# NEW YORK STATE CONGENITAL SYPHILIS ELIMINATION STRATEGIC PLANNING GROUP: ELIMINATION FRAMEWORK, 2024





### Congenital Syphilis Elimination Strategic Planning Group: Elimination Framework

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# Call to Action: Executive Summary

#### The increases in congenital syphilis will continue unless we act now.

Congenital syphilis (syphilis in infants) is preventable, however, despite decades of dedicated efforts to reduce syphilis transmission, rates have continued to rise over the past twenty years, with congenital syphilis disproportionately impacting communities of color. Building off strong community partnerships spearheaded in New York State to end epidemics such as HIV and hepatitis, we recognize that community partnerships are key for meaningful impact towards eliminating congenital syphilis.

New York State convened the Congenital Syphilis Elimination Strategic Planning Group (The Group) in March 2023 with the intent to create a comprehensive Congenital Syphilis Elimination Framework using a health equity lens. The Group was comprised of 43 community members divided into seven subcommittees. Each subcommittee had two New York State Department of Health support staff and subject matter experts. The Group was led by two community co-chairs, and eight steering committee members from the New York City Department of Health and Mental Hygiene and the New York State Department of Health. The Group's mission was to outline a coordinated, comprehensive, and systematic approach to reducing and eliminating congenital syphilis through the development of recommendations to be implemented across healthcare systems and public health sectors.

Those recommendations are outlined in this document and were conceptualized, developed, and prioritized by The Group. They include strategies to eliminate health inequities by ensuring equitable access to syphilis care and treatment, increasing screening opportunities at various points across the healthcare system, working with providers, and increasing data sharing, research, and messaging around equitable care and treatment.

The overarching goals from the recommendations include:

- Expanding access and testing opportunities in both traditional healthcare settings and non-traditional environments leveraging advances in testing technology,
- Educating and increasing awareness among patients, partners, and the public,
- Improving and ensuring provider education and accountability,
- Strengthening public health and partner collaboration,
- Increasing and supporting data sharing and surveillance, and
- Creating systems to support an immediate response.

# Purpose of this Document

This document outlines the vision of forty-three (43) New York State community members to eliminate congenital syphilis throughout the State with immediate and long-term support for all impacted groups, while also highlighting the persistent disparities in syphilis rates, and congenital syphilis for Black females compared to White females.

This document serves as the Congenital Syphilis Elimination Framework (The Framework), which is a summary of The Group's work from its inception in 2023 through 2024 and demonstrates the aligned efforts of New Yorkers working to address rising rates of congenital syphilis.

The Framework outlines recommendations developed by The Group to create a path for resources to address congenital syphilis to be allocated throughout New York State.

In addition to addressing congenital syphilis in New York State, it is The Group's goal that The Framework encourages and supports strategic thinking on ending congenital syphilis nationally. The Group also hopeful that other states can utilize this Framework to set objectives in their jurisdiction regarding congenital syphilis elimination efforts.

# Recommendations

The below recommendations, developed by the community members that make up The Group, incorporate their input and thus reflect their collective voice. Any occurrence in which The Steering Committee modified the language substantively is reflected in a footnote.

Each recommendation is numbered with the acronym **CSER** (Congenital Syphilis Elimination Recommendation) for reference. The recommendations below are divided into two categories: "**Prioritized Recommendations**" and "**General Recommendations**". Though the intention was to prioritize one recommendation from each of the seven subcommittees, two of the prioritized recommendations were combined due to their similarity. Therefore, the below six "**Prioritized Recommendations**" were those given priority by community members based on the magnitude of the work needing to be done, the immediacy, and other criteria. For more information on the prioritization process, please see <u>Appendix II</u>.

Under each recommendation, there is a list of *community-identified collaborators*. This list indicates the collaborators that The Group named as those who could support implementation of the specific recommendation and therefore be able to aid in this elimination effort; the list is not intended as a directive and is not to be considered exhaustive.

### Prioritized Recommendations

# CSER 1. Expand access points and integrate syphilis testing into existing sites and settings.<sup>1</sup>

Syphilis testing needs to be integrated into both clinical/traditional and nonclinical/non-traditional settings leveraging advances in testing technology to expand testing and increase access/opportunities.

<u>Clinical/traditional settings</u>: Syphilis testing, especially for persons of childbearing capacity should be expanded to primary care and specialty clinic settings.<sup>2</sup> Syphilis testing should be integrated into settings that are already offering other tests for HIV, sexually transmitted infections (STIs), and hepatitis C. In some settings, it is possible to conduct concurrent HIV and syphilis testing.

<sup>&</sup>lt;sup>1</sup> See CSER 18 and CSER 19

<sup>&</sup>lt;sup>2</sup> Including but not limited to: HIV/Methadone Assisted Therapy(MAT)/HIV Pre-exposure Prophylaxis/sexually transmitted infection care settings, Obstetric and Gynecologic (OB/GYN) health visits, mental health visits, urgent care, and inpatient and outpatient detox and rehabilitation programs.

<u>Non-clinical/non-traditional settings</u>: When serology testing is not possible, certain over the counter tests to perform at-home testing can and should be offered outside of a clinical setting.<sup>3</sup> As appropriate, providers can also implement point of care testing to expand opportunity for early identification and treatment (see also: CSER 18 and CSER 19). Organizations promoting or offering such services should take steps to minimizes the cost to the individual as costs for self-collection and/or point of care testing kits might present a barrier to access. With respect to any pregnant person testing positive for syphilis, non-clinical settings should link the individual to syphilis treatment and prenatal care.<sup>4</sup>

Community-identified collaborators: New York State Department of Health, harm reduction programs, syringe exchange programs, community-based organizations, faith-based organizations, Special Supplemental Nutritional Program for Women, Infants, and Children (WIC), mental and behavioral health agencies, substance use treatment facilities, correctional facilities, homeless shelters, food pantries, prenatal care providers, hospitals and emergency rooms, children's health centers, infectious disease providers, laboratories, local health departments, disease intervention specialists, and private insurance companies.

