Statutory Law in the USA: Requiring Silver Nitrate in Eyes of Newborns

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Introduction

During childbirth, the eyes of many infants are contaminated with bacteria, which infection — called ophthalmia neonatorum — can lead to serious eye damage and even blindness. In the year 1881, it was discovered that a drop of silver nitrate ($AgNO_3$) solution put in the eye of newborn infants prevented infection. State legislatures in the USA reacted by passing statutes that required physicians to put a drop of 1% silver nitrate solution in each eye of every newborn baby. However, silver nitrate is caustic and commonly produces pain and chemical conjunctivitis.

This essay is a case study in how these badly written statutes harmed people, by mandating antique therapy, after the late 1940s, when better prophylactic agents were available. In this essay, I argue that it was a mistake for legislators to prescribe specific medical prophylaxis in a statute. Instead, I believe the legislators should have simply required some kind of prophylaxis against ophthalmia neonatorum and given the choice of drug to the attending physician.

This essay presents general information about an interesting topic in law, but is *not* legal advice for your specific problem. See my disclaimer at http://www.rbs2.com/disclaim.htm .

Because of limits on my unpaid time and lack of a local major medical library, I have made only a quick search of the medical literature. On 8 Dec 2006, the Medline database lists more than 480 articles in the English language on ophthalmia neonatorum, including its etiology, prophylaxis, and treatment. On the other hand, my search of law review articles in Westlaw databases found nothing on state statutes requiring silver nitrate prophylaxis.

1. History of Prophylaxis of Ophthalmia Neonatorum

During childbirth, the eyes of some infants are contaminated with *Neisseria gonorrhea* or other bacteria, which infection can lead to serious eye damage and even blindness. In the year 1881, it was discovered that a drop of 2% silver nitrate ($AgNO_3$) solution put in the eye of newborn infants prevented gonococcal infection.[1] This landmark discovery decreased the frequency of neonatal blindness by at least a factor of thirty, and was an important advance in public health. During the years 1910-1940, many state legislatures in the USA reacted by passing statutes that required physicians to put a drop of 1% silver nitrate solution in each eye of every newborn baby.

side effects of silver nitrate

Silver nitrate is caustic and routinely produces chemical conjunctivitis. One study published in the year 1958 showed that after 2% solution of silver nitrate

> ... a discharge was present with inflamed eyes or [eye]lids were swollen in 46% of the infants on the first day after instillation of the silver nitrate. The incidence decreased steadily through the fifth day ... to 6% ....

Peter L. Mathieu, "Comparison Study: Silver Nitrate and Oxytetracycline in Newborn Eyes ...," *AMA Journal of Diseases of Children,* Vol. 95, pp. 609-611 (June 1958) at page 610.

The original work of Credé in Leipzig, Germany in 1881 used a 2% solution of silver nitrate. Apparently to minimize irritation of the eyes, the practice in the USA during the 1900s — often specified in state statutes —was to use a 1% solution of silver nitrate. There is one published suggestion[2] that concentrations of silver nitrate as low as 0.1% could be effective prophylaxis against *N. gonorrhoea.* One wonders if there was a scientific determination of the minimum effective concentration of silver nitrate during the years 1880-1940. Using the weakest possible solution would have minimized pain and conjunctivitis in the newborn infants.

The consensus seems to be that chemical conjunctivitis following administration of 1% silver nitrate usually disappears in 24 to 36 hours, but sometimes persists up to 72 hours. One study, which found only 10% of silver nitrate patients having "redness and swelling", reported discharge

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[1] Karl S. F. Credé, "Die Verhütung der Augenentzündung der Neugeborenen," *Archiv für Gynäkologie,* Vol. 17, pp. 50-53 (1881).

[2] Hiroshi Nishida and Herman M. Risemberg, "Silver Nitrate Ophthalmic Solution and Chemical Conjunctivitis," *Pediatrics,* Vol. 56, pp. 368-373 (1975), at pp. 370-371.

from the eyes in 4.6% of silver nitrate patients, but only in 1.5% of patients receiving erythromycin prophylaxis.[3]

In response to the pain of silver nitrate eye drops, newborn infants close their eyes. Because the infant closes *both* eyes in response to the silver nitrate in its first eye, it is difficult to treat the infant's second eye.[4]

Several medical studies have concluded that this pain interferes with mother-child bonding.[5] The significance of such interference with mother-child bonding is not clear, but seems *un*desirable. Some maternity wards delay applying the silver nitrate prophylaxis until between one and two hours after birth, but this delay could make the prophylaxis less effective.

Moreover, temporarily damaged conjunctiva (as shown by the conjunctivitis and discharge) caused by silver nitrate *may* have made the eye more vulnerable to infection after birth. There is a more insidious problem caused by chemical conjunctivitis and discharge after silver nitrate prophylaxis. The chemical conjunctivitis and discharge appears similar to an infection, which should be cultured, thus increasing the workload of nurses and bacteriologists, while finding that the patient has no infection.[6] Alternatively, if the physician dismisses the conjunctivitis and discharge as "probably a reaction to the silver nitrate", then there could be a delay in obtaining cultures and beginning treatment of an active infection.

Before the introduction of penicillin in the late 1940s, there was no effective treatment for gonococcal ophthalmia neonatorum, and silver nitrate was the *only* effective prophylaxis, therefore the risk of pain and temporary conjunctivitis was worth the benefit of avoiding corneal scarring and possible blindness from infections.

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[3] Joseph R. Christian, "Comparison of Ocular Reactions with the use of Silver Nitrate and Erythromycin in Ophthalmia Neonatorum Prophylaxis," *Journal of Pediatrics,* Vol. 57, pp. 55-60 (July 1960), at page 57.

[4] Vivian Wahlberg, "Reconsideration of Credé Prophylaxis," *Acta Paediatrica Scandinavica Supplement,* Vol. 295, pp. 1-73 (1982), at page 33.

[5] Perry M. Butterfield, Robert N. Emde, Bruce B. Platt, "Effects of Silver Nitrate on Initial Visual Behavior," clinical memorandum, *American Journal Diseases of Children,* Vol. 132, p. 426 (April 1978); Perry M. Butterfield, Robert N. Emde, and Marilyn J. Svejda, commentary, "Does the Early Application of Silver Nitrate Impair Maternal Attachment?" *Pediatrics,* Vol. 67, pp. 737-738 (May 1981); Vivian Wahlberg, "Reconsideration of Credé Prophylaxis," *Acta Paediatrica Scandinavica Supplement,* Vol. 295, pp. 1-73 (1982), especially at pages 10, 18-19, 45-46, and 49-56.

[6] Vivian Wahlberg, "Reconsideration of Credé Prophylaxis," *Acta Paediatrica Scandinavica Supplement,* Vol. 295, pp. 1-73 (1982), at page 33.

antibiotics

When antibiotics (e.g., penicillin, erythromycin, tetracycline) became available in the 1940s and 1950s, there were effective therapies for ophthalmia neonatorum. Some physicians doubted the need to continue routine prophylaxis against ophthalmia neonatorum in every childbirth. Routine prophylaxis at birth was discontinued in the United Kingdom in the late 1950s without any reported cases of blindness from infection.[7] If prophylaxis were to be done, one should use a drug that is less painful and less irritating than silver nitrate solution. However, physicians in some states in the USA were forced to continue using caustic silver nitrate, only because silver nitrate was required by statute, until legislatures amended the statutes.

