



Ophthalmia neonatorum caused by *N gonorrhoeae* or *C trachomatis*

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Background

Ophthalmia neonatorum (ON) is defined as conjunctivitis occurring within the first four weeks of life (1). Originally ON referred to infections caused by *Neisseria gonorrhoeae*, but it has been extended to include any conjunctivitis in this age group. *N gonorrhoeae* accounts for less than 1% of reported cases of ON in the United States and *C trachomatis* account for from 2% to 40% (1). These organisms are usually acquired from the mother during delivery. Without preventive measures, gonococcal ophthalmia neonatorum (GON) occurs in 30% of infants exposed during delivery (2, 3) and without treatment may progress rapidly to severe disease. Infants born to women with untreated chlamydia infection at delivery have a 30% to 50% risk of developing chlamydial ophthalmia neonatorum (CON) and a 10% to 20% risk of developing chlamydia pneumonia (4).



Silver nitrate prophylaxis against *N gonorrhoeae* ophthalmia neonatorum, first used by Dr. Carl Credé in 1880 (5) was an important preventive medicine advance in the pre-antibiotic era, at a time when there was no effective treatment for gonorrhea. Nevertheless, silver nitrate was not a perfect agent because it caused transient chemical conjunctivitis in 50% to 90% of infants. Silver nitrate eye drops are no longer available in Canada. Currently, erythromycin is the only product available in Canada for neonatal ocular prophylaxis.

However, failures have been reported and universal ocular prophylaxis was discontinued decades ago in several high-income European countries (6). In Canada, there is variation between provinces regarding laws about ocular prophylaxis. Routine screening and treatment of pregnant women for *N gonorrhoeae* and *C trachomatis* is now considered to be the standard of care in most developed countries and has been recommended in Canada since the mid-1990s (7–9).

National surveillance for GON and CON was discontinued in Canada in 2000 because of the low incidence (10). Infection rates are reported for infants less than 1 year of age. The average national rate between 2000 and 2016 was 5.5 per 100,000 for chlamydia infection and 0.5 per 100,000 for gonorrhea (11), with variability between provinces.

In March 2015, the Canadian Paediatric Society published a statement recommending discontinuation of mandatory ocular prophylaxis for ON because of questionable efficacy of erythromycin, and advocated enhancement of programs for routine screening and treatment of pregnant women (12). There are concerns about the implementation and effectiveness of screening and testing in pregnancy and fears that discontinuation of erythromycin ocular prophylaxis could result in increased rates of GON and CON (13). The fact that ON is no longer a notifiable disease nationally and in many provinces has raised concerns about the surveillance data available, and the ability to monitor the effect of changing policies.

Methods

Through the established methodology of the Canadian Paediatric Surveillance Program (CPSP), over 2,700 paediatricians and paediatric subspecialists will be actively surveyed monthly for new cases of gonococcal and chlamydial ophthalmia neonatorum. Participants will be asked to complete a detailed questionnaire for each case reported. Data to be collected will include the following, among others: patient demographics; information on maternal prenatal care, screening, treatment, and follow-up for *N gonorrhoeae* or *C trachomatis*; maternal risk factors for acquisition of sexually transmitted infections in pregnancy; premature rupture of membranes, perinatal history, and ocular prophylaxis; the infant's clinical presentation, microbiological results (including if *N gonorrhoeae* is isolated), and sensitivity to erythromycin; treatment and outcome.



Ophthalmia neonatorum (continued)

Case definition

Any patient less than 28 days of age (4 weeks) at onset of symptoms, with clinical features of ophthalmia neonatorum including at least one of the following:

- Conjunctival/ocular erythema
- Conjunctival/ocular discharge
- Conjunctival and/or peri-ocular swelling

AND

N gonorrhoeae isolated in culture or identified by nucleic acid amplification test in specimens from the eye, blood, CSF, or other sterile site

OR

C trachomatis isolated in culture or identified by nucleic acid amplification test in specimens from the eye, nasopharynx, or other respiratory tract specimen

Exclusion criteria

- Ophthalmia neonatorum associated with another microorganism

Objectives

- 1) Determine a minimum incidence rate of GON and CON in Canada.
- 2) Determine if infection rates differ in jurisdictions with mandatory ocular prophylaxis versus those without, noting that laws and protocols for mandatory prophylaxis may change during the surveillance period.
- 3) Determine if the Canadian Notifiable Disease Surveillance System reliably captures cases of ON in declarations of *N gonorrhoeae* and *C trachomatis* in children aged less than 1 year.

Duration

November 2018 to October 2020

Expected number of cases

Any gonorrhoea or chlamydia infections in children less than 1 year old are notifiable through the Canadian Notifiable Disease Surveillance System (CNDSS). Between 2000 and 2016 there were 33 cases of *N gonorrhoeae* infection (annual average of 1.9) and 336 cases of *C trachomatis* infection (annual average of 19.8) in infants less than 1 year old reported to the CNDSS (11). However, the data reflect all presentations of gonorrhoea or chlamydia infections in this age group and did not specify the number of GON and CON cases. Based on the available data it is estimated that there will be fewer than 5 cases of GON and 15 to 25 cases of CON annually.



Study limitations

Paediatricians and paediatric subspecialists participate in the CPSP on a voluntary basis. As with any voluntary reporting surveillance system, the CPSP recognizes that reporting on minimum incidence rates can have limitations, including under-representation of the disease/condition in the population. It is possible that not all cases will be reported. For example, cases from Northern communities might be under-represented, as very few paediatricians practise in these areas. However, surveillance data would be obtained if cases from Northern regions are transferred to referral centres for investigation and/or treatment by a paediatrician or paediatric subspecialist.

Despite its limitations, surveillance serves a very important purpose by providing rich clinical data that allow for a better understanding of the diagnosis, treatment, and preventive approaches of a specific disease/condition. Surveillance systems can also collect timely results that can accurately detect a trend that may lead to changes to medical practice or public health policies.

Ethics approval

Health Canada and the Public Health Agency of Canada's Research Ethics Board

Analysis and publication

The minimal incidence rates per 100,000 live births will be calculated using population data. Numbers of cases will be compared with those reported for children less than 1 year of age in the Canadian Notifiable Disease Surveillance System.

For data analysis, descriptive statistics will be used to summarize data. Proportions of infections occurring in infants of mothers who were screened in pregnancy, in infants of mothers who were treated in pregnancy, and in infants who received ocular prophylaxis will be determined.

Data analysis will be completed within six months of the closure of the study. Results will be presented at scientific meetings and submitted for publication in scientific peer-reviewed journals. Knowledge translation will provide information on infection rates and the potential effect of changing neonatal ocular prophylaxis practices on these rates.

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Ophthalmia neonatorum (continued)

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