

Law and Use of Newborn Eye Prophylaxis in Washington State

Jodilyn Owen
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Introduction

Washington state law mandates that healthcare providers administer antibiotic prophylaxis into the eyes of each newborn. However, many parents and providers have incomplete information regarding the applications of this law as well as the procedures to follow should a parent refuse this treatment for their newborn. This paper addresses the history of this law and its implications for parents and providers. It also presents the history of eye prophylaxis, options for specific agents and alternative treatments and the risks and benefits of administering these drugs into a newborn's eyes. Finally, this paper discusses procedures for parents to invoke their right to refuse this treatment for their newborns and for providers to effectively document this refusal.

History of Treatment

Up until the late 19th century, Ophthalmia Neonatorum (ON), or neonatal conjunctivitis, was a major public health issue, causing blindness in around 10% of newborns in Europe. Up to 50% of the students in schools for the blind were there because of ON.^{1 2} In 1880 Carl S.F. Crede´, a physician working in a maternity hospital in Leipzig, noticed that transmission of the bacteria occurred from mother to baby during birth, when the mother mostly carried *Neisseria Gonorrhoeae* (gonorrhea). He began to clean newborn's eyes with a 2% aqueous solution of silver nitrate just after birth. This procedure reduced the number of cases from 35 per year to only one in the second half of 1880.³

In 1881, Crede´ published a paper on his observations and practice. This led to the world-wide use of silver nitrate and subsequent reduction in the number of infants blinded as a result of contracting infections from their mothers. Silver nitrate has the benefit of providing a broad antimicrobial spectrum, but it also caused toxic, or chemical conjunctivitis in the newborns.^{4 5 6 7} There are also questions about its effectiveness against chlamydia, which is the most common cause of ON in developed countries.⁸

These problems with silver nitrate led others to explore possible alternatives for use in prevention of ON. The late 1940's brought the advent of antibiotics, which became the most commonly used medications for this treatment. Currently, the medications used to prevent ON around the world include erythromycin, tetracycline, and gentamicin in the form of ointment. In 1995 Drs. Eisenberg, Apt, and Woods used a 2.5% povidone-iodine solution for ophthalmia neonatorum prophylaxis in more than 3000 neonates in Kenya. That this study occurred in Kenya is noteworthy because the rate of gonorrheal infection among Kenyan women is significantly higher than the rate of infection among American women.⁹ Therefore, the opportunity to observe the effectiveness of povidone-iodine was much higher there than a study on American soil would provide.

According to their research findings, “Povidone-iodine ophthalmic solution is an effective antibacterial agent with broad antibacterial and antiviral activity to which no bacteria are known to be resistant, and it is far less expensive and less toxic than the other agents used to prevent neonatal conjunctivitis”. Their findings showed that povidone-iodine is more effective against a broader range of bacteria and viral species, and is less toxic than either ointment option or silver nitrate.¹⁰

In Washington State, most healthcare providers and institutions use the antibiotic erythromycin or tetracycline ointment and place it into the newborn’s eyes within the first hour of life. Silver Nitrate is no longer used in Washington State.

History of the Law

Washington Administrative Code (WAC) 246-100 was passed into law in 1981 to help protect the health and well-being of the public by controlling communicable and certain other diseases. This law provides practicing providers a methodology for handling communicable diseases. A revision process occurring during 2008 and 2009 will update the form, language, and content of the law with regards to installation of antibiotic prophylaxis into the eyes of newborns.

What the Law States

The policy statement addressing the installation of an antibiotic treatment into the newborn’s eyes authorizes use of 1.0% silver nitrate, 1.0% tetracycline ophthalmic ointment, or 0.5% erythromycin ophthalmic ointment. It further states that definitive evidence as to the timing of administration is not available, but recommends installation within the first hour of life.¹¹

The stated duty of healthcare providers specifically regarding administration of the antibiotic treatment is to administer a department-approved prophylactic ophthalmic agent into the conjunctival sacs of the infant within one hour after birth.^{12 13}

How is the ointment applied?

When tetracycline or erythromycin ointment is used, a line of ointment 1 to 2 cm long is placed in each lower conjunctival sac, if possible covering the whole lower conjunctival area. Care is taken to prevent injury to the eye and eyelid from the tip of the tube. The closed eyelids may be gently massaged to help spread the solution to all areas of the conjunctiva. After one minute, any excess ointment should be gently wiped from the eyelids and surrounding skin with sterile cotton. The eyes should not be irrigated in any way after the installation of an ointment¹⁴
¹⁵. Ideally, this process occurs while mother holds her baby.