Dr. Lehrfeld in Philadelphia conducted an experiment comparing 1% silver nitrate and an aqueous solution of penicillin in 1400 consecutive deliveries during 1948-49.[8] Penicillin was the better prophylactic, in that there were zero cases of ophthalmia neonatorum in infants treated with penicillin vs. five cases in infants treated with silver nitrate. Penicillin caused "not a single case of eye irritation", while there were 143 cases of chemical conjunctivitis after silver nitrate. Despite proving penicillin superior to silver nitrate, Dr. Lehrfeld was unable to use penicillin as a prophylactic after the experiment ended, "inasmuch as the State Department of Health still insists on 1% silver nitrate as a prophylactic."

Another early series of experiments on 4163 newborn infants during 1948-50 showed that penicillin ointment produced fewer infected eyes, as well as fewer cases of irritation and discharge, than silver nitrate solution.[9] However, penicillin was unable to be used routinely because of state statutes or regulations that specifically required silver nitrate prophylaxis. Four years later, writing an editorial note about permanent damage to the eyes of two newborn infants from routine prophylaxis with allegedly 1% silver nitrate solution, Dr. Eastman commented "... the tragic result for the infants could have been prevented by the use of penicillin ointment. But despite the many

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[7] Vivian Wahlberg, "Reconsideration of Credé Prophylaxis," *Acta Paediatrica Scandinavica Supplement,* Vol. 295, pp. 1-73 (1982), at pages 19, 32.

[8] Louis Lehrfeld, "Penicillin Prophylaxis in Ophthalmia Neonatorum," *Eye Ear Nose Throat Monthly,* Vol. 30, pp. 367-370 (July 1951); Louis Lehrfeld, letter, "Prevention of Blindness in the Newborn," *Journal of the American Medical Association,* Vol. 143, p. 1360 (12 Aug 1950).

[9] H.H. Davidson, Justina H. Hill, and N.J. Eastman, "Penicillin in the Prophylaxis of Ophthalmia Neonatorum," *Journal of the American Medical Association,* Vol. 145, pp. 1052-1055 (7 Apr 1951).

advantages of penicillin ointment, most obstetricians, pediatricians and ophthalmologists, as well as State Health Departments, just slumber on."[10]

Penicillin was used as prophylaxis against ophthalmia neonatorum in the late 1940s and early 1950s, but abandoned because topical use of penicillin sometimes caused patients to develop an allergy to penicillin.[11] Furthermore, by the late 1970s, many strains of *N. gonorrhea* were resistant to penicillin.

Due to effective antibiotic treatment of pregnant women, *Neisseria gonorrhea* is no longer the leading cause of neonatal ocular infection in the USA — since about 1975 infection of neonates with *Chlamydia trachomatis* has become more common than *N. gonorrhea.*[12] There is concern that silver nitrate is not effective in preventing infection with *Chlamydia,* which makes erythromycin preferable to silver nitrate. The erythromycin is typically given orally as a syrup, to prevent — or to treat — both ocular infections and pneumonitis.

A report of scientific research in a medical journal in 1975 by authors who favored continued use of silver nitrate said:

> Comparative studies with silver nitrate have shown that all of these [8] antibiotics are as effective as silver nitrate, but with no superiority except in the lower incidence of chemical conjunctivitis. **....** In spite of evidence that silver nitrate is effective and safe for the prophylaxis of ophthalmia neonatorum, more than 20% of the [100 major maternity] hospitals [in the USA] are still reluctant to use it, mainly because of the high incidence of chemical conjunctivitis associated with its use.

Hiroshi Nishida and Herman M. Risemberg, "Silver Nitrate Ophthalmic Solution and Chemical Conjunctivitis," *Pediatrics,* Vol. 56, pp. 368-373 (1975), at p. 371.

A review article in an optometry journal in 1984 summarized sixty articles in the medical literature:

> Each modern antibiotic [e.g., penicillin, erythromycin, tetracycline, etc.] produces less severe and less frequent chemical irritation than silver nitrate. Except for bacitracin, each agent was found to be as effective or superior to silver nitrate in preventing GC-ON [gonococcal ophthalmia neonatorum].

James M. Novak, "Current Status of Credé Prophylaxis," *American Journal of Optometry and Physiological Optics,* Vol. 61, pp. 340-346 (May 1984), at page 342.

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[10] N.J. Eastman, editorial note, "The Newborn," *Obstetrical & Gynecological Survey,* Vol. 10, p. 223 (1955).

[11] Paul C. Barsam, "Specific Prophylaxis of Gonorrheal Ophthalmia Neonatorum," *New England Journal of Medicine,* Vol. 274, pp. 731-734 (31 March 1966), at pp. 732.

[12] On the other hand, because *N. gonorrhea* ocular infections rapidly progress to causing permanent damage to the eye, gonorrheal infections are more serious than infections by some other bacteria.

iodine

Many other bacteria (e.g., *Staphylococcus*, *Streptococcus*, *Hemophilus,* etc.) are also clinically important in neonatal ocular infections, and no single antibiotic is effective against all of them, which makes antiseptic solutions attractive. Iodine is a wide-spectrum antiseptic that kills all bacteria, fungi, viruses, and *Chlamydia.* However, iodine stains tissue. A nonstaining, aqueous solution of iodine is polyvinylpyrrolidone-iodine, known by the generic name povidone-iodine and best known in the USA by the Betadine® trademark. Readers may recall their own experience that *tincture* of iodine hurts. The pain is caused by the alcohol solvent, *not* the iodine itself. Aqueous solutions of iodine, such as povidone-iodine, are painless.

In 1995, a group of physicians showed that a povidone-iodine solution was more effective than either silver nitrate or erythromycin in preventing ophthalmia neonatorum.[13] Furthermore, the povidone-iodine solution avoided the pain and conjunctivitis that is routinely produced by silver nitrate.[14]

Povidone-iodine has been used as an antiseptic, particularly for disinfection of skin prior to surgical incision, since the late 1950s.[15] The first publication of povidone-iodine as an ophthalmic antiseptic appears to be in 1966.[16] One wonders if the thirty-year delay in testing povidone-iodine ophthalmic solutions for prophylaxis of ophthalmia neonatorum might have been caused by the statutory requirement for silver nitrate prophylaxis.

I asked Prof. Isenberg, the lead author on the 1994-95 articles that showed povidone-iodine to be superior prophylaxis of ophthalmia neonatorum, to comment on the statutes in thirty states of the USA during the 1960s that required prophylaxis only with silver nitrate. Instead, he replied with a different concern about law and regulation in the USA:

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[13] Sherwin J. Isenberg, Leonard Apt, Robert Yoshimori, Rosemary D. Leake, and Roberta Rich, "The Use of Povidone-Iodine for Ophthalmia Neonatorum Prophylaxis," *American Journal of Ophthalmology,* Vol. 118, pp. 701-706 (15 Dec 1994); Sherwin J. Isenberg, Leonard Apt, and Mark Wood, "A Controlled Trial of Povidone-Iodine as Prophylaxis Against Ophthalmia Neonatorum," *New England Journal of Medicine,* Vol. 332, pp. 562-566 (2 Mar 1995).

[14] *Ibid.*

[15] See, e.g., L. Gershenfeld, "Povidone-iodine as a topical antiseptic," *American Journal of Surgery,* Vol. 94, pp. 938-939 (Dec 1957); J.F. Connell and L.M. Rousselot, "Povidone-Iodine: Extensive Surgical Evaluation of a New Antiseptic Agent," *American Journal of Surgery,* Vol. 108, pp. 849-855 (Dec 1964).

[16] G.T. Kiffney and A.C. Hattaway, "Povidone-Iodine as an Ophthalmic Antiseptic," *Surgical Forum,* Vol. 17, pp. 434-436 (1966).