# CSER 2. Create congenital syphilis education messaging for patients, their partners, and the public.

Efforts to increase knowledge and awareness of congenital syphilis should include targeted messaging and outreach to patients, their partners, and the public. This can involve creating advertisements for the general public on billboards, social media, buses, television, and radio. Additionally, distributing educational materials such as pamphlets, towels, diaper bags, and Quick Response (QR) codes to patients and their partners can help promote key messages.<sup>5</sup>

*Community-identified collaborators: New York State Department of Health Public Affairs Group, American College of Preventative Medicine, and the American Association of Nurse Practitioners.* 

# CSER 3. Partner with multi-specialty professional medical societies to increase education about syphilis and congenital syphilis.

<sup>&</sup>lt;sup>3</sup> Methadone clinics, shelters for persons who are unstably housed, syringe exchange programs, housing programs and pantries, department of health events, health fairs, outreach events at Job Corps, colleges/universities, within the criminal justice system, and Women, Infant and Children (WIC) appointments.

<sup>&</sup>lt;sup>4</sup> Though The Group identified the local health department as the intermediary to linking pregnant persons to care, this recommendation was modified to enable existing linkage arrangements to be leveraged.

<sup>&</sup>lt;sup>5</sup> The Group identified the following messages: 1. Prenatal care is important to keep you and your baby healthy; 2. Syphilis during pregnancy affects your baby: get tested for syphilis 3 times during pregnancy; 3. It is possible to get re-infected with syphilis. Protect your pregnant partner and your baby by getting tested and treated for syphilis; 4. You can enjoy sex while pregnant by using condoms and getting checked for syphilis; and 5. Keep babies safe from syphilis. Get tested and treated for syphilis; today.

The recent rise in congenital syphilis cases highlights a knowledge gap among some medical providers about the resurgence of syphilis. There is a need to bridge that knowledge gap by partnering with medical schools and professional medical associations. Collaboration is necessary, given the critical role of healthcare providers in combating syphilis and congenital syphilis. Furthermore, medical societies can play a vital role in disseminating accurate information and promoting evidence-based practices related to syphilis and congenital syphilis prevention. They can facilitate targeted educational initiatives to update members across various specialties on congenital syphilis case identification, management, and patient counseling, which would aid in prompt diagnosis and treatment of syphilis to reduce transmission and improve patient outcomes.

Community-identified collaborators: American College of Obstetricians and Gynecologists, Council on Resident Education in Obstetrics and Gynecology, American Academy of Pediatrics, American Academy of Family Physicians, American College of Emergency Physicians, American College of Nurse-Midwives, Society of Family Planning, Infectious Diseases Society of America, mid-level provider professional societies, The New York State Department of Health, and other relevant organizations and medical societies.

# CSER 4. Promote provider and healthcare system awareness and compliance with the third trimester syphilis screening mandate.

There needs to be increased awareness and compliance with New York State's third trimester syphilis screening mandate. The Group recommends raising awareness among providers and administrators at programs focused on pregnant people and those providing antenatal and post-partum care. This can be achieved through provider education, internal quality improvement projects, and advertisements.<sup>6</sup> Education is also necessary for regional health information organizations and risk management entities. This education should address potential concerns, including laboratory capacity, increased reporting of abnormal laboratory results, and navigating various electronic systems between laboratories, reporting entities, and health systems.

To increase compliance with New York State's mandate, third trimester syphilis screening should be integrated into electronic medical record order sets with appropriate laboratory selections.

Community-identified collaborators: Hospital chief information officers and quality assurance teams, American College of Obstetricians and Gynecologists, Clinical Education Initiative, community-based organizations, medical providers, New York State Department of Health, AIDS Institute, Congenital

<sup>&</sup>lt;sup>6</sup> The Group identified the following programs: delivery hospitals, emergency departments, primary care, infectious disease and control departments, prenatal care providers, midwives, obstetricians and gynecologists (OB/GYNS), lesbian, gay, bisexual, transgender, and queer (LGBTQ+) providers, STI care centers, harm reduction service centers, and medication assisted treatment (MAT) providers.

*Syphilis Elimination Strategic Planning Group members, local health departments, and the New York State Association of County Health Officials.* 

# CSER 5. Enable real-time access to all syphilis records to ensure timely diagnosis and treatment across New York State jurisdictions through the creation of statewide surveillance registry.

All healthcare providers should have direct access to historical syphilis serology, treatment data, and pregnancy status through a single system, allowing them to review all relevant information in one place without having to log into multiple systems.<sup>7</sup> Further, this system should enable healthcare providers to enter syphilis treatment or other relevant information. Lastly, any paper syphilis records should be digitized and entered into the electronic system.

The developed system needs quality control measures to ensure bidirectional data are accurately entered and that the data entry process is consistently and comprehensively shared with all healthcare providers.

Community-identified collaborators: AIDS Institute, Communicable Disease Electronic Surveillance System staff, Congenital Syphilis Elimination Strategic Planning Group members, Congenital Syphilis Response Team staff, Electronic Clinical Laboratory Reporting System staff, Health Commerce System staff, HIV community planning groups, local health departments, medical providers, Reginal Health Information Organizations, and syphilis registry and serology staff.

# CSER 6. Create a positive syphilis testing alert system within hospitals or birthing centers.

Create an alert system, similar to those used for Hepatitis B and C, to alert providers of a child being born to a birthing person with syphilis or with a reactive syphilis test at delivery. This would allow the provider to receive critical results and ensure timely and adequate treatment for the birthing parent and the infant. While this might not prevent an infant from being born with congenital syphilis, it will ensure the infant is started on an immediate treatment regimen. Currently, not every positive enzyme immunoassay (EIA) or chemiluminescence assay (CIA) result is reported to the health system. Implementing an alert system would ensure no positive syphilis test, including rapid plasma reagin (RPR) titers is overlooked.

Additionally, all positive syphilis test results in pregnant people should be immediately reported to the appropriate health department to ensure timely partner services and treatment.

<sup>&</sup>lt;sup>7</sup> The Group identified that this system should be the Health Commerce System, however, this recommendation was modified to enable a broader approach by the identified collaborators to fulfill the recommendation.

Community-identified collaborators: Prenatal providers, hospitals (labor and delivery, maternity, Emergency Rooms, children's health centers, infectious disease), laboratories, local health departments, New York State Department of Health, and insurance companies.

## General Recommendations

The remaining recommendations (CSER 7- CSER 24) were considered impactful by The Group but were identified as recommendations that may require more resources and extended planning for implementation. These recommendations are categorized as "**General Recommendations**."

