

Gonorrhea

Investigative Guidelines January 2021

1. DISEASE REPORTING

1.1 Purpose of Reporting and Surveillance

- 1. To assess trends in disease patterns, understand the impact of gonorrhea and better target population-level disease prevention efforts.
- 2. To assure adequate treatment for infected individuals, curtail infectiousness, prevent complications (e.g., infertility), and monitor for drug resistance.
- 3. To prevent transmission by identifying, informing, and referring to treatment recent sexual contacts of reported cases, and screening others at risk.

1.2 Legal Reporting Requirements

- 1. Health care providers must report a diagnosed or suspected case of gonorrhea within one working day to the Local Public Health Authority (LPHA) (OAR 333-018-0015).
- Laboratories must report all positive test results indicative of gonorrhea infection to the LPHA of the county where the patient resides within one working day from the time of positive result.

1.3 Local Health Jurisdiction Investigation Responsibilities

- 1. Begin follow-up case investigation within two working days of receiving the case report.
- 2. Report all presumptive and confirmed cases to the Public Health Division HIV/STD/TB (HST) Program through the Oregon Public Health Epidemiology User System (Orpheus) by the end of the calendar week of initial provider or laboratory report.

2. DISEASE AND EPIDEMIOLOGY

2.1 Etiologic Agent

Gonococcal (GC) infection caused by Neisseria gonorrhoeae bacterium

2.2 Description of Illness

- 1. Sites of infection include the urethra, endocervix, rectum, pharynx, and conjunctiva of the eye
 - A. Men with urethral gonorrhea are generally symptomatic. Symptomatic men usually have purulent urethral discharge, often accompanied by painful urination.
 - B. Most women with urogenital gonorrhea are asymptomatic. Symptomatic women may have abnormal vaginal discharge, abnormal menses, pelvic pain, or painful urination.
- 2. Extragenital infections are typically asymptomatic
 - A. Symptoms of pharyngeal infections may include pharyngitis, tonsillitis, or fever

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- B. Symptoms of rectal infections may include discharge, itching, soreness, bleeding, or painful bowel movements
- 3. Untreated GC may cause the following complications
 - A. Pelvic inflammatory disease (PID), ectopic pregnancy, premature delivery, infertility, epididymitis, urethral strictures, and disseminated gonococcal infection
 - B. Ophthalmia neonatorum (conjunctivitis) may occur in newborns of untreated mothers

2.3 Reservoirs

Humans

2.4 Sources and Modes of Transmission

Contact with secretions from mucous membranes of infected people during vaginal, anal, and oral sex.

Neonatal infection occurs during vaginal delivery if an infected mother has not received treatment.

2.5 Incubation Period

Among men, the incubation period ranges from 1 to 14 days, with symptoms typically occurring within 2-5 days of exposure.

Among women, the incubation period is variable. Symptoms, when they occur, usually appear within 10 days of exposure.

2.6 Period of Communicability

Gonorrhea is communicable from the time the infection is acquired until adequate treatment is received. Effective treatment ends communicability within hours.

2.7 Treatment

Ceftriaxone is the last remaining antibiotic known to be highly effective against *N. gonorrhoeae*. As of December 2020, dual therapy for gonorrhea is no longer recommended. See Box 1 for current gonorrhea treatment recommendations.

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BOX 1. CDC recommended regimens for uncomplicated gonococcal infections, 2020

Regimen for uncomplicated gonorrhea of the cervix, urethra, or rectum:

Ceftriaxone 500 mg IM as a single dose for persons weighing <300 lb

- For persons weighing ≥300 lb, 1 g of IM ceftriaxone should be administered.
- If chlamydia has not been excluded, add doxycycline 100 mg orally twice daily for 7 days. If pregnancy, doxycycline allergy, or adherence concerns are present, add azithromycin 1 g as a single dose instead.

Alternative regimen for uncomplicated gonorrhea of the cervix, urethra, or rectum if ceftriaxone is not available:

Cefixime 800 mg orally as a single dose.

