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## MCH Innovations Database Practice Summary & Implementation Guidance

# Preg-Out Program

Implementation of an opt-out laboratory-based and rapid syphilis testing program in the Emergency Department for pregnant individuals with no or limited prenatal care has substantially increased screening and treatment rates, particularly benefiting underserved minority populations.



Location

Houston, Texas



Topic Area

Health Screening,  
Reproductive Health,



Setting

Clinical



Population Focus

Women & Maternal



Date Added

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# Section 1: Practice Summary

## PRACTICE DESCRIPTION

In 2023 the Houston Health Department reported a syphilis outbreak responsible for a 128% increase in cases among women and a nine-fold rise in congenital syphilis (CS) in Houston and Harris County. Cases among women totaled 674 in 2022, up from only 16 cases in 2016. Infection rates and lack of proper screening are particularly prevalent in underserved communities, especially among women of color, those affected by substance use disorders, or individuals experiencing housing instability and other health inequities.

Given such a stark increase, new methodologies are required to address these changing circumstances. The Preg-Out program seeks to address this issue by: 1) implementing an opt-out system of syphilis screening at the time of any pregnancy testing, including ED visits, 2) utilization of rapid, point-of-care syphilis testing with immediate presumptive treatment at these visits and 3) patient-centered follow-up such as dedicated navigators to schedule appointments and follow-up with lab based results, referral to the local Health Department and other social services, partner testing/treatment, and appointment notification/transportation services.

## CORE COMPONENTS & PRACTICE ACTIVITIES

The goal of the Preg-Out program is to improve screening (and thus treatment) for syphilis across all points of pregnancy care to treat adult syphilis and prevent congenital syphilis. This was accomplished by switching to an opt-out system of testing across all points of patient contact, and utilization of a rapid point-of-care syphilis test with immediate presumptive treatment. The program also includes a variety of patient-centered navigator support for results management and linkage to care.

Core Components & Practice Activities		
Core Component	Activities	Operational Details
Improved diagnostics & treatment	Syphilis Health Check (SHC) by Diagnostics Direct (FDA approved and CLIA waived: 96% sensitive), and the lab-based standard-of-care syphilis test used for syphilis diagnosis performed at ED visit in pregnant individuals	The SHC rapid point-of-care test for diagnosis and treatment, especially in the ED setting, will increase treatment completion. The lab-based syphilis test will provide nontreponemal results for treatment monitoring



Opt-out screening regime	Including an opt-out system of syphilis screening, including at ED visits	Using an opt-out regime rather than opt-in can increase testing rates by simply removing the friction of getting a test. STI screening in particular carries a lot of stigma; this can be mitigated via an opt-out system. Additionally, ED visits are a critical missed opportunity to detect and treat pregnant patients with syphilis, which an opt-out regime can help improve.
Patient-centered approach with focus on pregnant individuals of color who face health inequities	Provide navigator services to improve treatment completion and perform needs assessments	Dedicated health navigators to schedule appointments with on-site clinics and follow up all lab-based results. Partners can be triaged through fast track or referral to local Health Department. Clinical services such as sonographic evaluation of fetus for congenital syphilis and social work, behavioral health referral, and appointment notification/transportation services provided
Well-trained health navigators	All hired personnel represent the community they serve and are focused on public and sexual health	Use of culturally sensitive language and interview skills focused on de-stigmatization of sexual health and sexually transmitted diseases
Ongoing partnership with Houston Health Department and Texas Dept of Health and Human Services	Quarterly updates of maternal and congenital syphilis epidemiology	Review Preg-Out results, population estimates and zip code surveillance to determine action items and future directions
Ongoing collaboration with ED leadership, hospital administration, hospital lab services and pharmacy.	Monthly meetings to discuss process, review results, and troubleshoot any issues	Discussions to brainstorm process, delays, and ongoing challenges, discuss areas to improve