# CSER 7. Expedite syphilis testing at delivery and require documentation of prenatal syphilis screening.

A newborn's syphilis status should be documented in the medical chart before discharge. This can be adequately done if the provider confirms antenatal screening results at entry into prenatal care, and during the first and third trimesters. A standard alert in hospital electronic medical records should be required for all antenatal, prenatal and post-natal admissions for the birthing parent and child to show complete screening documentation.

Further, to expedite infant syphilis test results in cases of inadequate screening or suspected congenital syphilis, newborn syphilis testing should be ordered immediately (STAT) to achieve a 24–48-hour turnaround time for the laboratory. There should be a rapid send-out protocol, including guides on how to send specimen to the State laboratory, when needed.<sup>8</sup> These guides should be widely disseminated and advertised broadly across the State. It is also crucial that all staff be trained to provide counseling and education with a trauma informed approach, including culturally and linguistically appropriate services standards used for health literacy.

Community-identified collaborators: Pediatricians, hospitals, laboratories – commercial and private, and electronic medical record systems.

# CSER 8. Ensure there is a comprehensive sexual health approach to increase screening and awareness of syphilis regardless of a patient entry point into care and/or their risk factors.

Similar to harm reduction interventions, HIV prevention, and Hepatitis C virus (HCV) elimination measures, a status-neutral<sup>1</sup> approach to combat congenital syphilis is key. A status-neutral approach to congenital syphilis prevention means offering syphilis screening and education to all patients, regardless of their perceived risk

<sup>&</sup>lt;sup>8</sup> The Group identified that this laboratory should be the Wadsworth perinatal laboratory, however, this recommendation was modified to enable a broader interpretation.

factors or pregnancy status. Offering syphilis screening and education at every entry point into prenatal healthcare allows for early detection and comprehensive care<sup>9</sup>.

Using a status-neutral approach to combatting syphilis aligns with holistic and person-centered healthcare, where treatment and services are tailored to individual need. This includes providing necessary services and support to pregnant people with and without syphilis, creating a non-judgmental environment where all patients feel comfortable accessing care, and identifying cases of syphilis early in pregnancy to prevent complications and transmission.

Normalizing syphilis screening and making it accessible to everyone regardless of their perceived risk, will help identify asymptomatic cases and ensure timely treatment, preventing potential pregnancy complications and transmission. This inclusive and comprehensive approach has the potential to significantly reduce the burden of syphilis.

Community-identified collaborators: Medical providers of any specialty, social workers, mental health providers, and researchers.

# CSER 9. Utilize a medical home model to improve syphilis treatment efforts for pregnant people.

Leveraging case/care management services, health homes, social workers, and community health workers can lead to the formation of a comprehensive, collaborative, and holistic care team to address syphilis during the antenatal and postnatal period. Social determinants of health can pose significant barriers to treatment and care; however, case management services can often effectively overcome these barriers. Similarly, community health workers from health departments can play a pivotal role in providing collaborative services. This model is like the <u>New Family Home Visits Initiative</u>, a New York City Initiative that offers support, services and referrals to new and expectant parents. Additionally, New York State Medicaid has expanded postpartum coverage from 60 days to one year, creating opportunities to ensure appropriate care continues after pregnancy.

Community-identified collaborators: Medicaid, community-based organizations, pregnant persons, multidiscipline provider teams, local health departments, and the American College of Obstetricians and Gynecologists.

### CSER 10. Ensure equitable access to syphilis treatment.

<sup>&</sup>lt;sup>9</sup> Status Neutral: Status Neutral, or Status Neutrality, is a 'whole person' approach to HIV prevention and care that emphasizes high quality care to engage and retain people in services regardless of if the services are for HIV treatment or prevention.

Access to injectable Bicillin L-A (penicillin G benzathine) is a recurring challenge. A statewide monitoring system and mechanism to share supplies across jurisdictions should be developed and maintained to ensure a collaborative approach between providers, health departments, and health systems during medication shortages.

Community-identified collaborators: New York State Department of Health, Communicable Disease Electronic Surveillance Systemstaff, medical providers, local health departments, American College of Obstetricians and Gynecologists, Clinical Education Initiative, pharmaceutical companies, pharmacies and pharmacists, and Medicaid.

### CSER 11. Use syphilis field testing and treatment services for sexual partners.

Field testing and treatment for sexual partners may bridge gaps in the spread of syphilis. Specifically, field testing with diagnostic or point-of-care testing can improve the identification of the partner's syphilis status and inform the administration of field-guided therapy. Ideally, all partners should be tested, but per the Centers for Disease Control and Prevention's (CDC's) most recent STI treatment guidelines, management of sexual partners includes presumptive treatment under several conditions.<sup>10</sup> Field testing and/or field-delivered treatment should be considered for partners meeting the conditions outlined in CDC's STI Treatment Guidelines.<sup>10</sup>

Community-identified collaborators: Office of the Professions, local health departments, New York State Department of Health, Communicable Disease Electronic Surveillance System staff, pharmacies and pharmacists, Medicaid, and researchers.

### CSER 12. Ensure better linkages between health departments and health systems to track pediatric populations impacted by congenital syphilis by use of a surveillance registry.

Expanded provider access to a surveillance registry that links patient identifiers for both parent and child, including prior serology and prior treatments, would be beneficial. These registries would track treatment completion and loss to follow-up, informing what additional health interventions are needed.

Community-identified stakeholders: New York State Department of Health, local health departments, Communicable Disease Electronic Surveillance System staff, hospital social worker, pediatricians, hospital systems, Medicaid, American Academy of Pediatrics, and the American Academy of Family Physicians.

<sup>&</sup>lt;sup>10</sup> <u>https://www.cdc.gov/std/treatment-guidelines/syphilis.htm</u>

# CSER 13. Utilize specialized disease intervention specialists or congenital syphilis investigators.

In addition to Disease Intervention Specialists (DIS) conducting routine disease intervention work, a subset of DIS should be specially trained in congenital syphilis prevention and care (e.g., Congenital Syphilis Investigators). A key role for these staff would be the implementation of community outreach as well as engagement with medical practices and STI testing sites within their catchment area. This will allow practices/providers to learn about expertise within health departments and ensure a direct point of contact for guidance and reporting within their catchment area.