• If chlamydia has not been excluded, add doxycycline 100 mg orally twice daily for 7 days. If pregnancy, doxycycline allergy, or adherence concerns are present, add azithromycin 1 g as a single dose instead.

Alternative regimen for uncomplicated gonorrhea of the cervix, urethra, or rectum if cephalosporin or penicillin allergy:

Gentamicin 240 mg IM as a single dose plus azithromycin 2 g orally as a single dose

- This regimen also treats chlamydia. No additional antibiotics are necessary.
- If azithromycin allergy, add doxycycline 100 mg twice a day x 14 days instead.

Recommended regimen for uncomplicated gonorrhea of the pharynx:

Ceftriaxone 500 mg IM as a single dose for persons weighing <300 lb

- For persons weighing ≥300 lb, 1 g of IM ceftriaxone should be administered.
- If chlamydia coinfection (any site) is identified when pharyngeal gonorrhea testing is performed, treat for chlamydia with doxycycline 100 mg orally twice a day for 7 days. If pregnancy, doxycycline allergy, or adherence concerns are present, add azithromycin 1 g as a single dose instead.
- No reliable alternative treatments are available for pharyngeal gonorrhea. For
 persons with an anaphylactic or other severe reaction (e.g., Stevens Johnson
 syndrome) to ceftriaxone, consult an infectious disease specialist for an alternative
 treatment recommendation.

Abbreviation: IM = intramuscular

Penicillin Allergy

Use of ceftriaxone or cefixime is contraindicated in individuals with a history of IgE-mediated penicillin allergy (e.g., anaphylaxis). See the CDC penicillin allergy factsheet for guidance on evaluating patient-reported penicillin allergy.

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2.8 Expedited Partner Therapy

Expedited partner therapy (EPT) is the practice of providing patients diagnosed with GC or chlamydia (CT) with a prescription or medication to be given to partners who are unable or unlikely to seek prompt medical care. See Box 2 for the EPT regimen for gonorrhea. All partners in the 60 days prior to diagnosis should be considered at risk for infection and treated. If the patient reports no partners in previous 60 days, the most recent partner(s) should be treated.

Visit the <u>OHA STD Program</u> site for the most current EPT guidelines and LPHA standard operating procedure for dispensing EPT. Refer pharmacists unfamiliar with the practice to the EPT materials on the <u>Board of Pharmacy</u> site.

BOX 2. EPT Regimen for Gonorrhea

Cefixime 800 mg orally as a single dose.

• If chlamydia has not been excluded, add doxycycline 100 mg orally twice daily for 7 days. During pregnancy, add azithromycin 1 g as a single dose instead.

2.9 Pre-Exposure Prophylaxis (PrEP)

All men who have sex with men (MSM) with rectal GC and women with GC should be offered pre-exposure prophylaxis (PrEP) for the prevention of HIV infection.

3. CASE DEFINITIONS, DIAGNOSIS, AND LABORATORY SERVICES

3.1 Gonorrhea Case Definition and Diagnosis

1. Clinical Description

A sexually transmitted infection commonly manifested by urethritis, cervicitis, proctitis, salpingitis, or pharyngitis. Infection many be asymptomatic.

- 2. Laboratory Criteria
 - A. Observation of gram-negative intracellular diplococci in a urethral smear obtained from a male or an endocervical smear obtained from a female, **OR**
 - B. Isolation of typical gram-negative, oxidase-positive diplococci by culture from a clinical specimen, **OR**
 - C. Demonstration of *N. gonorrhoeae* in a clinical specimen by detection of antigen or nucleic acid (NAAT)
- 3. Case Classification
 - Confirmed: A case that meets laboratory criteria B or C above
 - Presumptive: A case that meets laboratory criteria A above
 - Suspect Case: Do not use. If case does not meet the confirmed case definition, use "no case" status in Orpheus to reflect investigation of an unconfirmed case or when de-duplicating a laboratory report.
 - Guidance for determining when to report a positive laboratory report as a new case and de-duplication of laboratory reports can be found on the CDC website at https://www.cdc.gov/std/laboratory/.

