Management of Gonorrhea and Chlamydia in Patients with HIV

Sexually Transmitted Infections (STIs) Guideline Committee, March 2018

Contents

Purpose of this Guideline ................................................................. 2
Transmission and Prevention ............................................................ 4
Screening ........................................................................................ 5
Presentation, Diagnosis, and Reporting .......................................... 9
Treatment ...................................................................................... 12
Follow-Up and Management of Treatment Failure ..................... 15
Sex Partner Exposure to HIV and Gonorrhea/Chlamydia ............... 18
All Recommendations .................................................................... 27
How This Guideline Was Developed ............................................ 30
Management of Gonorrhea and Chlamydia in Patients with HIV

Purpose of this Guideline

Sexually Transmitted Infections (STIs) Guideline Committee, March 2018

This guideline on the treatment of uncomplicated gonococcal and chlamydial infections in adult patients with HIV was developed by the New York State (NYS) Department of Health (NYSDOH) AIDS Institute (AI) for clinicians in NYS who manage the care of patients with HIV who are at risk of or diagnosed with gonorrhea or chlamydia coinfection. Accordingly, this guideline addresses the following topics: transmission and prevention of gonorrhea and chlamydia, screening, presentation, diagnosis, reporting, and treatment and aims to achieve the following goals:

- Increase the numbers of NYS residents with HIV and gonococcal or chlamydial coinfection who are identified and treated with effective interventions.
- Support the following NYSDOH Prevention Agenda 2013-2018 goals: 1) reduce the gonorrhea case rate by 10% among persons aged 15 to 44 years to no more than 183.1 cases per 100,000 women and 199.5 per 100,000 men; and 2) reduce the chlamydia case rate by 10% among women aged 15 to 44 years to no more than 1,458 cases per 100,000 [Do, et al. 2001; Mayer, et al. 2012].
- Reduce the growing burden of morbidity associated with gonococcal and chlamydial infections.
- Integrate current evidence-based clinical recommendations into the healthcare-related implementation strategies of the Ending the Epidemic initiative, which seeks to end the AIDS epidemic in NYS by the end of 2020.

The Burden of Gonococcal and Chlamydial Infections

Gonorrhea, an infection caused by Neisseria gonorrhoeae, and chlamydia, an infection caused by the bacterium Chlamydia trachomatis, are among the most frequently reported sexually transmitted infections (STIs) in NYS [NYSDOH 2016; CDC 2017a]. These infections are the primary causes of pelvic inflammatory disease, which can lead to tubal infertility, ectopic pregnancy, and pelvic pain and tenderness in women [CDC 2017a, 2017c]. Complications in men include urethritis, epididymitis, and proctitis.

The most common forms of gonococcal and chlamydial infections occur at urogenital, anogenital, and/or pharyngeal mucosal sites; however, ocular infections may occur as well. Disseminated gonococcal infection, with infection spread throughout the body, occurs in up to 3% of individuals with gonorrhea [Rice 2005]. Reports of disseminated chlamydial infection are rare.

High prevalence and incidence of gonococcal and chlamydial infections have been reported in people with HIV [Do, et al. 2001; Mayer, et al. 2012; Pathela, et al. 2013; Taylor, et al. 2013], particularly in New York City [Pathela, et al. 2013; Taylor, et al. 2013]. In 2014, the burden of gonococcal infection in NYS was highest among young people aged 15 to 24 years; this age group accounted for 56% of cases overall in 2014. In NYS, the majority of chlamydia diagnoses in 2014 were among persons aged 20 to 24 years (70%) [NYSDOH 2016]. These findings are consistent with national surveillance data from the Centers for Disease Control and Prevention indicating that young people aged 15 to 25 years account for half of all new STIs [CDC 2017a]. Several studies have demonstrated that infection with N. gonorrhoeae or C. trachomatis may increase the risk of transmission and acquisition of HIV [Laga, et al. 1993; Cohen, et al. 1997; ACHSP 1998; Levine, et al. 1998]. However, with the exception of studies of women hospitalized with pelvic inflammatory disease, no formal studies have been published to date that evaluate differences in clinical presentation, diagnosis, or response to treatment of gonococcal or chlamydial infections in patients with HIV.

In patients with HIV, STIs increase transmission of HIV and can lead to costly health complications that may affect reproductive health and fetal and perinatal health [Ota, et al. 2009a]. Data suggest that the annual, direct cost of treating STIs in the United States is $15.6 billion [Radix, et al. 2012].
Box 1: Chlamydia and Gonorrhea Cases Reported in New York State and Nationwide, 2016 [CDC 2017a]

<table>
<thead>
<tr>
<th>New York State (including New York City)</th>
<th>Nationwide</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Chlamydia: 109,433 cases reported in 2016</td>
<td>• Chlamydia: 1,598,354 cases reported in 2016 (4.7% increase from 2015)</td>
</tr>
<tr>
<td>- Women: 67,602 cases</td>
<td>• Gonorrhea: 468,514 cases reported in 2016 (18.5% increase from 2015)</td>
</tr>
<tr>
<td>- Men: 41,722 cases</td>
<td></td>
</tr>
<tr>
<td>• Gonorrhea: 29,000 cases reported in 2016</td>
<td></td>
</tr>
<tr>
<td>- Women: 8,709</td>
<td></td>
</tr>
<tr>
<td>- Men: 20,224</td>
<td></td>
</tr>
</tbody>
</table>

The Role of New York State Primary Care Providers in Managing STIs

The goal of this guideline is to aid primary care providers and other clinicians in NYS in diagnosing and treating gonococcal and chlamydial infections in adult patients with HIV. Primary care providers are often the first to see patients with symptoms of an STI [CDC 2016a]. Nurses in NYS are authorized to execute non-patient specific orders and protocols (ordered by a physician or nurse practitioner) for administering HIV testing and medically screening at-risk persons for syphilis, chlamydia, and/or gonorrhea. As such, primary care providers and other clinicians assume an important role in the diagnosis and treatment of STIs in patients with HIV and in counseling patients to avoid or prevent high-risk behaviors that might expose them to STIs. In 2016, more than 75% of chlamydia cases were reported by sites other than STI clinics. Among women, about one-third of cases were reported from private physicians/health maintenance organizations, representing a change in the facilities reporting chlamydial infections over the last decade [CDC 2017a].

The NYSDOH AI STI Committee has developed a set of measures designed to assess providers’ quality of STI care and treatment and identify areas for improvement, with the goal of reversing the rising rate of STI transmissions and recognizing sexual health as a primary care priority.

Development of this Guideline

This guideline was developed by the Sexually Transmitted Infections Guidelines Committee of the NYSDOH AI Clinical Guidelines Program. The program is a collaborative effort of the NYSDOH AI Office of the Medical Director and the Johns Hopkins University School of Medicine, Division of Infectious Diseases.

Established in 1986, the goal of the Clinical Guidelines Program is to develop and disseminate evidence-based, state-of-the-art clinical practice guidelines to improve the quality of care provided to people with HIV, hepatitis C virus, and STIs and to improve drug user health and LGBT health throughout the state of New York. NYSDOH AI guidelines are developed by committees of clinical experts through a consensus-driven process. For more details on the guideline development process, please see How This Guideline Was Developed.

The NYSDOH AI Sexually Transmitted Infections Guidelines Committee was charged with developing evidence-based clinical recommendations for clinicians in NYS who treat adult patients with HIV who are at risk of or diagnosed with gonorrhea or chlamydia coinfection. The resulting recommendations are based on an extensive review of the medical literature and reflect consensus among Committee experts. Each recommendation is rated for strength and for quality of the evidence (see below). If recommendations are based on expert opinion, the rationale for the opinion is included.

| AIDS Institute HIV Clinical Guidelines Program Recommendations Rating Scheme |
|--------------------------------|-----------------------------------------------|
| Strength of Recommendation | Quality of Supporting Evidence |
| A = Strong | 1 = At least 1 randomized trial with clinical outcomes and/or validated laboratory endpoints |
| B = Moderate | 2 = One or more well-designed, nonrandomized trial or observational cohort study with long-term clinical outcomes |
| C = Optional | 3 = Expert opinion |
Transmission and Prevention

Sexually Transmitted Infections (STIs) Guideline Committee, March 2018

RECOMMENDATIONS

Transmission and Prevention
- Clinicians should inform patients with HIV about the risk of acquiring or transmitting chlamydia, gonorrhea, and other sexually transmitted infections (STIs) from close physical contact with all sites of possible exposure, including the penis, vagina, mouth, or anus. (A3)

Patient Education
- When patients with HIV are diagnosed with gonococcal or chlamydial infections, clinicians should educate patients about the following:
  - Risk-reduction strategies, including the value of correct condom use. (A2)
  - The potential for oral transmission of gonorrhea and chlamydia. (A3)
  - The benefits of identifying STIs early. (A3)
  - The need for prompt evaluation and treatment of partners. (A3)

Gonorrhea, chlamydia, and other STIs are transmitted primarily through close physical contact with genital, rectal, or oral mucosal surfaces. Clinicians should inform patients about the risk of acquiring gonorrhea and chlamydia at all sites of possible exposure and should educate patients about the value of male and female condom use. Consistent and correct condom use may reduce the risk of gonorrhea and chlamydia acquisition by 62% and 26%, respectively [Holmes, et al. 2004]; however, clinicians should inform patients that gonorrhea and chlamydia may be transmitted at areas that are not covered by a condom, such as the rectum or the mouth [Ward and Ronn 2010; CDC 2016c].

In patients with HIV, untreated STIs are associated with an increase in HIV shedding [Johnson and Lewis 2008; Ward and Ronn 2010] and have been associated with an increased risk of transmitting HIV to partners [Fleming and Wasserheit 1999].
Screening

Sexually Transmitted Infections (STIs) Guideline Committee, March 2018

RECOMMENDATIONS

Screening Frequency

- For men who have sex with men (MSM) and transgender women (individuals assigned male at birth but who identify as female) who have sex with men, clinicians should perform three-site screening (genital, pharyngeal, rectal) at the following intervals:
  - At first visit and annually thereafter if the patient is at low risk of infection. (A2)
  - At first visit and every 3 months thereafter if the patient is at high risk of infection. (A2)
  - See Box 2: Description of Risk Status for Sexual Exposure to Gonorrhea and Chlamydia.

- For all other patients, clinicians should perform genital screening (urine/urethra, vagina/cervix) and extragenital screening (pharyngeal and/or rectal) at sites of contact at the following intervals:
  - At first visit and annually thereafter if the patient is at low risk of infection. (A2)
  - At first visit and every 3 months thereafter if the patient is at high risk of infection. (A2)

- Clinicians should screen pregnant patients with HIV for gonococcal and chlamydial infections at the first prenatal visit. (A2)
  - See the Centers for Disease Control and Prevention’s (CDC) STD Treatment Guidelines for information about gonococcal and chlamydial screening in pregnant women.

