Syphilis Screening During Pregnancy: New York State Laws and Regulations

Frequently Asked Questions for Providers





General

1. Q: When during pregnancy is syphilis screening required?

- A: All pregnant persons are required to be screened serologically for syphilis at up to three times during pregnancy:
 - a. At the time pregnancy is first diagnosed¹
 - b. At 28 weeks of pregnancy, or as soon thereafter as is reasonably possible, but no later than at 32 weeks of pregnancy²
 - c. Again at delivery³

Practitioners are also encouraged to combine the third trimester syphilis screening with the recommended third trimester HIV screening per <u>New York State Department of Health AIDS Institute</u> <u>Clinical Guidelines</u>.

2. Q: When did syphilis screening requirements go into effect?

A: Syphilis screening at first exam: The requirement to submit the initial blood sample taken at the first exam has been a requirement in New York State since 1953.

Syphilis screening during the third trimester: Effective May 3, 2024, a syphilis test is required during the third trimester of pregnancy. This is an additional screening requirement due to an increase in pregnant persons acquiring syphilis later in pregnancy.

Syphilis screening at delivery: In December 1989, a requirement to screen the cord blood of infants for syphilis was added to the New York State health regulations (10 NYCRR). In practice, this requirement has been implemented as a screening for syphilis at delivery. The reasoning here is two-fold: 1) the law states that the cord blood screening requirement is waived if body blood from the pregnant person is tested for syphilis at the time of birth, so long as the infant's body blood is tested after any positive test result of the pregnant person's blood, and 2) cord blood testing has been associated with both false positive and false negative results.⁴

3. Q. Did the third trimester screening law change from testing at the time of delivery to third trimester screening?

A: No. As per Public Health Law Section §2308, in addition to testing at the time of first examination, every practitioner attending pregnant persons shall order a syphilis test during the third trimester of pregnancy consistent with guidance and regulations of the New York State Department of Health. There has been no change to the requirement in 10 NYCRR §69-2.2 to order a syphilis test again at delivery. Please see New York State's <u>interim guidance</u> for more information.

4. Q: Who is required to do the syphilis screening during pregnancy?

A: Every physician or other authorized practitioner attending pregnant persons in New York State.

5. Q: What if the pregnant person in my care states they have only one sexual partner, or they have not had sexual intercourse since their first trimester test, and are therefore not at risk of syphilis?

A: Syphilis screening requirements are not waived for pregnant persons who report one sexual partner, or for persons who have reported not being sexually active since the first trimester testing. However, it should be noted that for persons reporting only one sexual partner, transmission is still possible.

A <u>patient centered</u> approach to this sexual health conversation is recommended to promote a productive discussion and share decision making with the patient.

6. Q: What if the pregnant person refuses syphilis screening during their pregnancy?

A: The law requires practitioners to submit the initial blood sample taken at the first exam for serological testing for syphilis and a syphilis test during the third trimester. The law is intended to detect late seroconversion in pregnancy. If the patient refuses syphilis screening, document the refusal in the medical record.

7. Q: Are there other syphilis screening requirements if a person delivers a stillborn infant?

A: The New York regulation at 10 NYCRR §69-2.2 applies when an infant is born alive or dead after 22 weeks gestation; however, any person who delivers a stillborn infant after 20 weeks gestation should be tested for syphilis.⁵

8. Q: Why are these syphilis screening requirements in place?

A: Syphilis screening at first exam: This requirement is in place to promote a healthy start to a pregnancy, and to ensure the pregnant person is adequately treated prior to delivery. Early identification and treatment of syphilis is the best way to prevent transmission to the unborn infant, and to ensure the health status of the pregnant person.

Syphilis screening during the third trimester: For individuals who screen negative at their first exam, or who were unable to access prenatal care earlier, this third trimester screen allows adequate time for persons who seroconvert during their pregnancy to be appropriately treated prior to delivery, and it reduces the risk for congenital syphilis.

Syphilis screening at delivery: This requirement is a fail-safe intervention to ensure the syphilis status of newborns is known, and if positive, newborns are provided treatment.