3.2 Extragenital Screening

Extragenital screening should be routinely incorporated into STD prevention services. Men who have sex with men (MSM) are highly vulnerable to extragenital gonorrhea and chlamydia infections. Among MSM, nearly 90% of rectal chlamydia and rectal gonococcal

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infections are asymptomatic. Screening only urine would miss more than 75% of these infections. Among heterosexual women, screening only urine would miss up to 50% of rectal chlamydia and rectal gonococcal infections.

Non-urethral GC infections are typically asymptomatic. Persons with pharyngeal GC infections may have pharyngitis, tonsillitis, or fever. Persons with rectal GC infections may have discharge, itching, soreness, bleeding, or painful bowel movements.

The following strategies may improve implementation and uptake of extragenital screening:

- Opt-out approach: Implement an opt-out approach to STD screening. Offer patients the array of options (i.e., blood testing for syphilis and HIV, urine testing and swabs of the throat and rectum for gonorrhea and chlamydia) and allow the patient to choose which tests are applicable.
- Nurse-based screening: Nursing staff can offer extragenital screening to patients
 prior to appointments with their healthcare provider. Nursing staff could perform
 sample collection or patients may opt to self-collect samples prior to their screening
 visit.
- Self-collected rectal and pharyngeal swabs: Data show that quality of self-collected extragenital samples is equivalent to that of provider-collected extragenital samples among both men and women. Among HIV-positive patients who were offered and completed self-collection, more than 90% reported that it was easy and comfortable, that they would recommend self-collected screening to a friend, and that they would collect samples at home. Eighty-eight percent reported that they would prefer to collect their own samples and 77% reported that they would test more often if self-collection were an option.
 - i. **Note:** At present, OSPHL does not test patient-collected pharyngeal specimens.
 - ii. Self-collection visual aids can be ordered through the <u>University of</u> Washington STD Prevention Training Center.
- Home-based screening: Home-based self-collection for STD and HIV screening is used in many clinical studies and may be especially advantageous for individuals unlikely or unable to seek clinic-based screening. FDA-approved mail-in STD test kits such as myLAB Box (https://www.mylabbox.com/) are often costly but offer convenience and privacy.

3.3 Services Available at the Oregon State Public Health Laboratory (OSPHL)

The following specimen sources can be tested for gonorrhea at OSPHL:

- Urine
- Pharyngeal (clinician-collected only)
- Urethral (clinician-collected only)
- Endocervical (clinician-collected only)
- Vaginal (clinician-collected or patient-collected)
- Rectal (clinician-collected or patient-collected)

Patient-collected specimens must be collected in a medical facility; they cannot be collected at the patient's home. Gonorrhea testing is performed concurrently with chlamydia testing. Instructions for ordering, collecting, storing, and transporting specimens for gonorrhea and chlamydia testing are available on the OSPHL website at www.healthoregon.org/labtests.

3.4 Antibiotic Susceptibility Testing (AST)

1. Evaluating Suspected Treatment Failure

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Most suspected treatment failures are reinfections rather than true treatment failures. Treatment failure should be considered in 1) persons whose symptoms do not resolve within 3-5 days after appropriate treatment and report no sexual contact during the post-treatment follow-up period and 2) persons with a positive test-of-cure when no sexual contact is reported during the post-treatment follow-up period.

Retreat with a first-line regimen; if ceftriaxone 500 mg IM was not given initially, retreat with this first-line regimen if possible. Counsel to abstain from sex for 14 days. A test-of-cure at relevant clinical sites should be obtained 14 days after retreatment, preferably by culture and with simultaneous NAAT.

If *N. gonorrhoeae* is isolated, standard operating procedure for antibiotic susceptibility testing should be followed. Partners from the preceding 60 days should be evaluated promptly with culture and presumptively treated using the same regimen given to the patient.

2. Standard Operating Procedure for AST OSPHL does not routinely conduct AST of N. gonorrhoeae isolates. When gonorrhea treatment failure due to antibiotic resistance is suspected, specimens may be cultured and transported to the University of Washington STI Lab for AST. The standard operating procedure for requesting AST in cases of suspected gonorrhea treatment failure is presented in Appendix A.

