributed to updated national guidelines promoting specimen collection from oropharyngeal and rectal sites^{5,22} and antibiotic resistance.^{23,24} Between 2014 to 2016, a 70 per cent increase in the prevalence of *Neisseria gonorrhoeae* in BC has been noted, leading the BC CDC to collaborate with the National Microbiology Laboratory to determine the reason for this rapid rise.²⁰ The highest prevalence among people of reproductive age is among those aged less than 25 years. Rates for the

Overview, cont'd.

less than 1-year old group for *Chlamydia trachomatis* in BC between 2003 and 2016 are less than 3/100,000. During this time period, no cases of *Neisseria gonorrhoeae* in the same population group were reported except in 2014 (2.3/100,000), following the increase in prevalence observed in the adult population between 2014 and 2016.²⁰

Case For or Against Universal Eye Prophylaxis and Impact on Care

The Canadian Pediatric Society (CPS) 2015 Position Statement (reaffirmed 2018) on preventing Ophthalmia Neonatorum argues against universal mandated eye prophylaxis and recommends universal screening for Chlamydia trachomatis and Neisseria gonorrhoeae of all pregnant women at the first prenatal visit. Women (and sexual partners) who tested positive for Chlamydia trachomatis and/or Neisseria gonorrhoeae need to be treated and retested after treatment to ensure that the treatment was effective. The CPS recommends additional targeted testing during the third trimester of all pregnant women who tested positive for Chlamydia trachomatis and Neisseria gonorrhoeae during the first trimester, as well as all women at risk for contracting *Chlamydia trachomatis* and Neisseria gonorrhoeae. Rapid screening for Chlamydia trachomatis and Neisseria gonorrhoeae should be available for all women at delivery who were not screened during their pregnancy.² This position statement is not supported by the Canadian Association for Pediatric Ophthalmology and Strabismus (CAPOS) citing concerns with the quality of evidence against eye prophylaxis, and the increased risk to infants born to women of marginalized communities with limited access to prenatal care.²⁵ While the CPS Position Statement advocates for comprehensive antenatal screening for Chlamydia trachomatis and Neisseria gonorrhoeae, data collected between 2011 and 2014 in Manitoba indicates that antenatal screening is suboptimal and implies that some infants may be at higher risk to develop gonococcal Ophthalmia Neonatorum without universal eye prophylaxis.²⁶

Finding current evidence-based research relevant to the Canadian population, and specific to the British Columbia population, on Ophthalmia Neonatorum and eye prophylaxis is challenging. Much of the primary research was conducted in countries other than Canada, some dating back to the 1980s. The Canadian Agency for Drugs and Technologies in Health (CADTH) Rapid Response Report on neonatal eye prophylaxis (2016) concluded that the evidence for, or against, eye prophylaxis is of low quality due to different populations, settings and issues with heterogeneity.²⁷ A Cochrane systemic review on the interventions for preventing Ophthalmia Neonatorum is currently underway. The two main objectives of the Cochrane review are to determine if eye prophylaxis reduces the incidence of Ophthalmia Neonatorum, and if so, what eye prophylaxis is the most effective.²⁸

The only agent approved in Canada for eye prophylaxis is erythromycin.³ The efficacy of topical erythromycin to prevent *Chlamydia trachomatis* Ophthalmia Neonatorum is questionable^{29,30,31,32} and not recommended by the American Academy of Pediatrics¹⁴ and the Canadian Pediatric Society.¹⁷ Antimicrobial resistance is a global barrier to the successful treatment of *Neisseria gonorrhoeae* and will have a significant impact on the health and economic burden to manage this disease. The Canadian Antimicrobial Resistance Surveillance System (2017) reported a 32.5 per cent failure rate when treating *Neisseria gonorrhoeae* with erythromycin³³, and according to the Canadian Pediatric Society, is the reason for discontinuation of using erythromycin as ocular prophylaxis.¹²

The incidence of suboptimal antenatal screening rates, the prevalence of *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* infections in pregnant women, and the potential for adverse obstetric outcomes and newborn morbidities due to *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* lend support to the recommendation to improve antenatal screening and the continuation of universal newborn eye prophylaxis.

Recommendations

Screening

All women should be screened for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* at the first prenatal visit. Targeted screening is recommended in each trimester for women with ongoing risk factors.