What are the benefits of antibiotic treatment in the eyes?

1. Provides coverage for high risk mothers: Mothers who are unsure of their own or their partner’s sexual history (including during the current pregnancy) have an increased risk of carrying and transmitting gonococcal bacteria. This treatment prevents the transmission of gonorrhea to newborn babies.

2. Addresses uncertainties resulting from lack of prenatal care: Mothers who did not have standard prenatal screening and do not know if they carry the bacteria, can help spare their baby from having to fight an aggressive eye infection and prevent the permanent blindness which this infection causes by electing to use this treatment option.
3. Providers concerned with commitment to follow-up care can be assured of infection prevention.

What are the risks of antibiotic treatment in the eyes?

Use of the ointment carries the following risks:

1. Risk of resistance: Antibiotic resistance is “The ability of a microorganism to produce a protein that disables an antibiotic or prevents transport of the antibiotic into the cell.”^{16 17}. There are several ways that bacteria develop antibiotic resistance, including overuse of antibiotics in the hospital, community, and farms, use of low doses over long periods of time, and high levels of resistant bacteria being present. If a child develops a resistance to certain antibiotics, and they become ill, they will require ever-stronger medication to fight infection. Routine prophylaxis with topical antibiotics carries the risk of resistance, especially in patients with ON due to gonococcal infection¹⁸.
2. Pain for the newborn: The medications list as possible side effects the following: “some stinging, irritation, itching, redness, blurred vision (lasting about 30 minutes) or sensitivity to light may occur.” These symptoms have been observed by some health professionals as well.¹⁹
3. Blurred vision for the newborn: This is one of the potential side effects listed by the manufacturer. The baby’s vision capabilities at birth allows for a particular interaction between him or herself and mother. Interrupting this is considered by some to disrupt the bonding process as it would naturally occur.²⁰
4. Potential to miss an infection present in the mother: If a mother carries gonococcal bacteria, but has no symptoms, as is the case in around 80% of infected women, and the baby is treated preemptively, colonization of the gonococcal bacteria can grow unchecked on the mother, resulting in pelvic inflammatory disease (PID). PID can lead to internal abscesses (pus-filled “pockets” that are hard to cure) and long-lasting, chronic pelvic pain. PID can damage the fallopian tubes enough to cause infertility or increase the risk of a future ectopic pregnancy²¹

To Treat or Not to Treat: Is your baby at risk for this infection?

For mothers who did not receive standard prenatal care in Washington State, including screening for STDs, this treatment is the first level available to directly prevent the transmission of gonorrhea from mother to baby. A less direct approach would be to carefully watch the newborn for development of conjunctivitis and then seek appropriate medical care for both baby and mother. It is a common belief that this ointment will treat Chlamydia bacteria as well as gonococcal bacteria, yet the CDC does not consider this antibiotic ointment effective or appropriate treatment for chlamydia. For babies born to mothers who have chlamydia, the CDC guidelines state that “prophylactic antibiotic ointment is

not indicated, and the efficacy of such treatment is unknown. Infants should be monitored to ensure appropriate treatment if such an infection develops.” (Volume 51/RR-6 p.35) Even though chlamydia is the most common organism causing ophthalmia neonatorum in North America, the complications from gonococcal ophthalmia (gonorrhoea) are more severe, appear more rapidly, and are more likely to cause blindness. The transmission rate for gonorrhoea from an infected mother to her baby is 30%-50%.^{22 23 24}

A gonorrhoea infection in the baby’s eyes occurs when a mother has this infection on her cervix or in her vaginal area and the bacteria are transmitted to the baby during or after birth. If the mother does not have gonorrhoea, the baby cannot get it.

A mother or her partner can contract gonorrhoea before or during pregnancy. Either could contract it from a partner who engaged in sexual activity (vaginal, oral, or anal) with someone who has gonorrhoea. The symptoms are not always obvious and for some women there are no outward symptoms at all. If a woman’s partner is having sexual relationships with other people, she is at high risk for STDs. Some experts note that by choosing early intervention (watching the baby for signs of infection and then treating it), they also provide the mother with important care she would otherwise *not have known she needed*.

