

## Guidelines for Testing and Treatment of Gonorrhoea in Ontario, 2013

# Frequently Asked Questions

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## Background

### Q: Why are these Guidelines needed?

**A:** Based on available evidence there is the immediate threat of increasing cephalosporin resistance in *Neisseria gonorrhoeae* (*N. gonorrhoeae*) in Ontario and worldwide. Cephalosporins are the last available class of antibiotics recommended for the treatment of gonorrhoea. Antibiotic resistance in *N. gonorrhoeae* increases the risk of clinical failure and sequelae in an infected individual. Furthermore, inadequate treatment of antibiotic-resistant gonorrhoea can lead to the selection of drug-resistant strains, increasing the risk of untreatable gonorrhoea spreading more broadly in the population. These guidelines have been developed to address the cephalosporin resistance in *N. gonorrhoeae* by providing recommendations for testing, screening, treatment and follow-up for *N. gonorrhoeae* infections.

### Q: What are the differences between the Guidelines for Testing and Treatment of Gonorrhoea in Ontario, 2013 and the Canadian Guidelines on Sexually Transmitted Infections?

**A:** The *Canadian Guidelines on Sexually Transmitted Infections* (CGSTI), produced by the Public Health Agency of Canada, provide national recommendations for the prevention, diagnosis, treatment and management of STIs. The *Guidelines for Testing and Treatment of Gonorrhoea in Ontario, 2013* document, are the first Ontario-specific recommendations for the testing, treatment, and follow-up guidelines for gonorrhoea.

The *Guidelines for Testing and Treatment of Gonorrhoea in Ontario, 2013* are based on current scientific evidence and Ontario-specific epidemiology of gonorrhoea, including resistance profiles of *N. gonorrhoeae* in the province, and therefore differ somewhat from the CGSTI. Ontario is currently experiencing changes in the susceptibility of *N. gonorrhoeae* to antibiotics, and current treatment recommendations in the *Canadian Guidelines on Sexually Transmitted Infections* do not ensure adequate treatment.

**Q: Why are the changes in treatment necessary?**

**A:** Historically *N. gonorrhoeae* has developed resistance to all drugs used to treat it, including the sulfonamides, penicillin, tetracycline, and the fluoroquinolones, leaving the cephalosporins as the only antibiotic available to effectively treat *N. gonorrhoeae*. The cephalosporins recommended for the treatment of gonorrhoea include cefixime, an oral antibiotic and ceftriaxone, an injectable antibiotic.

In Ontario, decreasing susceptibility of *N. gonorrhoeae* to oral cefixime has been identified. As a result, oral cefixime is no longer considered an effective medication for the treatment of gonorrhoea in Ontario. To ensure cases of gonorrhoea receive adequate treatment, intramuscular ceftriaxone with the addition of oral azithromycin is now considered first line therapy for the treatment of gonorrhoea in Ontario.

Public Health Ontario (PHO) reviewed scientific evidence and consulted with experts from other countries that are experiencing similar changes in gonorrhoea susceptibility. These new treatment recommendations are similar to the treatment recommendations by the Center for Disease Control and Prevention, aimed to effectively treat gonorrhoea given current trends of antimicrobial resistance and progression of antimicrobial resistance in Ontario.

## Treatment Recommendations

**Q: What is the new recommended treatment for uncomplicated gonorrhoea based on Ontario epidemiology?**

**A:** First-line treatment for persons above nine years of age (including pregnant women and nursing mothers) with confirmed or suspected uncomplicated urogenital gonorrhoea (cervix, vagina, pharynx or rectum) and their sex partners is

*Ceftriaxone 250 mg x1 intramuscularly plus azithromycin 1 g x 1 orally*

**Q: Is the first line treatment recommendation ceftriaxone 250 mg IM plus azithromycin 1g PO safe in pregnancy?**

**A:** Yes, ceftriaxone 250 mg IM and azithromycin 1g PO are both safe if administered during pregnancy.

**Q: What do I do if my patient has an allergy to penicillin?**

**A:** Beta-lactams which include penicillins and cephalosporins (such as cefixime and ceftriaxone) are generally very safe, and only a small number of patients that are told that they have a penicillin allergy will have any reaction if they take one of these drugs. The estimated rates of severe reactions to the administration of a cephalosporin to an individual with a history of a penicillin allergy are between 0.0001 and 0.1%.