4. ROUTINE CASE INVESTIGATION

4.1 Provider Interview

Contact the health care provider to verify treatment and complete missing, unclear, or erroneous elements of the initial case report. Inform the provider that a public health professional will contact the case-patient (hereafter referred to as "case" or "client") directly for an interview. The provider interview can be conducted by phone or the provider can be sent a query letter to return by fax to the LPHA.

4.2 Case Reporting

1. Case Interview

An interview should be attempted for confirmed cases. LPHAs without the capacity to interview all gonorrhea cases should implement a system for prioritizing which cases to contact. Cases that should be prioritized for interview include, at minimum, individuals who are pregnant, individuals with rectal gonorrhea, and individuals co-infected with HIV. The STD Program is available to advise LPHAs on developing a prioritization system.

If the client cannot be reached by traditional methods (e.g., phone, mailed letters, field or clinic-based visit), consider using technology-based tools. Use of texting, internet, and mobile apps to contact clients should first be approved by LPHA management. Client privacy must be assured and maintained throughout the case investigation and interview.

All attempts to contact the client should be documented in Orpheus in real time when possible, or on the day of the attempt at minimum.

Consult with the LPHA administrator and/or STD program manager regarding investigation of cases involving individuals younger than 13 years old.

2. Orpheus Documentation

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Enter information collected from the client into the appropriate areas of the Orpheus case report interface. This includes the basic case information column (client name/case number, disease type, staging/status information, client demographics, ordering provider, local epi, and reason for exam), in addition to tabs labeled "Risks," "Clinical," and "Contacts."

If the client provides personal (non-clinical) information such as demographic or sexual exposure history that contradicts information collected from the provider report/interview, overwrite the provider response with the client response and make a note of the change in the "Notes" tab of the Orpheus case report.

Contacts Tab:

Record information about contacts directly into the "Contacts" tab and related subtabs of the case entry interface. Use the "+ Contact" button on the "Contacts" tab of the Orpheus case report to add each new contact. This list should include all named contacts within the appropriate interview period, including those from whom the client might have acquired infection and others whom the client might have exposed. If you have decided to collect information about associates and sex partners named by others, record their information here too. Record the type of contact (see Appendix B) in the field labeled "Referral basis." Record the date and final disposition (see Appendix B) of your efforts in the "Contacts" tab of the case entry form. If there are multiple contacts, be sure that the name of the partner for whom you wish to enter information has been selected in the "Contacts" tab before entering data in any of the sub-tabs.

- i. "Demographics" and "Notes" sub-tabs:
 Enter partner information in the "Demographics" sub-tab of the "Contacts" tab. The "Notes" text box is embedded within the "Demographics" sub
 - tab.

 Record the date and outcome of each attempt to interview each partner and record this information in the "Notes" sub-tab of the "Contacts" tab of
- the Orpheus case entry interface, along with any other useful information. ii. "Exposure" sub-tab:
 - Record the date of the first sexual encounter between this partner and the client and the date of the most recent encounter in the "Exposure" sub-tab of the "Contacts" tab. Record the outcome of efforts to contact the partner in the exposure sub-tab.
- iii. "Labs/Treatment" sub-tab:

 Record the dates and results of any laboratory tests conducted and the dates and details of any presumptive treatment or treatment of laboratory-confirmed infection in the "Labs/Treatment" sub-tab.

4.3 Managing Sexual Partners

1. Partner Notification

All sex partners in the 60 days preceding the client's positive laboratory test should be examined, tested and treated. If the client has not had sex within the interview period, the most recent partner should be examined, tested, and treated. EPT should be provided for partners who are unable or unwilling to seek medical care (§2.8).

If the client prefers to notify and refer partners, the LPHA should verify that the partners have been examined and treated. If the partner's treatment cannot be verified within a

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reasonable time frame (2–5 days), the LPHA should attempt to notify and refer the partner for examination and treatment.