Community-identified collaborators: National Coalition of STD Directors, National Network of Disease Intervention Training Centers, AIDS Institute Office of Sexual Health and Epidemiology, AIDS Institute Bureau of HIV/STI Field Services, AIDS Institute Office of the Medical Director, and Clinical Education Initiative.

# CSER 14. Develop a community advisory board focused on preventing congenital syphilis.

New York State jurisdictions (e.g., regions or counties) should develop a community advisory board in collaboration with community-based organizations and local residents to monitor rates of congenital syphilis, identify barriers to care and treatment, and make recommendations for early syphilis testing, linkage, and treatment strategies.

Community-identified collaborators: Community-based partners, provider organizations, county employees

### CSER 15. Increase syphilis data sharing with the community.

Improve the timeliness of publishing and sharing surveillance reports on congenital syphilis. This can be achieved through new surveillance dashboards, existing or forthcoming STI dashboards, or the sharing of interim data reports. The information should be accessible and written with health literacy in mind. Information shared can include incidence rates, prevalence rates, risk factors, and presented in simple format such as an infographic.

Community-identified collaborators: Local health departments, New York State Department of Health, general public, community-based organizations, medical providers, community leaders.

# CSER 16. Create a congenital syphilis screening quality measure for health systems.

Develop quality improvement measures for congenital syphilis or a value-based pay system linked to prenatal syphilis screening requirements to improve screening and hold healthcare systems accountable. Additional quality improvement measures can support and promote internal projects and funding. Specialists with experience in designing and implementing quality metrics in the development process and roll out should be included.

Community-identified collaborators: Congenital Syphilis Elimination Strategic Planning Group members, evaluation specialists, health insurance plans, medical providers, New York State of Health, Health Insurance Association of America, and New York State Department of Health.

# CSER 17. Improve communication of syphilis test results between laboratories and health departments.

Laboratories should be aware of codes for pregnancy and syphilis tests and link positive results for the same person (e.g., link positive pregnancy test results and positive syphilis results to same individual). Reporting these linked positive results will alert health departments to a pregnant person with syphilis, flagging it as a potential congenital syphilis case.

Community-identified collaborators: New York State Department of Health Offices of Sexual Health and Epidemiology and the Medical Director, Clinical Education Initiative, diagnostic laboratory companies.

### CSER 18. Implement point-of-care syphilis testing.

Providers should explore the feasibility of point-of-care testing for syphilis and other STIs. Specifically, they are encouraged to use of point-of-care syphilis tests at existing STI testing sites to expand testing and treatment efforts. Funding must be allocated to purchase test kits and to implement outreach efforts, especially in areas with high rates of new syphilis infections.

Community-identified collaborators: Community-based organizations, New York State Department of Health, laboratories with Clinical Laboratory Improvement Amendments (CLIA)-waived certificate of waiver.

### CSER 19. Identify and leverage statewide funding to increase syphilis testing.

Identify statewide funding to support syphilis testing, including point-of-care testing, at both traditional and non-traditional sites is essential for increasing testing opportunities.

Community-identified collaborators: New York State Department of Health, organizations that will receive funding for testing (community based-organizations, local health departments, etc), New York

State Legislative Officials to propose legislation for additional funding, and current stakeholders for existing grant-funded testing programs to provide guidance and recommendations.

# CSER 20. Increase research and publications on syphilis and congenital syphilis by developing partnerships with statewide health organizations.

Improve public health outcomes by strengthening research and enhancing collaboration between academia, researchers, health departments, and other health organizations. Stronger research efforts are needed to address public health challenges caused by syphilis and congenital syphilis. This comprehensive approach addresses the need for stronger evidence-based practices in identification, prevention, and treatment of syphilis.

Community-identified collaborators: AIDS Institute, local health departments, Regional Perinatal Centers in New York, New York State Association of County Health Officials, Clinical Education Initiative, Regional Health Information Organizations, New York City Department of Mental Health and Mental Hygiene, graduate-level Public Health programs in New York State, New York State Office of Drug User Health, American College of Obstetricians and GynecologistDistrict II, Title X Family Planning Clinics, syringe exchange programs, designated institutional officials of residency and fellowship programs in New York, Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), Medicaid Health Homes, and early childhood advocacy programs.

### CSER 21. Increase funding for staff dedicated to syphilis-related research.

Identify and utilize funding to support additional staff needed to conduct prospective and retrospective research related to congenital syphilis. Dedicated research staff will enable and foster relationships among academia, health departments, and other research organizations. Additionally, research staff should work with regional health information organizations to leverage data and statistics on access to care, syphilis testing and treatment, technical skills, and subject matter expertise.

Community-identified collaborators: AIDS Institute, local health departments, New York City Department of Mental Health and Mental Hygiene, New York State Department of Health, National Association of County Health Officials, Centers for Disease Control and Prevention, Association of State and Territorial Health Officials, New York State Association of County Health Officials, Regional Health Information Organizations, Congenital Syphilis Elimination Strategic Planning Group Committee Members, healthcare organizations, medical providers, academic institutions, National Coalition of STD Directors, American Sexual Transmitted Diseases Association, and National Alliance of State and Territorial AIDS Directors.

# CSER 22. Conduct focus groups for providers working with populations impacted by syphilis and congenital syphilis.

Conduct focus groups of different providers to identify gaps in provider knowledge of syphilis and congenital syphilis. This will enhance understanding of their knowledge, beliefs, attitudes, and behaviors among healthcare providers about syphilis and congenital syphilis. It will also allow for the testing of marketing messaging and materials to specific groups (e.g., obstetrics/gynecology, federally qualified health centers, urgent care providers, and emergency room providers).

*Community-identified collaborators: New York State Department of Health AIDS Institute- Office of Sexual Health and Epidemiology, and the New York State Department of Health Public Affairs Group.* 

### CSER 23. Create an ongoing interdisciplinary syphilis workgroup.

Create a collaborative workgroup to include local health departments, providers, community-based organizations, the New York City Department of Health and Mental Hygiene and the New York State Department of Health to guide congenital syphilis elimination. This will enable The Group to continue recommending new strategies and modifying existing strategies and action items.

Community-identified collaborators: Local health departments, New York State Department of Health, New York City Department of Health and Mental Hygiene, medical providers, and community-based organizations.

# CSER 24. Require laboratory reflex testing for initial syphilis tests, and universal standardization of syphilis screening algorithm during pregnancy.

