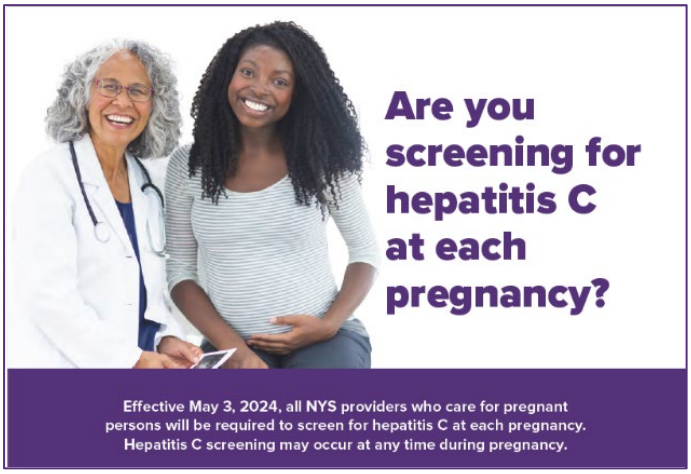
Hepatitis C Screening During Pregnancy Provider Toolkit - April 2024

Introduction and Purpose



This toolkit was developed to assist prenatal care and maternity settings with implementing the requirement of hepatitis C virus (HCV) screening of pregnant people, and linkage to care for those with diagnosed HCV infection. HCV screening is part of New York State's Hepatitis C Elimination Plan. Information about the number of new HCV diagnoses each year and specific metrics related to HCV elimination can be found on the NYS HCV Elimination Dashboard.

The toolkit provides impacted health care facilities, and the providers who work in them, with an overview of NYS requirements for HCV screening of pregnant people. It provides links to clinical guidance, resources, shares best practices, and information about how to request additional technical assistance. HCV is a bloodborne pathogen that is spread by contact with blood from a person with HCV infection. HCV can be transmitted from a pregnant person to their infant during pregnancy or delivery, with a vertical transmission risk of approximately 6%. HCV among the US obstetric population rose nearly 10-fold over the last 20 years. Because HCV screening increases the likelihood that past or current substance use may be identified, this toolkit provides important information about pregnancy and substance use, with a focus on providing affirming services for all pregnant people and their infants. This toolkit will be updated as new developments and best practices emerge.

Email hepatabc@health.ny.gov for the latest version and to request technical assistance.

CLINICAL EDUCATION INITIATIVE
NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE

Rationale for Hepatitis C Screening During Pregnancy

Why is supporting universal HCV screening among pregnant persons important?

- Hepatitis C rates increased significantly from 2016 through 2020 for pregnant persons aged 25 and over, in all pregnant person race and Hispanic-origin groups except non-Hispanic Asians (subsequently, Asians), among all pregnant person education levels, in pregnant persons who smoked cigarettes during pregnancy and those who did not, in all prenatal care categories, and in all source of payment groups except for the "other" category.[1]
- Studies found universal hepatitis C antenatal screening was cost-effective in all treatment eligibility scenarios (mean ICER <$3000/QALY gained). Screening remained cost-effective at a prevalence of 0.07%, which is the lowest estimated prevalence in the United States (in Hawaii).[2]
- Hepatitis C is a **curable** infection. Treating early decreases morbidity and mortality and is cost saving.

Why are closed-loop referrals important for pregnant persons with HCV and their HCV perinatally exposed infants?

- Linkage to care in the postpartum period for initiation of HCV treatment is the current standard of care, although studies have shown that greater than 90% of people do not receive treatment within the first year postpartum.
- Screening for infants with perinatal exposure is frequently missed, and utilization of HCV RNA testing as early as 2 months of age will improve infant screening rates.[3]
- Most practices lack established processes for closing the referral loop. Lack of referral tracking can lead to inefficiency and frustration. Up to 50% of referrals are not completed. Of the ones that are completed, notes are often not sent back to referring practices, leaving them unaware of new diagnoses or changes.
- Closing-the-loop requires bi-directional information sharing and communication between practices. Practices should log and track every referral request through completion. Receiving practices also should log referrals and notify requesting practices of the referral request disposition, including appointment date and time, and if the referral is not appropriate or if unable to schedule the appointment. Subsequent cancellations or no-shows also should be communicated. Following a referral visit, the receiving practice should send a timely and clear response note to the referring practice.
- Closing-the-loop for clinical referrals improves patient safety and satisfaction, as well as clinical care coordination.[4]
- Hepatitis C is a **curable** infection. Treating early decreases morbidity and mortality and is cost saving.

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[1] Ely, DM, Gregory, Elizabeth C.W. Trends and Characteristics in Maternal Hepatitis C Virus Infection Rates During Pregnancy: United States, 2016–2021. National Vital Statistics Reports; vol. 72, no. 3 https://stacks.cdc.gov/view/cdc/124659

[2] Chaillon A, Rand EB, Reau N, Martin NK. Cost-effectiveness of Universal Hepatitis C Virus Screening of Pregnant Women in the United States. Clin Infect Dis. 2019 Nov 13;69(11):1888-1895. doi: 10.1093/cid/ciz063.

[3] Fogel RS, Chappell CA. Hepatitis C Virus in Pregnancy: An Opportunity to Test and Treat. Obstet Gynecol Clin North Am. 2023 Jun;50(2):363-373. doi: 10.1016/j.ogc.2023.02.008.

[4] American College of Physicians. Closing-the-Loop: Lessons Learned, Transforming Clinical Practice Initiative.

Overview of New York State Requirement for Hepatitis C Screening of Pregnant People

New York State Law, and current clinical practice guidelines require that a hepatitis C virus (HCV) screening test be provided to every pregnant person during each pregnancy.

CONDUCT TESTING & DOCUMENT IN THE MEDICAL RECORD

- Every physician or other authorized practitioner, including midwives, shall order HCV screening for every pregnant person, with clinical benefit for testing as early as possible in the pregnancy.
- HCV testing is conducted under general medical consent. No special consent is required.
- The result should be prominently displayed in the medical record at or before the time of hospital admission for delivery.

CONFIRMATORY TESTING & LINKAGE TO CARE

- If the HCV screening test result is reactive, or positive, the health care provider must make sure an HCV RNA test is conducted on the same sample or second sample collected at the same time.
- If the person tested is diagnosed with HCV, the health care provider must either offer the person follow-up HCV health care and treatment, or they must refer the person to a health care provider who can.

An effective approach to meeting this requirement is to include the HCV test as part of the prenatal screening panel.

WHAT IS THE TESTING ALGORITHM FOR HEPATITIS C?

Current guidance recommends a two-step testing sequence for diagnosis of HCV infection. Testing is initiated with an HCV antibody test. When this test is reactive, an HCV RNA test is performed to confirm diagnosis of current infection. CDC recommends single-visit sample collection and use of laboratory reflex RNA testing to support complete testing for HCV. See HCV Screening Protocol.

CLINICAL AND PUBLIC HEALTH RATIONALE

New cases of HCV are on the rise, particularly among reproductive age adults. Most new infections occur among adults 20-39 years of age. HCV among pregnant people has increased over the last decade.

- Most people with HCV have no symptoms. Almost half of people with HCV are unaware of their infection. If left untreated, HCV can lead to serious liver disease and/or death.
- Screening pregnant people for HCV has a grade B rating from the US Preventive Services Task Force.
- More than 90% of people with HCV can be treated and cured with 8–12 weeks of oral therapy. Though treatment is not currently FDA approved during pregnancy, it may be considered on an individual basis based on provider/ patient discussion about risks and benefits.
- Approximately 6% perinatally exposed children (*i.e.,* those coming into contact with the virus during pregnancy or delivery) will acquire perinatal HCV infection.
- Prenatal testing alerts delivery room staff to take measures to reduce risk of exposure during delivery.
- Perinatally exposed infants should be screened with an HCV RNA test at 2-6 months.

CASE REPORTING REQUIREMENTS

- Reporting of suspected, or confirmed, HCV is mandated under the New York State Sanitary Code (10NYCRR 2.10). This includes patients with a reactive or positive HCV screening test and/or a detectable HCV RNA test.
- Reports should be made to the local health department in the county in which the patient resides, and they need to be submitted within 24 hours of diagnosis. Information on how to report is available here.
- Providers may be contacted by local health departments for additional information and should provide requested information promptly.

REIMBURSEMENT FOR HCV SCREENING DURING PREGNANCY

Medicaid and Medicare currently cover HCV screening for all adults and people at risk.

People with private insurance should refer to their policy or contact their carrier to see if the test is covered.