> At present there is probably no better agent for this purpose than povidone-iodine. It is being used all around the world for ophthalmia neonatorum prophylaxis; but not in the U.S.
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> About 10 years ago, I met with officials of the FDA to explore what would be needed for its use in the U.S. Despite the paper in the NEJM which essentially convinced the rest of the world, the FDA wanted an American trial.[17] The kind of trial that they wanted would cost nearly a million dollars then and closer to two million now. No pharmaceutical company was interested in pursuing such a trial for a drug that would net them about a dollar profit per use. A four million dollar profit a year is insufficient to interest them. The pity is that, currently, no inexpensive medication can undergo FDA testing since no one will allocate funding for this. Thus, povidone-iodine is not used in the U.S. for this purpose.
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> I believe that erythromycin ophthalmic ointment is the most commonly used medication in the U.S. [for prophylaxis of ophthalmia neonatorum]. Although good, it is not as effective as povidone-iodine. Silver nitrate is no longer manufactured in the U.S. and is seldom used anymore.

Sherwin J. Isenberg, M.D., personal communication, 13 Dec 2006.

my conclusion about medical history

In reading several dozen articles on this topic published since the mid-1950s in medical journals, I conclude that there are two camps of authors: traditionalists and modernists. The traditionalists believe that silver nitrate is the best — or at least acceptable — prophylaxis, because it had been used for more than seventy years.[18] The traditionalists totally ignore the pain caused by silver nitrate. The traditionalists admit the chemical conjunctivitis caused by silver nitrate, but dismiss this inflammation as harmless. The traditionalists seem afraid to change to a new prophylactic agent, for fear of making a mistake, an attitude that frustrates scientific progress. On the other hand, the modernists are aware of the problems with silver nitrate and eager to do research to find/use a better prophylactic agent. Medical committees seem to be dominated by traditionalists.[19]

I think it was abusive of the infants to continue to use the painful silver nitrate after about 1955, when topical antibiotics were available that were both less painful and at least as effective in preventing infection.

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[17] The *New England Journal of Medicine* (NEJM) article by Isenberg, et al. reported a trial in Kenya, where the incidence of gonorrhea in pregnant women is much higher than in the USA, thus giving a more severe test of prophylactic agents.

[18] When I wrote this essay in December 2006, silver nitrate prophylaxis has been used for more than 125 years.

[19] For examples of traditionalist positions, see, e.g., Committee on Medicolegal Problems, "Review of Status of State Laws Requiring Use of a Prophylactic in the Eyes of Newborn Infants," *Journal of the American Medical Association,* Vol. 169, pp. 1950-1952 (18 April 1959); Franklin M. Foote, et al., "Control of Ophthalmia Neonatorum," *The Sight-Saving Review,* Vol. 43, pp. 11-13 (Spring 1973); anonymous, "Maintaining the Birthright of Sight," *The Sight-Saving Review,* Vol. 49, pp. 53-60 (Summer 1979).

2. Litigation

I searched the Westlaw database for cases involving parents suing for injury to their newborn child caused by silver nitrate solution. I found no cases involving a challenge to a statute that required silver nitrate prophylaxis. That is not surprising. Parents could not sue the state for the badly written statute, because courts refuse to get involved with "political questions", such as the wisdom of a statute. Courts can overturn statutes that are *un*constitutional, but there is no constitutional guarantee of health care in the USA.[20]

There are two reported cases of eye damage by negligently administered silver nitrate prophylaxis, of which relevant portions of the judicial opinion are quoted below.

In April 1932, a child was born by Caesarian section. Because the amniotic sac was not ruptured there was no way that the baby's eyes could be infected by bacteria in the vagina, so prophylaxis was not necessary. However, a nurse administered the prophylaxis anyway and did it in a negligent manner:

> The obstetrical supervisor, Miss Morrison, a hospital employee, after swabbing the mouth and nose of the baby caused him to be removed from the operating room to the nursery on the floor below where the usual care was given by those in charge at the hospital. More than an hour later one of the nurses without the knowledge of the defendant undertook to administer the Crede treatment and selected a tube which had been supplied the hospital by the State Board of Health, containing a 1 per cent. silver nitrate solution, but she inadvertently squeezed the tube too tightly and lost the contents. This being the only tube available, Miss Morrison thereupon directed one of the nurses to go to the drug department of the hospital and prepare and bring her a 2 per cent. silver nitrate solution. The nurse brought her a brown bottle so labeled and from the contents she administered the treatment to the baby's eyes. An unexpected reaction immediately manifested itself and the eyes turned white. The nurse, thereupon, applied a saline solution, and having only one ounce present procured more from across the hall and continued to apply this solution until she had used four ounces. The eyes and lids were severely burned.

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[20] See, e.g., *Wideman v. Shallowford Community Hosp., Inc.,* 826 F.2d 1030, 1036 (11th Cir. 1987) ("The facts underlying this case are undeniably tragic. On April 12, 1984, Toni Wideman, who at the time was four months pregnant, began experiencing abdominal pain. She called her obstetrician, Dr. John Ramsey, who instructed her to come immediately to Piedmont Hospital. Ms. Wideman called the 911 emergency telephone number in DeKalb County and requested an ambulance to take her to Piedmont. Three employees of the DeKalb County Emergency Medical Service (EMS) responded to this call. Ms. Wideman claims that she again informed the EMS employees to take her to Piedmont where her doctor was waiting, but they refused and, instead, took her against her wishes to Shallowford Community Hospital. After a substantial delay, during which the attending physician at Shallowford spoke by phone with Dr. Ramsey, Ms. Wideman was transferred to Piedmont. At that point, however, Dr. Ramsey was unable to stop her labor, and Ms. Wideman gave birth to a premature baby, named Ebony Laslun Wideman, who survived for only four hours." **Held:** "... the fact that the County undertook to provide *some* ambulance service did not give rise to a constitutional duty to perform the particular service desired by this plaintiff." Affirmed summary judgment for defendants and dismissal of plaintiff's litigation.)

> .... [The surgeon-defendant] again visited the child about 7 o'clock that evening when he first learned that a so-called Crede treatment had been administered to the baby's eyes. He prescribed boric acid irrigations and warm and cold compresses to be applied to the eyes. The baby's eyelids continued to become inflamed and swollen and remained so for a long time. Dr. Rideout, an eye specialist, was called the second day after the baby's birth and he prescribed for it, approving the treatment already prescribed by Dr. Harlan.
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> The story of the parents' efforts to bring some measure of relief to their child by enlisting leading specialists of the Middle West is a most human and pathetic one. For a considerable time the child was blind, but later showed such remarkable improvement as to astound the eye specialists who had him in charge. At the time of trial in June, 1935, he had regained a substantial vision.

Harlan v. Bryant, 87 F.2d 170, 171 (C.C.A. 1936).

This appellate court held that the surgeon was *not* legally responsible for the negligence of the nurse.

