Public Health Nursing Webinar:
Hepatitis C

Dia J Obonyo, DrPH
Viral Hepatitis Program Lead

August 15, 2024

Kentucky Public Health
Prevent. Promote. Protect.

Accredited Health Department
PHAB
Advancing Public Health Performance
Public Health Accreditation Board

TEAM KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES

Objectives

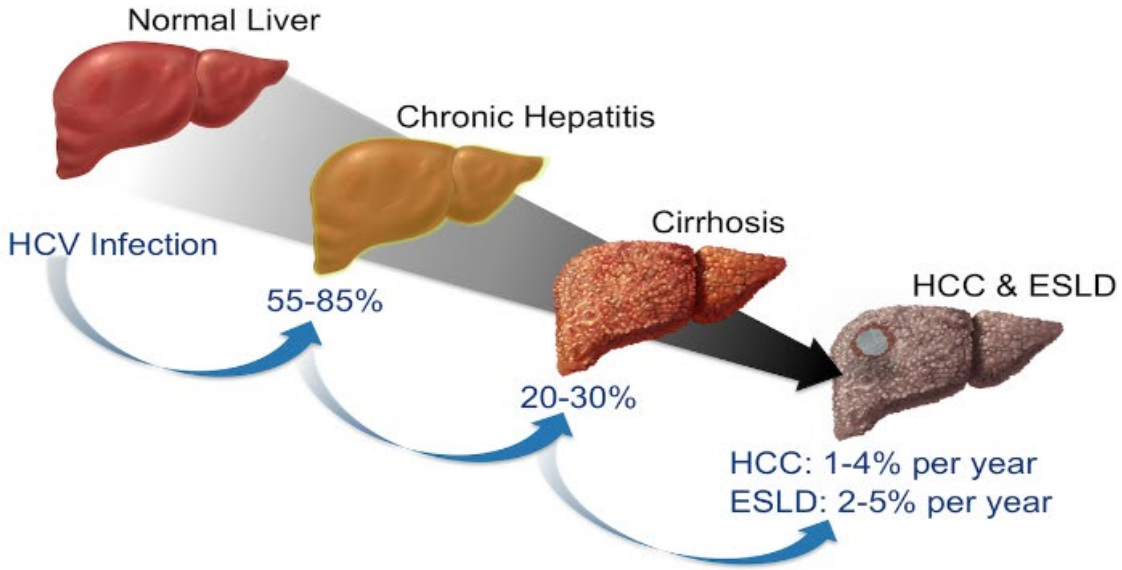
Learn about:

- the hepatitis C virus and rates in Kentucky
- risk factors and testing recommendations
- testing options and path to diagnosis
- what to do after diagnosing an individual

Hepatitis C

- Liver infection caused by the hepatitis C virus (HCV)
- Spread through contact with blood from an infected person
- Most common bloodborne infection; causes more deaths than any other infectious disease in the US
- Most people become infected by sharing needles or other equipment used to prepare and inject drugs