Billing Codes for HCV Testing

Test Type	CPT Code
HCV antibody test	86803
HCV RNA Qualitative	87521
HCV RNA Quantitative	87522

MEDICAID UPDATES (Click on links for detailed information)

1. Coverage for pregnant individuals during the post-partum period is increased from 60 days to 12 months, making HCV screening during pregnancy an important opportunity to identify future care needs for both the pregnant person and their baby.
2. HCV testing, including initial antibody and RNA tests, are covered under Medicaid Managed Care Plans and Medicaid Fee for Service.
3. Laboratories will be reimbursed for reflex testing (see page 13-14 of the linked document) without additional written orders from the physician. The preprinted requisition form must indicate that the test will be used in the reflex algorithm.
4. Removal of Prior Authorization for HCV medications in most circumstances.
5. Circumstances where Prior Authorization of HCV Agents is still required: re-treatment, for non-preferred drugs or compendia-supported diagnosis in history.

"New York State Requirement for Hepatitis C Screening During Pregnancy" a podcast with NYS Health Commissioner, James McDonald M.D. Click here to listen.

To request free technical assistance and clinical training for implementing HCV screening and linkage to care for pregnant people and their infants: Email hepatabc@health.ny.gov. See Page 3 for more details.

Technical Assistance and Clinical Education

To request technical assistance, please email hepatabc@health.ny.gov.

Tailored technical assistance is available to support prenatal care and maternity settings with implementing the requirement of HCV screening of pregnant people, and linkage to care for those with diagnosed HCV infection.

Below are examples of the range of types of technical assistance available, in-person or virtually based on the needs and preference of the healthcare setting:

- ☐ Meet with facility and/or clinic leadership to identify specific needs, introduce this toolkit, and review resources available.
- ☐ Facilitate a one-hour hepatitis C clinical training(s) or advanced hepatitis C clinical training to meet specific needs of facility and staff (in-person or virtual).
- ☐ Support to develop/implement an internal referral workflow for adult and pediatric patients who are diagnosed with HCV.
- ☐ Assistance to identify individuals within the facility who provide HCV treatment (including pediatrician/neonatologist) and create a process for patients who screen positive to go directly to an internal treatment provider.
- ☐ Ensure preparation for influx of patients identified with adoption of universal screening (e.g., training for specialists).
- ☐ Support to develop/implement policies and procedures, EMR prompts, workflows and reflex testing, as needed.
- ☐ Support to create an evaluation plan to allow for data-driven decision making and responsive programs.
- ☐ Assistance to identify available data and tailor recommendations for process and outcome indicators (i.e., Number pregnant people screened during XX period /Number screened during same period with goal of 100%).

Clinical Education

The Clinical Education Initiative (CEI)'s Hepatitis C and Drug User Health Center of Excellence offers free continuing medical education to enhance the capacity of New York State's diverse healthcare workforce to deliver high-quality clinical services and improve patient outcomes. CEI offers online live and on-demand trainings, intensive preceptorship programs, targeted technical assistance, free clinical tools and more.

The following courses are currently offered on demand by the Hepatitis C and Drug User Health Center of Excellence. Information, including course descriptions, learning objectives and online course recordings can be accessed by clicking on the hyperlinked course title.

Hepatitis C Testing and Pre-treatment Evaluation

Universal Hepatitis C Screening among Pregnant Persons to Reduce Stigma and Advance Elimination*

Hepatitis C among Women of Childbearing Age

Hepatitis C among Infants, Children and Adolescents*

Hepatitis C and Alcohol*

Hepatitis C and Injection Drug Use*

Plans of Safe Care (POSC): Developing Plans of Safe Care with a Patient-Centered Approach*

Caring for Pregnant Persons with Substance Use Disorder: Shifting from Criminalization to Chronic Disease Management

Substance Use, Pregnancy and Parenting: A Harm Reduction Approach

(*) accredited for Continuing Medical Education (CME), Continuing Nursing Education (CNE) and/or Continuing Pharmacy Education (CPE) credit

Additional trainings offered by CEI's Hepatitis C and Drug User Health Center of Excellence can be found at www.ceitraining.org. You may view the Training Calendar, search the Courses tab for HCV, or select CEI's Learning Pathways. All courses offered by the Hepatitis C and Drug User Health Center of Excellence can be provided via in-person or virtual delivery formats. To request a training, complete the Training Intake Survey.

Podcasts

One Step Closer: Introducing the New York State Hepatitis C Elimination Plan (podcast)
(25 min, released February 2022)

Universal Hepatitis C Screening among Pregnant Persons: The Time is Now (podcast)
(28 min, released October 2022)

New York State Requirement for Hepatitis C Screening During Pregnancy: Dr. James McDonald, the Commissioner of the New York State Department of Health (video)
(4min, released November 2023)

Clinical Resource

Screening for STIs, HIV, and Hepatitis B/C during Pregnancy in NYS

Clinical Support

CEI Line is available for clinical inquiries related to hepatitis C, drug user health, HIV, sexually transmitted infections, PEP and PrEP. Clinical providers can **call 866-637-2342** and **press 5** to speak with a clinical expert about hepatitis C screening, treatment, and recommended clinical follow-up for persons with hepatitis C in New York State.

HCV Clinical Guidelines

New York State Clinical Guidelines

The New York State Department of Health (NYSDOH) AIDS Institute (AI) Clinical Guidelines Program is a collaborative effort of the AI Office of the Medical Director and the Johns Hopkins University School of Medicine, Division of Infectious Diseases. The program produces and publishes evidence-based, state-of-the-art clinical practice guidelines that establish uniform standards of care for NYS to improve the health and well-being of all adults who receive prevention services or treatment for HIV, viral hepatitis, other sexually transmitted infections, and substance use disorders.

Hepatitis C Virus Screening, Testing, and Diagnosis in Adults

Treatment of Chronic Hepatitis C Virus Infection in Adults

HCV Testing and Management in Pregnant Adults

Substance Use Disorder Treatment in Pregnant Adults

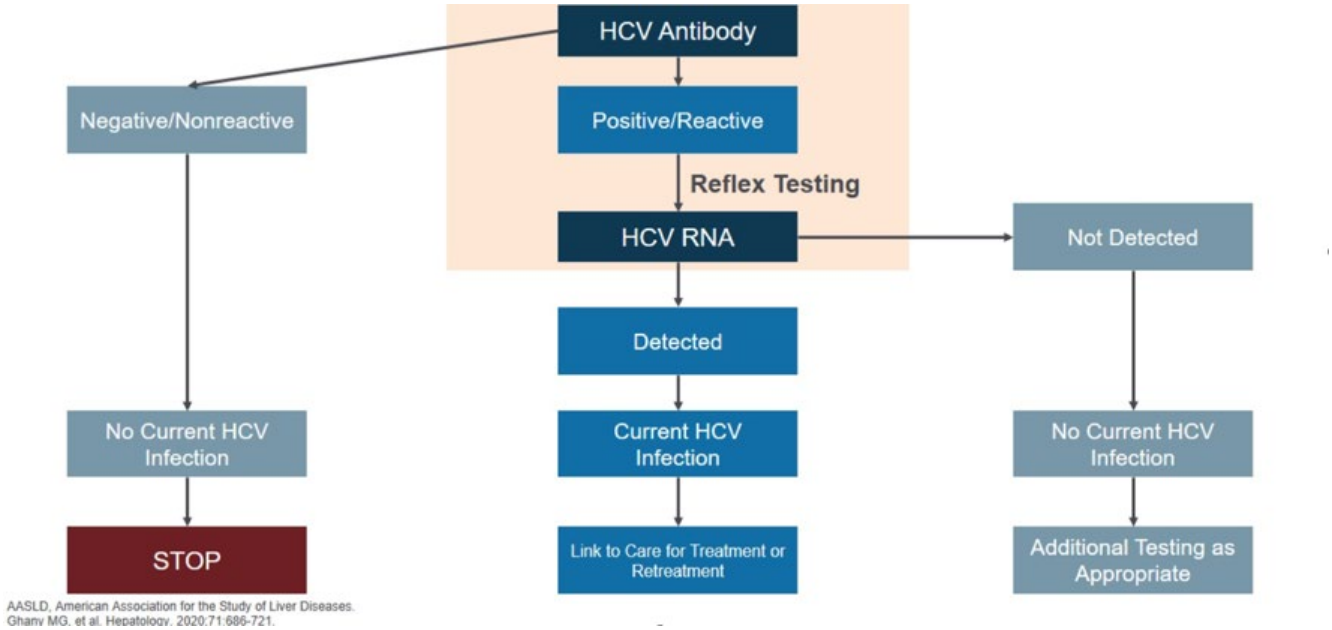
National Guidelines

AASLD/Infectious Diseases Society of America (IDSA) HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C

The American College of Obstetrics and Gynecologists Clinical Practices Guidelines: Viral Hepatitis in Pregnancy

CDC Recommendations for Hepatitis C Testing Among Perinatally Exposed Infants and Children — United States, 2023