In December 1943, a pregnant woman hired an experienced obstetrician to perform a Caesarian-section delivery on her. The experienced obstetrician delegated the care of the newborn child to an intern. The Pennsylvania Supreme Court then recites the facts that are relevant here:

> The operation was apparently a difficult one; the patient suffered profuse hemorrhages which required defendant's complete attention. When the child was delivered he turned it over to the interne for the purpose of tying the cord and applying a solution of silver nitrate to the infant's eyes. Silver nitrate is an extremely caustic drug requiring careful dosage, and proper technique calls for the application of only one or two drops in each eye followed by prompt irrigation. A subsequent analysis of the silver nitrate used on this occasion revealed that it was a 2.1 [%] solution which, it was testified, was not of excessive intensity. The insertion of silver nitrate or other approved prophylactic agent in the eyes of every new-born child is not only a regularly established practice in obstetrical cases but is required by the rules and regulations of the Department of Health of the Commonwealth, the purpose being to prevent the disease known as ophthalmia neonatorum. According to the testimony of Mrs. McConnell's nurse the interne in this case filled a syringe and squirted the solution once into the child's left eye and twice into its right eye, putting into the latter 'a great many drops'; moreover, he failed to irrigate the eyes during at least the period of five or ten minutes while this nurse remained in the operating room. The result was that the child lost the sight in her right eye completely, which was so badly burned that it had later to be excised, necessitating a plastic operation and the substitution of a glass eye which she will be obliged to wear throughout her life; the left eye was also severely and permanently scarred. Defendant himself testified that the insertion of the silver nitrate drops was not a job which required any special skill; he said that "it is done by midwives, nurses, students, physicians, and even those who are not educated in medicine in any way."

McConnell v. Williams, 65 A.2d 243, 244-245 (Pa. 1949).

This legal case turned on whether the intern was the "servant" of the experienced obstetrician who was the sole defendant[21] in this case. The Pennsylvania Supreme Court held that this was an issue for the jury to decide. *Id.* at 248. Incidentally, this case is well-known in the history of medical

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[21] At the time of this case, the hospital enjoyed immunity from litigation for negligence, because of a now-obsolete doctrine called "charitable immunity". The intern had negligible financial assets and so was not able to pay any judgment.

malpractice litigation, because it holds the surgeon to be "captain of the ship" and financially responsible in tort for everything that happens. The words quoted above are all that the reported opinion says about the injury from silver nitrate.

There are also two reported appellate cases[22] involving use of 10% or 30% solution of silver nitrate in eyes, instead of the proper 1% solution. There are also several reports in the medical literature of such injuries.[23] Such overdosage errors can occur with any drug, so these cases are not discussed here.

effect of statute on litigation

Statutes that required prophylaxis with silver nitrate had criminal penalties, typically a fine. But such statutes were also important in tort litigation (e.g., medical malpractice or negligence), where the statute establishes a legal duty (i.e., a minimum standard of conduct).[24] By failing to administer the prophylaxis prescribed in the statute, the physician breaches this duty. If the baby subsequently has a damaging infection of the eye(s), the parents can sue the physician in tort.

There are four reported cases[25] in which a physician had failed to use any prophylaxis, and the newborn baby was subsequently totally blinded by a gonococcal infection.

In the preceding two paragraphs, plaintiff can use the statute as a "sword", to establish a duty of care in alleged medical malpractice. But, since the 1950s, some state statutes continue to explicitly mention silver nitrate as an acceptable prophylaxis.[26] Defendant physicians can use these

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[22] *Covington v. Wyatt,* 145 S.E. 673 (N.C. 1928) (Nurse put 30% silver nitrate solution in newborn infant's eyes, "impairing" child's sight.); *Citizens Walgreen Drug Agency, Inc. v. Gulf Ins. Co.,* 213 So.2d 814 (Ala. 1968) (Prescription called for 10% solution, eyes of infant were "injured". Affirmed $75,000 verdict against physician and drugstore.).

[23] See, e.g., Louis Lehrfeld, "Penicillin Prophylaxis in Ophthalmia Neonatorum," *Eye Ear Nose Throat Monthly,* Vol. 30, pp. 367-370 (July 1951) at p. 369; R.B. Griffin, Jr., "Eye Damage in Newborns From Use of Strong Silver Nitrate Solutions," *California Medicine,* Vol. 107, pp. 178-181 (Aug 1967); Albert Hornblass, "Silver Nitrate Ocular Damage in Newborns," letter, *Journal of the American Medical Association,* Vol. 231, p. 245 (20 Jan 1975); Albert Hornblass, "Severe Silver Nitrate Ocular Damage," *New York State Journal of Medicine,* Vol. 76, pp. 1875-1878 (Oct 1976); P.A. Laughrea, et al., "Iatrogenic Ocular Silver Nitrate Burn," *Cornea,* Vol. 4, pp. 47-50 (1985-86).

[24] The general rule is given in Restatement Second of Torts, §§ 285(a), 286, 288B (1965).

[25] *Medlin v. Bloom,* 119 N.E. 773 (Mass. 1918); *Shovers v. Hahn,* 190 N.W. 432 (Wis. 1922); *Jordan v. Skinner,* 60 P.2d 697 (Wash. 1936); *Walden v. Jones,* 158 S.W.2d 609 (Ky. 1942).

[26] As explained below, at page 24, in November 2006 six states' statutes continue to explicitly mention silver nitrate as an acceptable prophylaxis.

state statutes as a "shield" to show that their obsolete care (e.g., using silver nitrate, instead of a safer antibiotic) was legally adequate care. However, compliance with a statute or regulation does not prevent a finding of negligence, if a reasonable physician "would take additional precautions".[27]

3. Old State Statutes

Obsolete state statutes are not currently available amongst the Westlaw databases, so the only way to find old state statutes is by quotation in a judicial opinion, by reading old volumes of statutes in a law library, or by reading old scholarly articles.

In the year 1908, the American Ophthalmological Society's Committee on Ophthalmia Neonatorum issued a report that mentioned state statutes on the subject. Remarkably, the early American statutes only required reporting of eye infections in newborn infants, and did *not* require prophylaxis. The "general form of the law" that was initially passed in Maine, and subsequently passed in twelve other states, was:

> Should one or both eyes of an infant become reddened or inflamed within ten days after birth, it shall be the duty of the midwife, nurse, or other persons having charge of said infant, to report the condition of the eyes at once to some legally qualified practitioner of medicine of the city, town, or district in which parents of the infant reside.

Lucien Howe, Edward Jackson, Peter A. Callan, "Report of the Committee on Ophthalmia of Infancy," *Transactions of the American Ophthalmological Society,* Vol. 11, pp. 741-747 (1908) at page 741. I find it astounding that this seven-page report does *not* mention silver nitrate prophylaxis, because there was no effective treatment of *N. gonorrhea* infections of the eye, prior to the availability of penicillin in the 1940s.

In 1917, a physician attended a birth at the home of the mother and the physician failed to use some prophylactic against inflammation in the eyes of her newborn infant. The physician was tried on criminal charges and convicted. An appellate court reversed, because the Ohio statute specifically referred to births at hospitals or "maternity homes", but not private homes of individuals:

> It shall be the duty of the physicians, midwives. or other persons in attendance upon a case of childbirth in a maternity home, hospital, public or charitable institution, in every infant immediately after birth, to use some prophylactic against inflammation of the eyes of the newborn and to make record of the prophylactic used.

"pertinent part" of Section 1248-5, General Code (106 O. L., 322) as quoted in *Noble v. Ohio,* 11 Ohio App. 495, 1918 WL 882, 31 Ohio C.A. 470 (Ohio App. 1918).

A 1936 case in the U.S. Circuit Court of Appeals in Illinois noted:

> In 1933 the Legislature of Illinois enacted a law making it the duty of any physician or nurse who attends or assists at the birth of a child to instill or have instilled in each eye of the

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[27] Restatement Second of Torts, § 288C (1965).

> new born baby, as soon as possible and not later than one hour after birth, a 1 per cent. solution of silver nitrate or some other equally effective prophylactic for the prevention of ophthalmia neonatorum (Smith-Hurd Ann.Stat. c. 91, Sec. 108). This law was not in force at the time of the injury complained of, but a somewhat similar act was, except that the provisions thereof were more of an advisory than a mandatory nature. The present act is referred to for the reason that it gives recognition to the attending nurse as a proper person to be intrusted with the duty of installation of the silver nitrate.