Sexual History

- Clinicians should ask all patients about sexual behaviors and new sex partners at each routine monitoring visit to assess for risk behaviors that indicate the need for repeat or ongoing screening. (A3)

Box 2: Description of Risk Status for Sexual Exposure to Gonorrhea and Chlamydia

<table>
<thead>
<tr>
<th>Risk Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>No/Low Risk</td>
<td>Patient reports no sexual activity or sex only within a mutually monogamous relationship within the year prior.</td>
</tr>
<tr>
<td>Moderate Risk</td>
<td>Patient reports a new sex partner within the year prior.</td>
</tr>
<tr>
<td>High Risk</td>
<td>Patient self-identifies as being at high risk of sexually transmitted infections (STIs) and/or reports any of the following for self or sex partner(s):</td>
</tr>
</tbody>
</table>
  - Multiple or anonymous sex partners. |
  - Bacterial STI diagnosed since last STI screening. |
  - Participation in sex parties or sex in other high-risk venues. |
  - Participation in any type of transactional sex. |
  - Use of recreational substances during sex. |

Rationale for Recommended Screening Frequency

A large proportion of gonorrheal and chlamydial infections are asymptomatic [CDC 2015, 2016b], which supports the recommendation for regular screening in individuals with HIV who are risk of acquiring sexually transmitted infections (STIs) [Aberg, et al. 2014; LeFevre 2014; CDC 2015]. Less than 50% of the estimated 820,000 cases of gonorrhea and 2.86 million cases of chlamydia each year are detected and reported to the CDC [CDC 2016b, 2016c]. Intensified gonorrhea and chlamydia screening (3 sites every 3 months) for individuals with HIV who are at high risk may result in early identification of disease and allow for early intervention to decrease complications and reduce rates of both transmission and reinfection [LeFevre 2014]. For women, early intervention can also prevent reproductive health complications [CDC 2015]. The purpose of screening, therefore, is to identify gonococcal and chlamydial infection in asymptomatic patients, prevent the spread of infection, and reduce morbidity associated with untreated infections.
KEY POINT

- Because most gonorrheal and chlamydial infections are asymptomatic [CDC 2016b, 2016c], regular screening is essential to protect patients’ health and prevent the spread of sexually transmitted infections. This is an essential component of patient education.

Rates of STIs are highest in sexually active women aged 25 years or younger and in sexually active MSM of any age [CDC 2015, 2017a]. Although data regarding STI rates in transgender populations are limited, higher rates of sexual risk behavior and laboratory-confirmed gonorrhea have been reported among transgender women [Nemoto, et al. 2004; Herbst, et al. 2008; Reisner, et al. 2015]. Studies have reported elevated rates of sexual risk behaviors among transgender men (individuals assigned female at birth but who identify as male) [Stephens, et al. 2011; Green, et al. 2015], highlighting the need for a careful sexual history to determine risk. Data on gonorrhea and chlamydia rates among women who have sex with women (WSW) are also limited. Although WSW are usually considered to be at lower risk of STIs, this group may engage in diverse sexual activity and a range of risk behaviors. In one study, a substantial proportion (5% to 28%) of WSW reported having sex with men in the year prior [CDC 2015]. Higher rates of sexual risk behaviors [Goodenow, et al. 2008] and higher rates of gonorrhea and chlamydia have been reported in women who have sex with men than in women who exclusively engage in sex with women [Muzny, et al. 2011]. Data from more than 9,000 family planning clinics indicated a higher rate of chlamydia infection (7.1%) in WSW and women who have sex with men and women (WSWM) than in women who exclusively engage in sex with men (5.3%) [Singh, et al. 2011]. In contrast, reported rates of chlamydial and gonococcal infection in women who are older than 25 years and in men who have sex with women are lower than in other groups [Ciemins, et al. 2000; Jackson, et al. 2015].

On the basis of the available evidence, this Committee recommends annual screening for gonococcal and chlamydial infections for all individuals with HIV. Those who engage, or whose partners may engage, in ongoing high-risk sex should be screened at least every 3 months. Factors that may prompt more frequent screening include multiple or anonymous sex partners, sexual activity at sex parties or other high-risk venues, or involvement in transactional sex (e.g., sex workers and their clients). The diagnosis of another bacterial STI in a patient with HIV or a patient’s sex partner should prompt a clinician to perform gonococcal and chlamydial screening tests and to consider screening every 3 months for gonorrhea and chlamydia. Screening at three sites (i.e., genital, pharyngeal, and rectal) is recommended for patients who are included in recognized high-risk groups and for those who report exposure at extragenital sites.

Some individuals for whom screening is indicated, such as MSM or women younger than 25 years of age, may report no sexual activity since their last STI screening. If an individual reports no sexual activity, then good practice is to document in the medical record the reason why screening was not performed.

KEY POINTS

- Gonococcal and chlamydial screening at least every 3 months is recommended for all individuals at high risk of exposure, including those who:
  - Have, or whose partners may have, multiple or anonymous sex partners.
  - Engage, or whose partners may engage, in sexual activity at sex parties or other high-risk venues.
  - Are, or whose partners may be, involved in transactional sex (i.e., sex workers and their clients).
  - Have been diagnosed, or whose partners have been diagnosed, with a bacterial STI in the previous 12 months.
  - Report recreational substance use during sexual activity.
  - Self-identify as at high risk for STIs.

New York State (NYS) closely monitors local epidemiology, and information is available regarding areas with a high incidence of STIs (see the CDC’s Sexually Transmitted Disease Surveillance [CDC 2017b] report and County Health Rankings & Roadmaps [RWJF/UWPHI 2012]).

Rationale for Extragenital (3-Site) Screening

Multiple studies have reported high rates of rectal and pharyngeal infections, mostly asymptomatic, among MSM [Kent, et al. 2005; CDC 2009; Mayer 2011; Peters, et al. 2011; Patton, et al. 2014; Chan, et al. 2016]. The CDC reports a higher burden of urethral, rectal, and pharyngeal infections with gonorrhea and chlamydia among MSM with HIV attending STI clinics than among MSM who do not have HIV [CDC 2017b]. The rectum and pharynx serve as reservoirs of gonococcal
and chlamydial infection and may be associated with persistent infection or transmission to sex partners [Marcus, et al. 2011; Rank and Yeruva 2014; Barbee, et al. 2016; Chow, et al. 2016]. Moreover, sexual histories are often incomplete for many reasons, such as patient or provider discomfort, time constraints, or limited training, and may not elicit important information on extragenital exposure [Cachay, et al. 2009; van Liere, et al. 2013; Barbee, et al. 2015].

In MSM, urine-based screening alone is not appropriate. It misses the majority of rectal and pharyngeal infections because of discordance between urethral and nonurethral gonococcal and chlamydial infections among MSM [Kent, et al. 2005; Mayer 2011; Peters, et al. 2011]. Among MSM attending STI clinics participating in the CDC STD Surveillance Network, more than 70% of extragenital gonococcal infections and 85% of extragenital chlamydial infections were associated with negative urethral tests at the same visit and would not have been detected with urethral screening alone [Patton, et al. 2014]. However, a review of multicity HIV clinics, including clinics in New York City (NYC) [Hoover, et al. 2010], found that less than 10% of MSM received nonurethral screening, indicating a need to increase screening that includes extragenital testing in this population.

Due to the high prevalence of asymptomatic rectal and pharyngeal infections in MSM who engage in high-risk behaviors and the low predictive value of patient sexual history to predict risk of extragenital exposure, this Committee supports routine three-site (urine, pharyngeal, and rectal) screening in sexually active MSM and transgender women who have sex with men. This Committee does not recommend screening only at sites where contact has been reported in these populations.

Available data are mixed regarding the benefit of routine nonvaginal gonococcal and chlamydial screening in all women. Most studies have utilized reported anatomic sites of sexual exposure to select women for extragenital screening and have demonstrated greater concordance between cervical and rectal infections in women [Dukers-Muijrers, et al. 2015; Chandra, et al. 2018]. Genital screening alone detects more infections in women than in MSM.

The recommendation for extragenital (three-site) screening should be discussed with the patient. If an individual opts out of three-site screening and testing only at sites of reported contact is performed, then the reasoning behind that decision should be noted in the medical record.

Self-collected screening specimens: Because evidence exists supporting the efficacy of self-collected rectal, pharyngeal, and vaginal swabs [Alexander, et al. 2008; Moncada, et al. 2009; Freeman, et al. 2011; Geelen, et al. 2013], these options may be considered when this is the patient’s preference. However, a thorough physical examination is still essential as part of the sexual health assessment (see NYS Department of Health [NYSDOH] AIDS Institute guideline Primary Care Approach).

**Obtaining a Sexual History**

To assess behavioral risk, clinicians should obtain a sexual history at each routine visit for patients with HIV. Information about the patient’s sexual behaviors informs decisions about the frequency and type (genital only or three-site) of screening and points clinicians to key areas to address in risk-reduction counseling. Respect, compassion, and a nonjudgmental attitude are essential components of effective sexual history-taking. Clinicians should ask open-ended questions using language that is clear, jargon-free, and not stigmatizing in discussing a patient’s sexual activities. The CDC recommends addressing the “Five Ps: Partners, Practices, Prevention of Pregnancy, Protection from STDs, and Past History of STDs,” as outlined in Box 3, below.