For mothers who are sure of their and their partner’s sexual history and who have been screened for STDs during their prenatal care, and feel confident that they do not have a gonorrhoea infection, considering the effects of this treatment on their newborn may lead them to opt to refuse this treatment. In some countries the standard of practice is to either stop prophylaxis altogether (such as England and Holland) and use early treatment instead²⁵(see above), and in other countries the use of povidone-iodine drops (see above) is preferred. Use of povidone-iodine is one tool to address the effects of urbanization and promiscuity on the part of one or both parents since it treats a wide spectrum of bacterial and viral infections. Currently, in Washington State, the antibiotic ointment is the only widely available option.

Right to Refuse Treatment: For Parents

According to CPS, a parent has the right to refuse medical treatment for their baby if they are competent surrogate²⁶ decision-makers and can make a choice that is in the best interests of the baby. If a parent gains informed consent through research and discussion, and understands the nature of this treatment and would like to refuse this treatment for their child, he or she needs to let the nurse (in hospital births) or midwife (at birth center and home births) know this. The provider will likely discuss this choice with you so that they can be confident that you understand and take responsibility for the decision. Your decision will be charted and you may be asked to sign a form indicating that you have chosen not to receive this treatment for your newborn. A few hospitals and birth centers will indicate that they will make a Child Protective Services referral in the event of

refusal. The referral is made by phone, mail, or electronic submission. The purpose of this measure is to help protect the provider in the case of future law suits, but unless there are other parenting risk factors present, including a clear concern for abuse or neglect, according to CPS, the referral becomes “Information Only” and no action is taken by CPS to investigate the parents.²⁷

Right to Refuse Treatment: For Providers

A parent has the right to refuse medical treatment for their baby if they are competent surrogate decision-makers and can make a choice that is in the best interests of the baby. Providers have a duty under the law of Washington State to administer this treatment. This puts providers in an awkward position. The pathway for care in this case involves a discussion to ensure your patient has made an informed decision and accepts responsibility for their decision to refuse this treatment. It should be noted in the chart that, “patient refused treatment after informed consent”. The provider can have the parent sign an additional form accepting responsibilities for any known or unknown consequences of this decision. Each hospital or birth professional must work with their own legal team to create this form.²⁸

There is no part of the Washington State law or duties that states that providers who have patients refuse *this treatment* need to call CPS and report them. CPS understands that some providers do this simply to add to the documentation that the lack of treatment was generated by patient refusal and not failure to comply on the part of the provider (there is no precedent in Washington State to indicate that this will absolutely be of help in a criminal or civil case). Unless there are other parenting risk factors present, including a clear concern for abuse and neglect, the referral becomes “Information Only” and no action is taken by CPS to investigate the parents^{29**} In Washington State newborns and children of all ages are only considered Wards of the State in the case where the department has filed a dependency claim in court and wins that claim. Determination of care for children is the responsibility of their parents.

Conclusion

Washington State considers parents the responsible party for deciding whether to accept or refuse treatment for potential neonatal ophthalmia for their newborn. Providers in Washington State use antibiotic ointment although povidone-iodine has shown a greater success rate with a broader spectrum of bacterial and viral infections with less pain and no blurred vision for the newborn. If a parent wants to invoke their right to refuse this treatment, they should demonstrate that they understand and give their informed consent to this decision, and the provider should note that in their charts. Additionally, parents may be asked to sign an informed consent statement which helps the provider show that they did not administer the ointment because of the parents refusal, and not their own failure to comply with state law.

**This information does not cover provider obligations outside the realm of installation of department-approved prophylactic ophthalmic agent into the

conjunctival sacs of the infant. Health care providers have a duty under the law to report positive findings of communicable diseases or parental neglect or abuse.

Glossary of Important Terms

antibiotic resistance The evolution of microorganisms that has provided them with mechanisms to block the action of antibiotics. Chance mutations have provided some bacteria with genes for enzymes that destroy antibiotics such as penicillins, cephalosporins, or aminoglycosides. Other mutations have changed the structure of bacterial cell walls previously penetrable by antibiotics or have created new enzymes for cellular functions that were previously blocked by drugs

aqueous (ā'kwē-ŭs) [L. *aqua*, water] 1. Of the nature of water; watery.

chlamydia trachomatis A species that causes a great variety of diseases, including genital infections in men and women. The diseases caused by *C. trachomatis* include conjunctivitis, epididymitis, lymphogranuloma venereum, pelvic inflammatory disease, pneumonia, trachoma, tubal scarring, and infertility.