HCV Screening Protocol from American Association for the Study of Liver Disease



Summary of Best Practices for Hepatitis C Screening in Pregnancy

1. **Order Reflex testing.**
   - Hepatitis C testing always should consist of a hepatitis C antibody test, which if positive, reflexively tests automatically for a hepatitis C viral load to determine if the individual has an active hepatitis C infection.
   - Automatic reflex testing circumvents the need for the patient return to the clinic for additional blood work, which can be a barrier for patients.[5]

2. **Explain the meaning of the hepatitis C screening test results (antibody positive/RNA negative; antibody positive/RNA positive) and implications for pregnancy, delivery, and follow-up.**
   - **Hepatitis C antibody positive/RNA negative:** the patient was exposed to hepatitis C previously but does not have an active hepatitis C infection. This means the patient has either cleared the hepatitis C infection spontaneously or was treated for hepatitis C previously. If spontaneous clearance of hepatitis C is suspected, best practice is to repeat the hepatitis C RNA in 3 months to ensure that the spontaneous clearance is durable. There are no further implications for future exposure to hepatitis C; education should be done with the patient to avoid future exposure to hepatitis C.
   - **Hepatitis C antibody positive/RNA positive:** the patient was exposed to hepatitis C previously and has an active hepatitis C infection. The patient should be educated regarding hepatitis C and linked with a provider who is experienced in treating hepatitis C, so the pregnant person can be treated post-partum and the infant can be assessed at 2-6 months of age.

3. **Rescreen patients who have ongoing risk, including third trimester testing.**
   - The hepatitis C antibody is not a protective antibody. Patients who have been exposed to hepatitis C previously and either spontaneously cleared hepatitis C or were treated previously for hepatitis C can be reinfected with hepatitis C if exposed again.
   - Individuals with ongoing potential exposure to hepatitis C should be tested periodically for hepatitis C. In pregnant persons with ongoing potential exposure to hepatitis C, they should be retested in the third trimester.
   - Individuals with a negative hepatitis C antibody and ongoing potential exposure should be screened with a hepatitis C antibody with reflex testing, if positive, to a hepatitis C viral load
   - Individuals with a positive hepatitis C antibody and a previously negative hepatitis C viral load with ongoing potential exposure to hepatitis C should be screened with a hepatitis C viral load.

[5] Centers for Disease Control and Prevention, Testing Recommendations for Hepatitis C Virus Infection

4. **Practice closed loop referrals – track your data, quality improvement, malpractice/liability considerations**
    - Closed loop referrals, meaning that you have verified that the referral you made was completed by the patient and the records have been received, are the standard of care.
    - Practices should track their referrals so they are aware of their data and can make practice improvements if referrals aren't completed.
    - It is the responsibility of the referring provider to ensure that the loop is closed on the referral. From a malpractice perspective, liability lies with the referring provider.

5. **Ensure follow up for parent and infant.**
    - When a pregnant person is found or known to be hepatitis C positive, the provider must ensure follow-up post-partum for BOTH the person who gave birth and the infant.
    - Many patients don't complete their postpartum visits. OB/GYN providers must ensure that postpartum patients with hepatitis C have seamless follow-up and linkage to care for hepatitis C treatment regardless of their attendance to their postpartum visit. The OB/GYN provider should establish relationships with providers who treat hepatitis C.
    - OB/GYN providers must ensure that the infant exposed to hepatitis C during delivery is linked to a pediatric provider and that the pediatric provider is aware of the hepatitis C exposure. It is the responsibility of the OB/GYN provider to have systems in place to ensure that this information regarding the infant is conveyed to the pediatric provider.

6. **Effectively communicate the birthing parent's HCV status to the pediatric provider**
    - The OB/GYN provider should communicate clearly with birthing parent about the timing of pediatric viral load testing for their infant exposed to hepatitis C (at 2-6 months of age).
    - The OB/GYN provider should communicate clearly with the pediatric provider about the infant's hepatitis C exposure.

7. **Convey basic harm reduction messages (e.g. avoid sharing equipment, etc.)**
    - The provider should do harm reduction education with the patient to decrease risk of hepatitis C acquisition, transmission, and reinfection with activities that put the individual at risk of ongoing exposure to hepatitis C.
    - Hepatitis C can be transmitted by sharing any equipment used to prepare or consume substances, including, but not limited to: needles, syringes, cookers, ties, water, stems, or straws, regardless of the route of administration. Hepatitis C can be transmitted by microscopic blood exposure, so visible blood need not be present.
    - Hepatitis C can be transmitted by personal hygiene items that may have been exposed to microscopic blood. Tweezers, razors, nail clippers, and toothbrushes should not be shared.

8. **Screen all pregnant persons for substance use using a verbal, validated tool**
    - Universal screening of all pregnant persons for substance use is best practice.
    - Screening should be with a verbal, validated tool.

- Urine toxicology testing of pregnant or postpartum persons does not diagnose substance use disorder, is not considered best practice, and can cause harm to the pregnant or postpartum person.
- **Substance use alone**, whether disclosed through development of a plan of safe care, self-report, screening, toxicology, or newborn symptoms, **is not evidence of child maltreatment**.[6]

9. Implement EMR best practices and default selections

- It is best practice to add the diagnosis of hepatitis C to the pregnant person's 'problem list' or medical history. If the OB/GYN has access, in a linked EMR, to the infant's chart, the exposure to hepatitis C should be added to their 'problem list' or medical history.
- As feasible, changes in guidance around syphilis screening, hepatitis B screening, and hepatitis C screening and follow-up provide an opportunity to leverage requests for changes to the EMR (drop down menus, default selections, reminders, etc.).

10. Hepatitis C treatment is available and hepatitis C is curable; refer to a provider experienced in hepatitis C treatment.

- Hepatitis C is a curable infection. Untreated hepatitis C increases mortality.
- Hepatitis C treatment is brief (8 or 12 weeks of medication), well tolerated, with few if any side effects.
- OB/GYN providers detecting hepatitis C in their pregnant patients have a responsibility to ensure that their patients access treatment for hepatitis C. OB/GYN providers should refer to a provider experienced in treating hepatitis C.

[6] NYS CAPTA CARA Information & Resources

BEST PRACTICE: Streamlined Sample Collection and Laboratory Procedures for HCV Screening and Diagnosis

Collecting Samples at a Single Visit

Current guidance for completion of HCV testing supports operational strategies that collect samples at a single visit, and automatic HCV RNA testing on all HCV antibody reactive samples. Use of strategies that require multiple visits to collect samples should be discontinued.

Resource: Updated Operational Guidance for Implementing CDC's Recommendations on Testing for Hepatitis C Virus Infection (2023)

Check with your laboratory for sample collection guidelines.

Lab Order Sets

Inclusion of HCV antibody screening test with reflex to HCV RNA testing in prenatal lab order sets can help increase HCV screening rates during pregnancy.

Below are examples of lab order sets from two commercial labs.

Lab	Panel	Link to Details
LabCorps	Pregnancy, Initial Screening Profile	144053
Quest Diagnostics	Obstetric Panel with Fourth Generation HIV, Hepatitis C Antibody with Reflex	12075

Remove Outdated Order Options

Remove any reference to lab order options for standalone HCV Antibody Testing (i.e. testing that does not include specific reference to reflex HCV RNA testing).

BEST PRACTICE: Use of Electronic Medical Record (EMR) or Electronic Health Record (EHR) Macros to Streamline Documentation

EMR/EHR macros, sometimes referred to as Smart phrases, Dot phrases or Quick phrases (depending on the EMR or EHR used) are tools that can be used to help providers document more efficiently by pulling in frequently used text and pulling data from the chart. These typically include a preformed block of text that is inserted using keyboard shortcuts, often preceded by a dot. Most EMR/EHRs have this capability, both for organization-level and individual user-created content.

Sample EMR/EHR Macros	
Perinatal HCV Exposure	Perinatal Hepatitis C exposure: The baby needs Hepatitis C RNA testing at 2-6 months of age by the (insert name) Hepatology team. The team has been emailed with the family's contact information and they will reach out to the family shortly to introduce themselves and the program. They will contact the family closer to 2-6 months of age as well to schedule the HCV testing. Contact information is (insert your contact name and number).
Hepatitis C – Obstetrics Note	Age, parity, with … Dated by Last Menstrual Period; dates confirmed by ultrasound 1. Clinical Assessment - HCV HCV quan RNA HepB surface Antigen/Antibody Hepatitis A Ab IgG Liver ultrasound 2. Co-morbid condition Substance Use (including alcohol use) HIV STIs 3. Counseling provided re: risk of sexual transmission as well as risk of perinatal HCV transmission. Patient counseled that perinatal transmission was ~ 6% and (i) there was no standard of care to provide treatment with antivirals to prevent perinatal transmission, and (ii) there were no proven benefits of c-section to prevent perinatal transmission. Patient counseled that the decision to treat during pregnancy, both for the prevention of perinatal transmission and the patient's health, will be made with the patient after a review of all test results and additional counseling. 4. Counseling provided re: association of HCV infection with an increased risk of intrahepatic cholestasis of pregnancy. 5. Counseling provided that HCV can be cured with antiviral treatment and that they will be referred post-delivery to a liver specialist. 6. Limit exposure of fetus intrapartum to maternal blood/body secretions. Avoid early amniotomy or scalp clips.