**Partners**

- “Do you have sex with men, women, or both?”
- “In the past 2 months, how many partners have you had sex with?”
- “In the past 12 months, how many partners have you had sex with?”
- “Is it possible that any of your sex partners in the past 12 months had sex with someone else while they were still in a sexual relationship with you?”
### Box 3: The Five P’s: Partners, Practices, Prevention of Pregnancy, Protection from STDs, and Past History of STDs

**Reprinted from CDC 2015 STD Treatment Guideline: Clinical Prevention Guidance**

<table>
<thead>
<tr>
<th>Practices</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>“To understand your risks for STDs, I need to understand the kind of sex you have had recently.”</td>
<td></td>
</tr>
<tr>
<td>“Have you had vaginal sex, meaning ‘penis in vagina sex’?” If yes, “Do you use condoms: never, sometimes, or always?”</td>
<td></td>
</tr>
<tr>
<td>“Have you had anal sex, meaning ‘penis in rectum/anus sex’?” If yes, “Do you use condoms: never, sometimes, or always?”</td>
<td></td>
</tr>
<tr>
<td>“Have you had oral sex, meaning ‘mouth on penis/vagina’?”</td>
<td></td>
</tr>
<tr>
<td>For condom answers:</td>
<td></td>
</tr>
<tr>
<td>- If “never”: “Why don’t you use condoms?”</td>
<td></td>
</tr>
<tr>
<td>- If “sometimes”: “In what situations (or with whom) do you use condoms?”</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prevention of Pregnancy</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>“What are you doing to prevent pregnancy?”</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Protection from STDs</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>“What do you do to protect yourself from STDs and HIV?”</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Past History of STDs</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>“Have you ever had an STD?”</td>
<td></td>
</tr>
<tr>
<td>“Have any of your partners had an STD?”</td>
<td></td>
</tr>
</tbody>
</table>

**Additional questions to identify HIV and viral hepatitis risk include:**

| “Have you or any of your partners ever injected drugs?”                     |                                                                 |
| “Have your or any of your partners exchanged money or drugs for sex?”       |                                                                 |
| “Is there anything else about your sexual practices that I need to know about?” |                                                                 |

When obtaining a sexual history, questions should focus primarily on the patient’s sexual behavior and not solely on sexual and gender identity (e.g., avoid use of such labels as “lesbian,” “homosexual,” “gay,” or “transgender”). A study conducted in NYC found that self-reported sexual identity could not independently establish patients’ risk. Many MSM in the study did not identify as “gay,” underscoring the importance of assessing sexual behavior when determining a patient’s risk [Pathela, et al. 2006; Bernstein, et al. 2008]. Transgender people differ widely in terms of sexual behavior and anatomy. It is helpful to ask about the type of sex a person is having and the parts of anatomy used for sex, as well as about the anatomy of partners [TransHealth 2016]. A patient’s openness to discuss his or her sexual and gender identity may be important for the clinician’s understanding of health status and the individual’s perceived stigma and ability to accurately assess the patient’s risk of acquiring or transmitting STIs. Therefore, clinicians should stress the confidential nature of discussions about sexual activities and maintain a nonjudgmental attitude to encourage patients to disclose all sexual behaviors.

Clinicians who are uncomfortable discussing sexual behaviors may benefit from training to increase their comfort level and assist in development of a nonjudgmental approach to educating patients about the importance of STI screening. The NYSDOH Clinical Education Initiative Line (866-637-2342) enables clinicians in NYS to discuss post-exposure prophylaxis, pre-exposure prophylaxis, HIV, hepatitis C virus, and STI management with a specialist, and the NYC STD/HIV Prevention Training Center provides HIV-related educational resources and training for providers. The CDC’s Guide to Taking a Sexual History offers parameters for discussing sexual health issues with patients. The NYC Department of Health and Mental Hygiene’s one-page sexual history and counseling form is available online. More information on sexual history and risk assessment among transgender people is available from the Center of Excellence for Transgender Health, Department of Family and Community Medicine, University of California San Francisco.
Presentation, Diagnosis, and Reporting

Sexually Transmitted Infections (STIs) Guideline Committee, March 2018

RECOMMENDATIONS

Presentation of Symptomatic Infection

- When patients with HIV present with symptoms suggestive of gonococcal or chlamydial infection, clinicians should perform diagnostic testing as recommended in Table 1, below. (A1)
- Clinicians should include lymphogranuloma venereum (LGV) infection in the differential diagnosis for patients who test positive for rectal chlamydial infection or who present with such symptoms as rectal pain, tenesmus, bloody rectal discharge, or isolated, atypical perianal ulcerative lesions and adenopathy. (A2)
  - See the Centers for Disease Control and Prevention's (CDC) guideline on LGV.

Laboratory-Based Diagnosis

- Clinicians should obtain nucleic acid amplification testing (NAAT) on samples collected from genital and extragenital sites (A1); if NAAT is not available, clinicians should:
  - Send alternative samples for culture in accordance with the protocols of the laboratory performing the analysis, with the understanding that culture is significantly less sensitive than NAAT. (A1)
- If a patient has a known exposure to a cephalosporin-resistant strain of gonorrhea, clinicians should obtain samples for both culture/susceptibility and NAAT testing from the patient and his/her sex partner(s). (A3)
- Clinicians should perform syphilis testing for any patient with HIV who is diagnosed with a gonorrheal or chlamydial infection. (A2)
  - For more information, contact the NYSDOH Wadsworth Center Laboratory at 1-518-474-4177.

Reporting

- New York State (NYS) Public Health Law requires that clinicians report within 24 hours from the time a case is first seen all suspected or confirmed gonorrhea and chlamydia diagnoses to the local health department of the area where the patient resides.
  - See NYSDOH Communicable Disease Reporting, and NYC DOHMH Reporting Diseases and Conditions
  - Clinicians can contact local health departments to obtain previously reported test results and treatment histories. See Sexually Transmitted Disease Clinics in NYS for contact information for clinics in each county.

Presentation of Symptomatic Infection

There have been no reports of atypical presentations of gonococcal or chlamydial infections in patients with HIV.

In men, genital symptoms and signs of either gonococcal or chlamydial infection may include dysuria or urethral discharge; in cases in which urethral infection is complicated by epididymitis, patients may report testicular pain [CDC 2016b, 2016c]. A woman with symptomatic genital gonococcal or chlamydial infection may present with dysuria, increased vaginal discharge, or vaginal bleeding between periods [CDC 2016b, 2016c].

Rectal gonococcal and chlamydial infections may be asymptomatic in both men and women. When present, symptoms and signs may include anal itching, soreness, proctitis, discharge, and/or bleeding.

Pharyngeal gonococcal infection may cause symptoms in the throat, with or without cervical lymphadenopathy, but this infection is often asymptomatic [CDC 2016c]. Reports of pharyngeal symptoms associated with chlamydial infection are extremely rare, and chlamydial infection is not thought to cause pharyngitis [CDC 2016b]. Gonococcal infection should be considered as part of the differential diagnosis for sexually active patients who present with pharyngeal symptoms.

Spread of N. gonorrhoeae into disseminated gonococcal infection may cause arthritis, tenosynovitis, skin lesions, and sepsis in both men and women [Belkacem, et al. 2013].

Lymphogranuloma venereum: LGV is caused by unique serovars of C. trachomatis (L1, L2, L3) that are unlike those that typically cause urethritis, cervicitis, and proctitis (D through K). LGV should be included in the differential diagnosis for all
patients with HIV who test positive for rectal chlamydial infection or who present with rectal signs or symptoms, such as rectal pain; tenesmus; bloody rectal discharge; or isolated, atypical genital or perianal ulcerative lesions and adenopathy. LGV is typically diagnosed based on clinical examination because testing to determine LGV serovars is often unavailable. The classic presentation of LGV infection is unilateral or bilateral tenderinguinal lymphadenopathy that evolves dramatically 2 to 6 weeks after the primary ulcerative lesion. However, in both men and women, infection occurring as a result of anal intercourse can cause proctocolitis. Colonic mucosal ulcerations develop and may be replaced by progressively enlarging areas of granulation tissue, which, in time, lead to fistulas and strictures. Clinicians should have a low threshold for empirically treating patients with suspected LGV or documented rectal chlamydia infection. For information regarding diagnosis, including instructions for obtaining chlamydial polymerase chain reaction testing, and treatment of LGV, see the CDC’s guideline on LGV.

→ KEY POINT

- Although LGV occurs only sporadically in the United States, outbreaks of LGV proctocolitis have been reported among men who have sex with men (MSM) in New York and other U.S. cities [Ahdoot, et al. 2006; Martin-Iguacel, et al. 2010], and many of these cases occurred in individuals with HIV [Ahdoot, et al. 2006; Martin-Iguacel, et al. 2010].

Laboratory-Based Diagnosis of Gonorrheal and Chlamydial Infections

Whenever possible, NAAT should be performed to detect and diagnose gonococcal and chlamydial infection. NAAT is more sensitive than culture, particularly for detecting *C. trachomatis* and *N. gonorrhoeae* in extragenital samples [Schachter, et al. 2008; Ota, et al. 2009b]. Although the U.S. Food and Drug Administration has not yet approved use of NAAT for rectal and pharyngeal specimens, this Committee concurs with the Centers for Disease Control and Prevention (CDC) recommendation that NAAT should be used to detect rectal and pharyngeal infection. NAAT should be performed by a laboratory with a Clinical Laboratory Evaluation Program (CLEP)-specified protocol.

Performance specifications for use of NAAT on rectal and pharyngeal samples have been established according to CLEP regulations by a number of laboratories. The NYSDOH and CDC strongly recommend that laboratories adopt CLEP testing protocols for rectal and pharyngeal specimens. CLEP specifications for rectal and pharyngeal testing and information about participating laboratories can be obtained by contacting the NYSDOH Wadsworth Center Laboratory at 1-518-474-4177.

For clinicians who are unable to obtain NAAT, culture may be used for the diagnosis of gonorrhea. Antimicrobial sensitivity testing cannot be performed on NAAT specimens.

Although there are limited data available specifically regarding the rate of syphilis coinfection identified in patients diagnosed with gonococcal or chlamydial infections, surveillance reports identify high rates of gonococcal or chlamydial infections and syphilis among MSM. Because exposure resulting in the acquisition of one sexually transmitted infection (STI) has long been recognized to be a risk for other STIs/HIV, this Committee recommends testing for syphilis when a patient is diagnosed with a new gonococcal or chlamydial infection [Bala, et al. 2011; Foschi, et al. 2014; CDC 2017b].

<table>
<thead>
<tr>
<th>Exposure Site</th>
<th>Sample Collection Method [a]</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urethra</td>
<td>First-catch urine for nucleic acid amplification testing (NAAT) [b]</td>
<td>+ In males, for ease of collection, first-catch urine [c] is recommended over urethral swab. Some studies have demonstrated equal specificity but lower sensitivity with urethral swab compared with urine for NAAT [CDC 2014]. However, additional data are needed to establish the relative effectiveness of these collection methods.</td>
</tr>
</tbody>
</table>
Table 1: Sample Collection and Testing Methods for Laboratory Detection of Gonococcal and Chlamydial Infection

<table>
<thead>
<tr>
<th>Exposure Site</th>
<th>Sample Collection Method [a]</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Vagina/cervix | Vaginal or cervical swab (recommended) or first-catch urine (alternative) NAAT | • The recommended sample collection method is a vaginal swab for testing with a U.S. Food and Drug Administration (FDA)-approved assay; this method is equivalent to cervical swab [CDC 2014].  
• First-catch urine testing, which is inferior to swab, may be used as an alternative.  
• Some NAAT assays are approved for self-collected vaginal samples and perform as well as NAAT for other specimens [Soni and White 2011]. |
| Rectum        | Males and females: Rectal swab for NAAT [b] | • Culture is not sufficiently sensitive for detection of rectal C. trachomatis. |
| Pharynx       | Males and females: Pharyngeal swab for NAAT [b] | • Culture is not sufficiently sensitive for detection of pharyngeal C. trachomatis.  
• The incidence of pharyngeal chlamydial infection is lower than pharyngeal gonorrheal infection [Ota, et al. 2009a; Soni and White 2011; Radix, et al. 2012], and data on the clinical benefit of treating patients with asymptomatic pharyngeal infection are limited.  
• To reduce the risk of transmission, this Committee recommends treatment for pharyngeal chlamydial infection, even if the pharynx is the only site of infection. |

---

a. Handling of specimens: Conditions for collection and transport of samples for laboratory testing for C. trachomatis and N. gonorrhoeae may greatly affect the sensitivity of culture because the organisms can degrade easily during transport [Human and Jones 2004; Rishmawi, et al. 2007]. Guidance regarding sample collection with either direct plating or the use of specialized transport media for culture should be obtained from the clinician’s laboratory. After collection, culture samples should be stored in the referring laboratory’s recommended transport media and transported at ≤4°C to the laboratory within 24 hours [CDC 2014].

b. NAAT testing is more sensitive than culture for the detection of gonococcal or chlamydial infections. Although NAAT has not yet received FDA approval for rectal or pharyngeal specimens, NAAT performed by a laboratory with a Clinical Laboratory Evaluation Program-specified protocol is recommended for detecting both rectal and pharyngeal C. trachomatis and N. gonorrhoeae. If NAAT is not available, then culture should be obtained according to the protocols of the clinician’s institution.

c. For urine screening, clinicians should provide patients with clear instructions for obtaining a first-catch sample.