In industrialized nations *C. trachomatis* is a commonly sexually transmitted pathogen (causing an estimated 3 to 4 million new infections each year in the US). Men with chlamydial infection experience penile discharge and discomfort while urinating. Women may be asymptomatic or may experience urethral or vaginal discharge, painful or frequent urination, lower abdominal pain, or acute pelvic inflammatory disease, which may result in infertility.

Transmission of the disease can be prevented by avoiding contact with infected persons and by using condoms during intimate sexual activity

erythromycin (ě-rĭth"rō-mĭ'sĭn) [" + *mykes*, fungus] An antibiotic derived from *Streptomyces erythraeus*, used primarily to treat gram-positive and atypical microorganisms, such as streptococci, mycoplasma, and legionella. Its primary side effects are nausea, vomiting, abdominal pain, bloating, and diarrhea.

gonorrhea (gŏn"ō-rē'ă) [" + *rhoia*, flow] A sexually transmitted infection caused by the gram-negative diplococcus *Neisseria gonorrhoeae*. The disease often causes inflammation of the urethra, prostate, cervix, fallopian tubes, rectum, and/or pharynx. Blood-borne infection may spread to the joints and skin, and congenitally transmitted infection to the eyes of a newborn may cause neonatal conjunctivitis. Infection around the liver may result from peritoneal spread of the disease. Although members of either sex with urogenital gonorrhea may be asymptomatic, women are much less likely to notice burning with urination, urethral discharge, or perineal pain than men, in whom these symptoms are present 98% of the time. Coinfection with *Chlamydia trachomatis* is common in both sexes: some studies have shown simultaneous infection with both organisms to be as high as 30%. Even though syphilis rarely accompanies gonorrheal infection, patients with gonorrhea are routinely tested for this disease. Young, sexually active inner-city teens are at highest risk for contracting gonorrhea. In 2001 in the U.S. 362,000 cases of gonorrhea were reported

ointment (oynt'měnt) [Fr. *oignement*] A viscous, semisolid vehicle used to apply medicines to the skin. Ointments differ from creams or lotions in their superior ability to occlude the skin and improve the uptake of drugs. The base or vehicle of an ointment typically includes petrolatum, fats, oils, resins, or water-based or water-soluble compounds.

ophthalmia neonatorum Severe purulent conjunctivitis in the newborn.

ophthalmic (ōf-thäl'mīk) Pertaining to the eye

prophylactic (prō-fī-lāk'tīk) [Gr. *prophylaktikos*, guarding] 1. Any agent or regimen that contributes to the prevention of infection and disease.

prophylaxis (prō-fī-lāk'sīs) (prō-fīl-āks'īs) [Gr. *prophylassein*, to guard against] Observance of rules necessary to prevent disease

sexually transmitted disease (STD) Any disease that may be acquired as a result of sexual intercourse or other intimate contact with an infected individual. A more inclusive term than "venereal disease," STDs include disease caused by bacteria, viruses, protozoa, fungi, and ectoparasites.

tetracycline (tět"rā-sī'klēn) A bacteriostatic antibiotic used, for example, to treat acne, chlamydia, and atypical pneumonia. Pharmaceutical warning: CAUTION: Tetracyclines should not be given to pregnant women or young children, because they damage developing teeth and bones

**All terms unless otherwise noted are as defined in Tabers Medical Dictionary, 2007*

¹ Klauss V, Schwartz EC. Other conditions of the outer eye. In: Johnson GJ, Minassian DC, Weale R, eds. *The epidemiology of eye disease*. London, Chapman & Hall, 1998.

² Klauss V, Fransen L. Neonatal ophthalmia in tropical countries. In: Bialasiewicz AA, Schaal KP, eds. *Infectious diseases of the eye*. London, Butterworth-Heinemann, 1994.

³ Crede' CSF. [Prevention of inflammatory eye disease in the newborn]. *Archiv für gynaekologie*, 1881, 17: 50–53 (in German).

⁴ Klauss V, Schwartz EC. Other conditions of the outer eye. In: Johnson GJ, Minassian DC, Weale R, eds. *The epidemiology of eye disease*. London, Chapman & Hall, 1998.