HCV Care and Treatment Resources

NYSDOH AIDS Institute Provider Directory
The New York State Department of Health AIDS Institute's online directory provides information regarding participating hepatitis C providers across New York State. Participation in the directory is voluntary. Inclusion in this directory does not confer any endorsement by the NYSDOH nor does it establish NYSDOH credentialing or certification in a specialty.

Hepatitis C Care and Treatment Programs Supported by the NYSDOH
The New York State Department of Health provides funding to 13 primary care sites across NYS to provide Hepatitis C care and treatment. In addition to primary care, these providers offer HCV related services including HCV treatment, education, care coordination, and support connecting with community resources.

NYC Health Map can be used to locate health services in New York City by address, zip code or borough, including available HCV testing, treatment, and harm reduction services. Additionally, locations offering free and low-cost hepatitis C testing and treatment, as well as patient navigators who can provide support throughout the process can be found at www.nyc.gov/health/hepc.

Treatment In Pregnancy for Hepatitis C: The TiP-HepC Registry collects and documents the outcomes of birthing parent-infant pairs exposed to HCV treatment during pregnancy from routine clinical practice in hepatitis treatment programs and treatment centers worldwide. The project aims to describe the frequency and timing of known cases of persons exposed to treatment during pregnancy, assess the safety of treatment in pregnancy for birthing parent-infant pairs, and evaluate the effectiveness of treatment in pregnancy for achieving cure for birthing parents and reducing transmission to their infants. This project is an initiative of the Coalition for Global Hepatitis Elimination (CGHE) at the Taskforce for Global Health and supported by the Centers for Disease Control and Prevention.

Pregnancy and Substance Use Brief

- Exact prevalence rates of substance use in pregnancy are not well known. Most data on substance use in pregnancy is self-reported and likely underreported, given the stigma associated with substance use in pregnancy and the consequences of such disclosure.
- Stigma towards persons who use substances is widespread. Stigma is amplified if a person who uses substances is pregnant or parenting. Such stigma has a significant impact on pregnant persons. Pregnant persons are less likely to disclose substance use and less likely to engage in either prenatal care or substance use disorder treatment if they experience stigma in health care services delivery or anticipate involvement of child welfare agencies.
- Outcomes for both the pregnant person and the developing fetus will improve with engagement in prenatal care even with ongoing substance use in pregnancy.
- It is a common assumption that illicit substance use (with opioids, cocaine, methamphetamine, etc.) is more potentially harmful than licit substance use (with alcohol, tobacco, cannabis). It is imperative to learn the facts about substance use in pregnancy and the potential risks associated with individual substances, whether licit or illicit.
- Substance use typically decreases in pregnancy by trimester. If use doesn't decrease, then the pregnant person may have developed a substance use disorder and is unable to decrease use.
- There are effective treatments, both pharmacological and non-pharmacological, for substance use in pregnancy. The standard of care for opioid use and opioid use disorder in pregnancy is the use of medication for opioid use disorder, specifically methadone or buprenorphine.
- Pregnant persons who use substances want themselves and their developing fetuses to be as healthy as possible. Pregnant and parenting persons who use substances love their children-to-be and their children as much as any other parent. Pregnant and parenting persons who use substances should be supported to be as healthy as they can be.
- Most importantly, substance use in and of itself by pregnant and parenting persons is not indicative of child abuse, neglect, or maltreatment.

Resources:

Ramsey KS, Cunningham CO, Stancliff S, et al.; Substance Use Guidelines Committee. Substance Use Disorder Treatment in Pregnant Adults [Internet]. Baltimore (MD): Johns Hopkins University; 2021 Jul. Available from: https://www.ncbi.nlm.nih.gov/books/NBK572854/

New York State Department of Health AIDS Institute Clinical Guidelines Program, "Substance Use Disorder Treatment in Pregnant Adults." Available from: https://www.hivguidelines.org/guideline/substance-use-treatment-pregnancy/?mycollection=substance-use

National Harm Reduction Coalition and Academy of Perinatal Harm Reduction; Pregnancy and Substance Use: A Harm Reduction Toolkit [internet]. NHRC, last modified 9/2023. Available from: Pregnancy and Substance Use: A Harm Reduction Toolkit - National Harm Reduction Coalition

HCV Screening and Identification of Substance Use Among Pregnant People:

A Brief Summary of Key Points to Consider

Required HCV screening increases the likelihood that a pregnant person's past or current substance use will come to the attention of the health care provider. Providers should avoid making assumptions about a person's use, which may range from one occasion of past use to substance use disorder. Regardless of use, health care providers should recognize that individuals are doing their best, in the context of their lives, to have a healthy pregnancy and baby. Focus should be on meeting each person in an affirming manner.

What does it mean to provide affirming services to pregnant people who use drugs and their infants?

Pregnant people who use drugs often experience stigma that serves as a disincentive to engage in care. Efforts that support engagement in care promote better health outcomes for the pregnant person and their infant and are consistent with the ethical standards of the practice of medicine. Providing affirming care is something that should be a focus for all members of the care team: prescribers, nursing, social services, receptionists, and billing. Providing affirming services means holding every individual in unconditional positive high regard. Important practices include:

- Avoiding the use of stigmatizing language and using person-first language.
- Using motivational interviewing to build trust and identify options for improving health that meet the patient where they are in their life.
- Providing trauma-informed care.

Plan of Safe Care

A Plan of Safe Care (POSC) is a tool that can be used to support individuals or families impacted by substance use or taking medications to treat substance use disorders. The purpose of developing a POSC with a family is to ensure that families are receiving comprehensive support, care, and treatment that meets their needs. A POSC is a document which identifies how a provider, family, and community can support the safety and well-being of the newborn and person who gave birth. A POSC should be personalized and can address basic needs, identify support systems, and create linkages to necessary services and/or community-based organizations as appropriate.

A POSC should be developed for pregnant individuals who:

- are diagnosed with a substance use disorder; or
- are receiving medication for addiction treatment (MAT) for a substance use disorder; or
- are under the care and supervision of a healthcare provider who has prescribed opioids

Pregnant individuals are also encouraged to bring the POSC with them to the hospital or birth center. Discharge instructions for families impacted by substance use should include a reference to following the POSC. For pregnant or birthing individuals affected by substance use who do not have a POSC, or if the existing POSC does not include services for the newborn, the post-birth discharge plan serves as the start of a POSC and should include a warm linkage to appropriate community-based supports, healthcare or other providers to further develop the POSC. This is consistent with 10 NYCRR 405.9(f), which requires hospitals to link patients affected by substance use to appropriate services at discharge. For more information about this requirement, please see DAL 18-13.

Substance Use Disorder Treatment Options For Pregnant and Postpartum Individuals

Pregnant and post-partum individuals with current or past substance use may benefit from discussions and referrals to substance use disorder treatment. There are safe treatment options for substance use disorders involving different classes of drugs. NYS Office of Addiction Services and Supports (OASAS) prioritizes pregnant people for admission and treatment.

Toxicology Testing of Pregnant People

The American College of Obstetricians and Gynecologists recommends universal **verbal screening** for substance use during pregnancy; They **do not recommend routine toxicology testing during pregnancy and delivery, or for the newborn.** Toxicology testing should only be performed when medically indicated as part of the work up for the pregnant individual and infant to determine the appropriate medical treatment.

Preventing Overdose

Both pregnant and post-partum persons should be educated about the risk of overdose with any use of substances from the unregulated drug supply (e.g., anything purchased on the street). The unregulated drug supply is unpredictable and increasingly lethal. Persons using substances purchased on the street may not be getting what they intended to consume. Patients should be educated on the use of test strips (fentanyl test strips, xylazine test strips, as well as other available test strips) as well as overdose prevention. They should be provided with naloxone or educated about how to obtain it. Patients and their supports (family, friends, partners) should be educated on the importance of assessing and supporting airway and breathing (head tilt/chin lift, rescue breathing, recovery position) in the context of an overdose, whether an opioid or polysubstance overdose. Pregnant and post-partum persons with substance use and/or substance use disorder should be supported with wraparound, community-based services to help them navigate this potentially risky time.