---

**Reporting**

**NYS Law:** Prompt reporting of suspected or confirmed cases of gonorrhea and chlamydia is mandated under the NYS Sanitary Code (10NYCRR 2.10). In NYS, cases must be reported to the local health department where the patient resides within 24 hours from the time the case is first seen.

For more information about disease reporting, clinicians should contact the local health department where the patient resides or the NYSDOH Bureau of Communicable Disease Control at 518-473-4439 (after hours: 1-866-881-2809). To obtain reporting forms, call 518-474-0548.

**NYC Law:** NYC’s Health Code Article 11 requires that all cases of gonorrhea and chlamydia be reported using the Universal Reporting Form, which can be submitted online, by fax (call 866-692-3641 for the appropriate fax number), or by mail (NYC Department of Health and Mental Hygiene, 42-09 28th Street, CN-22, Long Island City, NY 11101). See How to Report Diseases, Events, and Conditions to the NYC Health Department for more information.

- For more information, see NYC DOHMH Diseases and Conditions Reporting.

**Partner notification:** The local health department may contact the patient for epidemiological investigation or to offer assistance with partner notification.
Treatment

Sexually Transmitted Infections (STIs) Guideline Committee, updated June 2019

RECOMMENDATIONS

Treatment of Uncomplicated Gonococcal Infection

• Clinicians should treat uncomplicated gonococcal infections of the cervix, urethra, rectum, or pharynx as follows:
  • Preferred: Ceftriaxone 250 mg intramuscular (IM) injection in a single dose plus azithromycin 1 g by mouth in a single dose. (A2)
  • Alternative, for patients who are allergic to azithromycin: Ceftriaxone 250 mg IM in a single dose plus doxycycline 100 mg by mouth twice daily for 7 days. (A2)
  • Alternative, if ceftriaxone is not available: Cefixime 400 mg by mouth in a single dose plus azithromycin 1 g by mouth in a single dose. This regimen is not recommended for treatment of pharyngeal infection. (A2)

• Clinicians should instruct patients to abstain from sexual activity for at least 7 days after starting treatment, and to continue to abstain until symptoms resolve and all sex partners have completed treatment. (A2)

Treatment of Gonococcal Infection in Patients with Penicillin Allergy

• For patients without prior severe allergic responses to penicillin (e.g., severe IgE-mediated response, such as anaphylaxis or urticaria with pruritic rash; or a severe non-IgE-mediated response, such as Stevens-Johnson syndrome, toxic epidermal necrolysis, or drug-induced hypersensitivity with inflammation of internal organs), clinicians should treat gonococcal infection with a cephalosporin-containing regimen, as recommended above, and monitor carefully for adverse effects. (A2)

• For patients with prior severe allergic responses to penicillin, clinicians should treat gonococcal infection with a single dose of azithromycin 2 g by mouth plus a single dose of either gentamicin 240 mg IM or gemifloxacin 320 mg by mouth. (A2)

Treatment of Uncomplicated Chlamydial and LGV Infections

• Clinicians should treat uncomplicated chlamydial infection of the cervix, urethra, rectum, or pharynx as indicated in Table 2: Recommended Treatment for Uncomplicated Chlamydial and Lymphogranuloma Venereum (LGV) Infections. (A2)

• Clinicians should treat symptomatic chlamydial proctitis with a medication regimen sufficient to treat lymphogranuloma venereum (LGV). (A3)

Treatment of Uncomplicated Gonococcal Infection

Treatment of gonorrhea and chlamydia in patients with HIV is the same as for patients who do not have HIV [CDC 2015]. The New York State Department of Health and the Centers for Disease Control and Prevention (CDC) recommend ceftriaxone 250 mg IM plus 1 g of azithromycin by mouth as a single dose for effective treatment of uncomplicated gonococcal infections of the cervix, urethra, rectum, or pharynx. Ideally, this regimen should be administered together simultaneously onsite under direct observation to maximize treatment adherence [CDC 2015]. Regimens containing alternatives to ceftriaxone are no longer recommended as first-line treatment for gonococcal infections due to increasing gonococcal antibiotic resistance in the United States and worldwide [CDC 2012b; NYSDOH 2012; Kirkcaldy, et al. 2016]. Combination treatment with two drugs with different mechanisms of action is recommended to slow emergence and spread of gonococcal antibiotic resistance. Ceftriaxone has remained highly effective in the United States, although several other countries have reported decreased susceptibility [CDC 2015; Kirkcaldy, et al. 2016]. Reduced susceptibility of N. gonorrhoeae to azithromycin has increased in recent years but remains low [Kirkcaldy, et al. 2016; NYCDHMH 2016]. Alarmingly, a small cluster of cases with decreased susceptibility to ceftriaxone and azithromycin were reported in Hawaii in 2016, and a case of ceftriaxone-resistant N. gonorrhoeae was reported in Canada in 2017, leading to increased concern about emergence of resistance to this last remaining effective regimen [Papp, et al. 2017; Lefebvre, et al. 2018]. It is essential that clinicians follow up-to-date treatment recommendations and immediately report cases of treatment failure to local health departments to prevent further development of resistance [CDC 2015; Bolan 2017].
Azithromycin is preferred as the second antimicrobial in the treatment regimen because of the higher prevalence of gonococcal resistance to tetracycline reported by the Gonococcal Isolate Surveillance Project [Kirkcaldy, et al. 2014; CDC 2017a]. In cases of azithromycin allergy, doxycycline 100 mg by mouth twice daily for 7 days may be substituted. Both azithromycin and doxycycline are also effective against concomitant chlamydial infections, which are common among patients with gonorrhea [CDC 2015].

When ceftriaxone is not available, a single dose of cefixime 400 mg can be substituted in combination with a single dose of azithromycin 1 g by mouth. However, ceftriaxone is preferred whenever possible because rising minimum inhibitory concentrations for cefixime suggest that resistance may develop in the near future, and continued use of cefixime may also contribute to development of resistance to ceftriaxone. In addition, cefixime has a lower cure rate for pharyngeal gonorrhea [CDC 2015].

Data are limited regarding recommendations for alternative antimicrobials if treatment with a cephalosporin is unavailable, declined, or cannot be used due to a drug allergy (see Treatment of Gonococcal Infection in Patients with Penicillin Allergy, below). Azithromycin monotherapy is no longer recommended due to concerns about development of resistance and documented treatment failures [CDC 2015; Kirkcaldy, et al. 2016; NYCDHMH 2016; Papp, et al. 2017]. Treatment with a single dose of either gemifloxacin 320 mg by mouth or gentamicin 240 mg IM plus a 2 g dose of azithromycin by mouth has been effective [Kirkcaldy, et al. 2014]. If regimens other than those recommended above are used, culture and antibiotic susceptibility testing should be performed to guide treatment. If susceptibility testing is not available, then a test of cure should be performed 2 weeks after completion of treatment (see the Follow-Up and Management of Treatment Failure section of this guideline).

> KEY POINTS

- Directly observed treatment provided on site maximizes adherence [CDC 2015].
- *N. gonorrhoeae* has developed resistance to nearly all previously effective antimicrobials, leaving cephalosporins as the only available class of drugs recommended for treatment of gonococcal infections [CDC 2015].
- Cephalosporin-resistant *N. gonorrhoeae* has been reported outside of the United States [CDC 2011; Bolan, et al. 2012], and reduced susceptibility to cephalosporins has been observed with isolates of *N. gonorrhoeae* from residents of New York City [NYCDHMH 2013].
- Combination treatment with two antimicrobials with different mechanisms of action is recommended to slow further emergence of resistance [CDC 2015].
- People infected with *N. gonorrhoeae* are frequently coinfected with *C. trachomatis* [Lyss, et al. 2003].
- Significant levels of quinolone-resistant *N. gonorrhoeae* are present in the United States (26.9% of isolates in 2016) [CDC 2017a].
- Because of fluoroquinolone-resistant *N. gonorrhoeae* in the United States, fluoroquinolones other than gemifloxacin* should not be used to empirically treat proven or suspected gonococcal infections [CDC 2007]; however, if fluoroquinolones are being considered, then clinicians should perform fluoroquinolone susceptibility testing before initiating treatment.

For additional information regarding antibiotic-resistant *N. gonorrhoeae*, refer to CDC > Antibiotic-Resistant Gonorrhea, which provides updated information and resources on surveillance and trends.

*Gemifloxacin was shown to have in vitro activity against gonorrhea (including quinolone-resistant organisms) [Pottumarthy, et al. 2006] and in one clinical trial when dosed with azithromycin [Lyss, et al. 2003].

### Treatment of Gonococcal Infection in Patients with Penicillin Allergy

With the emergence of antibiotic-resistant *N. gonorrhoeae*, patients should be treated for gonococcal infection with a regimen including ceftriaxone unless contraindicated. Most patients who report a previous penicillin allergy can be treated safely with ceftriaxone when monitored for side effects since allergy to penicillin does not appear to predict severe reaction to cephalosporins [Yates 2008; Campagna et al. 2012; Novalbos et al. 2001; Pichichero and Casey 2007]. Rates of cross-reactivity between penicillins and cephalosporins are lower than previously reported and are highest for 1st-generation and 2nd-generation cephalosporins, particularly with amoxicillin, which has a similar side chain [Campagna et al. 2012]. Rates of cross-reactivity between penicillins and 3rd-generation cephalosporins are negligible [Yates 2008; Campagna et al. 2012; Novalbos et al. 2001; Pichichero and Casey 2007; Pichichero 2005]. Rates of anaphylaxis to cephalosporins among patients with penicillin allergy are rare (0.0001%-0.1%) [Pegler and Healy 2007; Meyers 1985; Lin 1992].
An accurate history of the nature of past reactions is important to determine the circumstances before identifying the patient as allergic. Many patients who have experienced a side effect of the drug may have been incorrectly identified as having a penicillin allergy [Saxon, et al. 1987]. Previous reactions that are less concerning when subsequent use of cephalosporins is considered include diarrhea, nausea, mild nonpruritic rash, or pain and inflammation at the injection site. These reactions can be anticipated and managed carefully.