¹ New York State Public Health Law §2308 (the phrase "at the time of first examination" is interpreted to mean "at the time pregnancy is first diagnosed")

² New York State Public Health Law §2308, effective May 3, 2024

³ New York State Public Health Law §§2500-a, 2308; 10 New York Codes, Rules and Regulations (NYCRR) §69-2.2

⁴ Papp JR, Park IU, Fakile Y, Pereira L, Pillay A, Bolan GA. CDC Laboratory Recommendations for Syphilis Testing, United States, 2024. MMWR Recomm Rep 2024;73(No. RR-1):1–32. DOI: <u>http://dx.doi.org/10.15585/mmwr.rr7301a1</u>

⁵ https://www.cdc.gov/std/treatment-guidelines/syphilis-pregnancy.htm

9. Q: When should syphilis testing occur for a pregnant person if the first examination or the third trimester screening is missed?

A: If a pregnant person misses the first examination and/or the third trimester screening, they should be tested as soon as possible. Additionally, if a pregnant person has not received prenatal care before delivery, they should be tested at the time of delivery. As a reminder, timely syphilis testing is crucial to prevent complications and to ensure the well-being of both the pregnant person and their baby. <u>Syphilis During Pregnancy - STI Treatment Guidelines (cdc.gov)</u>

10. Q: If a pregnant person tests positive for syphilis, should they be screened for other sexually transmitted infections, including HIV?

A: Pregnant persons who test positive for syphilis should be tested for other sexually transmitted infections, including HIV.

11. Q: Does a pregnant person with syphilis require any special obstetric care?

A: Yes, a pregnant person diagnosed with syphilis will require treatment and follow-up throughout the pregnancy, at the time of birth, and postpartum.

For pregnant persons diagnosed with syphilis in the second half of pregnancy, the Centers for Disease Control and Prevention <u>STI Treatment Guidelines</u>, 2021 recommend the following:

- A sonographic exam of the fetus. Findings of fetal or placental syphilis should be managed in conjunction with an obstetric specialist.
- Pregnant patients should be advised to seek care after treatment of syphilis if they experience fever, contractions, or decreased fetal movement due to concern for a Jarisch-Herxheimer reaction, which may be associated with preterm labor and/or fetal distress.

Serologic Screening

1. What is considered "standard serological tests for syphilis"?

A: <u>Standard serologic screening for syphilis</u> during pregnancy includes both the <u>traditional</u> (beginning with a quantitative nontreponemal test) and <u>reverse screening algorithms</u> (beginning with a treponemal antibody test). As both screening approaches (traditional and reverse) are valid, neither the Centers for Disease Control and Prevention nor the New York State Department of Health endorses one algorithm over the other.

Per the latest Centers for Disease Control and Prevention <u>Laboratory Recommendations for Syphilis Testing</u> dated February 8, 2024, non-treponemal (lipoidal antigen) and treponemal tests should be interpreted in the same manner regardless of pregnancy status. Practitioners should be aware that in the setting of early primary syphilis (when a chancre first develops), both treponemal and non-treponemal tests may be false negative. In the absence of obvious or visible signs of syphilis and a negative initial treponemal or non-treponemal test, practitioners may perform more frequent testing than the recommended 3 testing periods, especially if there are indications of activities that pose a higher risk of syphilis acquisition, such as sex work, erratic prenatal care, substance abuse, or having an untested or untreated partner. For additional diagnostic considerations, please see the <u>STI Treatment Guidelines,</u> <u>2021</u> from the Centers for Disease Control and Prevention.

Timing of Screening

- 1. Q: If a pregnant person is admitted for delivery, but is discharged home undelivered, does the pregnant person need to be retested for syphilis when admitted for the actual delivery encounter even if they had a valid third trimester screening?
 - A: Yes. The third trimester screening is a separate requirement and does not impact the existing requirement to screen at delivery. We suggest working with your organization's general legal counsel regarding the best way to comply with the requirement for testing at delivery, which has not changed.

2. If a pregnant person delivers before their third trimester, do they still need syphilis screening on admission to delivery?

A: Yes. The delivery screening requirement is still in place.

3. Should I test my pregnant patients more than what is required by the laws and regulations?

A: Further testing may be indicated based on the patient-centered risk factors throughout their pregnancy.

4. The <u>interim guidance</u> states that pregnant persons "should" be tested between 28 and 32 weeks. Could third -trimester syphilis screening be done before 28 weeks, such as at 24 weeks or between 37 and 38 weeks?

A: The Centers for Disease Control and Prevention recommends testing between 28 and 32 weeks. It is advisable for practitioners to use a patient-centered approach to determine the most appropriate timing for third trimester screening that account for the patient's access to prenatal care and individual risk. This decision-making process may be impacted by other factors such as stigma and health disparities. An open dialogue offers an opportunity to build trust, particularly among marginalized and disenfranchised communities.