Harlan v. Bryant, 87 F.2d 170, 172 (C.C.A. 1936).

A 1959 review article in the *Journal of the American Medical Association* cited an October 1957 compilation of state laws by the National Society for the Prevention of Blindness:

> Sixteen states require the use of silver nitrate and do not allow, by either statute or regulation, the use of any other substance. Seven states allow substances other than silver nitrate for investigative purposes only. Five states, California, Idaho, Iowa, South Dakota, and Oklahoma, specifically, allow the use of penicillin ointment. Four states permit the use of silver nitrate or an equally effective agent. Three states allow substances other than silver nitrate to be used only by physicians in hospitals, and Missouri permits the use of other substances in certain hospitals only. Tennessee and Washington allow the use of an antibiotic only with the specific approval of the proper health agency. Montana and New Jersey do not stipulate what substances must be used, while Nevada requires only the use of a germicide of proved efficiency. Delaware and New Mexico permit the use of silver nitrate, Argyrol, or Protargol, or their therapeutic equivalent, while Alabama allows only the use of these three prophylactics. Texas allows antibiotics only for the purpose of medical school teaching, and Maryland allows antibiotics to be used only by physicians. Florida and Wyoming permit the use of erythromycin in addition to silver nitrate.

Committee on Medicolegal Problems, "Review of Status of State Laws Requiring Use of a Prophylactic in the Eyes of Newborn Infants," *Journal of the American Medical Association,* Vol. 169, pp. 1950-1952 (18 April 1959), at page 1951.

> All states but 1 now require by law some form of prophylaxis against ophthalmia neonatorum. Twenty-two state require the instillation of silver nitrate, and none prohibit its use.

Ibid., at p. 1952.

A 1960 medical journal article quotes the then current Illinois state regulation:

> It shall be the duty of any physician, midwife or nurse who attends or assists at the birth of a child to instill or have instilled in each eye of the newborn baby, as soon as possible and not later than one hour after birth, a one percent (1%) solution of silver nitrate or some other equally effective prophylactic for the prevention of ophthalmia neonatorum approved by the State Department of Public Health. The Illinois Department of Public Health approves only 1% silver nitrate solution as a prophylactic for ophthalmia neonatorum.

Joseph R. Christian, "Comparison of Ocular Reactions with the use of Silver Nitrate and Erythromycin in Ophthalmia Neonatorum Prophylaxis," *Journal of Pediatrics,* Vol. 57, p. 55 (July 1960). The first sentence of the quotation sounds like a state statute.

A 1966 review article in the *New England Journal of Medicine* cited an October 1965 compilation of state laws by the National Society for the Prevention of Blindness:

> Twenty-two states now require the use of silver nitrate as the sole prophylactic agent specified by law or regulation. Eight states permit the substitution of other substances for investigation purposes only. Alaska, California, Iowa, Maryland, Mississippi and Missouri specifically allow for the administration of penicillin. Idaho, which was previously included in the list, discontinued the use of penicillin effective February, 1964. Five states allow for the alternative use of silver nitrate or "an equally effective agent." In 4 states substance other than silver nitrate may be given only by physicians in hospitals. Montana, Nevada and Ohio make no stipulation about the substance that may be administered. Wyoming requires the use of erythromycin ophthalmic ointment, but an attending physician can prescribe any additional medication. Alabama, Delaware and New Mexico allow for the use of silver nitrate, [A]rgyrol, or [P]rotargol, or acceptable equivalents as specified by the state board of health. Seven states permit the administration of antibiotics *in addition* to silver nitrate. Finally, the health departments of 33 states furnish silver nitrate for use as prophylaxis. No other prophylactic agent is similarly supplied by any state.

Paul C. Barsam, "Specific Prophylaxis of Gonorrheal Ophthalmia Neonatorum," *New England Journal of Medicine,* Vol. 274, pp. 731-734 (31 March 1966), at pp. 731-732.

A 1973 article cited an August 1968 compilation of state laws by the National Society for the Prevention of Blindness:

> The use of a prophylactic agent in the eyes of all newborn babies is required by law or regulation in 47 states and the District of Columbia. **....**
>
> Silver nitrate is the only prophylactic agent specified or approved for use in 15 states; in 33 states and the District of Columbia, silver nitrate or "other equally effective agent" may be used. In two states, a particular prophylactic agent is not designated.

Franklin M. Foote, et al., "Control of Ophthalmia Neonatorum," *The Sight-Saving Review,* Vol. 43, pp. 11-13 (Spring 1973), at p. 13.

In 1978, three groups in the USA (i.e., the National Society to Prevent Blindness, U.S. Government's Centers for Disease Control, and the American Academy of Pediatrics) issued new recommendations for prophylaxis of gonococcal ophthalmia neonatorum. These new recommendations required prophylaxis with either (1) 1% silver nitrate solution, (2) tetracycline ointment or solution, or (3) erythromycin ointment or solution. Three years after these new recommendations, 11 states continued to require 1% silver nitrate solution, with no alternatives.[28]

A 1986 survey of health departments in all fifty states, Washington, DC, and Puerto Rico found:

> Topical prophylaxis against gonococcal ophthalmia neonatorum is required by law in 49 of 52 health departments surveyed. Prophylactic eye care is not addressed in the health codes of Nebraska, North Dakota, and Vermont, although it was reported that it is widely practiced in these states. Eight departments provide for parental refusal of prophylaxis (three based on religion and five based on personal beliefs).

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[28] Hugh C. Dillon, Jr., "Prevention of Gonococcal Ophthalmia Neonatorum," *New England Journal of Medicine,* Vol. 315, pp. 1414-1415 (27 Nov 1986).

> Forty-two of the health departments allow for erythromycin or tetracycline as alternatives to silver nitrate. Five of the 42 permit any proven effective prophylaxis. Mississippi allows only erythromycin, and Pennsylvania allows only tetracycline as alternatives. In the states of Alaska and Maryland, topical eye prophylaxis is waived when parenteral antibiotics are given. The specified interval of time for prophylaxis varies from immediately to three hours after birth.
>
> Several states, in an attempt to avoid code revisions by legislative action, require that all current recommendations and future revisions should reflect those provided by the Centers for Disease Control.

Salvatore J. Caravella, David A. Clark, and Harry S. Dweck, "Health Codes for Newborn Care," *Pediatrics,* Vol. 80, pp. 1-5 (July 1987), at p. 2.

Summarizing this history, in 1957 statutes or regulations in 23 states specifically required silver nitrate prophylaxis of ophthalmia neonatorum and did not permit any other prophylactic agent, except for "investigative purposes" in seven states. Eight years later, in 1965, the number of states requiring only silver nitrate in routine practice (i.e., *not* "investigation purposes") had increased to 30. Ironically, between 1957 and 1965, while silver nitrate was becoming more popular with legislators, there were many publications in the medical literature showing that antibiotics were better (i.e., less irritation, more effective at preventing infection) than silver nitrate. In 1986, statutes in 5 states required only silver nitrate prophylaxis, largely as a result of legislators delegating the choice of prophylactic agent to the state health department.