## HEALTH EQUITY

Preg-Out improves health equity via two primary methods. The first is improved screening and treatment for syphilis (opt-out and rapid point-of-care screening) in non-traditional settings, meeting patients where they are at. Underserved communities often lack the full range of prenatal care, so by screening at every contact point, we greatly increase the chance of detecting infection in a patient who may have challenges with access to healthcare. Rapid point-of-care screening also helps with this and increases the likelihood that a disadvantaged patient will start treatment. Furthermore, this approach can assist patients facing challenges such as unstable



housing, transportation disparities, intimate partner violence, cultural factors, or other related difficulties. Minority women of color disproportionately experience these socioeconomic challenges and providing opportunities for testing and treatment for syphilis and providing support for care is key for equitable care by providing a more patient -centered care approach.

The second method is by providing a range of navigator services following screening. Disadvantaged patients often lack the health literacy, finances, transportation, etc. to fully access the care they need. Dedicated navigator support and referral to appropriate social services will improve equitable outcomes.

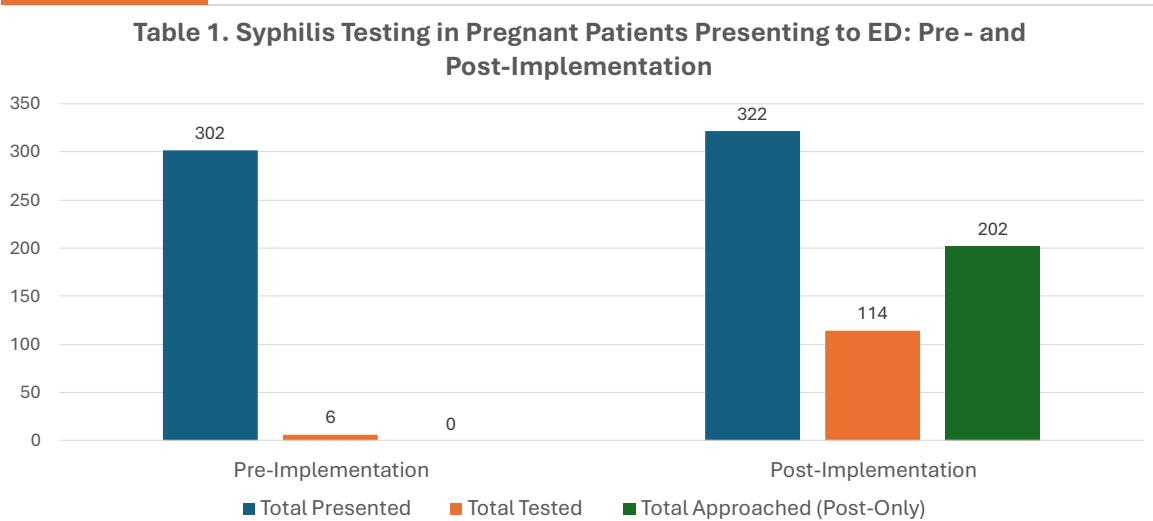
## EVIDENCE OF EFFECTIVENESS

Program efficacy was analyzed using a pre-post assessment by measuring rates of syphilis testing in pregnant patient ED visits.

- Pre-implementation: 11/2023 - 02/2024 vs. Post: 03/2024 - 06/2024
- Pre-implementation: 302 pregnant patients at ED, only 6 (2%) underwent syphilis testing
- Post-implementation: 322 pregnant patients at ED and 79 (24.5%) tested for syphilis, representing a **12.3-fold increase in screening (p < 0.001)**
  - ~ 3.8% prevalence

70% of those who tested positive were scheduled for care by navigators and 100% were treated in the ED.