Patients with a history of a severe reaction to penicillin, or any allergic reaction to the cephalosporins should be prescribed a non-cephalosporin based regimen for any suspected or confirmed gonorrhea infection and referred to a drug allergy clinic if available. Therapies to consider in this context include spectinomycin 2 g intramuscularly plus azithromycin 1 g orally, or azithromycin 2 g orally. It is important to note that both of these treatments do require a test of cure.

**Q: What do I do if my patient has an allergy to azithromycin?**

**A:** Allergies to azithromycin are extremely rare. In the instance of allergy to azithromycin, doxycycline 100 mg PO BID x 7 days plus ceftriaxone 250 mg IM is recommended.

**Q: Can ceftriaxone 250 mg IM be used for empiric treatment while waiting for results?**

**A:** Yes, Ceftriaxone 250 mg intramuscularly plus azithromycin 1 g orally is recommended as first line treatment for suspect and confirmed cases of gonorrhea. This includes use for empiric therapy based on symptoms and/or risk factors even when test results are not yet available.

**Q: Is the azithromycin being used to treat chlamydia or gonorrhea?**

**A:** Yes, azithromycin is being used to treat gonorrhea, with recognition that it is also effective in the treatment of chlamydia.

**Q: Why is it recommended we use two antimicrobials to treat gonorrhea?**

**A:** Treatment of gonorrhea with two antimicrobials is recommended on the theoretical basis that this may offer synergistic therapy, potentially improving treatment efficacy and delaying the emergence and spread of resistance in *N. gonorrhoeae*. Cephalosporin – azithromycin combination therapy has also been found to be more effective in treating pharyngeal infections, which are usually asymptomatic.

**Q: If an individual was treated only with ceftriaxone, would you advise that I re-treat with both azithromycin and ceftriaxone?**

**A:** In the situation where an individual was not treated with first line therapy, a test of cure is recommended to ensure the infection has been cleared.

For test of cure, regardless of presence or absence of symptoms, the preferred testing method is culture. Test of cure using culture should be performed after four days post-treatment. If culture is not locally available, NAAT testing is a second-line option, but should be performed at earliest two weeks post-treatment.

If infection is cleared, no additional treatment is necessary. If gonorrhoea infection is still present, treatment with both ceftriaxone and azithromycin is recommended. Chlamydia testing should also be ruled out as a possible co-infection for all individuals who have been identified with gonorrhoea. If chlamydia infection is identified, treatment is suggested as per the CGSTI.

**Q: Why is the recommendation for second line treatment 400 mg of cefixime with azithromycin and not 800mg of cefixime?**

**A:** In Canada, the CGSTI have retained the use of cefixime at a higher dose of 800 mg as a potential first-line cephalosporin agent for gonorrhoea infections with the exception of pharyngeal infections and infections in the men who have sex with men population. However, there is a lack of scientific evidence to support the superiority of 800 mg over 400 mg of cefixime. In Ontario, cefixime is not considered optimal therapy for the treatment of gonorrhoea at any dose.

**Q: How long do cases have to abstain from sex following this new treatment?**

**A:** Patients and contacts should abstain from unprotected intercourse until 7 days post treatment. There is no change to the recommended amount of time individuals need to abstain from sexual activity after treatment with the new first line recommended therapy.

## Treatment of Contacts

**Q: What should I use to treat an asymptomatic contact?**

**A:** First-line treatment is recommended for the treatment of asymptomatic sexual contacts of cases.

First-line treatment is

Ceftriaxone 250 mg x 1 intramuscularly plus azithromycin 1 g x 1 orally

First-line treatment is recommended for suspect and confirmed cases of gonorrhoea. To reduce the transmission of gonorrhoea, first-line therapy is recommended for empiric therapy based on symptoms or risk factors. This recommendation includes the treatment of asymptomatic and symptomatic contacts.

## Administration and Access to STI medications

**Q: Who is eligible to access publicly-funded STI medications in Ontario?**

**A:** In Ontario, STI medications are available at no cost to clients with an STI (i.e., laboratory confirmed case or those requiring empiric treatment) to ensure timely and effective treatment and reduced transmission of infections.