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⁷ Isenberg SJ et al. Povidone-iodine for ophthalmia neonatorum prophylaxis. *American Journal of Ophthalmology*, 1994, 118:701–706.

⁸ Isenberg SJ, Apt L, Del Signore M et al; A double approach to ophthalmia neonatorum prophylaxis. *British Journal of Ophthalmology*, 2003; 87: 1449-1452.

⁹ At the time of the Isenberg et al study, there was a 1.6% or less rate of infection in the U.S., and a 23% rate of infection in Kenya. *The Tech*, Volume 115 , Issue 8 : Friday, March 3, 1995 . These numbers were confirmed by Dr. Isenberg during a personal communication November 2007.

¹⁰ Isenberg SJ et al. Povidone-iodine for ophthalmia neonatorum prophylaxis. *American Journal of Ophthalmology*, 1994, 118:701–706.

¹¹ Washington State Department of Social and Health Services, Division of Health. Policy Statement of ophthalmic agents approved for the prevention of ophthalmia neonatorum in the newborn, June 1981.

¹² Washington State Statutory Authority: RCW 70.24.380. 05-11-110. 246-100-202, filed 5/18/05, effective 6/18/05

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¹⁴ Canadian Paediatric Society. (1983). Recommendations for the prevention of neonatal ophthalmia. *Canadian Medical Association Journal*, 129, 544-545.

¹⁵ American Academy of Pediatrics and The American College of Obstetricians and Gynecologists. (1997). *Guidelines for Perinatal Care*. (4th ed.).

¹⁶ <http://www.biochem.northwestern.edu>

¹⁷ Frye, Anne: *Understanding Diagnostic Tests in the Childbearing Year*, Labrys Press (1997), 477-478.

¹⁸ Ulrich C. Schaller & Volker Krauss : Is Crede´'s prophylaxis for ophthalmia neonatorum still valid?. *Bulletin of The World Health Organization*, 2001, 79, 262-263.

¹⁹ Feder, Lauren: *Natural Baby and Childcare*, Hatherleigh (March 17, 2006), 336-339

²⁰ Varney, Helen, CNM, MSN, DHL. (Hon.) FACNM, Professor, Nurse-Midwifery Specialty, Yale University School of Nursing, *Varney's Midwifery*, Jones and Bartlett Publishers (2004), 978

²¹ <http://www.cdc.gov/std/PID/STDFact-PID.htm>

²² O'Hara, M. (1993). Ophthalmia neonatorum. *Pediatric Clinics of North America*, 40 (4), 715-725

²³ Hammerschlag, M. (1993). Neonatal conjunctivitis. *Pediatric Annals*, 22(6), 346-351.

²⁴ Zaroni, D., Isenberg, S., & Apt, L. (1992). A comparison of silver nitrate with erythromycin for prophylaxis against ophthalmia neonatorum. *Clinical Pediatrics*, 31, 295-298

²⁵ On page 481 of *Understanding Diagnostic Tests in the Childbearing Year* (1997), Anne Frye explains that those who choose the early treatment option need to be vigilant parents who have the means and access to bring their child in for treatment within 24 hours of the onset of redness, discharge, and swelling or other suspicious symptoms to ensure proper treatment can be administered.

²⁶ In this case, surrogate is defined as one who makes decisions for another person, and has no relation to the topic of surrogate pregnancy

²⁷ Crede´'s CSF. [Prevention of inflammatory eye disease in the newborn]. *Archiv fu"r gynaekologie*, 1881, 17: 50-53 (in German).

²⁸ St. Joes Hospital in Tacoma, WA is known to have an excellent form that nursing staff are familiar with in terms of both location and content

²⁹ Crede´'s CSF. [Prevention of inflammatory eye disease in the newborn]. *Archiv fu"r gynaekologie*, 1881, 17: 50-53 (in German).

Personal Communications

Washington State Department of Health
Maternal and Infant Health
PO Box 47880
111 Israel Rd SE
Olympia, Washington 98504-7880

Washington State Department of Social and Health Services
Children's Administration
DSHS Constituent Services
PO Box 45130
Olympia, WA 98504-5130

Sherwin J. Isenberg, M.D., November 2007 re: understanding the research, function, and geographical use or non-use of povidone-iodine

Donald F. Everett, M.A., National Eye Institute, November 2007 re: validity of research

David J. Balint, Washington State Attorney, February 2007 re: defining tort law

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