Currently, Perinatal Services BC (PSBC) recommends that all women should be offered screening for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* at the first prenatal visit. In addition to screening all women at the first prenatal visit, additional screening is recommended in each trimester for women with ongoing risk factors.¹

Maternal Risk factors are as follows:

- 25 years or younger and sexually active^{9,23,24,34,35,36,37,38}
- New and/or more than one sex partner^{9,24,36,37,38}
- Previous documented diagnosis of *Chlamydia trachomatis* and/or *Neisseria* gonorrhoeae^{5,9,35,36,37,38,39}
- Sexual contact with a person with suspected or confirmed *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* infection^{5,35,36}
- Unprotected sex with a resident from area with high prevalence of Chlamydia trachomatis and/or Neisseria gonorrhoeae infection^{5,36}
- Unprotected sexual contact with resident from area with high risk of antimicrobial resistance to *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae*^{5,36}

Maternal health care providers must inform newborn's health care providers regarding maternal risk factors, screening results and treatment for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* as this will direct the care of the newborn related to Ophthalmia Neonatorum.²

For the most current information on disease prevalence in an area consult the BC Centre for Disease Control Reportable Disease Dashboard: www.bccdc.ca/health-info/disease-system-statistics/reportable-disease-dashboard

Recommendations, *cont'd.*

Eye Prophylaxis

Universal eye prophylaxis of all newborns to prevent Ophthalmia Neonatorum caused by *Chlamydia trachomatis* and *Neisseria gonorrhoeae* is recommended.

While the law mandating universal eye prophylaxis has been repealed, PSBC and CAPOS continue to recommend universal eye prophylaxis of the newborn until there is a safe alternative to erythromycin such as rapid maternal screening at the time of delivery for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*.

Currently erythromycin 0.5% ointment is the only ocular prophylactic agent approved in Canada and needs to be administered within two hours after birth.³

Procedure to Administer 0.5% Erythromycin Ointment

- 1. Use gloves when administering erythromycin.
- 2. To prevent cross contamination, use a single-use tube of 0.5% erythromycin and discard remainder of tube after administering to both eyes.
- 3. Before administration, wipe each eyelid gently with sterile cotton to remove foreign matter and to permit adequate eversion of the lower lid.
- 4. Apply a line of 0.5% erythromycin ointment, about 1 cm long, in the inferior conjunctival fornix, by pulling the lower eyelid gently down. Care is needed to prevent injury to the eye or the eyelid from the tip of the tube.
- 5. Gently massage the closed eyelids to help spread the solution to all areas of the conjunctiva.
- 6. In the very premature newborns whose eye lids are fused at the time of birth, apply the erythromycin ointment without separating the eyelids. Ointment absorption through the immature skin is expected.

Recommendations, cont'd. =

Monitor for Signs and Symptoms of Ophthalmia Neonatorum

It is imperative for both health care providers and parents to recognize the signs and symptoms of Ophthalmia Neonatorum and to respond appropriately.^{2,4,5,6}

Advise mother or caregiver of all newborns how to recognize Ophthalmia Neonatorum prior to discharge and when to contact a health care provider (see Appendix A: Information for Families).

How to Recognize Ophthalmia Neonatorum^{10,40}

Clinical presentation	Neisseria gonorrhoeae	Chlamydia trachomatis	Other causes
Onset (age)	Within first 4 days of life	5-14 days of life	Variable
Erythema of eyes	Yes	Yes	Variable
Inflammation of eye lids	Extensive and excessive	Minimal	Minimal
Corneal involvement	Usual, risk of corneal ulceration or rupture	Rarely	Rarely
Discharge	Acute bilateral mucopurulent discharge	Unilateral or bilateral mucopurulent conjunctivitis	Minimal, tends to unilateral
Additional concerns	Perforation of the globe leads to visual impairment	Chlamydial pneumonia. Infant will be afebrile with nasal congestion, prolonged cough, tachypnea and rales	



Chlamydia Conjunctivitis in a newborn male Hahn B, Giunta YP. *Annals of Emergency Medicine*. 2007. 49(6), p 823, 831.



Swelling and purulent drainage are characteristic of gonococcal ophthalmia neonatorum.

www.pediatricsconsultantlive.com/articles/ gonococcal-conjunctivitis

Management of the Newborn at Risk for Exposure to Neisseria gonorrhoeae

Currently, erythromycin 0.5% ointment is the only prophylactic agent approved in Canada and needs to be administered within two hours after birth.³ It is recommended that erythromycin eye prophylaxis continues to be administered to all newborns until there is a safe alternative, including newborns at risk of exposure to *Neisseria gonorrhoeae*.

Advise mother or caregiver how to recognize Ophthalmia Neonatorum prior to discharge and when to contact a health care provider (see Appendix A: Information for Families). If there is any concern that the mother or caregiver may not recognize the signs of Ophthalmia Neonatorum and/or respond appropriately, consider administering a single dose of cefotaxime IM prior to discharge if the newborn is discharged before five days of age.