Laboratories should be required to always perform confirmatory reflex testing when a nontreponemal test (an RPR) is ordered for initial syphilis screening. The implementation of this recommendation requires education on syphilis testing for pregnant people. A testing algorithm for adults from the CDC Morbidity and Mortality Weekly Report (MMWR) is included below. For pregnant individuals and those who test positive using the traditional algorithm, laboratories should reflexively perform a treponemal-specific test, regardless of the provider's order. Delaying this reflexive test at the laboratory level delays the confirmation of the initial rapid plasma reagin (RPR) test in the traditional algorithm.

Additionally, education is needed for providers and health systems about standardizing testing in their order sets. Instead of alternating between traditional and reverse algorithms, one algorithm should be selected to be universally used for screening and follow-up testing. The Group prefers the "reverse syphilis algorithm" where screening starts with a treponemal-specific test.

Pediatric guidelines do not recommend treponemal tests in newborns and infants. Positive treponemal tests can reflect the passive transfer of antibodies between a pregnant person and the fetus and require a large quantity of blood draws, so an RPR titer is sufficient. Healthcare facilities that provide testing for neonates with suspected syphilis must have a workflow in place to provide rapid results to guide the infant's management.

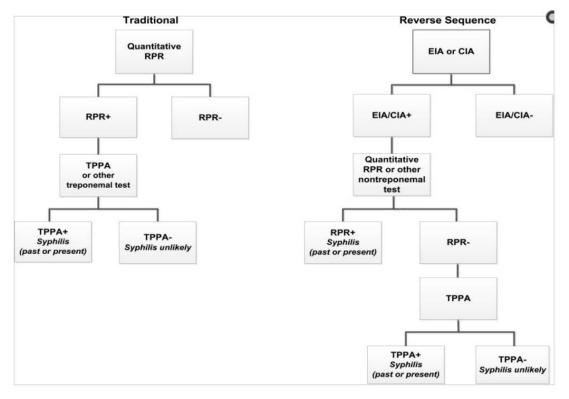


Figure 1 Syphilis Serologic Screening Algorithms\*

\* Adapted from: Centers for Disease Control and Prevention (CDC). Discordant results from reverse sequence syphilis screening – five laboratories, United States, 2006-2010. *MMWR Morb Mortal Wkly Rep.* 2011;60(5):133-7.

Community-identified collaborators: Local health departments, New York State Department of Health, New York City Department of Health and Mental Hygiene, medical providers, hospital systems, and laboratories.

# Appendix I: The Burden of Congenital Syphilis in New York State

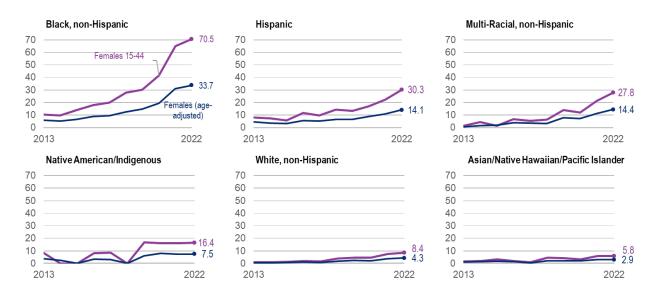
Congenital syphilis is the result of untreated syphilis infection in pregnancy.<sup>11</sup> The consequences for an infected infant are potentially severe and can result in stillbirth, neonatal death, low birth weight, neurological defects like blindness and deafness, bone abnormalities, skin lesions, and other manifestations.

The below data on syphilis and congenital syphilis reflect the most up to date data available to The Group at the time in which The Framework was being drafted. For more up to date data, please visit:

https://www.health.ny.gov/statistics/diseases/communicable/std/

In New York State, congenital syphilis cases increased **325%** from 2015 to 2022, with **females of color disproportionately impacted**.<sup>12</sup> Primary and secondary syphilis are the most infectious stages of syphilis and rates in females have increased tenfold since 2013 (0.5 per 100,000 in 2013 to 5 per 100,000 in 2022).<sup>12</sup> Syphilis rates among females remain highest among persons of childbearing age and disproportionately impact females who are Black and non-Hispanic (figure 1).<sup>12</sup>

**Figure 1.** Early syphilis rates among **females ages 15-44** and **all females (age-adjusted** per 100,000 by race/ethnicity and year, New York State, 2013–2022

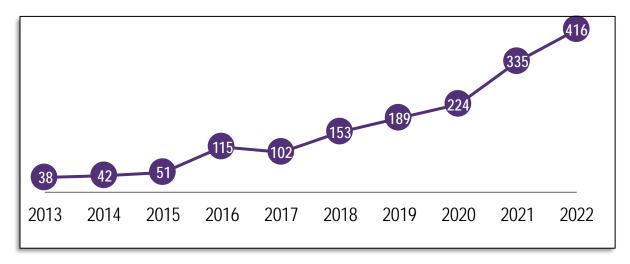


<sup>&</sup>lt;sup>11</sup> New York State Department of Health, Congenital Syphilis, (last accessed on Oct. 2, 2024), *available* at <u>https://www.health.ny.gov/community/health\_equity/congenital\_syphilis.htm</u>.

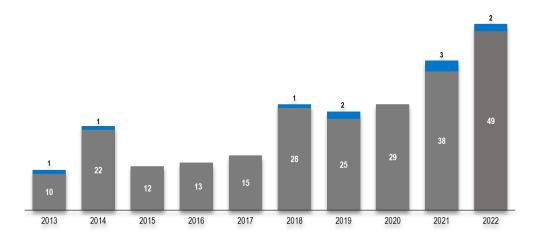
<sup>&</sup>lt;sup>12</sup> Data provided by the Office of Sexual Health and Epidemiology, AIDS Institute, New York State Department of Health.; reported sex at birth is used throughout as data do not reflect individuals identified gender.

As the number of primary and secondary syphilis cases among **females aged 15-44** increases in New York State (figure 2), we will continue to see increases in congenital syphilis and, most likely, syphilitic stillbirths and syphilis related neonatal deaths (figure 3).

**Figure 2.** Primary and Secondary syphilis diagnoses among **females aged 15-44** have been increasing over time in New York State, 2013-2022.