Severe penicillin reactions may include IgE-mediated responses, such as anaphylaxis or urticaria with pruritic rash, or non-IgE-mediated responses, such as Stevens-Johnson syndrome, toxic epidermal necrolysis, or drug reaction with eosinophilia and systemic symptoms involving inflammation of internal organs. Before treating patients who report penicillin allergy but for whom the history is unclear, or in whom desensitization may be applicable, consultation with a clinician (e.g., allergist) who has experience managing drug allergies is advisable.

In the case of prior severe allergic response to penicillin, cephalosporins are not recommended. Gentamicin 240 mg IM in a single dose or gemifloxacin 320 mg by mouth in a single dose have been effective alternatives to cephalosporins in recommended treatment regimens. To prevent future development of gonococcal resistance, these drugs should be used in combination with a single dose of azithromycin 2 g by mouth, which is double the dose used in the standard treatment regimens [Kirkcaldy, et al. 2014; CDC 2015; NYCDHMH 2016]. Oral doses of two-gram azithromycin have been associated with gastrointestinal events, including nausea, loose stools, vomiting, and abdominal pain. In one study, nearly 7.7% of patients reported vomiting within 1 hour of gemifloxacin/azithromycin administration, and 3.3% reported vomiting within 1 hour of gentamicin/azithromycin administration, necessitating retreatment [Kirkcaldy, et al. 2014; CDC 2015].

Penicillin skin testing may also be useful in cases in which history is unclear. Protocols for desensitization to cephalosporins are available for patients with a history of severe IgE-mediated penicillin reaction, avoiding the need for alternative treatment with potentially less effective antimicrobials [Castells 2009]; however, they may be difficult to administer in an outpatient setting. Ceftriaxone 250 mg IM plus a single 1 g dose of azithromycin by mouth may be prescribed after negative skin testing, and, if necessary, desensitization to ceftriaxone.

### Treatment of Uncomplicated Chlamydial and LGV Infections

<table>
<thead>
<tr>
<th>Infection</th>
<th>Regimen</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncomplicated cervical, urethral, rectal, or pharyngeal infection</td>
<td><strong>Recommended:</strong>&lt;br&gt;• Azithromycin 1 g by mouth as a single dose OR&lt;br&gt;• Doxycycline 100 mg by mouth twice daily for 7 days.&lt;br&gt;<strong>Alternatives:</strong>&lt;br&gt;• Erythromycin base 500 mg by mouth four times per day for 7 days OR&lt;br&gt;• Erythromycin ethylsuccinate 800 mg by mouth four times per day for 7 days OR&lt;br&gt;• Levofloxacin 500 mg by mouth once daily for 7 days OR&lt;br&gt;• Ofloxacin 300 mg by mouth twice per day for 7 days.</td>
<td>• Treat asymptomatic pharyngeal infection even if it is the only site of infection.&lt;br&gt;• Alternative regimens are NOT recommended for pharyngeal infections.</td>
</tr>
<tr>
<td>Symptomatic proctitis</td>
<td>• Doxycycline 100 mg by mouth twice daily for 21 days OR&lt;br&gt; • Azithromycin 1 g by mouth as a single dose once weekly for 3 weeks [Blanco, et al. 2019].*</td>
<td>• Presumptively treat for LGV; see the CDC’s guideline on LGV.&lt;br&gt;• If LGV is excluded by testing, then patients should complete the standard seven-day regimen for uncomplicated chlamydial infection.</td>
</tr>
</tbody>
</table>

*Added June 13, 2019.

Treatment of chlamydia for patients with HIV is the same as for patients who do not have HIV [CDC 2015]. The recommended treatment for uncomplicated chlamydial infections of the cervix, urethra, rectum, or pharynx is either 1 g...
of azithromycin by mouth as a single dose or 100 mg of doxycycline by mouth twice daily for 7 days. Once-daily, delayed-release doxycycline (200 mg) was as effective as the recommended twice-daily dosing of doxycycline in one study [Geisler, et al. 2012]. Erythromycin, levofloxacin, and ofloxacin in 7-day dosing regimens are also acceptable alternatives [CDC 2015].

Although antimicrobial-resistant \textit{C. trachomatis} is thought to be rare [Ison 2012; Ljubin-Sternak, et al. 2013], some studies have suggested that treatment with doxycycline may be more effective than azithromycin, particularly in rectal sites of infection. However, there may be greater concerns about patient adherence with the 7-day doxycycline regimen [Lau and Qureshi 2002; Schwebke, et al. 2011; Hathorn, et al. 2012; Sena, et al. 2012; Manhart, et al. 2013; Geisler, et al. 2015]. Patients with symptomatic chlamydial proctitis should be treated empirically for LGV with 100 mg of doxycycline by mouth twice daily for 21 days [CDC 2015] or azithromycin 1 g weekly for 3 weeks [Blanco, et al. 2019]. Doxycycline has been the recommended therapy for many years. Azithromycin was recently found to be equivalent in a randomized trial conducted in patients with HIV diagnosed with LGV proctitis. The impact of longer courses of azithromycin on the possible development of gonococcal or mycoplasma resistance is not known. If additional laboratory testing to differentiate LGV from non-LGV serovars is available, then the duration of treatment can be limited to 7 days of doxycycline or 1 dose of azithromycin if LGV is reliably ruled out.

Although transmission of \textit{C. trachomatis} from the pharynx has been documented [Bernstein, et al. 2009; Marcus, et al. 2011], the clinical benefit of treating patients with asymptomatic pharyngeal infection is less well studied than treatment of genital and rectal infections. To reduce the risk of transmission, this Committee concurs with the CDC recommendation to treat pharyngeal chlamydial infection, even if the pharynx is the only site of infection. Patients should be treated with azithromycin 1 g by mouth as a single dose or doxycycline 100 mg by mouth twice daily for 7 days. The efficacy of alternative treatment regimens is not known [CDC 2015].

Follow-Up and Management of Treatment Failure

Sexually Transmitted Infections (STIs) Guideline Committee, March 2018

<table>
<thead>
<tr>
<th>RECOMMENDATIONS</th>
</tr>
</thead>
</table>

**Post-Treatment Follow-Up**

- Clinicians should follow up with patients who have completed treatment for gonococcal and chlamydial infections as detailed in \textit{Table 3: Recommended Follow-Up after Completion of Treatment for Uncomplicated Gonococcal and Chlamydial Infection}. (A3)
- Clinicians should rescreen patients who had confirmed gonococcal or chlamydial infection at 3 months post-treatment for evidence of reinfection. (A2)

**Retreatment of Uncomplicated Gonococcal Infection After Suspected Treatment Failure**

- Clinicians should re-treat cases of uncomplicated gonococcal infection following suspected treatment failure according to recommendations in \textit{Table 4: Recommended Retreatment Regimens after Suspected Failure of Treatment for Uncomplicated Gonococcal Infection}. (A3)

**New York State Reporting Requirement**

- Clinicians must report cases of suspected gonorrhea treatment failure that are not due to reinfection:
  - Report suspected treatment failures to the local health department within 24 hours.
  - Call 866-692-3641 to notify the health department of suspected treatment failures.
# Post-Treatment Follow-Up

## Table 3: Recommended Follow-Up after Completion of Treatment for Uncomplicated Gonococcal and Chlamydial Infection (Adapted from Centers for Disease Control and Prevention [CDC], 2015 [CDC 2015])

<table>
<thead>
<tr>
<th>Clinical Circumstance</th>
<th>Recommended Clinician Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gonococcal Infection</strong></td>
<td></td>
</tr>
</tbody>
</table>
| Asymptomatic after treatment with recommended regimen:  
  - Urogenital or rectal infection treated with preferred or appropriate alternative regimens.  
  - Pharyngeal gonorrhea treated with preferred regimen. |  
  - Retest at 3 months (or as close to 3 months as possible) post-treatment to assess for reinfection.  
  - If laboratory test is positive for *N. gonorrhoeae*, assess for re-exposure and partner treatment, and re-treat with recommended regimen. |
| Asymptomatic after possibly ineffective course of treatment:  
  - Urogenital or rectal infection treated with regimen other than preferred or alternative regimens.  
  - Pharyngeal gonorrhoea treated with an alternative regimen.  
  - Suspected nonadherence to full course of treatment. |  
  - Assess for re-exposure and partner treatment.  
  - Perform a test of cure at site of infection with *N. gonorrhoeae* nucleic acid amplification test (NAAT) 14 days after completion of treatment.  
  - If test of cure is positive, perform culture and susceptibility testing before retreatment and re-treat with recommended regimen if possible.  
  - If recommended regimen cannot be used, re-treat with an alternative regimen or according to susceptibility test results. |
| Symptomatic post-treatment:  
  Persistent symptoms post-treatment; infection at any site. |  
  - Assess for re-exposure and partner treatment.  
  - Assess patient adherence and use of preferred or appropriate alternative regimen.  
  - Swab symptomatic site(s) for *N. gonorrhoeae* culture and antibiotic susceptibility testing ≥72 hours after treatment. NAAT may be obtained in addition to culture ≥7 days after treatment.  
  - Re-treat for suspected treatment failure (see Table 4, below).  
  - Assess for other sexually transmitted infections (STIs) that may cause persistent or recurrent symptoms.* For persistent or recurrent urethritis negative for *N. gonorrhoeae* and *C. trachomatis*, treat empirically for *M. genitalium* and/or *T. vaginalis* according to CDC recommendations [CDC 2015].  
  - Assess for non-STI etiologies as part of the differential diagnosis if a patient is repeatedly symptomatic. |
| **Chlamydial Infection** |                                   |
| Asymptomatic after treatment with preferred or alternative regimen. |  
  - Retest at 3 months (or as close to 3 months as possible) post-treatment to assess for reinfection.  
  - If laboratory test is positive for *C. trachomatis*, assess for re-exposure and partner treatment and re-treat with recommended regimen. |
| Symptomatic post-treatment:  
  Persistent symptoms post-treatment; infection at any site. |  
  - Perform a test of cure at site of infection with *C. trachomatis* NAAT 3 weeks after treatment.  
  - If test of cure is positive, assess for re-exposure and partner treatment, and re-treat with recommended treatment regimen using azithromycin or doxycycline. Azithromycin is preferred to maximize adherence.  
  - If test of cure is negative, consider other STIs* that may cause persistent or recurrent symptoms.  
  - Consider non-STI etiologies as part of the differential diagnosis when the patient is repeatedly symptomatic. |