# Results



**Patient testimonials:**

*"This is so great that I can get my syphilis results in 15 minutes and not have to wait"*

*"I like having a finger stick to test for syphilis, getting my blood drawn sucks"*

*"Its really hard for me to get to clinic during normal hours, thank you for testing me here in the Emergency Room"*



## Section 2: Implementation Guidance

### COLLABORATORS AND PARTNERS

The leadership of the Preg-Out program involved the physician champion, Dr Irene Stafford and her Departmental chair, Dr Sean Blackwell. With engagement of the Houston Health Department, The Department of Ob Gyn began educating institutional and city-wide providers regarding the syphilis epidemic, demonstrating epidemiologic data and health maps of syphilis in the city. ED and OB triage quality data were reviewed demonstrating STI testing, particularly syphilis, which was particularly low in the ED setting. In fact, only 2% of pregnant patients without a documented result or prenatal care were tested for syphilis over the prior 3 months.

These same educational webinars and meetings were extended to hospital administration, ED physician leadership, Dr Carrie Bakunas, and nursing leadership, the quality department, and pharmacy and laboratory services that support the institutional ED. After regular meetings, the decision to start testing and treating in the ED using the rapid SHC test and opt-out lab-based testing was supported by all as a Quality Initiative project. Diagnostics Direct agreed to support the program by donating 500 test kits for use.

With the following conditions:

- 1) Health navigators identify pregnant patients in ED with triage RN notification and EMR (UPT, sonogram or beta HCG)
- 2) Health navigators approach patients and offer opt-out testing via SHC and lab-based syphilis testing. The SHC is a portable hand device, requiring no refrigeration
- 3) Health navigators document all SHC results (positive and negative) and notify primary RN and MD
- 4) IF positive by SHC, will notify Houston Health department and assist in staging and treatment plan in ED
- 5) Health navigators assist ED in scheduling follow up in clinics affiliated with UTH or Harris Health
- 6) Health navigators follow all opt-out lab-based results, even after hours and notify Houston Health Dept lab-based tests are positive
- 7) If positive lab-based only, health navigators will contact patients and arrange visit with Houston Health Department or UTH clinic for staging and treatment

Further collaboration includes monthly meetings with hospital and departmental leadership, the Houston Health Department and research staff where all data is reviewed, and challenges or concerns can be addressed.



## Practice Collaborators and Partners

Partner/ Collaborator	How are they involved in decision-making throughout practice processes?	How are you partnering with this group?	Does this stakeholder have lived experience/come from a community impacted by the practice?
Emergency Department Staff	Implementation done in partnership with all levels of ED staff	Cross-training between the ED and Obstetrics & Gynecology. Work collaboratively with ED staff to identify, test and treat pregnant patients with EMR support	Our healthcare system is dramatically impacted by adult and congenital syphilis. Disadvantaged patients with syphilis disproportionately utilize emergency departments.
Local Health Departments	Local HDs provide health data to assist providers and ensure adequate surveillance and partner services and notification services	Local HDs provide access to health records to improve diagnostics	HD is a pivotal partner in managing underserved populations
Hospital Administration, laboratory and pharmacy services	Provide support and approvals. Engaged in quality results to tailor efforts for populations in need and reduce maternal and congenital syphilis	Monthly check-ins and provide information to move the program forward	The Houston Hospital System where this program was initiated experienced over 130 admissions for congenital syphilis and are highly invested in reducing this devastating outcome
Diagnostics Direct	Provided Syphilis Health Check (SHC) rapid testing kits and training for the program	Manufacturer of the syphilis-only rapid POC test, FDA-approved and CLIA waived	Diagnostics Direct has provided SHC and education for multiple programs in the U.S.

## REPLICATION

Our practice has now been implemented in Harris Health Care systems, particularly the UTH based hospital which after QI data revealed a 2.2% prevalence in maternal and congenital syphilis. These increased dramatically to 2.2% from 2017- 2022 after the COVID pandemic. The Houston health map of syphilis supported this data and after introduction of the Preg-out program, Harris Health Care systems supported initiating Preg-out in this hospital system which serves the underserved Black and Hispanic community in the greater Houston area.