**Figure 3.** Congenital syphilis is on the rise and has resulted in ten stillbirths since 2013 in New York State.



Furthermore, there were **multiple syphilitic stillbirths/deaths reported in the last five years**. Seventy percent of syphilitic stillbirths that occurred in New York State between 2013-2022 were amongst non-Hispanic Black or Hispanic individuals. Elevated levels of congenital syphilis births continued in 2023, with preliminary case counts exceeding the number of cases reported in 2022.<sup>13</sup>

It is important to note that over 20% of the total congenital syphilis cases reported over the past ten years occurred in 2022, with half of syphilitic stillbirths occurring in the 2021and 2022 alone.

New York State has reduced the number of syphilis and congenital syphilis cases before. In the early 1990's, there were over **700 congenital syphilis** cases reported in a single year. With resources, a National Plan to Eliminate Syphilis, and dedicated outreach, New York State was able to reduce statewide cases of congenital syphilis to **less than 30** in 2000.<sup>14</sup> During the same year, there were less than 600 diagnoses of early syphilis. Despite previously observed decreases in syphilis diagnoses , there were over 9,000 early syphilis diagnoses and over 50 congenital syphilis cases in 2022 in New York State.<sup>13</sup>

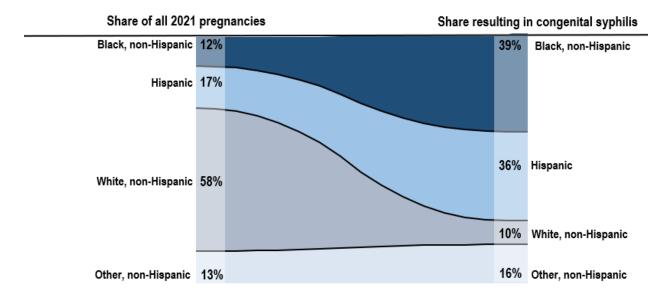
Increases in congenital syphilis cases highlight health inequities in New York State, for example:

- Between 2013 to 2022, the majority of all congenital syphilis cases were linked to gaps in testing and treatment during the birthing person's pregnancy (see figure 5).
- In 2021, approximately 30% of total live births were among non-Hispanic Black or Hispanic people in New York State. However, 75% of all babies with congenital syphilis were born to non-Hispanic Black or Hispanic people, emphasizing the stark disparities in testing and treatment. It is crucial to note that these inequities show how social determinants of health, like systemic racism, can impact public health outcomes.

<sup>14</sup> National Plan to Eliminate Syphilis is available here: https://stacks.cdc.gov/view/cdc/6805#:~:text=In%20the%20plan%2C%20C

<sup>&</sup>lt;sup>13</sup> Personal communication with New York State Department of Health and New York City Department of Health and Mental Hygiene; May 31, 2024

Figure 4. Congenital syphilis pregnancy outcomes disproportionately impact persons identifying as Black or Hispanic in New York State.



1. Data for all pregnancies from Vital Statistics <a href="https://www.health.nv.gov/statistics/vital\_statistics/2021/table29.htm#1">https://www.health.nv.gov/statistics/vital\_statistics/2021/table29.htm#1</a> 2. Other, non-Hispanic includes Asian/Native Hawaiian/Other Pacific Islander, American Indian/Alaska Native, Multi-Race, Other, and Unknown, and where race was missing.

3. Data for 2021 only.

4. Share for all pregnancies in NYS (n = 145,021).

5. Share resulting in congenital syphilis (n = 41).

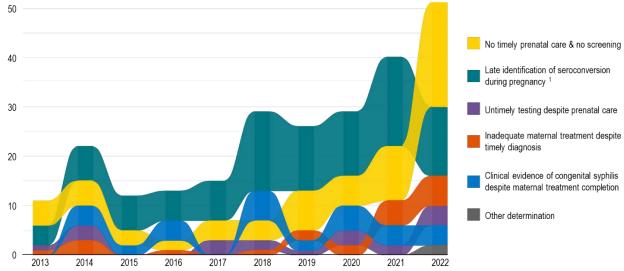
In New York State, syphilis seroconversion and late or no screening during prenatal care are the most common missed opportunities in preventing congenital syphilis.<sup>15</sup> Seroconversion later in pregnancy is an increasing concern in New York State and highlights the necessity of third trimester syphilis screening.<sup>16</sup> As of 2023, New York State mandates third trimester syphilis screening to ensure pregnant people who acquire syphilis during their pregnancy will receive adequate and timely care and treatment, potentially preventing congenital syphilis.<sup>17</sup>

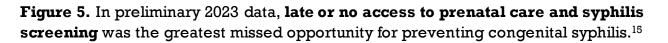
https://www.health.ny.gov/diseases/communicable/std/docs/syphilis\_guidance.pdf.

<sup>&</sup>lt;sup>15</sup> Data accurate as of October 2, 2024; Seroconversion later in pregnancy is defined here as a pregnant person with access to prenatal care who screened negative for syphilis in their first trimester, but who was positive for syphilis at delivery.

<sup>&</sup>lt;sup>16</sup> This includes pregnant persons who screened negative for syphilis during their third trimester and seroconverted after

<sup>&</sup>lt;sup>17</sup> Interim Guidance for Public Health Law §2308 to require additional third trimester syphilis screening for pregnant persons: Chapter 57 of the Laws of 2023, New York State Department of Health, (July 10, 2023), available at





<sup>1</sup> This includes pregnant persons who seroconverted after screening negative for syphilis during their third trimester.

# Appendix II: Overview of Congenital Syphilis Elimination Strategic Planning Group

### Convening of the Congenital Syphilis Elimination Strategic Planning Group

The New York State Department of Health AIDS Institute considers the promotion of meaningful community and consumer engagement a priority. To build upon a history of collaborative work with community members and providers, in 2022, the AIDS Institute's Office of Sexual Health and Epidemiology convened a meeting of community members and providers to discuss congenital syphilis elimination. The Congenital Syphilis Elimination Strategic Planning Group (The Group) was subsequently conceptualized with a goal of creating a comprehensive Congenital Syphilis Elimination Framework (The Framework) using a health equity lens.

