Evidence Based Birth

<u>Is Erythromycin Eye Ointment Always Necessary for Newborns?</u>



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What is the history of using eye ointment in newborns?

The use of erythromycin eye ointment in newborns has its roots in the late 1800s. During that time period, approximately 10% of newborns born in maternity hospitals across Europe developed **ophthalmia neonatorum (ON)**. This is a type of pink eye that caused blindness in 3% of infants who were affected (<u>Schaller and Klauss 2001</u>). This means that during the late 1800s, before antibiotics were discovered, 0.3% of infants (3 out of 1,000) were blinded from ON.

In 1881, a physician named Carl Crede realized that infants were catching ON during vaginal delivery, and that the **infections were caused by gonorrhea—a sexually transmitted infection.** Dr. Crede found that by putting **silver nitrate** in the eyes of newborn babies, he could prevent ON. In fact, the number of newborn ON infections in Dr. Crede's hospital went from 30-35 cases per year to 1 case in the first six months he started using silver nitrate.

Today, more than 130 years after Dr. Crede made his discovery, quite a few things have changed. First, the development of antibiotics has made it possible to treat an infant who contracts ON—thus making blindness highly unlikely. Also, silver nitrate is no longer used in most developed countries, because it is highly irritating to the eye and can cause severe pain, chemical pink eye, and temporary vision impairment. Silver nitrate is also not effective with infections caused by chlamydia, the most common cause of ON today. Furthermore, silver nitrate and tetracycline eye

ointment (another antibiotic that has been used in the past to prevent ON) are no longer available in the U.S. For these reasons, 0.5% **erythromycin ophthalmic ointment** is used in the U.S. and Canada to prevent ON infection.

What causes ophthalmia neonatorum?

Pink eye, or conjunctivitis, can be caused by viruses (ex. Herpes), bacteria, chemicals, and blocked tear ducts. One type of pink eye called ophthalmia neonatorum (ON). ON is a conjunctivitis or pink eye that occurs during the first month of life and is contracted during birth. The two main causes of ON are chlamydia or gonorrhea, both of which are sexually transmitted infections (Ali, Khadije et al. 2007). For the rest of this article, whenever I say "ON," I am referring to chlamydial or gonorrheal ON. Without treatment, ON can potentially lead to permanent eye damage or blindness. However, this is a treatable disease, and blindness can be avoided if oral or intravenous antibiotics are administered promptly after an infant develops ON (Darling and McDonald 2010).

The only way for a newborn to contract ON is if the mother is infected with chlamydia or gonorrhea. If the mother does not have chlamydia or gonorrhea, then the newborn cannot catch it. Also, if a baby is born by C-section and if the mom's water never broke before surgery, then it is extremely unlikely that the baby could catch ON (Medves 2002).

How do you know if a mother is at risk for chlamydia or gonorrhea?

Anyone who is sexually active can contract chlamydia or gonorrhea. You can avoid both chlamydia and gonorrhea if you are in a long-term, mutually faithful relationship in which both partners have been tested and are uninfected. Your risk of contracting chlamydia or gonorrhea is higher if you are young (under the age of 25), if you have multiple sexual partners, or if you live in an area where there are high rates of infection. In the U.S., gonorrhea rates are lower now than they have been in the past, while chlamydia rates are rising (CDC, 2010). In Africa and in some developing countries rates of these infections are much higher.

Most people who have chlamydia or gonorrhea do not have any symptoms, so you can have an infection and not know it. Chlamydia and gonorrhea can cause serious health consequences, such as infertility, ectopic pregnancy, pelvic inflammatory disease and preterm birth. For these reasons, most women in developed countries are screened for chlamydia and gonorrhea (CDC, 2012).

Why is erythromycin used to prevent ON?

One way to prevent ON is to give all newborns an eye treatment (such as erythromycin) that would **prevent** the infection. This is called **prophylaxis** ("Pro- fuh-LAX-is"). Prophylaxis means taking action ahead of time to prevent something bad from happening. Automatic newborn prophylaxis with eye ointment is currently recommended by multiple health organizations in the United States, including the <u>U.S. Preventive Services Task Force</u>, the American Association of Family Physicians, and the American Academy of Pediatrics.