To order publicly-funded STI medications, please contact your local public health unit. To find the public health unit nearest you, please visit:

<http://www.health.gov.on.ca/en/common/system/services/phu/locations.aspx>

**Q: Should health care practitioners keep a limited stock of STI medications in the clinic?**

**A:** Yes. To ensure timely treatment of patients and reduced transmission of STIs, it is recommended that health care practitioners keep a limited stock of STI medications in their clinic. Please discuss with your local public health unit to determine the specific amount of STI medications required for your clinic. Contact details for public health unit can be found at: <http://www.health.gov.on.ca/en/common/system/services/phu/locations.aspx>

**Q: Are health care practitioners encouraged to provide treatment at their clinics to the clients with a reportable STI, or those requiring empiric treatments for an STI?**

**A:** Yes, it is strongly recommended that health care practitioners provide treatment of clients with an STI (i.e., laboratory confirmed case or those requiring empiric treatment) at their clinic. Timely treatment of STIs is important.

**Q: How should the ceftriaxone for IM injection be stored?**

**A:** Ceftriaxone for injection sterile powder should be stored at 15-30°C and protected from light.

**Q: What diluents should be used for reconstitution of ceftriaxone for IM injection?**

**A:** For detailed information about the agent used as a diluent for the specific product received from your local health unit please refer to a **Product Monograph** enclosed within the package of vials.

**Q: Should ceftriaxone 250 mg IM be administered with safety engineered needles?**

**A:** As per Needle Safety Ontario Regulation 474/07 safety engineered needles are required unless specified under Section 4(3) Ontario Regulation 474/07. Ontario Regulation 474/07 can be found at: [http://www.e-laws.gov.on.ca/html/regs/english/elaws\\_regs\\_070474\\_e.htm](http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_070474_e.htm)

## Treatment Failure

**Q: What is the definition of gonorrhoea treatment failure?**

**A:** Gonorrhoea treatment failures are defined as treated individuals with confirmed gonorrhoea and a positive test of cure (NAAT or culture) in the absence of risk of reinfection (i.e., patient denies potential sexual re-exposure).

**Q: What do I do if I am concerned that my patient has failed treatment?**

**A:** If first-line therapy was used, suspected or confirmed treatment failures should be re-treated with a higher dose of ceftriaxone and azithromycin (1 g ceftriaxone IM + 2 g azithromycin), and a test of cure using culture should be performed three to four days post re-treatment. If first-line treatment was not used initially, you are encouraged to use the first-line treatment.

Health care practitioners should report any suspected or confirmed gonorrhoea treatment failures to your local public health unit.

Once notified of a suspect or confirmed case of gonorrhoea treatment failure, the local health unit will work with the responsible health care practitioner to complete Public Health Ontario's (PHO) enhanced surveillance form for gonorrhoea treatment failures, and notify PHO of the suspected or confirmed case as soon as possible to discuss any further public health action that may be required.

**Q: Why do I need to disclose treatment failures to my local Public Health Unit and Public Health Ontario?**

**A:** It is imperative for Ontario to maintain adequate surveillance of multi-drug resistant *N. gonorrhoeae* to ensure individuals are being treated effectively for gonorrhoea and to limit ongoing transmission. In order to do this, community health care practitioners, local public health units and Public Health Ontario must work together to make sure each is aware of treatment failures.

## Case Follow-Up

**Q: When should treated cases of gonorrhoea be rescreened?**

**A:** Individuals diagnosed with gonorrhoea are at high risk of reinfection, as seen in Ontario data. Consistent with the CGSTI, rescreening is recommended for all individuals who are diagnosed with gonorrhoea six months after initial diagnosis **or when they next seek medical care within the next 12 months.**

## Resources

**Q: Where can I go to get more information?**

**A:** There are several resources to turn to for more information regarding multi-drug resistant *N. gonorrhoeae*, the Ontario treatment recommendations and how to access publicly funded medication.

Your local health unit is always a good resource to turn to with questions regarding gonorrhoea testing or treatment.

To access the *Guidelines for Testing and Treatment of Gonorrhoea in Ontario, 2013* please visit the Public Health Ontario website <http://www.oahpp.ca/resources/gonorrhoea-guideline.html>

To access information regarding the provision of publicly funded medications please visit the Ministry of Health and Long Term Care website <http://www.health.gov.on.ca/en/>.