The creation of a coordinated and comprehensive statewide strategy to eliminate congenital syphilis was identified as an immediate need. The New York State Department of Health and the New York City Department of Health and Mental Hygiene are separately funded to support congenital syphilis prevention efforts, but there is recognition that a statewide approach, inclusive of New York City, is critical in preventing congenital syphilis. The New York City Department of Health and Mental Hygiene is a critical partner in eliminating congenital syphilis. Without this partnership and joint leadership between state and city, this important work would not be possible.

### Mission

The mission of The Group is to outline a coordinated, comprehensive, and systematic approach to reducing and eliminating congenital syphilis.

### Vision

A state where congenital syphilis has been eliminated and where all people have equitable access to necessary sexual health care services free from stigma and discrimination.

### Steering Committee

A steering committee was assembled to develop a charter for The Group, identify a process for recruiting group members from the community, and implement a community co-chair type structure. The co-chairs provided direction and coordination in The Framework's development. The steering committee consisted of representatives from the New York State Department of Health AIDS Institute and the

New York City Department of Health and Mental Hygiene's, Bureau of Hepatitis, HIV, and Sexually Transmitted Infections, and two selected community co-chairs.

The steering committee identified seven subcommittees responsible for developing recommendations for The Framework. The subcommittees were Surveillance and Research; Policy and Planning; Marketing and Advocacy; Education; Prevention; Community Based Programming; and Medical Care and Treatment.

### **Community Members**

A survey was distributed broadly through existing communication channels to identify community members for The Group. Individuals could nominate themselves for potential membership to The Group, or could suggest colleagues. Membership decisions were based on diversity of demographics, areas of expertise, and experience, and potential members underwent a vetting process before being invited to join. Members were asked to focus on five areas identified as missed opportunities contributing to the spread of congenital syphilis, including:

- 1. Late identification of seroconversion during pregnancy
- 2. Lack of timely prenatal care and syphilis screening
- 3. Lack of timely syphilis screening despite having timely prenatal care
- 4. Inadequate treatment despite timely syphilis diagnosis
- 5. Clinical evidence of congenital syphilis despite treatment completion

### Community Co-chairs

Individuals were asked if they wanted to be considered for the role of community co-chair, as well as what subcommittees they wanted to join and if they would be willing to serve as a subcommittee lead. Interviews were held with the potential co-chairs and two individuals were selected.

### Subcommittees

A total of 43 community members were divided into seven subcommittees based on their identified preferences, while ensuring diversity across the groups. Each subcommittee had specific goals and aided in the development of recommendations for The Framework.

### Subject Matter Experts

Subject Matter Experts (SMEs) were a key part of The Group. SMEs were responsible for providing key facts and information as requested, which supported the subcommittees in developing recommendations. SMEs included staff from the New York State Department of Health and New York City Department of Health and Mental Hygiene as well as representatives from the Clinical Education Initiative.<sup>18</sup>

<sup>&</sup>lt;sup>18</sup> <u>https://ceitraining.org/about</u>

### Full Body Meetings

The Group had its initial meeting virtually on March 31, 2023. Forty-three members (43) and twenty (20) SMEs were present, in addition to health department staff. The Group was provided with background information about congenital syphilis in New York State and were welcomed by New York State and New York City health commissioners.

### Subcommittee name and goal:



<u>Prevention:</u> Prevent the acquisition and transmission of syphilis before and during pregnancy.



<u>Education</u>: Build knowledge and awareness of the prevalence of congenital syphilis. Provide education on transmission, prevention, care, and treatment to provide equitable access to all those impacted.



<u>Community-Based Programming:</u> Develop, implement, monitor, evaluate, and support equitable and accessible community-based programs.



<u>Surveillance and Research</u>: Increase and prioritize research, advance implementation science, and enhance existing surveillance infrastructure related to sexual health.



<u>Medical Care and Treatment:</u> Develop and maintain comprehensive and equitable clinical screening, treatment, prevention, and access infrastructure to achieve the highest quality of care.



<u>Policy and Planning</u>: Recommend implementing effective and equitable policy change and responsive planning.



<u>Marketing and Advocacy</u>: Increase the visibility of congenital syphilis by promoting communication and messaging to reach, engage, inform, and empower impacted communities and providers.

The Group met seven times both virtually and in-person, as outlined below, though subcommittees met between full-body meetings to develop their recommendations.

- Match 31, 2023: Initial virtual meeting finalizing subcommittees and their respective goals and establishing regular check-ins outside of full group meetings.
- May 1, 2023: Virtual meeting to clarify goals and start developing recommendations.
- August 7, 2023: In-person meeting in New York City with presentations on congenital syphilis prevention.
- October 7, 2023: In-person meeting in Albany to discuss health equity and trauma implications and dividing recommendations into care continuums.
- December 8, 2023: Virtual meeting with presentations from various advisory bodies and an introduction of a prioritization process.
- February 28, 202: Virtual meeting presenting the results of the prioritization process and peer review of finalized recommendations.
- April 16, 2024: In-person finalized and approved recommendations by the community.

### **Recommendation Prioritization Process**

To ensure objectivity and support the allocation of resources, each subcommittee prioritized draft recommendations using an electronic tool administered by the AIDS Institute's Office of Program Evaluation and Research (OPER). The number of recommendations varied by subcommittee and the tool was customized for each subcommittee to facilitate prioritization of recommendations along five predefined criteria.

Prioritization Criteria and Definitions

- 1. Magnitude of Impact: Likely to have a significant impact on congenital syphilis elimination.
- 2. Immediacy of Impact: Likely to have an immediate impact on congenital syphilis elimination.
- 3. Funding/Resources: Likely to be implemented with limited resources or with existing resources.
- 4. Sustainability: Likely to be maintained over time.
- 5. Ease of Implementation: Likely to be implemented with ease.