Care for an Alcohol or Substance-Exposed Newborn

Some infants born to pregnant people who use substances may require assessment and special care. Hospitals and birthing centers should have policies to care for newborns who:

- Display symptoms of substance withdrawal **and** have a positive toxicology screen
- Receive a diagnosis of Neonatal Abstinence Syndrome (NAS)
- Receive a diagnosis of Neonatal Opioid Withdrawal Syndrome (NOWS)
- Receive a diagnosis of a Fetal Alcohol Spectrum Disorder (FASD)

Breast-Chest Feeding

Decisions around breast/chest feeding, use of formula, or both, are very personal. Respect for personal choice is important during conversations about infant feeding. Information on medications and their safety during pregnancy and lactation can be found at LactMed.

Child Protective Services

- **Substance use alone**, whether disclosed through development of a POSC, self-report, screening, toxicology, or newborn symptoms, **is not evidence of child abuse, neglect or maltreatment.**
- When there is **reasonable cause**, beyond substance use, to suspect a child is at risk of abuse, neglect or maltreatment, hospitals and birth centers should continue to follow existing policies and protocols for making a report to the Statewide Central Register for Child Abuse and Maltreatment (SCR).

Pain Control

Providing affirming care for pregnant people who use drugs includes acknowledging that they experience the same level of post-partum pain as any other post-partum individual. It is important to work with each individual to establish a plan for pain control that meets their needs and individual circumstances.

Resources

Pregnancy and Substance Use: A Harm Reduction Toolkit

NYS CAPTA CARA Information and Resources

CAPTA CARA Dear Colleague Letter

Substance Use Disorder in Pregnancy Position Statement

National Institute on Drug Abuse: Words Matter – Terms to Use and Avoid When Talking About Addiction

National Institute on Drug Abuse: Your Words Matter – Language Showing Compassion and Care for Women, Infants, Families, and Communities Impacted by Substance Use Disorder

National Institute on Drug Abuse: Preferred Language for Talking About Addiction

New York State Department of Health AIDS Institute Clinical Guidelines for Substance Use Disorder Treatment in Pregnant Adults

Dear Colleague Letter - New York State Hepatitis C Screening Requirements for Pregnant People, May 2024

Dear Colleague Letter - New York State Hepatitis C Screening Requirements for All Adults, May 2024

Educational Materials to Promote HCV Testing During Pregnancy

The New York State Department of Health offers limited quantities of free educational materials to New York State residents and organizations.

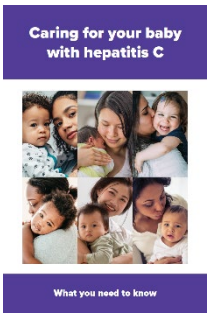
- No more than 10 different publications may be ordered at a time.
- You may order up to 200 copies of each (up to 10 copies for posters) or provide details on why more are needed.
- For fastest delivery, please list items in numerical order by code number. These orders will be processed first.
- Bulk orders cannot be delivered to post office box numbers.

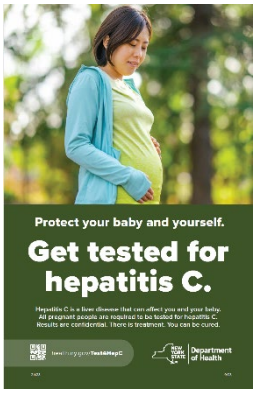
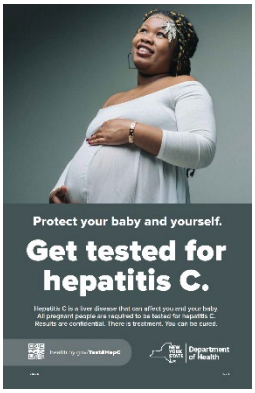
Complete this form including the requested publication title and publication number, language and quantity requested. Email the completed form to OGS.SM.GDC@OGS.NY.GOV

Materials for Consumers

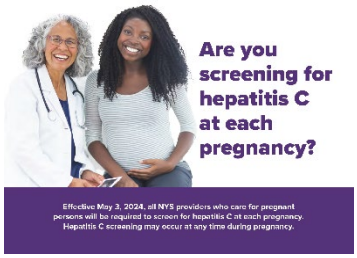
To view or print consumer education materials click on the blue links below for each material.

Title	Language	Publication #
NYS Hepatitis C Testing Requirements: Consumer Fact Sheet This 2-page fact sheet for consumers provides information about hepatitis C screening in New York and the meaning of the results. 9/2023	English	1821
	Spanish	16152
Protect yourself. Protect your baby (Consumer postcard) **–** This 2-sided postcard aims to encourage hepatitis C testing among pregnant people and follow-up testing for infants exposed to hepatitis C during pregnancy and birth. 9/2023  	English	16140
	Spanish	16142
Hepatitis C and Pregnancy – This 10-page booklet addresses hepatitis C among people who are or may become pregnant. It includes basic information on HCV, testing, treatment, and considerations for people who are pregnant. 2/2024 	English	16039
	Spanish	16040

Title		Language	Publication #
Caring for Your Baby with Hepatitis C – What you need to know – This 8-page booklet provides information for caregivers about the follow-up care needed for infants exposed to hepatitis C during pregnancy and birth. 10/2023		English	21432
		Spanish	21433
Protect Your Baby and Yourself – Poster This 11x17 poster aims to encourage hepatitis C testing among pregnant people. 9/2023		English	21420
		Spanish	21426
Protect Your Baby and Yourself – Poster This 11x17 poster aims to encourage hepatitis C testing among pregnant people. 9/2023		English	21421
		Spanish	21427
Protect Your Baby and Yourself – Poster This 11x17 poster aims to encourage hepatitis C testing among pregnant people. 9/2023		English	21422
		Spanish	21428

Title		Language	Publication #
Protect Your Baby and Yourself – Poster This 11x17 poster aims to encourage hepatitis C testing among pregnant people. 9/2023		English	21423
		Spanish	21429
Protect Your Baby and Yourself – Poster This 11x17 poster aims to encourage hepatitis C testing among pregnant people. 9/2023		English	21424
		Spanish	21430
Protect Your Baby and Yourself – Poster This 11x17 poster aims to encourage hepatitis C testing among pregnant people. 9/2023		English	21425
		Spanish	21431

Materials for Health Care Providers

Title	Language	Code #
New York State Requirements for Universal Hepatitis C Testing: Health Care Provider Fact Sheet - This 2- page fact sheet for health care providers reviews New York State hepatitis C screening requirements. 9/2023	English	1820
Are you screening for hepatitis C at each pregnancy?: Provider Postcard This 2-sided postcard alerts healthcare providers about the New York State hepatitis C screening requirements during pregnancy. 9/2023 	English	16135

Additional Educational Resources

Additional information about the Test4HepC campaign can be found at: health.ny.gov/Test4HepC

More hepatitis C related consumer educational resources are available at: https://www.health.ny.gov/diseases/communicable/hepatitis/hepatitis_c/educational_materials.htm

Screening for STIs, HIV, and Hepatitis B/C during Pregnancy in NYS

Infection	1st Prenatal Visit	3rd Trimester	Delivery	Screening Test
Syphilis^	Everyone	Everyone	Everyone	Syphilis Serology
Gonorrhea*	If <25, or ≥25 at risk	If at risk	N/A	GC NAAT
Chlamydia*	If <25, or ≥25 at risk	If <25, or ≥25 at risk	N/A	CT NAAT
HIV	Everyone	Everyone	If not tested during this pregnancy or at risk	HIV-1/2 Ab/Ag
Hepatitis B^	Everyone	N/A	If not tested during this pregnancy or at risk	HBsAg
Hepatitis C^	Everyone	If not tested during this pregnancy or at risk	If not tested during this pregnancy or at risk	HCV Ab with reflex to HCV RNA

^Testing mandated by NYS Public Health Law.
*Repeat screen 3 months after treatment of documented gonorrhea or chlamydia infection during pregnancy.

Risk factors for STI/HIV and hepatitis B and C may include: History or current diagnosis of an STI; new partner(s); pregnant person or partner with multiple partners; sex partner with an STI; condomless sex not in a tested negative mutually monogamous relationship; transactional sex; history of incarceration; pregnant person or partner with injection drug use; high incidence/prevalence setting.

Compiled from NYS, USPSTF, and CDC screening guidelines and NYS public health laws and regulations.