4. November 2006 State Statutes

In November/December 2006, I searched all current[29] state statutes in the Westlaw database for each of the following queries:

- SILVER /3 NITRATE
- OPHTHALMIA NEONATORUM
- (PHYSICIAN MIDWIFE NURSE) /P EYE /P (PROPHYLA! PREVENT!)
- (BABY BIRTH NEW-BORN INFANT) /P (EYE OPHTHALMIA) /P (PROPHYLA! PREVENT!)

and found the following. Most of these current statutes are revisions of statutes originally enacted sometime during the years 1910-1940. I have *not* quoted here the statutes that require either (1) reporting of cases of ophthalmia neonatorum or (2) regulating midwives. In the citations below, I give the date of the first enactment of each statute (when that date is available in Westlaw) and the date of the most recent amendment. There are typically several amendments in between.

Alabama

> Any physician, midwife, nurse or other person in attendance on a confinement case shall, within two hours after the birth of the child, use one of the following prophylactic solutions for the prevention of infantile blindness or ophthalmia neonatorum, two drops of the solution to be dropped in each eye after the eyelids have been opened:

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[29] The Westlaw databases do *not* contain old state statutes, which have been repealed or amended.

(1) A one percent fresh solution of nitrate of silver, or
(2) Such other solution as may be prescribed by the State Board of Health.

Ala.Code § 22-20-2 (first enacted 1919, amended 1981).

California

It is the duty of any physician, surgeon, obstetrician, midwife, nurse, maternity home or hospital of any nature, parent, relative, and any person or persons attendant upon, or assisting in any way whatsoever, either the mother or child, or both, at childbirth, to treat both eyes of the infant within two hours after birth with a prophylactic efficient treatment, and
.... [reporting of ophthalmia neonatorum omitted].

California Business & Professional Code § 551 (first enacted 1937, amended 1978).

Colorado

(1) It is the duty of the department of public health and environment:
(a) To officially name and approve a prophylaxis to be used in treating the eyes of newly born infants, which may be a solution of nitrate of silver or such other prophylaxis as the board shall from time to time approve;
....

Colorado Statutes § 25-4-302 (first enacted 1935, amended 1977).

It is the duty of any physician, nurse, or other person who assists or is in charge at the birth of any infant or has the care of the same after birth to treat the eyes of the infant with a prophylaxis approved by the department of public health and environment. Such treatment shall be given as soon as practicable after the birth of the infant and always within one hour.
.... [reporting omitted]

Colorado Statutes § 25-4-303 (first enacted 1935, amended 1977).

Connecticut

(a) Any inflammation, swelling or unusual redness in the eyes of any infant, either apart from or with any unnatural discharge from the eyes of such infant, occurring at any time within two weeks after the birth of such infant, shall, for the purposes of this section, be designated as "inflammation of the eyes of the newborn". The person in attendance at the birth of any infant shall instill into the eyes of such infant, immediately after birth, a prophylactic preparation approved by the Department of Public Health for the purpose of preventing inflammation of the eyes of newborns. Any person who violates any provision of this section shall be fined not less than ten dollars nor more than fifty dollars.

(b) The prophylactic treatment required by subsection (a) of this section shall not apply to any infant whose parents object to the treatment as being in conflict with their religious tenets and practice. Any person who objects to such treatment shall indemnify attending medical personnel for expenses incurred in connection with any civil action based on lack of such treatment. For purposes of this subsection, "expenses" includes, but is not limited to, judgments, settlements, attorneys' fees and court costs.

Connecticut Statutes § 19a-219 (first enacted 1902, amended 1918, ..., 1997).

Delaware

(a) The Department of Health and Social Services shall regulate the type of prophylactic treatment to be employed against inflammation of the eye(s) of the newborn, the conditions under which such prophylaxis will be employed and the diseases for which reporting is required. Such regulation shall conform with standards promulgated by the United States Center for Disease Control, United States Public Health Service. A record of the prophylactic used and details thereof shall be recorded on the birth certificate.

(b) Nothing in this section shall require medical treatment for the minor child of any person who is a member of a recognized church or religious denomination and whose religious convictions, in accordance with the tenets and practices of the person's church or religious denomination, are against medical treatment for disease.

Delaware Code title 16, § 803 (first enacted 1917, amended 1995).

District of Columbia

The Mayor may, upon the advice of the Commissioner of Public Health and pursuant to subchapter I of Chapter 5 of Title 2, issue rules to prevent and monitor the occurrence of ophthalmia in newborns. Unless the Mayor provides otherwise, each physician or nurse-midwife who delivers or otherwise assumes the initial care of a newborn shall immediately upon that delivery or assumption of care administer to each eye of the newborn a 1% solution of silver nitrate, an ophthalmic ointment containing either 1% tetracycline or 0.5% erythromycin, or another prophylactic approved by the Mayor.

D.C. Statutes § 7-801 (first enacted 1937, amended 1986).

Florida

Every physician, midwife, or other person in attendance at the birth of a child in the state is required to instill or have instilled into the eyes of the baby within 1 hour after birth an effective prophylactic recommended by the Committee on Infectious Diseases of the American Academy of Pediatrics for the prevention of neonatal ophthalmia. This section does not apply to cases where the parents file with the physician, midwife, or other person in attendance at the birth of a child written objections on account of religious beliefs contrary to the use of drugs. In such case the physician, midwife, or other person in attendance shall maintain a record that such measures were or were not employed and attach thereto any written objection.

Florida Statutes § 383.04 (first enacted 1941, amended 1998).

Idaho

It shall be unlawful for any physician or midwife practicing midwifery to neglect, or otherwise fail to instill or have instilled immediately upon its birth, in the eyes of the newborn babe, some germicide of proved efficiency in preventing the development of ophthalmia neonatorum.

Idaho Code § 39-903 (first enacted 1921, still current).

Illinois

> **....** It shall be the duty of any physician, midwife or nurse who attends or assists at the birth of a child, to instill or have instilled in each eye of the new born baby, as soon as possible and not later than one hour after birth, a one per cent (1%) solution of silver nitrate or some other equally effective prophylactic for the prevention of ophthalmia neonatorum approved by the State Department of Public Health.

Illinois Compiled Statutes ch. 410, § 215/3 (first enacted 1915, amended 1933, still current).

Indiana

> A person in professional attendance at a birth shall carefully examine the eyes of the infant and if there is reason for suspecting infection in one (1) or both eyes, the person in professional attendance at the birth shall apply such prophylactic treatment as may be prescribed by the state department.

Indiana Code 16-41-15-6 (first enacted 1949, still current).

Iowa

> A physician attending the birth of a child shall cause to be instilled into the eyes of the newly born infant a prophylactic solution approved by the department. This section shall not be construed to require treatment of the infant's eyes with a prophylactic solution if the infant's parent or legal guardian states that such treatment conflicts with the tenets and practices of a recognized religious denomination of which the parent or legal guardian is an adherent or member.

Iowa Code § 139A.38 (first enacted 1921, amended 2000).

Kansas

> Any physician or any person authorized by law to act as an obstetrician shall immediately upon the birth of an infant instill into the eyes of such newly born infant a prophylactic solution approved by the secretary of health and environment: *Provided, however,* That any person or parent shall not be required to employ such prophylactic if objection is made by written statement to the attending obstetrician within three days from the birth of said child: *And provided further,* That said written statement shall be attached to the birth certificate.

Kansas Statute § 65-153b (first enacted 1929, amended 1974).

Louisiana

> A. All persons covered by the provisions of R.S. 40:1102 shall routinely apply or be reasonably certain that others have already applied any prophylactic which the department directs for the prevention of ophthalmia neonatorum, whether or not ophthalmia neonatorum is indicated, and to do so in the manner that the department directs. The provisions of this Section shall be inoperative in those instances where:
> (1) There are no indications of the existence of ophthalmia neonatorum; *and*[30]
> (2) The mother states in writing that she objects to the application of such prophylactic on religious grounds.