Prioritization was accomplished in four main steps. First, subcommittee members evaluated the relative importance of the prioritization criteria, and their input was used to calculate the relative weighted averages for the criteria. To determine these averages, OPER staff used a systematic ranking process employing prioritization matrices through the Full Analytical Criteria Method.<sup>19</sup> For each member's online tool response, the weighting process was repeated. The prioritization criteria weighting process involved pairwise comparisons, resulting in scaled numeric values, ranging from 10 (much more important) to 0.1 (much less important), assigned to each comparison. Each time a numeric value was recorded in a matrix row cell, its reciprocal value was recorded in the corresponding matrix column cell. Subsequently, row totals were calculated to derive the overall importance of each criterion. Next, criteria weighting was computed by dividing each row total by the grand total, with higher scores indicating higher importance (Example 1).

| Example Matrix         | Magnitude<br>of Impact | Immediacy<br>of Impact | Funding/<br>Resources | Sustainability | Ease of<br>Implementation | Row<br>Total | Relative<br>Weighting<br>Score |
|------------------------|------------------------|------------------------|-----------------------|----------------|---------------------------|--------------|--------------------------------|
| Magnitude of Impact    |                        | 10                     | 10                    | 1              | 5                         | 26.0         | 0.4094                         |
| Immediacy of<br>Impact | 0.1                    |                        | 5                     | 10             | 5                         | 20.1         | 0.3165                         |
| Funding/               | 0.1                    | 0.2                    |                       | 0.2            | 5                         | 5.5          | 0.0866                         |

Example 1. Determining the relative importance of the five prioritization criteria

19 Minnesota Department of Health. (2022, October 3). Prioritization Matrix. Retrieved from <a href="https://www.health.state.mn.us/communities/practice/resources/phgitoolbox/prioritizationmatrix.html">https://www.health.state.mn.us/communities/practice/resources/phgitoolbox/prioritizationmatrix.html</a>

| Resources                 |     |     |     |     |             |      |        |
|---------------------------|-----|-----|-----|-----|-------------|------|--------|
| Sustainability            | 1   | 0.1 | 5   | -   | 5           | 11.1 | 0.1748 |
| Ease of<br>Implementation | 0.2 | 0.2 | 0.2 | 0.2 |             | 0.8  | 0.0126 |
|                           |     |     |     |     | Grand Total | 63.5 |        |

\*Higher relative weighting scores indicate higher importance

Second, each recommendation was assessed against all other subcommittee-specific recommendations, one at a time, along the five criteria (Example 2). Recommendations underwent a similar weighting process as the prioritization criteria.

Example 2. Pairwise-comparison of five subcommittee X recommendations along "Magnitude of Impact".

| Example Combined<br>Recommendation Matrix | Rec 1 | Rec 2 | Rec 3 | Rec 4 | Rec 5       | Row<br>Total | Relative<br>Weighting<br>Score |
|---|-------|-------|-------|-------|-------------|--------------|--------------------------------|
| Rec 1                                     |       | 5     | 0.2   | 0.1   | 0.1         | 5.4          | 0.0828                         |
| Rec 2                                     | 0.2   |       | 0.2   | 0.1   | 0.1         | 0.6          | 0.0092                         |
| Rec 3                                     | 5     | 5     |       | 1     | 1           | 12.0         | 0.1840                         |
| Rec 4                                     | 10    | 10    | 1     |       | 5           | 26.0         | 0.3988                         |
| Rec 5                                     | 10    | 10    | 1     | 0.2   |             | 21.2         | 0.3252                         |
|   |       |       |       |       | Grand Total | 65.2         |                                |

\*Higher relative weighting scores indicate higher importance

Third, individual scores were weighted, combined, and averaged to derive the relative priority scores for each subcommittee's recommendations. This was accomplished by populating a summary matrix with the prioritization criteria at the top of each column and recommendations in rows (Example 3). Cell values were calculated through the multiplication of criteria and recommendation weighting values.

Example 3. Summary matrix of recommendation relative priority scores

| Example Summary<br>Matrix | Magnitude<br>of Impact | Immediacy<br>of Impact | Funding/Resources | Sustainability | Ease of<br>Implementation | Row<br>Total | Relative<br>Priority<br>Score | Rank     |
|---------------------------|------------------------|------------------------|-------------------|----------------|---------------------------|--------------|-------------------------------|----------|
| Recommendation<br>1       | 0.0322                 | 0.0289                 | 0.0675            | 0.0573         | 0.0439                    | 0.2297       | 0.2297                        | 2        |
| Recommendation<br>2       | 0.0171                 | 0.0158                 | 0.0550            | 0.0396         | 0.0522                    | 0.1796       | 0.1796                        | 4        |
| Recommendation<br>3       | 0.0731                 | 0.0538                 | 0.0292            | 0.0542         | 0.0287                    | 0.2390       | 0.2390                        | 1        |
| Recommendation<br>4       | 0.0431                 | 0.0365                 | 0.0172            | 0.0256         | 0.0120                    | 0.1344       | 0.1344                        | 5        |
| Recommendation<br>5       | 0.0632                 | 0.0678                 | 0.0216            | 0.0417         | 0.0229                    | 0.2173       | 0.2173                        | 3        |
| STT-1                     |                        | 1                      |                   | 1              | Grand Total               | 1.0          |                               | <u> </u> |

\*Higher relative priority scores indicate higher importance

Fourth and final, the relative priority scores were used to rank-order the recommendations within each subcommittee (Example 4). Preliminary prioritization results were shared and discussed with Subcommittees.

Example 4. Priority ranking of five subcommittee recommendations, considering the relative importance of the five criteria.<sup>20</sup>

| Example Rankings | <b>Relative Priority Score</b> | Rank |
|------------------|--------------------------------|------|
| Recommendation 3 | 0.2390                         | 1    |
| Recommendation 1 | 0.2297                         | 2    |
| Recommendation 5 | 0.2173                         | 3    |
| Recommendation 2 | 0.1796                         | 4    |
| Recommendation 4 | 0.1344                         | 5    |

<sup>1-</sup> Minnesota Department of Health. (2022, October 3). Prioritization Matrix. Retrieved from <a href="https://www.health.state.mn.us/communities/practice/resources/phqitoolbox/prioritizationmatrix.html">https://www.health.state.mn.us/communities/practice/resources/phqitoolbox/prioritizationmatrix.html</a>

# Appendix III: Additional Information

# Congenital Syphilis Elimination Strategic Planning Group Directory:

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**Resources:** 

Congenital Syphilis Information for Providers (ny.gov)

About the AIDS Institute - Sexual Health Epidemiology (ny.gov)

Considerations for the Implementation of Point of Care Tests for Syphilis (hhs.gov)

STI Treatment Guidelines (cdc.gov)

Congenital Syphilis - STI Treatment Guidelines (cdc.gov)

<u>Missed Opportunities for Prevention of Congenital Syphilis — United States. 2018 | MMWR</u> (cdc.gov)

Syphilis - NYC Health

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