5. Q: If a pregnant person is required to undergo serologic syphilis screening at the time of pregnancy diagnosis, do they have to wait until initiating prenatal care with an obstetric provider for screening?

A: No. Syphilis testing can be performed when the pregnant person presents to an emergency room, clinical or urgent care setting, or other settings where medical care is provided (e.g., correctional facility). New York State recommends screening within those settings to help reduce missed opportunities in preventing congenital syphilis.

6. Q: If a provider diagnoses pregnancy but is referring the patient for prenatal care, are they required to order the syphilis testing?

A: It is advisable to consult with each health facility's executive team and/or legal department. Effective communication and integrated care play a crucial role in ensuring that pregnant persons are tested to prevent a missed opportunity in avoiding congenital syphilis. The ideal practice is that syphilis testing is ordered when the pregnancy is diagnosed. If this is not feasible, a best practice for such providers is to ensure a prenatal appointment, and ensure that syphilis testing and other necessary first trimester pregnancy screenings are scheduled.

7. Q: If a patient presents for a medication abortion visit in the first trimester and no lab work is being ordered, do they need syphilis testing?

A: No. However, syphilis and HIV testing are strongly encouraged, and it is advisable to discuss and support sexual health needs during counseling and follow-up.

Treatment

1. What is the recommended treatment for pregnant persons testing positive for syphilis?

A: Pregnant persons should be treated with the recommended regimen per their specific stage of infection with Penicillin G (Bicillin L-A®). For more information, please refer to the <u>STI Treatment Guidelines, 2021</u>.

For clinical questions regarding syphilis staging, patient and infant treatment, partner treatment, and recommended clinical follow up for pregnant persons with syphilis in New York State, practitioners/clinical providers can call 1-866-637-2342. They will receive a return call promptly.

2. Q: What if there is a shortage of Bicillin L-A®?

A: If there is a known or anticipated shortage, practitioners should review their existing Bicillin L-A[®] inventory and reserve Bicillin L-A[®] for pregnant persons and infants with congenital syphilis. If supply is low, doxycycline is the alternative recommendation that can be used to treat any sexual partner(s) of the pregnant person, and practitioners should closely follow patients to encourage completion of the medication course. Doxycycline should **not** be used to treat pregnant persons as it is contraindicated during pregnancy. For guidance and recommendations for syphilis treatment when there is a known shortage of Bicillin L-A, please see previously released New York State Department of Health Advisories: June 2023 and January 2024.

The Food and Drug Administration has announced the availability of Extencilline to address an ongoing shortage of Bicillin L-A[®] initially reported in 2023. Please note that the preparation and administration of Extencilline, as well as the contraindications for prescribing, differ from those for Bicillin-LA[®]. Extencilline will be available only by prescription in the United States. For additional information, refer to FDA Announcement on Availability of Extencilline | Dear Colleague Letters | NCHHSTP | CDC.

Partner Management

- 1. Q: If the pregnant person in my care tests positive for syphilis, what support is there for treating their sexual partner(s)?
 - A: <u>Partner services</u> are available, as needed, to support the care management of the pregnant persons sex partner(s). For more information about this service, please refer to <u>Accessing Partner Services</u>.

2. Q: Can Expedited Partner Treatment (EPT) be offered to pregnant persons who test positive for syphilis during pregnancy?

A: The <u>provision of EPT</u> is not permissible for persons diagnosed with syphilis in New York State.

3. Q: Can doxycycline be prescribed as post exposure prophylaxis to sexual partner(s) of pregnant persons who test positive for syphilis?

A: There are currently no guidelines for regularly prescribing doxycycline as post-exposure prophylaxis (Doxy-PEP) to sexual partners of pregnant persons diagnosed with syphilis. For more information on Doxy-PEP: <u>Doxycycline Post-Exposure Prophylaxis to Prevent Bacterial</u> <u>Sexually Transmitted Infections (9/25/23) – Clinical Guidelines</u> <u>Program (hivguidelines.org).</u>

Reporting

1. Q. Is it a requirement to report positive syphilis results?

- A: Yes. For all New York State jurisdictions, physicians are required by law to:
 - Report cases to the local health officer (Public Health Law §2101; 10 NYCRR §2.10), and
 - Cooperate with state and local health officials' efforts to determine the source and control the spread of sexually transmitted infections (10 NYCRR §2.6).