The only difference is that the lab-based syphilis test in the EMR for this hospital is labeled in order to triage the lab-based results to the Ob/Gyn service leadership and health navigators if positive.

### INTERNAL CAPACITY

Preg-Out has received tremendous support from all stakeholders. The majority of the planning and work started with protocol design by Dr Stafford in collaboration with Dr Carrie Bakunas, medical director of the hospital ED. Key staff included the Ob Gyn departmental research manager who leads all research and QI projects conducted at UTH affiliated hospitals. Dr Sunbola Ashimi, Research manager (.10 FTE) for QI processes including protocol submission to Institutional Review Board, contracts, approvals with UTH hospital systems and oversees navigator schedules and payroll. Dr Ashimi also sees day to day activities with the program director, Dr Stafford. Dr Stafford has research time (.10 FTE) to dedicate to daily check ins with navigators and follow up of results with navigators and with the ED leadership, Dr Bakunas. Dr Stafford works closely with Dr Ashimi, Dr Bakunas, lab services, pharmacy and hospital administration to ensure that all objectives are met. The health navigators dedicated to the project have training in research and are experienced in the field of public and sexual health. They have worked on NIH funded grants surrounding syphilis care and work closely with patients and help schedule visits and transportation assistance with our clinic at UTH. These navigators work closely with the Houston Health Department and have attended the Texas Congenital Syphilis and HIV review board meetings quarterly over the last two years and are intimately aware of critical missed opportunities for congenital syphilis prevention. Navigators worked in eight-hour shifts, three times a week (.60 FTE)

Future goals include validating the SHC in our hospital lab so that rapid testing can be performed using the same sample collected for the lab-based testing for syphilis or any other indicated test performed on pregnant patients in the ED (type and screen, beta HCG, Syphilis lab-based test). This way, navigators will not be required to perform testing and testing can be performed at all hours. Results will return within 45 minutes and prior to discharge of the patient.

### PRACTICE TIMELINE

For additional implementation information contact Irene Stafford at [Irene.Stafford@uth.tmc.edu](mailto:Irene.Stafford@uth.tmc.edu).

Phase: Planning/Pre-Implementation		
Activity Description	Time Needed	Responsible Party
Develop partnership with target ED leadership	1 month; ongoing	Program Director
Connect with local health departments to obtain population statistics to improve targeting, and	1-2 months; ongoing	Program Director



potentially set up triage pipeline to handle positive screenings and inform surveillance efforts		
Hire for any vacant health navigator positions	3-6 months	Research Manager or Program Director
Contact IT services & ED leadership to consider updating EMR order sets to include lab-based syphilis test alongside other indicated pregnancy order sets (beta-HCG, type and screen, etc.)	1-2 months	IT Services, ED Leadership, Program Director
Coordinate with ED lab & pharmacy to implement results management process for positive screens	1 month	Program Director & health navigators
Review script for patient approach for opt-out syphilis testing, ensuring it uses culturally-sensitive and gender-neutral language	2 weeks	Program Director

**Phase: Implementation**

<b>Activity Description</b>	<b>Time Needed</b>	<b>Responsible Party</b>
Train ED staff on new process to implement SHC & lab-based syphilis testing	1-2 months	ED Leadership
Train health navigators on performing SHC test (Note: See training resources from manufacturer in Appendix)	1 week	Program Director



Purchase & distribute SHC test kits (Note: see Implementation Protocol template in Appendix for detailed implementation information from manufacturer)	1 month	Research Manager/Program Director
Brief weekly in-service with all ED clinical staff to remind them of new process & troubleshoot any issues that arise	1 month (at the beginning)	Research Manager, Program Director, health navigators

**Phase: Sustainability**

Activity Description	Time Needed	Responsible Party
Monitor testing rates and other metrics to ensure ED staff adherence to new processes	Ongoing	Program Director
Regular check-ins with navigators to review results	Ongoing	Program Director
Monthly meetings with ED leadership, health departments, department leadership, etc. to provide updates and troubleshoot any issues	Ongoing	Program Director

## PRACTICE COST

The following table is reflective of the startup and maintenance costs of Preg-Out. Future directions include validation of the SHC in the hospital-based lab so that rapid testing can be performed using blood that is routinely collected in the ED for pregnant patients (beta HCG, type & screen and syphilis lab-based tests). This would mitigate the cost of health navigators and would increase rapid testing to 24 hours a day, seven days a week.