Louisiana Statute title 40, § 1103 (first enacted 1914, amended 1988).

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[30] Italics added by Standler.

Maine

> Every physician, midwife or nurse in charge shall instill or cause to be instilled into the eyes of an infant upon its birth one or 2 drops of a prophylactic solution prescribed by the department and provided without cost by the department, except an infant whose parents object to this procedure on the grounds that it conflicts with their religious tenets and practices. **....** [reporting inflammation omitted] Failure to comply with this section shall be punishable by a fine of not more than $100 or by imprisonment for not more than 6 months.

Maine Statutes, title 22, § 1531 (1954, amended 1983).

Maryland

> (a) Immediately after the birth of a child, the attending physician or attending nurse midwife shall use in the eyes of the child a prophylactic, approved by the Department, against gonococcal ophthalmia neonatorum.
> (b) **....**

Maryland Code Health § 18-308 (amended 1982).

Massachusetts

> The physician, or hospital medical officer registered under section nine of chapter one hundred and twelve, if any, personally attending the birth of a child shall treat his eyes within two hours after birth with a prophylactic remedy furnished or approved by the department. Whoever violates this section shall be punished by a fine of not more than one hundred dollars.

Massachusetts General Laws, ch. 111, § 109A (first enacted 1936, amended 1968).

Michigan

> A licensed health professional in charge of the care of a newborn infant, or if none, the licensed health professional in charge at the birth of an infant, shall treat the eyes of the infant with 1 or more of the prophylaxes approved by the department within 1 hour after the birth of the infant, or as soon after the birth of the infant as the health professional is present.
> **....** [reporting omitted]

Michigan Compiled Laws, ch. 333, § 5125 (first enacted 1913, amended 1978, 1989).

Minnesota

> The [state] commissioner [of health] may adopt reasonable rules pursuant to chapter 14 for the preservation of the public health. The rules shall not conflict with the charter or ordinance of a city of the first class upon the same subject. The commissioner may control, by rule, by requiring the taking out of licenses or permits, or by other appropriate means, any of the following matters:
> **....**
> (8) The prevention of infant blindness and infection of the eyes of the newly born by the designation, from time to time, of one or more prophylactics to be used in those cases and in the manner that the commissioner directs, unless specifically objected to by a parent of the infant; **....**

Minnesota Statutes, ch. 144, § 12 (amended 1987).

Mississippi

> It shall be the duty of the state board of health: **....**
> (3) to provide for the gratuitous distribution of a scientific prophylactic for inflammation of the eyes of the new born, together with proper directions for the use and administration thereof, to all physicians and midwives as may be engaged in the practice of obstetrics or assisting at childbirth; **....**

Mississippi Code § 41-35-7 (first enacted 1930, amended 1942, still current).

> It shall be the duty of the physicians, midwives, or other persons in attendance upon a case of childbirth in a maternity home, hospital, public or charitable institution, in every infant immediately after birth, to use some prophylactic against inflammation of the eyes of the new born and to make record of the prophylactic used. It shall be the duty of such institution to maintain such records of cases of inflammation of the eyes of the new born as the state board of health shall direct.
> **....** [duty of midwife omitted]

Mississippi Code § 41-35-9 (first enacted 1930, amended 1942, still current).

Missouri

> Every physician, midwife or nurse who shall be in attendance upon a newborn infant or its mother, shall drop into the eyes of such infant immediately after delivery, a prophylactic solution approved by the state department of health and senior services, and shall within forty-eight hours thereafter, report in writing to the board of health or county physician of the city, town or county where such birth occurs, his or her compliance with this section, stating the solution used by him or her.

Missouri Statutes § 210.070 (first enacted 1899, revised 1939, still current).

Nevada

> It shall be unlawful for any physician or midwife practicing midwifery to neglect or otherwise fail to instill or have instilled in the eyes of the newborn baby, immediately upon its birth, some germicide of proven efficiency in preventing the development of ophthalmia neonatorum.

Nevada Statute, title 40, § 442.050 (first enacted 1921, still current).

New Hampshire

> I. The physician, hospital, nurse midwife, midwife, or other health care provider attending a newborn child shall, after washing the lids and adjacent tissues immediately following birth, place into each eye of every child a single drop of a one percent solution of nitrate of silver or some equally efficient solution.
> II. **....** [reporting omitted]

N.H. Statutes § 132:6 (first enacted 1911, amended 1999).

North Dakota

> All physicians, midwives, or other persons in professional attendance upon a birth always shall examine the eyes of the infant carefully. If there is the least reason to suspect the presence of a disease of the eyes, such person shall apply such prophylactic treatment as may be recognized as efficient in medical science.

North Dakota Code § 23-07-10 (first enacted 1911, amended 1943, still current).

Ohio

> The department of health shall: **....**
> (C) Provide for the gratuitous distribution of a scientific prophylactic for inflammation of the eyes of the newborn, together with directions for its proper use and administration, to all physicians and certified nurse-midwives engaged in the practice of obstetrics or assisting at childbirth; **....**

Ohio Code § 3701.54 (effective 1996).

> Every physician, certified nurse-midwife, or other person in attendance at childbirth shall, immediately after the birth, use in the eyes of the newborn child some prophylactic against inflammation of the eyes of such child, and shall make a record on the birth certificate of the prophylactic used.

Ohio Code § 3701.55 (effective 1996).

Oklahoma

> It shall be unlawful for any physician, osteopath, chiropractor, or other person attendant upon the birth of a child to fail to instill immediately upon its birth, in both eyes of the newborn child, a one percent (1%) solution of nitrate of silver; provided, that the State Board of Health shall have authority to approve the use of antiseptics,[31] other than nitrate of silver, for use in the eyes of newborn children, and to prescribe the manner of their use. Should a physician or a parent of a child deem it best for the interests of the child not to use any prophylactic, he shall not be required to do so provided that he states fully, in writing, to the local health officer, within three (3) days from the birth of the child, the reason for not doing so.

Oklahoma Statutes, title 63, § 1-511 (first enacted 1921, amended 1963).

Rhode Island

> (a) Any diseased condition of the eye or eyes of an infant in which there is inflammation, redness, swelling, or any unnatural discharge at any time within two (2) weeks after birth shall, for the purpose of §§ 23-13-4 — 23-13-8 be deemed to be ophthalmia neonatorum.
> (b) It shall be the duty of the physician, nurse, or midwife attending the birth of an infant immediately after such birth to treat the eyes of that infant with any approved prophylactic remedy as may be recommended by the department of health.
> (c) **....** [midwives omitted]

Rhode Island General Laws 23-13-4 (first enacted 1914, amended 1979).

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[31] Strictly speaking, Oklahoma does not allow prophylaxis with antibiotics, which differ from antiseptics. In my opinion, the lack of understanding of the difference between antibiotics and antiseptics shows that Oklahoma legislators should not be telling physicians how to practice medicine.

South Carolina

> Every doctor, midwife, nurse or other person attending the delivery at birth of a child in this State shall instill, or have instilled, into the eyes of the baby, within one hour after birth, some effective prophylactic approved by the Department of Health and Environmental Control, for prevention of blindness from ophthalmia neonatorum. A record of such administration or instillation shall be reported on the birth certificate, showing the time with respect to the birth and the kind of prophylactic administered.

South Carolina Code § 44-37-20 (first enacted 1939, amended 1962).

South Dakota

> Any physician, surgeon, obstetrician, nurse, or midwife in attendance on or having charge of a case of childbirth shall, immediately after the birth of the infant for the prevention of ophthalmia neonatorum, use such prophylactic measures as are approved for such purpose by the State Department of Health, unless specifically objected to by the parents or parent or guardian of the infant.