*Other STIs may include *M. genitalium*, *T. vaginalis*, herpes simplex virus, adenovirus, and enteric bacteria.*
Retreatment After Suspected Treatment Failure

Table 4: Recommended Retreatment Regimens after Suspected Failure of Treatment for Uncomplicated Gonococcal Infection (Adapted from Centers for Disease Control and Prevention, 2015 [CDC 2015])

<table>
<thead>
<tr>
<th>Clinical Circumstance</th>
<th>Recommended Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Possible reinfection (most cases).</td>
<td>Ceftriaxone 250 mg by mouth in a single dose plus azithromycin 1 g by mouth in a single dose.</td>
</tr>
<tr>
<td>Low reinfection risk; initial treatment was incomplete or regimen administered was not preferred or alternative.</td>
<td>Ceftriaxone 250 mg by mouth in a single dose plus azithromycin 1 g by mouth in a single dose.</td>
</tr>
<tr>
<td>Low reinfection risk; initial treatment with cefixime and azithromycin [CDC 2012a].</td>
<td>Ceftriaxone 250 mg by mouth in a single dose plus azithromycin 2 g by mouth in a single dose.</td>
</tr>
<tr>
<td>Low reinfection risk; initial treatment with ceftriaxone 250 mg intramuscular (IM) and azithromycin 1 g by mouth.</td>
<td>Gentamicin 240 mg IM or gemifloxacin 320 mg by mouth plus azithromycin 2 g by mouth in a single dose.</td>
</tr>
<tr>
<td>Reduced susceptibility to relevant antibiotics on antimicrobial susceptibility testing.</td>
<td>Consult local health department.</td>
</tr>
<tr>
<td>Patient cannot follow above regimens due to allergies.</td>
<td>Obtain clinical consultation with infectious disease specialist.</td>
</tr>
</tbody>
</table>

The majority of infections identified after treatment with one of the recommended regimens results from reinfection rather than from treatment failure [Hosenfeld, et al. 2009; Kissinger, et al. 2009]. Clinicians should consider the following when assessing patients for apparent treatment failure:

- A patient may be reinfected by a new partner or an untreated current partner.
- Treatment of the patient and partner may not have overlapped, allowing the infection to pass back and forth between partners.
- Treatment may fail to eradicate organisms from the pharynx of the patient or partner [Ota, et al. 2009a].

**→ KEY POINT**

- Gonococcal and chlamydial reinfection rates are high among people who have been successfully treated [Hosenfeld, et al. 2009; Kissinger, et al. 2009].

Test of cure for gonorrhea includes nucleic acid amplification test (NAAT) testing performed at least 2 weeks after treatment to avoid false-positive results and should also include culture and susceptibility testing when the purpose is to evaluate cephalosporin-resistant *N. gonorrhoeae* (see Table 3: Recommended Follow-Up after Completion of Treatment for Uncomplicated Gonococcal and Chlamydial Infection, above). If the patient is symptomatic, culture and sensitivity may be performed after 3 to 5 days of treatment; however, NAAT testing should be delayed for at least 7 days after treatment. Test of cure for chlamydia includes NAAT testing at least 3 weeks after the course of treatment is finished [CDC 2015].

Because of current concerns regarding cephalosporin-resistant gonococcal infections, and the previous difficulty in eradicating pharyngeal gonococcal infections [Ota, et al. 2009a], a test of cure for pharyngeal infections treated with alternative therapy should be performed.

Surveillance data from the Centers for Disease Control and Prevention (CDC) have demonstrated patterns of isolates of gonococcal infection with increased minimum inhibitory concentrations (MICs) of oral cephalosporins that may indicate early stages of clinically significant cephalosporin resistance in the United States [CDC 2013]. Treatment failure should be considered in patients who report no sexual contact in the post-treatment period and have persistent symptoms for 3 to 5 days after appropriate treatment and/or a positive test of cure [CDC 2015]. Isolates from suspected treatment failures should be tested for antibiotic resistance [Bolan, et al. 2012; NYCDMHMH 2013]. Cephalosporin treatment failure should also be considered among patients with elevated cephalosporin MICs on antibiotic susceptibility testing (cefixime MIC ≥0.25 μg/mL or ceftriaxone MIC ≥0.125 μg/mL), even if the patient reports sexual activity in the post-treatment period [CDC 2012a, 2015]. Cases of suspected treatment failure after completion of a recommended or alternate regimen and with a low risk of reinfection should be reported to the local health department.
Other sexually transmitted infections (STIs) should be considered in patients whose symptoms persist after appropriate treatment, especially when test of cure is negative. Urethritis, cervicitis, and proctitis caused by other sexually transmitted pathogens may be clinically indistinguishable from gonococcal and chlamydial infections. *Mycoplasma genitalium* is a common cause of urethritis in men, accounting for 10% to 35% of nongonococcal and nonchlamydial urethritis and up to 40% of cases of persistent urethritis after treatment with doxycycline [Taylor-Robinson and Jensen 2011; Jensen, et al. 2016]. *M. genitalium* also has been associated with cervicitis and pelvic inflammatory disease among women [Falk, et al. 2005; Lis, et al. 2015]. Other pathogens to consider include *T. vaginalis*, herpes simplex virus, adenovirus, and enteric bacteria. Trichomoniasis or bacterial vaginosis may cause cervicitis, and syphilis or herpes simplex virus may cause proctitis. For additional information on diagnosis and management of other STIs that cause urethritis, cervicitis, and proctitis, refer to the CDC’s STD Guidelines.

Other pathogens that are not sexually transmitted may be responsible for continuing symptoms. For patients with persistent symptoms suggestive of gonococcal or chlamydial infection, assessment for non-STI etiologies, such as Reiter’s syndrome, strictures, hemorrhagic cystitis, or candidal urethritis, should be performed.

### Sex Partner Exposure to HIV and Gonorrhea/Chlamydia

*Sexually Transmitted Infections (STIs) Guideline Committee, March 2018*

<table>
<thead>
<tr>
<th><strong>RECOMMENDATIONS AND REQUIREMENTS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Management of HIV Exposure in Sex Partners</strong></td>
</tr>
<tr>
<td>• Clinicians should educate patients with partners who do not have HIV or partners of unknown HIV status to be vigilant for any post-exposure acute HIV symptoms in their partners, such as febrile illness accompanied by rash, lymphadenopathy, myalgias, and/or sore throat. (A3)</td>
</tr>
<tr>
<td>- See the NYSDOH AI guideline <em>Diagnosis and Management of Acute HIV</em></td>
</tr>
<tr>
<td>• Partners who present within 36 hours of an HIV exposure should be evaluated as soon as possible for initiation of post-exposure prophylaxis therapy. (A2)</td>
</tr>
<tr>
<td>- See the NYSDOH AI guideline <em>PEP for Non-Occupational Exposure to HIV (nPEP)</em></td>
</tr>
<tr>
<td><strong>Management of Partners Exposed to <em>N. gonorrhoeae</em> or <em>C. trachomatis</em></strong></td>
</tr>
<tr>
<td>• Clinicians should advise their patients that sex partners who were exposed up to 60 days before the source case’s onset of symptoms or diagnosis of gonococcal or chlamydial infection should seek evaluation and treatment and HIV testing. (A2)</td>
</tr>
<tr>
<td>• When a patient with HIV is diagnosed with gonorrhea or chlamydia, clinicians should advise the patient to encourage sex partners to seek medical care for possible exposure to HIV and gonorrhea and chlamydia and should inform the patient that NYSDOH Partner Services offers free, confidential partner notification assistance. (A2)</td>
</tr>
<tr>
<td><strong>New York State Reporting Requirements</strong></td>
</tr>
<tr>
<td>• <em>NYS Public Health Law</em> mandates that medical providers report all suspected or confirmed HIV, gonorrhea, and chlamydia diagnoses to the local health department in the area where the patient resides.</td>
</tr>
<tr>
<td>- See <em>NYSDOH Communicable Disease Reporting Requirements</em></td>
</tr>
<tr>
<td>• <em>NYS Public Health Law</em> mandates that medical providers talk with individuals with HIV about their options for informing their sexual partners that they may have been exposed to HIV.</td>
</tr>
<tr>
<td>- See <em>NYSDOH Protocol – Domestic Violence Screening in Relation to HIV Counseling, Testing, Referral &amp; Partner Notification</em>.</td>
</tr>
<tr>
<td>- See <em>NYSDOH Regional Contacts for Partner Services</em> or <em>New York City (NYC) Contact Notification Assistance Program</em> for sexually transmitted infection (STI)/HIV partner notification assistance.</td>
</tr>
</tbody>
</table>
RECOMMENDATIONS AND REQUIREMENTS

Expedited Partner Therapy

- NYS Public Health Law allows expedited partner therapy (EPT) for the treatment of exposure to chlamydial infection. It cannot be used to treat other STIs or for patients also infected with gonorrhea, syphilis and/or HIV.
  - For information about EPT in NYS and NYC, see the following:
    o NYSDOH > Expedited Partner Therapy
    o NYC Health > Expedited Partner Therapy

Management of HIV Exposure in Sex Partners

Presentation of a new STI in a patient with HIV suggests exposure of both HIV and the STI to their sex partner(s). However, offering non-occupational post-exposure prophylaxis (nPEP) to partners is usually not an option because the period before STI symptom onset is usually longer than the 36-hour window for initiating HIV nPEP. Therefore, clinicians should inform patients that any sex partner who does not have confirmed HIV infection should have sequential HIV testing for early identification of HIV acquisition. However, if a patient with an HIV exposure does present within 36 hours, evaluation for nPEP should occur.

When possible, onsite availability of HIV testing and STI treatment for partners is ideal because it may increase the likelihood that partners will receive timely access to HIV testing and appropriate treatment, including HIV post-exposure prophylaxis and treatment for the STI as needed (see the NYSDOH AI guideline PEP for Non-Occupational Exposure to HIV). Such strategies may also increase identification of individuals who require ongoing medical care. Partner education about reducing high-risk behaviors, including counseling about the use of barriers, such as male and female condoms, and making condoms visibly available in the clinic, may further decrease the risk of transmission of both HIV and other STIs.

Condoms, dental dams, and lubricants are available to non-profit organizations and healthcare facilities through the NYS Condom Program and can be ordered online. In NYC, free male and female condoms can be obtained through the NYC Free Condom Initiative, which includes a condom locator that can be downloaded to a smartphone. Patient handouts on how to properly use male and female condoms are available online through the NYSDOH publications office.

KEY POINTS: PATIENT EDUCATION

- When a patient with HIV is diagnosed with gonococcal or chlamydial infection, the clinician should inform the patient about the implications of the diagnosis for his/her sex partner(s):
  - A new STI diagnosis signals that the patient was engaging in sexual behaviors that place any sex partner at increased risk of acquiring HIV, and sex partners should be tested for HIV.
  - A sex partner also may have been exposed to gonorrhea or chlamydia and should be tested and evaluated for treatment.
  - A local health department may contact sex partners confidentially about the potential exposure and treatment options.
- Clinicians should provide patients with information and counseling about risk reduction and safer sex practices.