The costs of the SHC is \$200 per kit (\$10 per test) and is reimbursable under CPT code 86780QW for \$13.24 per test.

Budget			
Activity/Item	Brief Description	Quantity	Total
Salaries and fringe benefits	Administrative work with hospital. Salaries for navigators Schedules	.10 FTE	\$20,000
Staff training And development	SHC training, EMR training	\$100 per staff member	\$400
Navigator services	Screening and testing eligible pregnant patients	.6 FTE	\$2,500 per navigator/month
Syphilis Health Checks – Diagnostics Direct, LLC	Rapid point-of-care tests	500	Preg-out – donated, costs for future use \$200 per kit (\$10 per test)
*Lab-based syphilis test (reverse algorithm)	Lab-based test – EIA/CIA followed by Nontreponemal (RPR) and reflex second treponemal test if indicated		
Supplies	Alcohol swabs, lancets, band aids, gloves	500	\$1,200
<b>Total Amount:</b>			<b>\$29,100</b>

*\*Cost dependent on individual hospital and insurance. Syphilis testing covered by all government and private health plans during pregnancy. Out of pocket costs \$16*



## LESSONS LEARNED

Implementation of an opt-out and rapid syphilis testing program in the Emergency Room for underserved pregnant patients in a high prevalence region increased testing from 2% to 24.5%, reflecting a 12.3-fold increase in testing.

During the first three months of Preg-out, the diagnosis of syphilis increased dramatically. Because of this program, 3 cases of congenital syphilis were averted.

Opt-out strategies remove stigmatization of STI testing and were welcomed across disciplines in care and patients.

Regulatory lab requirements for CLIA waived tests require validation and business plans that may delay program initiation.

## NEXT STEPS

Going forward, our next goal is to expand it to other hospital systems that are experiencing high prevalence of sexually transmitted infections, particularly syphilis.

Implementing it into the EMR as a BPA would be the next best step so that it is automatic. We are already working into the order set for evaluations of pregnant persons - similar to the already in place opt-out HIV test. This would remove the need for reminders and make the process even smoother.

Development of patient-centered, feasible, and affordable implementation strategies for syphilis testing programs such as Preg-out are urgently needed for underserved pregnant populations throughout the nation. Given the feasibility of point of care syphilis testing with opt-out lab-based confirmation for hospital systems and patients, we advocate for advancement of these aims and collection of data to inform scale-up. Expanding partnerships between public health entities, prenatal care providers, emergency departments, and pregnant populations have shown to improve timely treatment of syphilis during pregnancy to reduce devastating complications, including congenital syphilis.

## RESOURCES PROVIDED

- <https://diagnosticsdirect2u.com/> for package insert and ordering information.
- Press release: <https://www.prnewswire.com/news-releases/new-posters-on-preg-out-program-highlight-impact-of-syphilis-health-check-in-emergency-departments-underscoring-urgent-need-for-rapid-testing-solutions-302291572.html>
- SHC Finger Stick Procedure: <https://www.youtube.com/watch?v=gKxjf8XP1xg>
- ACOG Webinar: <https://orasure.com/webinars/syphilis-in-pregnancy.html>



## APPENDIX

- <https://diagnosticsdirect2u.com/shc-on-demand-training/>
- <https://diagnosticsdirect2u.com/wp-content/uploads/2024/11/Implementation-Protocol-Template-for-Syphilis-Health-Check -a-Point-of-Care-Rapid-Test-for-Syphilis-Digital.pdf>