It is important for the Physician/Offices to report and complete demographic data, especially the pregnancy status of the patient.

2. Q: Is negative syphilis test reporting a requirement?

A: In New York State outside of New York City: There is currently not a requirement for laboratories to report negative syphilis tests.

In New York City: An <u>amendment</u> to Health Code § 13.03(b)(2) requires laboratories to report all negative syphilis test results. The Health Code previously required the reporting of all positive and indeterminate syphilis test results, but only some negative syphilis test results. The New York City Board of Health amended the Health Code to enable the collection of all negative syphilis test results to improve the diagnosis and treatment of patients and their sexual partners.

Costs of Syphilis Screening

1. Q: Is the cost of these syphilis tests covered by Medicaid?

A: For both fee-for-service (FFS) and Medicaid Managed Care (MMC), <u>New York State Medicaid</u> coverage of syphilis screening tests align with syphilis screening requirements during pregnancy. This requires practitioners to order a syphilis screening test for pregnant individuals during their third trimester of pregnancy, in addition to testing at the time of their first exam, and again at delivery.

Compliance

1. Q: What are the Department's expectations around compliance?

A: In New York State outside of New York City: With the lack of a reporting requirement for negative syphilis screening results outside of New York City, compliance can only be routinely monitored among pregnancies that result in a congenital syphilis case, which is considered a sentinel event. The New York State Department of Health responds to these sentinel events with timely investigation/review to identify systems, processes, and conditions which caused and/or contributed to the resultant outcome. These investigations/reviews are conducted under the New York State Department of Health's authority pursuant to Public Health Law Article 21 and 10 NYCRR Part 2 as part of public health surveillance, and epidemiologic and patient follow-up. Subsequent recommendations and corrective action, if indicated, may be issued by the New York State Department of Health. Beginning in 2023, all birthing hospitals associated with a reported congenital syphilis case will be issued a notification letter with recommended action items.

Contract entities and other Article 28 facilities might be subjected to retrospective chart reviews to determine compliance.

In New York City: The New York City Department of Health and Mental Hygiene responds to reports of congenital syphilis with timely investigation/review to identify systems, processes, and conditions which caused and/or contributed to the congenital syphilis case. These investigations/reviews are conducted under Article 11 Section §11.03 of the New York City Health Code as part of public health surveillance, and epidemiologic and laboratory investigation activities. Subsequent recommendations and corrective action, if indicated, may be issued by the New York Department of Health and Mental Hygiene. All health care providers associated with a reported congenital syphilis case are issued a notification letter with recommended action items.

Training, Education, and Resources

1. Q: How can I acquire more information on syphilis screening and treatment for syphilis, syphilis in pregnant persons, and congenital syphilis?

- A: a. For access to free clinical education, or to request training on syphilis or congenital syphilis, please go to <u>Clinical Education</u> <u>Initiative Training</u>.
 - b. For access to free clinical materials, including palm cards with information on syphilis in pregnancy and congenital syphilis, and an information sheet on <u>screening for STIs</u>, <u>HIV</u>, and <u>Hepatitis B/C</u> <u>during pregnancy</u>, please go to the <u>CEI Sexual Health Center of Excellence- Materials Order Form</u>.

Real-time clinical support is available through the Clinical Education Initiative Sexual Health Center of Excellence's Clinical line for syphilis and other sexually transmitted infection related questions: Call the **Ask an Expert Clinical Education Initiative Line** at **1-866-637-2342**.

New York City: practitioners can access information on syphilis and other sexually transmitted infections and training resources by visiting the New York City Department of Health and Mental Hygiene website: <u>Sexually Transmitted Infections - Providers - NYC Health</u>.

National: The Centers for Disease Control and Prevention offers diagnosis and treatment of syphilis and congenital syphilis at <u>Sexually Transmitted Infections Treatment Guidelines, 2021 (cdc.gov)</u>. Additional Centers for Disease Control and Prevention resources can be found at <u>STI Treatment Guidelines (cdc.gov)</u> and <u>STD Facts - Syphilis (cdc.gov)</u>. A recent health advisory provided the latest epidemiologic data for syphilis among females and for congenital syphilis; an announcement of the availability of Extencilline[®] as a treatment option; and recommendations for health care providers related to screening, diagnosis, treatment, and counseling at <u>han-advisory-4.pdf (nyc.gov)</u>.