If the LPHA is handling notification, named partners should be contacted within two working days of the initial case interview by phone, field visit, or other method, and referred to the LPHA or another health care provider for evaluation, testing, and treatment. Generally, LPHA staff should try to contact the partner three times before determining that the partner cannot be located. Attempts should be made to contact the partner on alternate days and times of day. When possible, alternate contact methods should also be tried. For example, if calls and texts have not been successful, a field visit should be considered. For information about technology-based STD/HIV partner services, consult the CDC report *Introducing Technology into Partner Services: A Toolkit for Programs*.

2. Orpheus Documentation

When a partner is reached, all personal information reported by the provider should be confirmed and any outstanding information (indicated by the "Contacts" tab of the Orpheus case entry form) should be collected. The date and outcome of every attempt to interview each partner should be documented. The dates and results of any laboratory tests and the dates and details of any treatment should also be documented. When partner notification and treatment have been completed, the date and outcome (disposition) of the efforts should be documented and any additional pertinent information should also be recorded. Contact type codes and disposition codes are presented in Appendix B.

4.4 Out-of-Jurisdiction Cases/Contacts

Jurisdiction for a case belongs to the LPHA for a patient's county of residence. If the LPHA that received the initial report discovers that the case resides in a different county, the LPHA may transfer the case to the LPHA with jurisdiction via Orpheus by updating the home address in the case record and marking it for transfer when prompted by Orpheus. If the patient identifies a partner who lives outside of the local health jurisdiction, the contact may be transferred to the appropriate jurisdiction via Orpheus by entering the contact's address and marking it for transfer when prompted by Orpheus. For partners residing out of state, LPHA staff should provide the state STD Program (971.673.0153) with the relevant information for necessary follow-up.

5. CONTROLLING FURTHER SPREAD

5.1 Education

Patients should be advised to take all medications as directed, avoid sex for at least seven days after completion of treatment, avoid sex with partners until at least seven days after they have completed treatment, and use condoms to reduce the risk of acquiring sexually transmitted infections in the future.

All men who have sex with men (MSM) with rectal GC and women with GC should be offered pre-exposure prophylaxis (PrEP) for the prevention of HIV infection.

5.2 Case Follow-Up

Repeat testing is recommended three months post-treatment for all patients with gonorrhea. Test-of-cure is not recommended for patients with uncomplicated urogenital or rectal gonorrhea treated with a recommended or alternative regimen. Test-of-cure is

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recommended for patients with pharyngeal gonorrhea 14 days after treatment, regardless of treatment regimen.

Patients with persistent symptoms should seek medical evaluation. See §3.4 for guidance with evaluating suspected gonorrhea treatment failure.

All persons with gonorrhea should be tested for chlamydia, syphilis, HIV and other STDs.

6. MANAGING SPECIAL SITUATIONS

6.1 Pregnancy

Doxycycline is contraindicated for use in pregnancy. All other medications included in the treatment recommendations (i.e., ceftriaxone, cefixime, azithromycin, and gentamicin) are safe for use in pregnancy.

6.2 Co-infection with HIV

Patients with HIV should receive the same gonorrhea treatment as those who do not have HIV.

7. APPLICABLE RULES

7.1 Reporting

OAR 333-018-0000 through 333-018-0020

7.2 Investigation

OAR 333-019-0000 and 333-019-0002

8. REFERENCES

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9. UPDATE LOG

- 04/2014 Drafted. (Schafer)
 06/2014 Revised based on CLHO feedback. (Schafer)
 08/2014 Revised based on CLHO feedback: revised list of information items that must be reported by laboratories; added information about repeat testing during pregnancy. (Schafer)
 05/2019 Extensive formatting and language revisions. Updated in accordance with 2015 CDC STD Treatment Guidelines, Orpheus changes, and recent research findings. (Garai)
 10/2019 Minor revisions before publication of the updated guidelines. Added update log. (Garai)
- 01/2021 Revisions of §2.7, 2.8, 3.4, 5.2, and 6.1 in line with the 2020 Update to CDC's Treatment Guidelines for Gonococcal Infection. Additional minor formatting and language revisions.