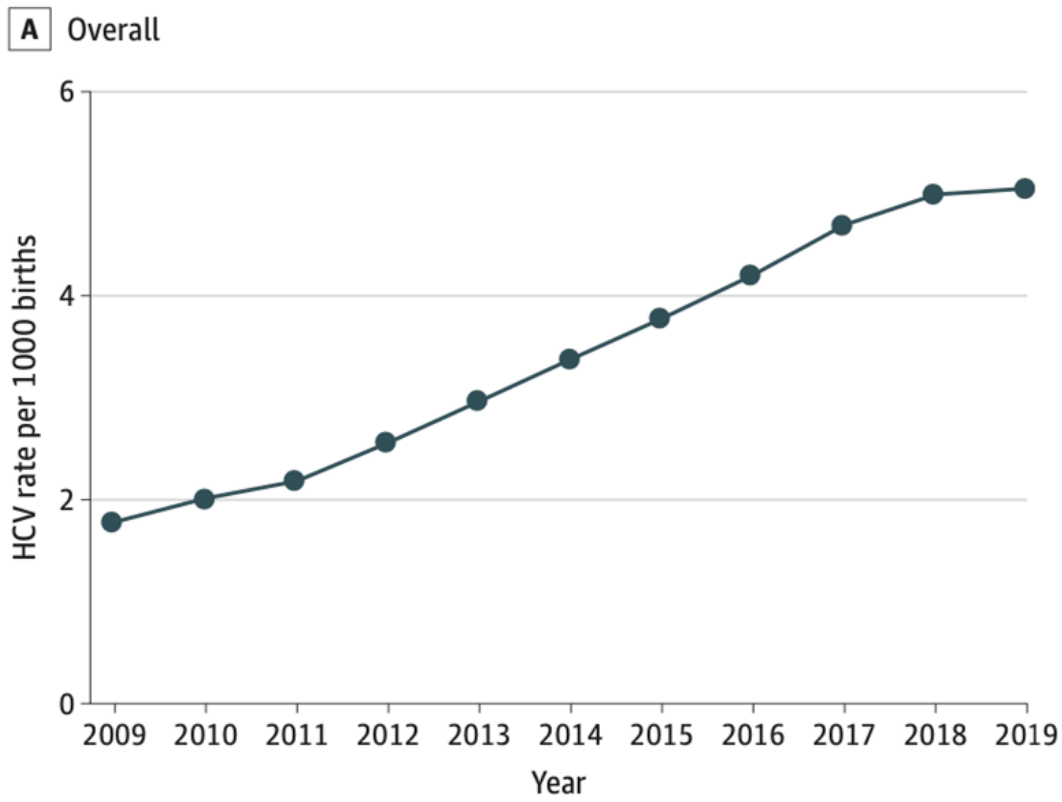
Clinical Questions: CEI Line 866-637-2342

CEI CLINICAL EDUCATION INITIATIVE

Screening for Hepatitis C Virus during Pregnancy

Hepatitis C Virus (HCV) in Pregnant Persons in the US, *2009-2019*

- All US births from 2009-19 using data from National Center for Health Statistics (CDC) and Area Health Resource File
  - » 39,380,122 pregnant persons
  - » 138,343 (0.4%) with HCV
- **Rate increased from 1.8 to 5.1 per 1,000 births**

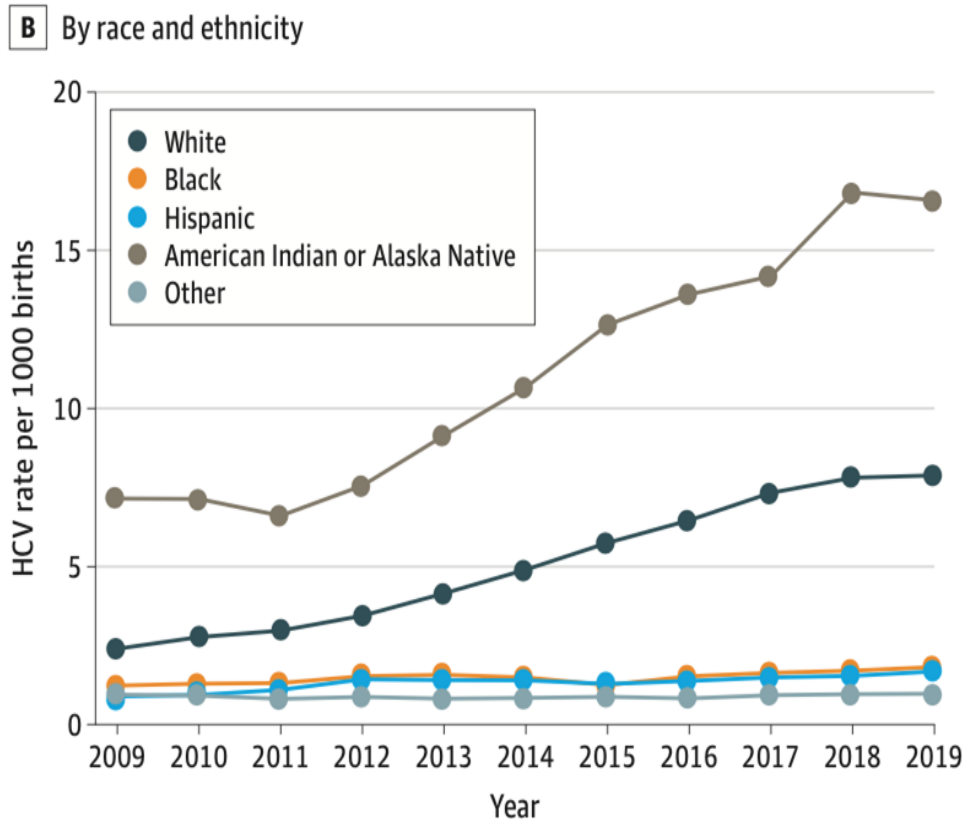


Patrick S et al. JAMA Health Forum October 2021.

Hepatitis C Virus (HCV) in Pregnant Persons in the US, *2009-2019*

Higher rates among:

- **American Indians, Alaska Natives, White persons**
- Persons with less than 4-year college degree
- Persons with Medicaid or self-pay
- Persons who lived rurally
- Locations with a lower density of OB providers
- Persons who were on unemployment



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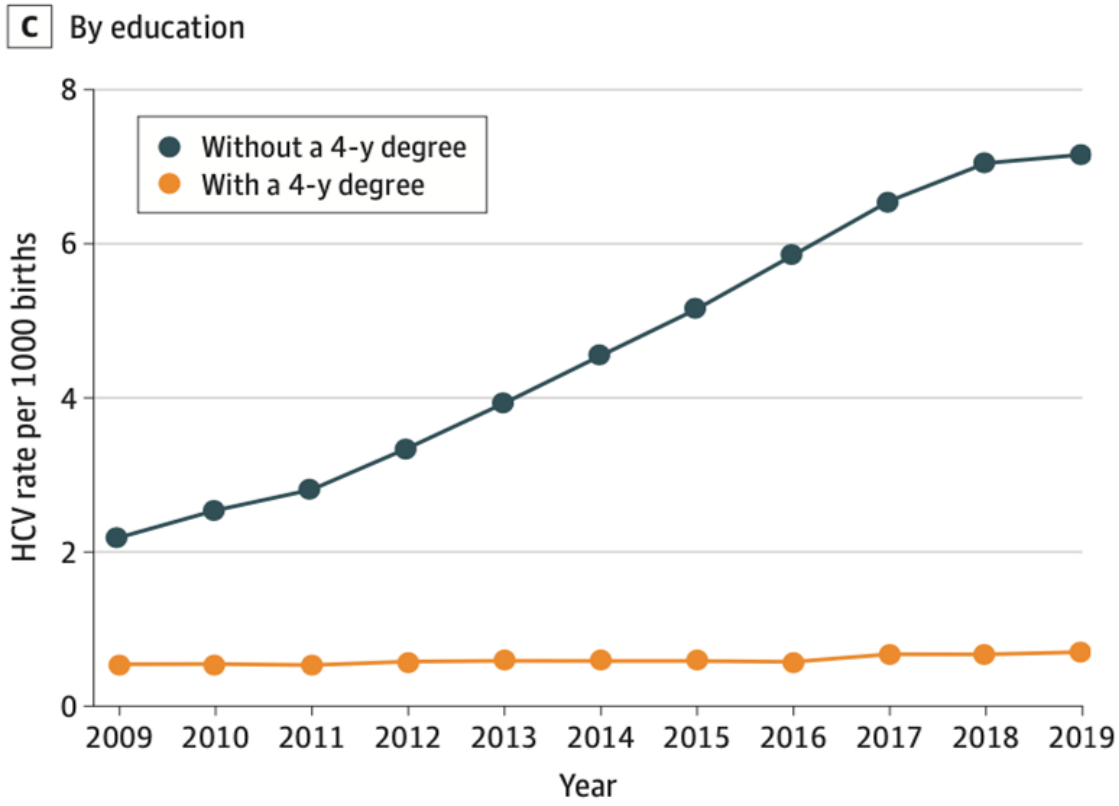