Management of Newborn Born to Mother with Untreated Neisseria gonorrhoeae at Time of Birth

Asymptomatic

- 1. Collect conjunctival specimen for gram stain and *Neisseria gonorrhoeae* culture, also test for *Chlamydia trachomatis*.
- 2. Administer erythromycin eye prophylaxis.
- 3. Follow appropriate infection prevention and control precautions.
- 4. Administer a single dose of cefotaxime [see note below].^{2,6}
- 5. Observe for signs and symptoms of Ophthalmia Neonatorum.^{2,4,5,6}
- 6. Advise mother or caregiver how to recognize Ophthalmia Neonatorum prior to discharge and when to contact a health care provider (see Appendix A: Information for Families).

Symptomatic

- 1. Collect conjunctival specimen for gram stain and *Neisseria gonorrhoeae* culture, also test for *Chlamydia trachomatis*.
- 2. Administer erythromycin eye prophylaxis.
- 3. Follow appropriate infection prevention and control precautions.
- 4. Consult an ophthalmologist if eye discharge is noted to guide ophthalmic management.
- 5. Remove discharge by irrigating eyes with sterile normal saline. Repeat hourly if necessary to eliminate discharge.^{2,5} Clinician must wear gloves to prevent spread of infection.
- 6. If the infant is unwell do a full septic work-up; collect urine, blood and CSF specimens for routine septic workup as well as gram stain and *Neisseria gonorrhoeae* culture.
- 7. Treat the unwell infant with empiric antibiotics of ampicillin and cefotaxime. Dosing and frequency of administration are determined by weight and postnatal age.⁴¹ Please consult local guidelines for neonatal dosing.
- The newborn with a confirmed diagnosis of gonococcal disease will need additional investigations and management; consult a specialist in pediatric infectious diseases and consider referral to higher level of care.⁵

Cefotaxime is recommended for infants at risk for Ophthalmia Neonatorum caused by *Neisseria gonorrhoeae*.

Although ceftriaxone can be used for infants at risk for exposure to *Neisseria gonorrhoeae*, as well for asymptomatic infants born to mothers with untreated Gonorrhea at time of birth, it is **contraindicated** in infants:

- With elevated bilirubin as ceftriaxone displaces bilirubin from albumin binding sites increasing the risk of developing bilirubin encephalopathy.^{7,8}
- Receiving calcium containing intravenous solutions such as Total Parenteral Nutrition because of the risk of death associated with the precipitation of ceftriaxone-calcium salt in the lungs and/or kidneys.^{7,8}

Management of the Newborn at Risk of Exposure to *Chlamydia trachomatis*

- 1. Administer erythromycin eye prophylaxis.
- 2. Routine cultures not advised on asymptomatic newborn.²
- 3. Prophylactic antibiotic treatment is not indicated unless follow up with physician cannot be guaranteed.^{14,17}
- 4. Newborns should be monitored for signs of *Chlamydia trachomatis* infection (conjunctivitis and/or pneumonitis).^{2,4,5,6}
- 5. Advise mother how to recognize Ophthalmia Neonatorum prior to discharge and when to contact a health care provider (see Appendix A: Information for Families).

Management of Ophthalmia Neonatorum Caused by Chlamydia trachomatis

- 1. Collect conjunctival swabs obtained from the everted eyelid. Specimens must contain conjunctival cells, not just exudate.³⁰ Test for *Neisseria gonorrhoeae* at the same time.
- 2. Treat infant if test is positive for *Chlamydia trachomatis* with oral or intravenous erythromycin.^{4,6,9,10} Dosing and frequency of administration are determined by weight and postnatal age.⁴¹ Consult local guidelines for neonatal dosing information.
- 3. Consider referral to higher level of care if indicated.
- 4. There is a documented association between orally administered erythromycin and infantile hypertrophic pyloric stenosis* especially in newborns less than two weeks of age.^{4,10,42}
- 5. Inform parents about the signs and potential risks of developing infantile hypertrophic pyloric stenosis* (nonbilious and forceful vomiting immediately after feed).
- Follow up visit with newborn three to four weeks after completion of the treatment is recommended since the efficacy of erythromycin therapy is approximately 80%. A second course of treatment may be required.⁴

^{*} Functional gastric outlet obstruction leading to forceful vomiting

Appendix A: Information for Families: Eye Infection and Your Newborn Baby

Perinatal Services BC An agency of the Provincial Health Services Authority

INFORMATION FOR FAMILIES: Eye Infection and Your Newborn Baby

Most of the time, puffy or red eyes in your baby are caused by a blocked tear duct or infection by viruses or bacteria. Some eye infections may be serious and need special medication.

Contact your doctor or go to the emergency department or health clinic at once if your baby is under two weeks and:

- Your baby's eyes are red
- Your baby's eyes have thick pus
- Your baby's eyelids are swollen or puffy

Your baby's eye needs to be examined to find out if it is an infection that needs to be treated.





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