Management of Partners Exposed to *N. gonorrhoeae* or *C. trachomatis*

To prevent serial reinfection and curtail further transmission, sex partners of patients with gonococcal and chlamydial infections should be treated or referred for treatment if the sex partner was exposed within 60 days before symptom onset or diagnosis. No data are available regarding the optimal contact interval.

The NYS EPT policy allows healthcare providers who diagnose chlamydial infection in a patient to prescribe or provide prescription antibiotics to that patient’s sex partner(s) without examining the sex partner(s). However, EPT is not recommended for partners of patients with chlamydial infection who also have gonorrhea, syphilis, and/or HIV because partners should also receive medical care, including testing for STIs and HIV. For general information about EPT, see the CDC’s Expedited Partner Therapy. For information about EPT in NYS and NYC see the following: NYSDOH > Expedited Partner Therapy and NYC Health > Expedited Partner Therapy.
References


All Recommendations

**Transmission and Prevention**

- Clinicians should inform patients with HIV about the risk of acquiring or transmitting chlamydia, gonorrhea, and other sexually transmitted infections (STIs) from close physical contact with all sites of possible exposure, including the penis, vagina, mouth, or anus. (A3)

**Patient Education**

- When patients with HIV are diagnosed with gonococcal or chlamydial infections, clinicians should educate patients about the following:
  - Risk-reduction strategies, including the value of correct condom use. (A2)
  - The potential for oral transmission of gonorrhea and chlamydia. (A3)
  - The benefits of identifying STIs early. (A3)
  - The need for prompt evaluation and treatment of partners. (A3)

**Screening Frequency**

- For men who have sex with men (MSM) and transgender women (individuals assigned male at birth but who identify as female) who have sex with men, clinicians should perform three-site screening (genital, pharyngeal, rectal) at the following intervals:
  - At first visit and annually thereafter if the patient is at low risk of infection. (A2)
  - At first visit and every 3 months thereafter if the patient is at high risk of infection. (A2)
  - See Box 2: Description of Risk Status for Sexual Exposure to Gonorrhea and Chlamydia.
- For all other patients, clinicians should perform genital screening (urine/urethra, vagina/cervix) and extragenital screening (pharyngeal and/or rectal) at sites of contact at the following intervals:
  - At first visit and annually thereafter if the patient is at low risk of infection. (A2)
  - At first visit and every 3 months thereafter if the patient is at high risk of infection. (A2)
- Clinicians should screen pregnant patients with HIV for gonococcal and chlamydial infections at the first prenatal visit. (A2)
  - See the Centers for Disease Control and Prevention’s (CDC) STD Treatment Guidelines for information about gonococcal and chlamydial screening in pregnant women.

**Sexual History**

- Clinicians should ask all patients about sexual behaviors and new sex partners at each routine monitoring visit to assess for risk behaviors that indicate the need for repeat or ongoing screening. (A3)

**Presentation of Symptomatic Infection**

- When patients with HIV present with symptoms suggestive of gonococcal or chlamydial infection, clinicians should perform diagnostic testing as recommended in Table 1, below. (A1)
- Clinicians should include lymphogranuloma venereum (LGV) infection in the differential diagnosis for patients who test positive for rectal chlamydial infection or who present with such symptoms as rectal pain, tenesmus, bloody rectal discharge, or isolated, atypical perianal ulcerative lesions and adenopathy. (A2)
  - See the Centers for Disease Control and Prevention’s (CDC) guideline on LGV.
**Laboratory-Based Diagnosis**

- Clinicians should obtain nucleic acid amplification testing (NAAT) on samples collected from genital and extragenital sites (A1); if NAAT is not available, clinicians should:
  - Send alternative samples for culture in accordance with the protocols of the laboratory performing the analysis, with the understanding that culture is significantly less sensitive than NAAT. (A1)
- If a patient has a known exposure to a cephalosporin-resistant strain of gonorrhea, clinicians should obtain samples for both culture/susceptibility and NAAT testing from the patient and his/her sex partner(s). (A3)
- Clinicians should perform syphilis testing for any patient with HIV who is diagnosed with a gonorrheal or chlamydial infection. (A2)
  - For more information, contact the NYSDOH Wadsworth Center Laboratory at 1-518-474-4177.

**Reporting**

- **New York State (NYS) Public Health Law** requires that clinicians report within 24 hours from the time a case is first seen all suspected or confirmed gonorrhea and chlamydia diagnoses to the local health department of the area where the patient resides.
  - See [NYSDOH Communicable Disease Reporting](https://www11.health.ny.gov/communicable_diseases) and [NYC DOHMH Reporting Diseases and Conditions](https://www1.nyc.gov/site/doh/services/communicable-disease-reporting.page)
  - Clinicians can contact local health departments to obtain previously reported test results and treatment histories. See [Sexually Transmitted Disease Clinics in NYS](https://www1.nyc.gov/site/hc/about/hc-agencies-pages/disease-control/prevention/ssd-clinics.page) for contact information for clinics in each county.

**Treatment of Uncomplicated Gonococcal Infection**

- Clinicians should treat uncomplicated gonococcal infections of the cervix, urethra, rectum, or pharynx as follows:
  - Preferred: Ceftriaxone 250 mg intramuscular (IM) injection in a single dose plus azithromycin 1 g by mouth in a single dose. (A2)
  - Alternative, for patients who are allergic to azithromycin: Ceftriaxone 250 mg IM in a single dose plus doxycycline 100 mg by mouth twice daily for 7 days. (A2)
  - Alternative, if ceftriaxone is not available: Cefixime 400 mg by mouth in a single dose plus azithromycin 1 g by mouth in a single dose. This regimen is not recommended for treatment of pharyngeal infection. (A2)
- Clinicians should instruct patients to abstain from sexual activity for at least 7 days after starting treatment, and to continue to abstain until symptoms resolve and all sex partners have completed treatment. (A2)

**Treatment of Gonococcal Infection in Patients with Penicillin Allergy**

- For patients without prior severe allergic responses to penicillin (e.g., severe IgE-mediated response, such as anaphylaxis or urticaria with pruritic rash; or a severe non-IgE-mediated response, such as Stevens-Johnson syndrome, toxic epidermal necrolysis, or drug-induced hypersensitivity with inflammation of internal organs), clinicians should treat gonococcal infection with a cephalosporin-containing regimen, as recommended above, and monitor carefully for adverse effects. (A2)
- For patients with prior severe allergic responses to penicillin, clinicians should treat gonococcal infection with a single dose of azithromycin 2 g by mouth plus a single dose of either gentamicin 240 mg IM or gemifloxacin 320 mg by mouth. (A2)

**Treatment of Uncomplicated Chlamydial and LGV Infections**

- Clinicians should treat uncomplicated chlamydial infection of the cervix, urethra, rectum, or pharynx as indicated in Table 2: Recommended Treatment for Uncomplicated Chlamydial and Lymphogranuloma Venereum (LGV) Infections. (A2)
- Clinicians should treat symptomatic chlamydial proctitis with a medication regimen sufficient to treat lymphogranuloma venereum (LGV). (A3)
☑ All RECOMMENDATIONS: MANAGEMENT OF GONORRHEA AND CHLAMYDIA IN PATIENTS WITH HIV

Post-Treatment Follow-Up
- Clinicians should follow up with patients who have completed treatment for gonococcal and chlamydial infections as detailed in Table 3: Recommended Follow-Up after Completion of Treatment for Uncomplicated Gonococcal and Chlamydial Infection. (A3)
- Clinicians should rescreen patients who had confirmed gonococcal or chlamydial infection at 3 months post-treatment for evidence of reinfection. (A2)

Retreatment of Uncomplicated Gonococcal Infection After Suspected Treatment Failure
- Clinicians should re-treat cases of uncomplicated gonococcal infection following suspected treatment failure according to recommendations in Table 4: Recommended Retreatment Regimens after Suspected Failure of Treatment for Uncomplicated Gonococcal Infection. (A3)

New York State Reporting Requirement
- Clinicians must report cases of suspected gonorrhea treatment failure that are not due to reinfection:
  - Report suspected treatment failures to the local health department within 24 hours.
  - Call 866-692-3641 to notify the health department of suspected treatment failures.

Management of HIV Exposure in Sex Partners
- Clinicians should educate patients with partners who do not have HIV or partners of unknown HIV status to be vigilant for any post-exposure acute HIV symptoms in their partners, such as febrile illness accompanied by rash, lymphadenopathy, myalgias, and/or sore throat. (A3)
  - See the NYSDOH AI guideline Diagnosis and Management of Acute HIV
- Partners who present within 36 hours of an HIV exposure should be evaluated as soon as possible for initiation of post-exposure prophylaxis therapy. (A2)
  - See the NYSDOH AI guideline PEP for Non-Occupational Exposure to HIV (nPEP)

Management of Partners Exposed to N. gonorrhoeae or C. trachomatis
- Clinicians should advise their patients that sex partners who were exposed up to 60 days before the source case’s onset of symptoms or diagnosis of gonococcal or chlamydial infection should seek evaluation and treatment and HIV testing. (A2)
- When a patient with HIV is diagnosed with gonorrhea or chlamydia, clinicians should advise the patient to encourage sex partners to seek medical care for possible exposure to HIV and gonorrhea and chlamydia and should inform the patient that NYSDOH Partner Services offers free, confidential partner notification assistance. (A2)

New York State Reporting Requirements
- NYS Public Health Law mandates that medical providers report all suspected or confirmed HIV, gonorrhea, and chlamydia diagnoses to the local health department in the area where the patient resides.
  - See NYSDOH Communicable Disease Reporting Requirements
- NYS Public Health Law mandates that medical providers talk with individuals with HIV about their options for informing their sexual partners that they may have been exposed to HIV.
  - See NYSDOH Regional Contacts for Partner Services or New York City (NYC) Contact Notification Assistance Program for sexually transmitted infection (STI)/HIV partner notification assistance.

Expedited Partner Therapy
- NYS Public Health Law allows expedited partner therapy (EPT) for the treatment of exposure to chlamydial infection. It cannot be used to treat other STIs or for patients also infected with gonorrhea, syphilis and/or HIV.
  - For information about EPT in NYS and NYC, see the following:
    - NYSDOH > Expedited Partner Therapy
    - NYC Health > Expedited Partner Therapy
How This Guideline Was Developed

**Sexually Transmitted Infections (STIs) Guideline Committee (see below), March 2018**

The New York State Department of Health (NYSDOH) AIDS Institute (AI) protects and promotes the health of New York State’s diverse population through disease surveillance and the provision of quality services for prevention, health care, and psychosocial support for those affected by HIV/AIDS, sexually transmitted infections, viral hepatitis, and related health concerns. In addition, the NYSDOH AI promotes the health of LGBT populations, substance users, and the sexual health of all New Yorkers.