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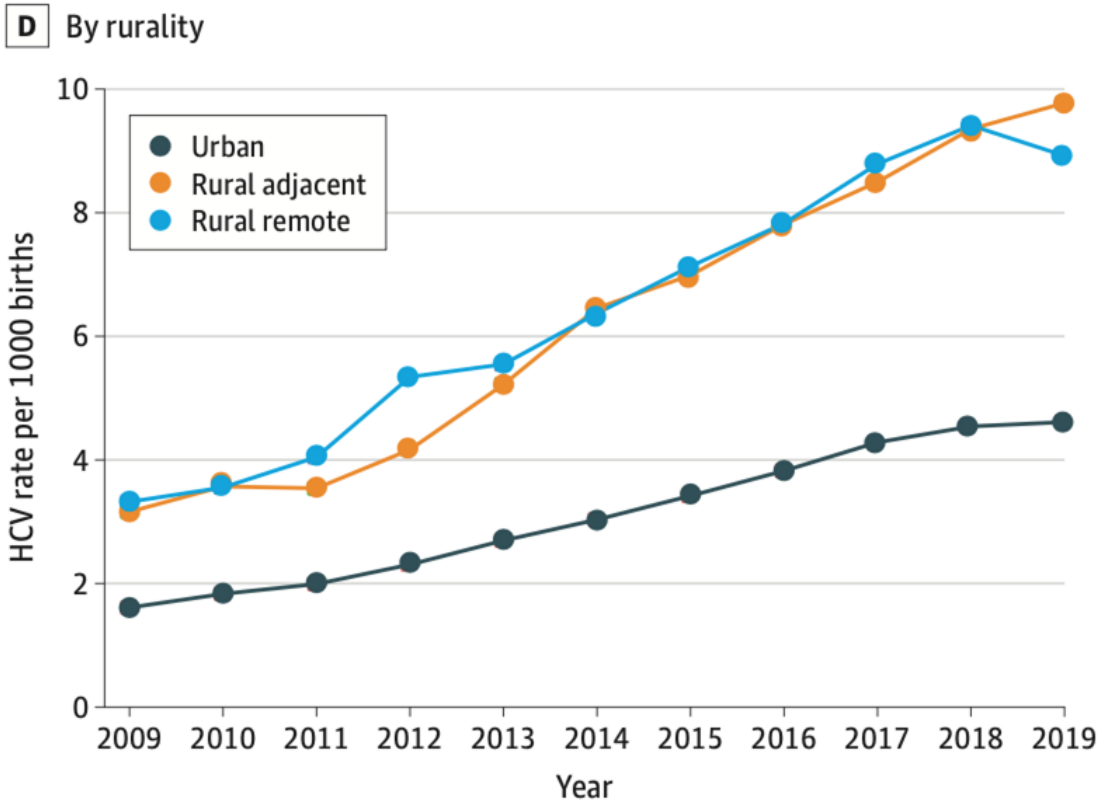
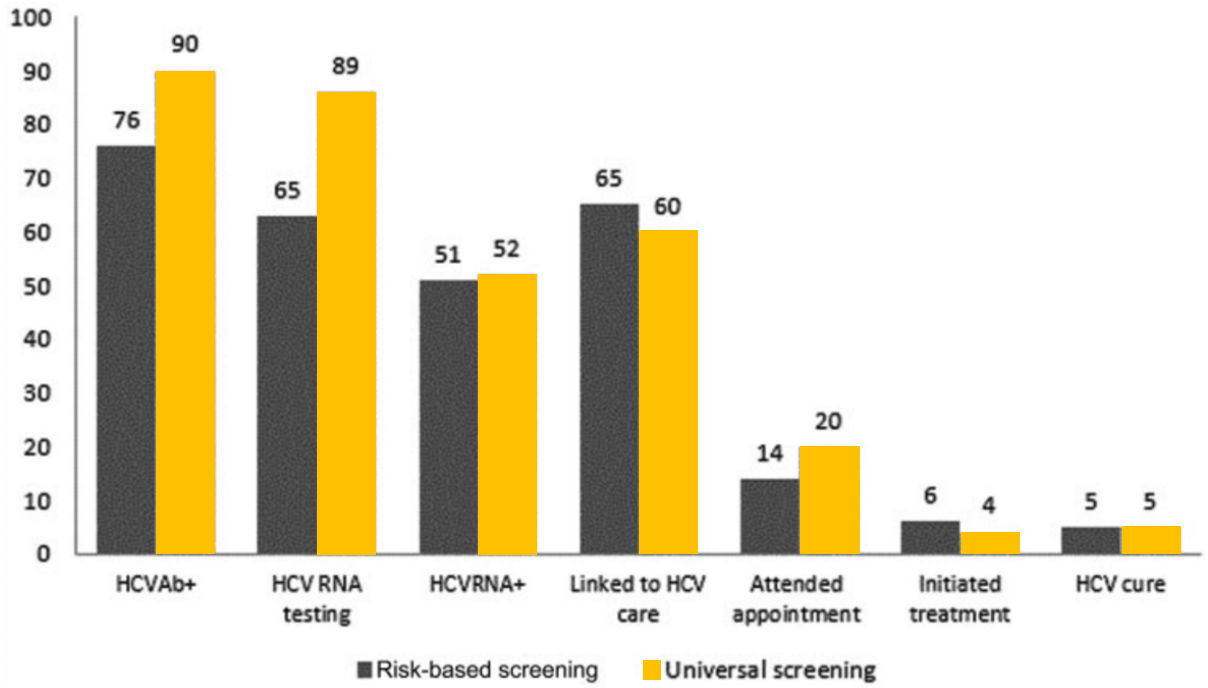


Patrick S et al. JAMA Health Forum October 2021.

Does risk-based HCV screening in pregnancy work?

Retrospective cohort study at tertiary care center for pregnant persons with risk-based screening (2014-2016) vs. universal screening (2016-2018):

- **29%** (76/266) positive in risk-based arm vs. **1.3%** (90/6,773) in universal arm
- Only **69%** (62/90) of HCVAb+ in universal arm **met criteria for risk-based screening**



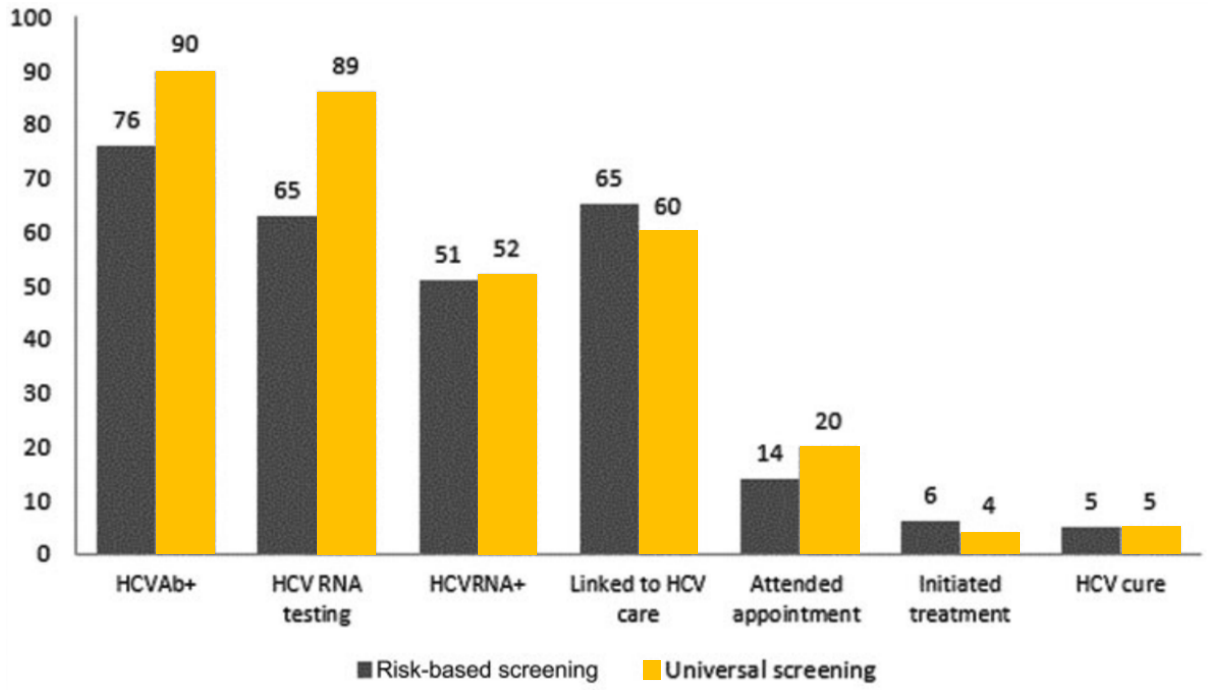
Bushman E et al. Am J Perinatology 2021.

Does risk-based HCV screening in pregnancy work?

Retrospective cohort study at tertiary care center for pregnant persons with risk-based screening (2014-2016) vs. universal screening (2016-2018):

"Universal HCV screening in pregnancy identified **an additional 31% of HCVAb+** pregnant persons compared with risk-based screening.