Newborn eye prophylaxis is also mandated by state law in most U.S. states. In 2006, a search of state law databases found that at least 32 U.S. states had laws requiring newborn prophylaxis against ON (Standler 2006). In these states, health care providers are required to administer the eye ointment in every newborn, regardless of the mother's chlamydia or gonorrhea status, and regardless of whether or not the baby was born vaginally or by C-section. Some states, such as New York, do not allow parents to exercise their right to informed refusal, and hospital employees in New York will go so far as to call Child Protective Services if the parents do not want the erythromycin ointment.

On the other hand, automatic erythromycin prophylaxis is no longer used in the United Kingdom, Australia, Norway, or Sweden (<u>Darling and McDonald</u>, <u>2010</u>).



A healthy newborn girl was immediately taken away from her mother in order to have erythromycin ointment and other routine newborn procedures. Copyright: Evidence Based Birth

What is the evidence for erythromycin prophylaxis to prevent newborn pink eye?

In a 2010 meta-analysis, researchers combined results from 8 semi-randomized trials that looked at the effectiveness of various eye ointments to prevent ON (<u>Darling and McDonald 2010</u>). The use of erythromycin was evaluated in 4 of those studies. As you can see from looking at the table below, erythromycin was more effective than silver nitrate at preventing chlamydial ON, but it is not any better than silver nitrate at preventing gonorrheal ON. Only one study compared erythromycin to no prevention, and it found no differences in ON rates between newborns who received erythromycin and those who did not receive any.

Study author (year)	Participants	Findings
Isenberg (1995)	3,117 newborns in a hospital setting in Kenya	When compared to silver nitrate, erythromycin resulted in a 30% reduced risk of chlamydia ON. Erythromycin resulted in no reduction in the risk of gonorrhea ON when it was compared to silver nitrate.
Chen (1992)	4,544 newborns in a hospital in Taiwan	Erythromycin did not make any difference in the rates of chlamydia ON when compared to no prophylaxis at all.
Hammerschlag (1989)	230 newborns born to mothers with chlamydia in New York, as well as the overall 12,431 newborns born during the study period	When compared to silver nitrate, erythromycin led to a 28% reduction in the risk of chlamydia ON. Erythromycin did not reduce the risk of gonorrhea ON (when compared to silver nitrate).
Hammerschlag (1980)	60 newborns born to mothers who all had chlamydia at the time of birth in Seattle, Washington	There were no cases of chlamydia ON, so researchers could not tell if erythromycin was more effective than silver nitrate.

The overall quality of these clinical trials was low, and so it is necessary to look at other types of studies to determine the effects of ON prophylaxis. In a large observational study in South Africa, no eye prophylaxis was used for a certain amount of time, and then 3 hospitals started using silver nitrate and erythromycin. When they compared no prophylaxis to prophylaxis among 30,530 newborns, the number of gonorrheal ON infections dropped from 273 cases per 100,000 births to 34 cases per 100,000 births. However, there was a 20% failure rate, meaning that the prophylaxis was not perfect—it failed to work 20% of the time (Lund et al., 1987).

It may be helpful to summarize the risks and benefits of erythromycin like this:

Benefits:

- Erythromycin can reduce the risk of chlamydial and gonorrheal ON (<u>Darling</u> and McDonald 2010)
- Erythromycin prophylaxis may be helpful if the mother was not screened for chlamydia/gonorrhea, screening results were not correct, or if there is a sexual partner who may be re-infecting her (Medves 2002)
- Erythromycin prophylaxis may be especially helpful in geographic regions where rates of chlamydia and gonorrhea are very high (Medves 2002)
- Erythromycin ointment is inexpensive (<u>Darling and McDonald 2010</u>)

Risks:

- Adverse effects <u>include eye irritation and blurred vision</u>, which may interfere with bonding
- Widespread use may contribute to the development of antibiotic resistant bacteria (Hedbert et al. 1990)
- Erythromycin is not 100% effective at preventing ON (it has a 20% failure rate)
 (<u>Lund et al., 1987</u>)
- It's possible that care providers may not be watchful for ON because they assume the infant was "already treated," but prophylaxis does not work all the time (Lund et al., 1987)
- Drug shortages happen occasionally. In 2009, there was an erythromycin shortage in the U.S. and providers began using alternative medicines that had never been tested in newborns. One of those medications—gentamicin—was later found to have severe adverse effects in newborns (CDC, 2010).

Are there any other options beside the erythromycin?

One option is for the mother to be screened for sexually transmitted infections during pregnancy and receive antibiotic treatment if needed. If the mother is treated, then she would need follow-up testing to make sure the treatment was effective. If a mother is not infected with chlamydia or gonorrhea and is in a mutually faithful relationship with an uninfected partner, then newborn eye ointment may be reasonably declined (Medves, 2002).

The benefits of this option are that a potentially harmful sexually transmitted infection can be detected and treated. This improves the health of both the mother and the newborn. The disadvantages are that if this is done on a large scale, it requires a well-organized maternity care system in which all pregnant women are screened for sexually transmitted infections. Although this is do-able in some countries, it may not be feasible in others. Another disadvantage is that a woman may test negative for chlamydia or gonorrhea, but then be infected by a partner before giving birth.

The U.S. Centers for Disease Control recommends that all pregnant women be screened for chlamydia at the first prenatal visit, and that women at high risk for gonorrhea be screened as well. In a recent study of 1.29 million pregnant women, researchers found that 57-59% of U.S. women were screened at least once during pregnancy for chlamydia or gonorrhea. Of these women who were screened, 3.5% tested positive for chlamydia and 0.6% tested positive for gonorrhea. The majority of the women who tested positive (76-68%) were re-tested again. A small number of these women were still positive for chlamydia (6%) or gonorrhea (3.8%) at the last test before giving birth (Blatt et al. 2012)

Another option is to wait and see if a newborn develops ON. If the newborn baby shows signs of ON, treatment can be started with systemic antibiotics. This method is currently used in the United Kingdom. In 1998, there were 31 cases per 100,000 newborns born in the United Kingdom. In the year 1999 in Canada—where they use erythromycin eye ointment—the rate of ON was 49.5 per 100,000 newborns (Medves 2002).

Another option is Povidone-iodine, a disinfectant drop that can be placed into the newborn's eyes. Povidone-iodine is becoming popular in developing countries because it is less expensive than erythromycin. This disinfectant does NOT increase the risk of antibiotic resistance and it is just as effective as erythromycin and silver nitrate at preventing gonorrheal ON. Povidone iodone is also more effective than

silver nitrate and equally effective as erythromycin at preventing chlamydial ON. However, newborn eye drops made out of povidone-iodine are not yet available in the United States (Darling and McDonald 2010).

In summary

- ON is a preventable and treatable newborn eye infection caused by chlamydia and gonorrhea
- Options include screening for chlamydia and gonorrhea, using erythromycin eye ointment after birth, a "wait and see" approach in which antibiotics are used only when necessary, or using povidone-iodine eye drops after birth
- Erythromycin eye ointment can be reasonably declined if the mother is not infected with chlamydia or gonorrhea and if she is in a mutually faithful relationship with an uninfected partner
- It is highly unlikely that a baby that is born by C-section could catch ON as long as the mother's membranes were intact at the time of surgery
- Laws in most U.S. states mandate the use of erythromycin with all newborns even though the erythromycin is not always necessary and even though other options are available
- Given the fact that other options can be used to safely prevent and treat newborn eye infections, the mandatory nature of these erythromycin state laws should be re-evaluated

What are the laws about newborn erythromycin ointment in your country or state? Do you agree with my conclusion that erythromycin is not always necessary?

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