South Dakota Laws § 34-24-8 (first enacted 1925, amended 1978).

Tennessee

> (a) It is the duty of any physician, nurse or midwife, who assists and is in charge at the birth of any infant, or has the care of the same after birth, to treat the eyes of the infant with a prophylaxis approved by the department of health; and such a treatment shall be given as soon as practicable after the birth of the infant and always within one (1) hour; and
> **....** [reporting omitted]

Tennessee Code § 68-5-202 (first enacted 1915, amended 1989).

Texas

> (a) A physician, nurse, midwife, or other person in attendance at childbirth shall use or cause to be used prophylaxis approved by the board to prevent ophthalmia neonatorum.
> (b) **....**

Texas Health & Safety Code § 81.091 (amended 2001).

Virginia

> In order to prevent ophthalmia neonatorum, the physician, nurse or midwife in charge of the delivery of a baby or, if none, the first attending physician shall, immediately after the baby's birth, perform upon such baby the procedure prescribed by the Board. Such action shall be duly recorded in the medical record of the baby.

Virginia Code § 32.1-62 (amended 1979).

West Virginia

> It shall be unlawful for any physician, nurse-midwife or midwife, practicing midwifery, or other health care professional to neglect or otherwise fail to instill or have instilled, immediately upon its birth, in the eyes of the newborn babe, the contents of a single-use tube of an ophthalmic ointment containing one percent tetracycline or one half of one percent erythromycin or the equivalent dosage of such medications or other appropriate medication approved by the director for prevention of inflammation of the eyes of the newborn. Every physician, nurse-midwife or midwife or other health care professional shall, in making a report of a birth, state the name of the appropriate medication which was instilled into the eyes of said infant. The director shall establish a list of appropriate medications for prevention of inflammation of the eyes of the newborn. The list shall be kept current and distributed to appropriate health care facilities and such other sources as the director may determine to be necessary.

West Virginia Code § 16-3-10 (first enacted 1919, amended 1981).

> It shall be the duty of the state director of health:
> (a) To enforce the provisions of sections seven through thirteen, inclusive, of this article;
> (b) To provide for the gratuitous distribution of one percent solution of silver nitrate outfits,[32] together with proper directions for the use and administration thereof, to all physicians and midwives who may be engaged in the practice of obstetrics, or assisting at childbirth;
> (c) **....**

West Virginia Code § 16-3-12 (first enacted 1919, amended 1977).

Wisconsin

> (1) For the prevention of ophthalmia neonatorum or infant blindness the attending physician or midwife shall use a prophylactic agent approved by the department.
> (2) **....**

Wisconsin Statutes § 253.11 (first enacted 1909, amended 1993).

my comments

A 1986 survey of health departments in all fifty states and Washington, DC found that 47 states plus DC had statutes or regulations requiring prophylaxis against ophthalmia neonatorum.[33] Only Nebraska, North Dakota, and Vermont did not have such legal requirement in 1986. However, my searches of state statutes in Nov/Dec 2006, show only 32 states plus DC have such statutes. I am unable to explain the discrepancy of 15 states. It may be that my searches failed to find *all* of the state statutes. It may be that some states require prophylaxis in *regulations*

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[32] Note the inconsistency in West Virginia statutes. Section 10 requires tetracycline, erythromycin, or "other appropriate medicine" determined by the state health department. But section 12(b) continues the old requirement of requiring the state director of health to give away free silver nitrate solution.

[33] See the paper by Caravella, Clark, and Dweck, which was quoted above at page 14.

from the state health department (e.g., see Minnesota, above), which regulations are authorized in some general state statutes that escaped my searches specifically for ophthalmia or eye(s).

In my opinion, prophylaxis against ophthalmia neonatorum is *not* a subject for legislation. Instead, it is one of many things that a physician or midwife should do at birth, in order to provide competent care. Minimum standards for competent care can be developed by medical societies (e.g., ophthalmologists or pediatricians). Alternatively, standards can be written by committees of local physicians who write a standard operating procedure for use by their hospital, as a checklist to prevent errors. Such standards can be used by licensing boards of state governments, as well as by juries in medical malpractice trials, to determine competent practice of medicine.

In my opinion, the best of these current statutes (e.g., California, Idaho, Mississippi, Nevada, North Dakota, Ohio) require some kind of efficacious prophylaxis, but leave the choice of drug to the attending physician. New Hampshire's statute mentions 1% silver nitrate as the standard of efficacy, but allows the physician to use any drug that is at least as effective as silver nitrate.

The most common current statutes (e.g., Colorado, Connecticut, Delaware, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Virginia, Wisconsin) require use of a drug chosen by the state health department. At least the legislature or other politicians are not choosing drugs, but one wonders if the state health department is current in its reading of specialty medical journals (e.g., ophthalmology and pediatrics) or if the health department recognizes *all* of the special cases where an alternative drug might be more appropriate for a specific patient. Alabama, Illinois, and Oklahoma specify *either* silver nitrate *or* some other prophylaxis approved by the state health department, which makes silver nitrate acceptable, even if the state health department were opposed to silver nitrate. Florida delegates the choice of drug to a committee of the American Academy of Pediatrics — one wonders what will happen if the AAP disbands their committee or if the committee stops recommending drugs.

The worst of these statutes — thankfully all now repealed — specifically required silver nitrate, with no alternative. Suffering from the same legislative design flaw, but recognizing better medical practice, are those statutes (e.g., District of Columbia, West Virginia) that require specific antibiotics.

Particularly egregious is the District of Columbia, which permits the *mayor* (!) to approve a prophylactic agent other than silver nitrate, tetracycline, or erythromycin.

In November 2006 — more than fifty years after silver nitrate prophylaxis became obsolete because of antibiotics — six states' statutes (e.g., Alabama, Colorado, District of Columbia, Illinois, New Hampshire, and Oklahoma) continue to mention silver nitrate. In the year 1995, medical journals reported a successful clinical trial of povidone-iodine, for prophylaxis of ophthalmia neonatorum, but eleven years later, no state statute mentions povidone-iodine.

This delay shows the reluctance of legislatures to amend statutes to conform to modern scientific discoveries, which means that it is *not* appropriate to specify a particular drug or method in a statute.

Conclusion

A drop of silver nitrate solution in each eye of a newborn infant was the *only* effective prophylaxis for gonococcal ophthalmia neonatorum prior to the availability of penicillin in the 1940s. However, it was a mistake for legislatures to write this specific silver nitrate prophylaxis into statutes for several reasons:

1. New drugs — both antibiotics (e.g., penicillin, erythromycin, tetracycline) and antiseptics (e.g., povidone-iodine) — became available.
2. The specific prescription of silver nitrate in statute may have discouraged physicians and drug companies from doing research to find better (e.g., less irritating, more effective) prophylactic agents than silver nitrate.
3. Even if silver nitrate were the drug of choice for nearly all patients, prescribing it in statute usurps the role of the attending physician to choose another drug for good reason(s) in a specific patient.

The point of this essay is that — because of continually changing pharmacopeia, changing clinical importance of pathogens, bacteria developing resistance to antibiotics, current local conditions, etc. — the choice of drug(s) should be made by the treating physician, *not* by politicians in the legislature.

The history of American experience with state statutes that require a drop of silver nitrate solution to be placed in the eye of every newborn infant should be a lesson for legislators. The appropriate choice of a specific drug or method of treatment should be made by the attending physician, *not* by politicians in the legislature.

This document is at **www.rbs2.com/SilvNitr.pdf**
My most recent search for cases and statutes on this topic was in December 2006.
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