Given low rates of HCV follow-up and treatment regardless of screening modality, <u>further studies are needed to address barriers to postpartum linkage to care</u>."



Bushman E et al. Am J Perinatology 2021.

Rationale for Universal HCV Screening in New York State

- In 2017, 59% (1,914) of all new female cases of HCV reported in New York State (excluding NYC) were among persons of childbearing age
  - » In NYC, 38.7% (783) of all new female cases of HCV were among persons of childbearing age
- Concern for birthing parent-to-child (vertical) HCV transmission
- In areas of high prevalence, 10-28% of pregnant persons with HCV are not identified by risk-based screening
- Identifying HCV presents an opportunity to ensure linkage to care, guide obstetric clinicians on the birthing parent and fetal risks in pregnant persons with HCV
- Universal HCV screening during pregnancy appears cost-effective, compared to current practice
- Alignment with CDC recommendations for universal HCV screening in individuals who are pregnant or planning to become pregnant (screening should be repeated during each pregnancy)

https://www.hivguidelines.org/hepatitis-care/treatment-with-daa/#tab_4

What is the management approach to an individual who screens positive in pregnancy?

a) Counsel on potential risks associated with HCV in pregnancy

b) Counsel on risk of birthing parent-to-child transmission

c) Discuss plan for HCV treatment

d) Plan linkage to care post-delivery

What are the risks seen with HCV in pregnancy?

There is likely a negative impact due to HCV in pregnancy, but it is difficult to isolate the effects of HCV from the effects of associated factors, such as injection drug use.

» **Meta-analysis of >4m pregnant persons and >5000 HCV infection cases**

- Preterm birth - OR 1.62 (95% CI 1.48-1.76)[1,]
- IUGR - OR 1.53 (95% CI 1.40-1.68)[2]
- Low birth weight – OR 1.97 (95% CI 1.43-2.71) [2]

» **Swedish birth registry of >1 m pregnant persons, >2000 HCV births births, 2001-2011**

- Preterm birth (aRR 1.32 (95% CI 1.08-1.60)
- Late neonatal death (aRR 3.79 (95% CI:1.07-13.79)

» **Italian study of >45k pregnant pregnant persons screened for HCV, 2009-2018[3]**

- Cholestasis of pregnancy **10x** higher; Gestational DM 2x higher in HCV positive

[1]Huang Q, et al. *J of Viral Hepatitis 2015.*
[2]Huang Q, et al. *Medicine 2016.*
[3]Stokkeland K, et al. *Eur J Epidemiol 2017.*
Piffer S, et al. *European Journal of Obstetrics & Gynecology 2021.*

Are HCV associated risks an effect of HCV viremia itself?

- Population-based study in Ontario, 2000-2016
  - » 2170 HCV AB positive pregnancies; 1780 RNA+ pregnancies

Effect of birthing parent HCV viremia on probability of peripartum outcomes in infants born to pregnant persons with HCV.

Outcomes	OR	95% CI	p-value
Gestational diabetes[1]	**0.71**	**0.47 - 1.06**	**0.0958**
Intrahepatic cholestasis of pregnancy[2]	**4.55**	**1.64 - 12.64**	**0.0036**
Small for gestational age[3]	1.10	0.80 - 1.51	0.5716
Large for gestational age[4]	1.25	0.81 - 1.93	0.3153
Postpartum or antepartum hemorrhage[5]	**1.78**	**1.11 - 2.87**	**0.0173**
Preterm delivery[3]	**1.84**	**1.27 - 2.67**	**0.0013**

Kushner T, et al. *Journal of Hepatology* 2022.

Can we do anything to prevent birthing parent-to-child transmission?

Variable	Studies; # women	Strength of Evidence	Summary of findings
Elective C/S vs. vaginal delivery	4 cohort studies; N=2080	Low	No differences, but trends in opposite directions in highest quality studies
All C/S vs. vaginal delivery	11 cohort studies; N=2308	Moderate	No association
Invasive fetal monitoring vs. none	3 cohort studies; N=928	Insufficient	Inconsistent but one good quality study OR=6.7 (95% CI 1.1-36)
Prolonged rupture of membranes vs. no	2 cohort studies; N=245	Low	Yes with > 6 hours having OR=9.3 (95% CI 1.5-18)
Breastfeeding	14 cohort studies; 2971 patients	High	No association

Cottrell, et al. *Ann Intern Med*, 2013.
Rac, et al. *Obstet Gynecol Clin North Am*, 2014.
Hughes, et al. *Society for Maternal Fetal Medicine*, 2017.

Screening Recommendations for Infants Born to Pregnant Persons Living with HCV

NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE

CLINICAL GUIDELINES PROGRAM

- Clinicians should refer infants born to mothers with HCV to pediatricians with experience in HCV care. (A3)

Recommendations for HCV Testing of Perinatally Exposed Children and Siblings of Children With HCV Infection	
RECOMMENDED	RATING
All children born to HCV-infected women should be tested for HCV infection. Testing is recommended using an antibody-based test at or after 18 months of age.	I, A
Testing with an HCV-RNA assay can be considered in the first year of life, but the optimal timing of such testing is unknown.	IIa, C
Testing with an HCV-RNA assay can be considered as early as 2 months of age.	IIa, B
Repetitive HCV RNA testing prior to 18 months of age is not recommended.	III, A
Children who are anti-HCV positive after 18 months of age should be tested with an HCV-RNA assay after age 3 to confirm chronic hepatitis C infection.	I, A
The siblings of children with vertically-acquired chronic HCV should be tested for HCV infection, if born from the same mother.	I, C

AASLD
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

https://www.hivguidelines.org/

https://www.hcvguidelines.org/

Postpartum Linkage to Care

> **"HCV-infected pregnant women** [*pregnant persons with HCV infection*] **should be linked to care so that antiviral treatment can be initiated at the appropriate time."**

Huge challenge to ensure linkage to care:

- Women with HCV experience longer delays to HCV treatment than men
- African Americans experience longer delays (280 vs. 165 days in non-Hispanic whites, $P<0.05$)
  - » HCV treatment uptake is lower in African Americans (70.4% vs. 74.4% in non-Hispanic whites, $P<0.05$)
- Postpartum period has very high rate of loss to follow-up

Gomes C et al. *J Transl Int Med* 2020.

CDC Perinatal HCV Screening Recommendations

- Perinatally exposed infants should receive an HCV RNA at age 2-6 months.
  - Infants with detectable HCV RNA: refer to health care provider with expertise in pediatric HCV management.
  - Infants with undetectable HCV RNA: no further follow-up needed.

Clinical Guidelines for the Management of Pregnant Persons with HCV and/or Substance Use Disorder

New York State Department of Health AIDS Institute, *Hepatitis C Testing and Management in Pregnant Adults*

» https://www.hivguidelines.org/guideline/hcv-treatment/?mycollection=hepatitis-care#tab_2

American Association for The Study of Liver Diseases (AASLD) / Infectious Diseases Society of America (IDSA), *Hepatitis C in Pregnancy*

» https://www.hcvguidelines.org/unique-populations/pregnancy

New York State Office of Addiction Services and Supports (OASAS), *Treatment Guidelines for Pregnant and Parenting Persons*

» https://oasas.ny.gov/treatment/pregnant-and-parenting-persons

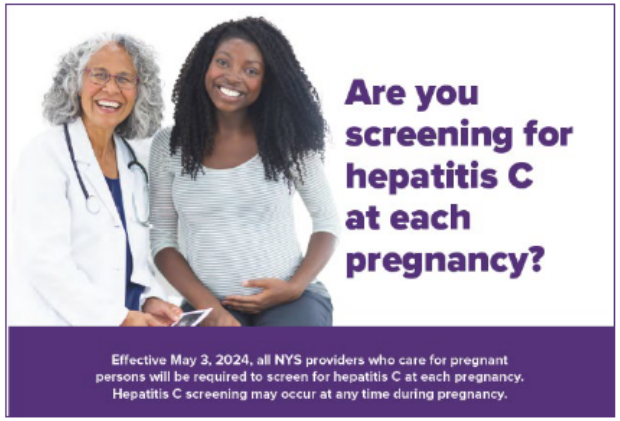
Clinical Resources

Visit us online: **https://ceitraining.org/**

Hepatitis C Screening During Pregnancy Provider Toolkit - February 2024

Introduction and Purpose

This toolkit was developed to assist prenatal care and maternity settings with implementing the requirement of hepatitis C virus (HCV) screening of pregnant people, and linkage to care for those with diagnosed HCV infection. HCV screening is part of New York State's Hepatitis C Elimination Plan. Information about the number of new HCV diagnoses each year and specific metrics related to HCV elimination can be found on the NYS HCV Elimination Dashboard.



https://ceitraining.org/documents/HCV%20Screening%20for%20Pregnant%20People%20-%20Provider%20Toolkit%20FEB%202024.pdf