**Sexually Transmitted Infections Guidelines Committee**

The NYSDOH AI charged the Sexually Transmitted Infections (STI) Guidelines Committee (see Box 4, below) with developing evidence-based clinical recommendations for primary care clinicians in NYS who treat individuals with gonorrhea or chlamydia and HIV coinfection. The purpose of the *Management of Gonorrhea and Chlamydia in Patients with HIV* clinical practice guideline is to aid primary care providers and other clinicians in New York State who manage the care of adult patients with HIV who are at risk of or diagnosed with gonorrhea or chlamydia coinfection.

**Committee Makeup:** Members of the STI Guidelines Committee (see Box 5, below) were appointed by the Medical Director of the NYSDOH AI to ensure representation of clinical practice in all major regions of the state, relevant medical disciplines and sub-specialties, key NYS agencies, community stakeholders, and patient advocates. Individuals confirmed as Committee members are required to disclose any potential conflicts of interest; disclosures are reviewed and approved by the NYSDOH AIDS Institute Office of the Medical Director (see the section on Funding and Financial Disclosure of Potential Conflicts of Interest, below).

**Committee Role:** Committee members actively participated in guideline development, reviewed and approved all recommendations, and reviewed and commented on the manuscript.

**Committee Leadership:** Working with a contractual medical writer, Celine Daly, MD, the STI Committee Chair and the Vice-Chair reviewed and refined the manuscript, facilitated consensus approval of all recommendations, and addressed feedback from committee members, peer reviewers, consumer reviewers, and members of the Medical Care Criteria Committee (MCCC), which is charged with developing clinical guidelines for the care of adults with HIV.

**External review:** Two external peer reviewers recognized for their experience and expertise in STI and HIV care were identified by program leaders (see Box 4, below). Peer reviewers were asked to review the guideline for accuracy, balance, clarity, and practicality of the recommendations for primary care providers. The Committee leadership addressed peer review feedback; any conflicting opinions were resolved by the Committee chairs. Members of NYSDOH AI Community Advisory Committee also reviewed and commented on the guideline.

---

**Box 4: STI Guidelines Committee Leaders, Members (when this guideline was developed), and Guideline Reviewers**

<table>
<thead>
<tr>
<th>Leadership</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chair:</strong> Marguerite A. Urban, MD, University of Rochester Medical Center, Rochester, NY</td>
</tr>
<tr>
<td><strong>Vice-Chair:</strong> Michael H. Augenbraun, MD, FACP, FIDSA SUNY Downstate, Brooklyn, NY</td>
</tr>
<tr>
<td><strong>Acting Medical Director:</strong> Lyn Stevens, MS, NP, ACRN, New York State Department of Health AIDS Institute, Albany, NY</td>
</tr>
<tr>
<td><strong>JHU Principal Investigator:</strong> Christopher J. Hoffmann, MD, MPH, Johns Hopkins University School of Medicine, Division of Infectious Diseases, Baltimore, MD</td>
</tr>
</tbody>
</table>

---
Box 4: STI Guidelines Committee Leaders, Members (when this guideline was developed), and Guideline Reviewers

Contributing Members

- Elizabeth Asiago-Reddy, MD, SUNY Upstate, Syracuse, NY
- Gale R. Burstein, MD, MPH, FAAP, Erie County Department of Health, Buffalo, NY
- Michael M. Gaisa, PhD, MD, Mount Sinai, New York, NY
- Shelley Gilroy, MD, Albany Medical College, Albany, NY
- Sachin Jain, MD, Albert Einstein College of Medicine/Montefiore Medical Center, Bronx, NY
- Marla J. Keller, MD, Albert Einstein College of Medicine/Montefiore Medical Center, Bronx, NY
- Anita P. LaSala, MD, Columbia University Medical Center, New York, NY
- Robert Murayama, MD, MPH, Apicha Community Health Center, New York, NY
- Michel Ng, NP, Mount Sinai School of Medicine, New York, NY
- Thomas Panzella, PAC, HEAT/Downstate, Brooklyn, NY
- Asa Radix, MD, MPH, FACP, AAHIVS, Callen-Lorde Community Health Center, New York, NY
- David W. Rosenthal, DO, PhD, Northwell Health Physician Partners, Great Neck, NY
- Heather M. Territo, MD, University at Buffalo-SUNY, Buffalo, NY

Agency, Consumer, and Program Liaisons

- Bisrat K. Abraham, MD, NYC DOHMH, Long Island City, NY
  New York City Department of Health and Mental Hygiene
- Beatrice Aladin, MD, MPH, NYSDOH AI, New York, NY
  New York State Department of Health AIDS Institute Clinical Education Initiative
- Richard Greene, MD, FACP, FIDSA, New York, NY
  New York City Health + Hospitals
- David Martin, New York, NY
  New York State Department of Health AIDS Institute Consumer Advisory Committee
- Tarek Mikati, MD, MPH, NYC DOHMH, Long Island City, NY
  New York City Department of Health and Mental Hygiene

Medical Care Criteria Committee (Adult HIV guidelines) Reviewers

- Chair: Samuel T. Merrick, MD, New York Presbyterian-Weill Cornell, New York, NY
- Vice-Chair: Joseph P. McGowan, MD, FACP, FIDSA, North Shore University Hospital, Manhasset, NY
- Chair Emeritus: Judith A. Aberg, MD, FIDSA, FACP, Icahn School of Medicine at Mount Sinai, New York, NY

Peer Reviewers

- Anna Huang, MD, Bureau of STD Control, New York City Department of Health and Mental Hygiene, New York, NY
- Allison Muse, MPH, Emerging Infections Program, New York State Department of Health, New York, NY

Johns Hopkins University (JHU) Editorial Role: The JHU editorial team coordinated, guided, and documented all Committee activities, and edited the guideline material for clarity, flow, and style.

AIDS Institute and JHU editorial and program management team:

- Laura Duggan Russell, MPH, AIDS Institute Guidelines Program Coordinator
- Mary Beth Hansen, MA, JHU Guidelines Project Director
- Christina Norwood, MS, ELS, JHU Senior Editor
- Johanna Gribble, MA, JHU Medical Editor
- Jen Ham, MPH, JHU Medical Editor
- Jesse Ciekot, JHU Program Coordinator

Funding and Disclosure of Potential Conflicts of Interest (COIs)

Funding: New York State funds supported development of the Management of Gonorrhea and Chlamydia in Patients with HIV guideline through a grant awarded to the Johns Hopkins University School of Medicine, Division of Infectious Diseases, from the New York State Department of Health AIDS Institute.
Conflicts of interest: All active STI Guidelines Committee members, invited consultants and coauthors, peer reviewers, and program staff are required to disclose financial relationships with commercial entities, including gifts that may be actual conflicts of interest or may be perceived as conflicts. These individuals must disclose financial relationships annually, for themselves, their partners/spouses, and their organization/institution. On their annual disclosures, STI Guidelines Committee members are asked to report for the previous 12 months and the upcoming 12 months. Box 5, below, lists reported conflicts.

Management of COIs: All reported financial relationships with commercial entities are reviewed by the NYSDOH AI guidelines program to assess the potential for undue influence on guideline recommendations made by the Committee. For the Committee members reporting potential conflicts, it was determined that the nature of the reported financial relationships with commercial entities would not pose undue influence on the guideline recommendations.

All guideline recommendations received consensus approval of the full STI Guidelines Committee, and the final review and approval of the recommendations was performed by the Committee Chair, and the NYSDOH AI Deputy Medical Director, none of whom reported conflicts of interest.

External peer reviewers were also required to submit conflict of interest/financial disclosure information, which were similarly screened. Neither peer reviewer reported conflicts.

Box 5: Reported Conflicts of Interest/Financial Disclosure Results

<table>
<thead>
<tr>
<th>Committee Member’s Role</th>
<th>Disclosures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vice-Chair</td>
<td>Grant/research support: Starpharma Holdings Limited; Becton Dickinson</td>
</tr>
<tr>
<td>Contributor</td>
<td>Speakers’ Bureau: Gilead</td>
</tr>
<tr>
<td>Contributor</td>
<td>Pharmacy and Therapeutic Committee: Capital District Physicians’ Health Plan, Inc.; Research support: Gilead, KOWA Pharmaceuticals</td>
</tr>
</tbody>
</table>

Evidence Collection and Review and Rating of Recommendations

The NYSDOH AI guideline development process is based on a strategic search and analysis of the published evidence.

- NYSDOH AI and STI Guidelines Committee defined the goal of the guideline: To provide evidence-based clinical recommendations for the management of gonorrheal and chlamydial infection in individuals with HIV.
- JHU engaged a contractual medical writer and researcher, Celine Daly, MD, to conduct an extensive literature search in PubMed using MeSH terms, with the goal of identifying studies of human subjects published in English within the previous 5 years.
- The medical writer reviewed and summarized the evidence related to guideline recommendations, updated the text of the guideline, and submitted it for review and approval of the STI committee leadership, the MCCC leadership, and the full STI committee.
- Once consensus was reached on all recommendations, four committee members independently assigned a two-part rating to each recommendation to indicate the strength of the recommendation and the quality of the supporting evidence (see below). Raters then reviewed evidence and ratings collectively to reach consensus on each rating.
- NYSDOH AI will publish a comprehensive update 5 years after the original publication date.

AIDS Institute HIV Clinical Guidelines Program Recommendations Rating Scheme

<table>
<thead>
<tr>
<th>Strength of Recommendation</th>
<th>Quality of Supporting Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>A = Strong</td>
<td>1 = At least 1 randomized trial with clinical outcomes and/or validated laboratory endpoints</td>
</tr>
<tr>
<td>B = Moderate</td>
<td>2 = One or more well-designed, nonrandomized trial or observational cohort study with long-term clinical outcomes</td>
</tr>
<tr>
<td>C = Optional</td>
<td>3 = Expert opinion</td>
</tr>
</tbody>
</table>
Guideline Updates

Clinical Guideline Program committee members will monitor developments in the management of gonorrhea and chlamydia in patients with HIV in an ongoing structured manner to maintain guideline currency. Once the guidelines are published on the program website: www.hivguidelines.org, any updates will be made to the HTML document as needed as new peer reviewed literature on the management of gonorrhea and chlamydia in general and in the setting of HIV infection specifically is published. The full guideline will be reviewed and updated on the 4th anniversary of original publication to prepare for publication of an updated guideline on or before the 5th anniversary of original publication.

June 2019

Azithromycin 1 gm by mouth as a single dose once weekly for 3 weeks was added as an alternative regimen for treatment of symptomatic proctitis. Go to the updated page.

March 2018

The March 2018 edition of this guideline reflects a comprehensive revision and replaces entirely all previous editions.