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GONORRHEA

APPENDIX A

Standard Operating Procedure:
Antibiotic Susceptibility Testing for Suspected Gonorrhea Treatment Failure

DEFINITIONS

AST: antibiotic susceptibility testing LHD: local health department OHA: Oregon Health Authority

OSPHL: Oregon State Public Health Laboratory

PURPOSE

To describe the process for sending specimens to the UW STI Lab for AST when gonorrhea treatment failure due to antibiotic resistance is suspected.

PROCEDURE

- 1. LPHA/other provider contacts OHA STD Nurse Consultant to report case of suspected treatment failure and request AST.
- 2. STD Nurse Consultant contacts Dr. Sancta St. Cyr, CDC GISP Project Officer, to discuss case.

Follow steps below if approval is received to submit a potential treatment failure isolate.

- 3. STD Nurse Consultant requests that OSPHL send InTray GC device by courier to LPHA/other provider managing suspect case.
 - If LPHA/other provider contacts OSPHL directly to request AST, OSPHL contact will inform STD Program Nurse Consultant of case.
- 4. LPHA/other provider completes OSPHL General Microbiology Request Form (#60) found on the OSPHL website and sends completed form with InTray GC device to OSPHL.
 - On the form, LPHA/other provider finds the "Referral Testing/Send-outs" box on the bottom right and selects the drop-down choice "Neisseria gonorrhoeae AST" under "Studies."
- 5. OSPHL completes CDC specimen submission <u>form</u> (CDC Form 50.34) and ships isolate per CDC instructions.
- 6. OSPHL communicates AST results to STD Nurse Consultant and LPHA/other provider.

CONTACTS

STD Program	OSPHL
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Josh Ferrer, HIV/STD Prevention & TB Program Manager

APPENDIX B

Contact Type and Disposition Codes

Table B1. Contact Type Codes

CONTACT TYPE	DISPOSITION CODE	USE
PARTNERS	P-1	Sex partner
	P-2	Needle partner
	P-3	Sex and needle partner
SOCIAL CONTACTS	S-1	Named by this case patient; has symptoms suggestive of disease
	S-2	Named by this case patient; is a sex partner of <i>another</i> person who is known to be infected
	S-3	Named by this case patient; needs exam; not S-2 or S-3
ASSOCIATES	A-1	Named by someone who is not infected; has symptoms suggestive of disease
	A-2	Named by someone who is not infected; is a sex partner of someone who is infected
	A-3	Named by someone who is not infected; could benefit from exam; not A-2 or A3

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APPENDIX B (Continued)

Contact Type and Disposition Codes

Table B2. Disposition Codes for Partners and Associates

DISPOSITION CODE	USE
A - Preventive Therapy	Sex partner or associate of case, treated, no treponemal or nontreponemal test available
B - Refused Preventive Therapy	Sex partner or associate of case, refused treatment, no treponemal or non-treponemal test available
C - Infected, Brought to Treatment	Sex partner or associate meets probable or confirmed case definition (any stage), treated
D - Infected, Not Treated	Sex partner or associate meets probable or confirmed case definition (any stage), not treated (e.g. refused, lost to follow-up)
E - Previously Treated for this Infection	Sex partner or associate meets probable or confirmed case definition (any stage), treated by another healthcare provider prior to interview
F - Not Infected	Serologic tests results available for sex partner or associate and not consistent with probable or confirmed case definition (any stage)
G - Insufficient Information to Begin Investigation	Named suspect or associate without sufficient available information (such as telephone, address, or email) to attempt to contact
H - Unable to locate	Attempted but unable to locate sex partner or associate
J - Located, Refused Examination	Successfully located sex partner or associate, but refused testing or treatment
K - Out of Jurisdiction	Sex partner or associate resides in another state, country or county.
L - Other	Outcome of attempt to locate other than listed elsewhere in table.
M - Reverse Contact Link	Sex partner or associate also meets probable or confirmed case definition (any stage) and is likely source to current case. In this circumstance laboratory and treatment outcome is stored with the sex partner or associate's case information. This code is used to avoid "double counting" partners who are "reciprocally listed" on cases for which they were the source.

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