https://www.cdc.gov/hepatitis/hcv/index.htm; Jordan et al. 2020

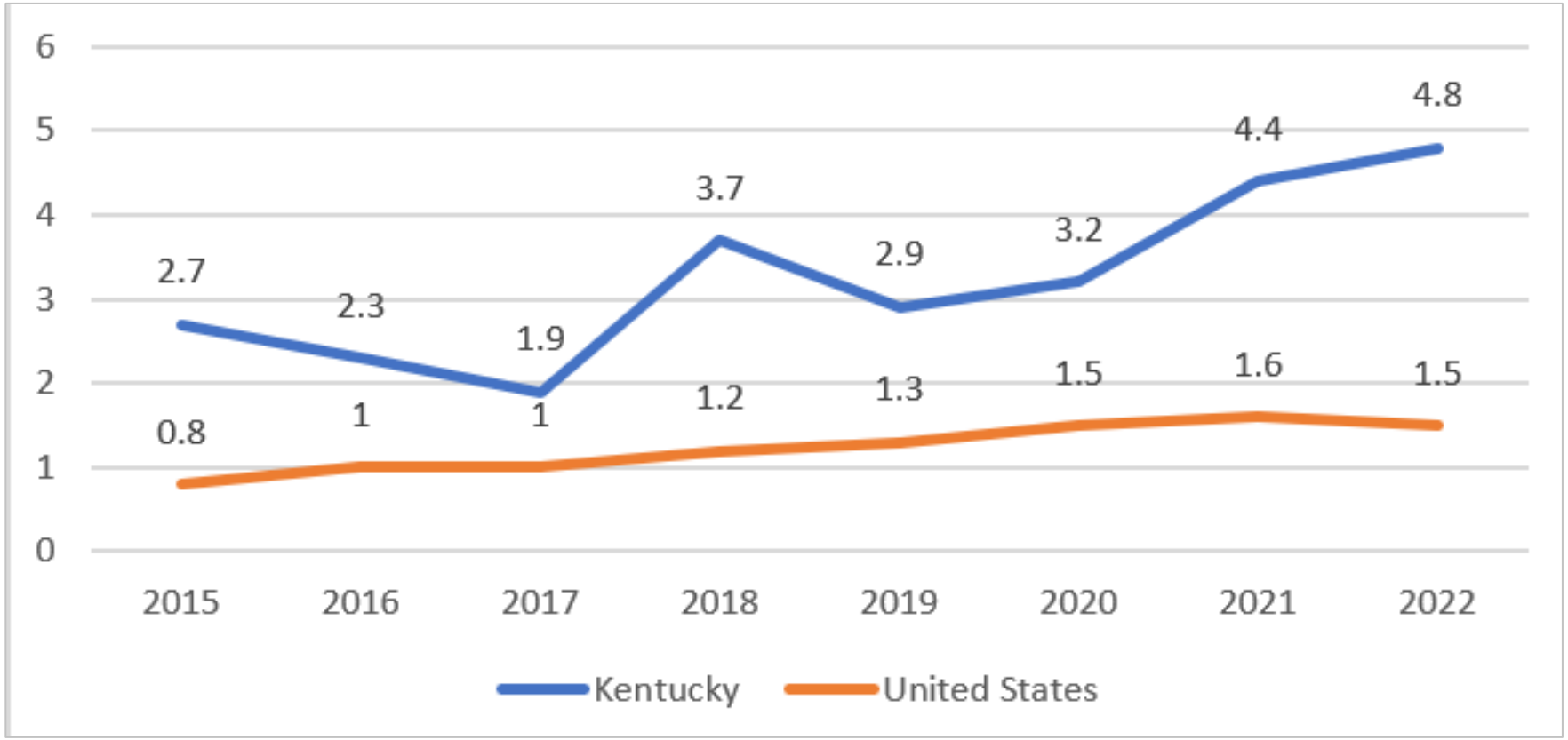


Natural History Following Initial Infection with HCV
ESLD: end-stage liver disease; HCC: hepatocellular carcinoma

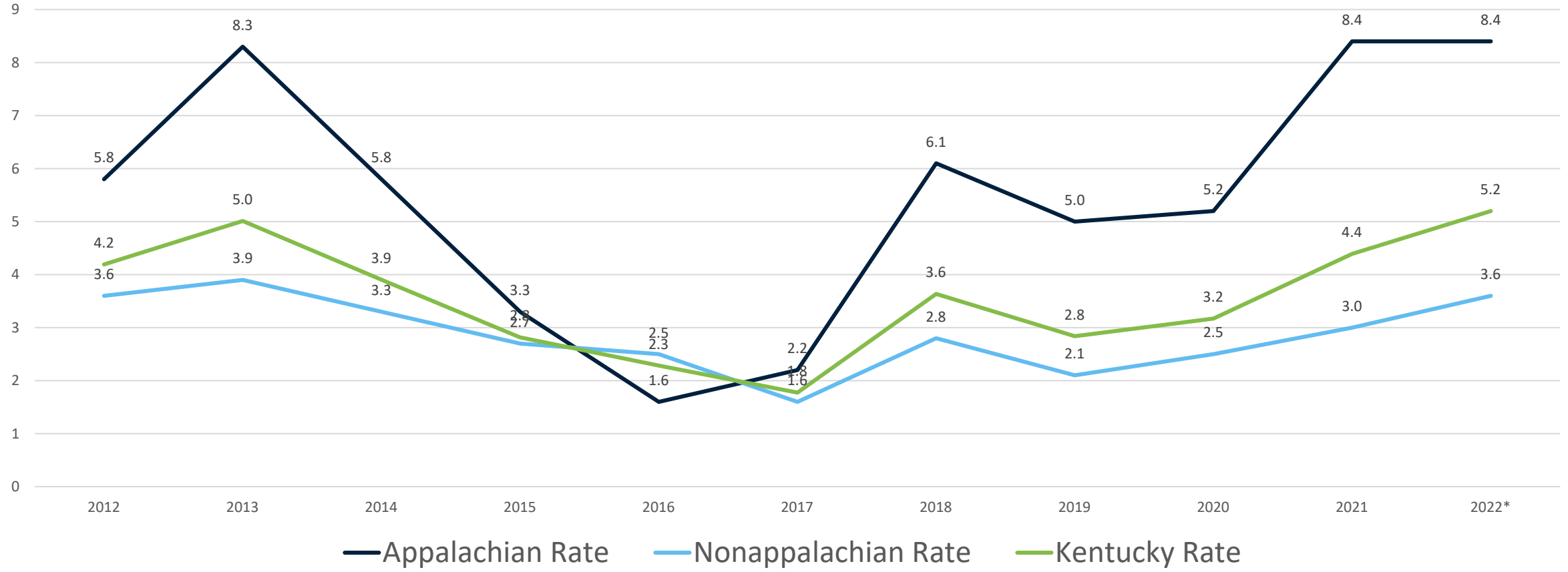
- Approximately 55-85% will develop chronic infection

https://www.hepatitis.va.gov/hcv/background/natural-history.asp

Rates of Acute Hepatitis C per 100,000 Kentucky and United States, 2015-2022



Acute Hepatitis C Rates by Appalachian Designation, Kentucky, 2012 – 2022



Kentucky Department for Public Health, Viral Hepatitis Program

Hepatitis C Cure

- Highly-effective, well tolerated oral medications
- 8-12 week treatment
- **Cure rate: >95%**
- However, few are linked to care
- High cost

[Too Few People Treated for Hepatitis C | VitalSigns | CDC]

Cost-Effectiveness

Treatment for HCV saves patients money despite high up-front costs

PBS NEWS HOUR

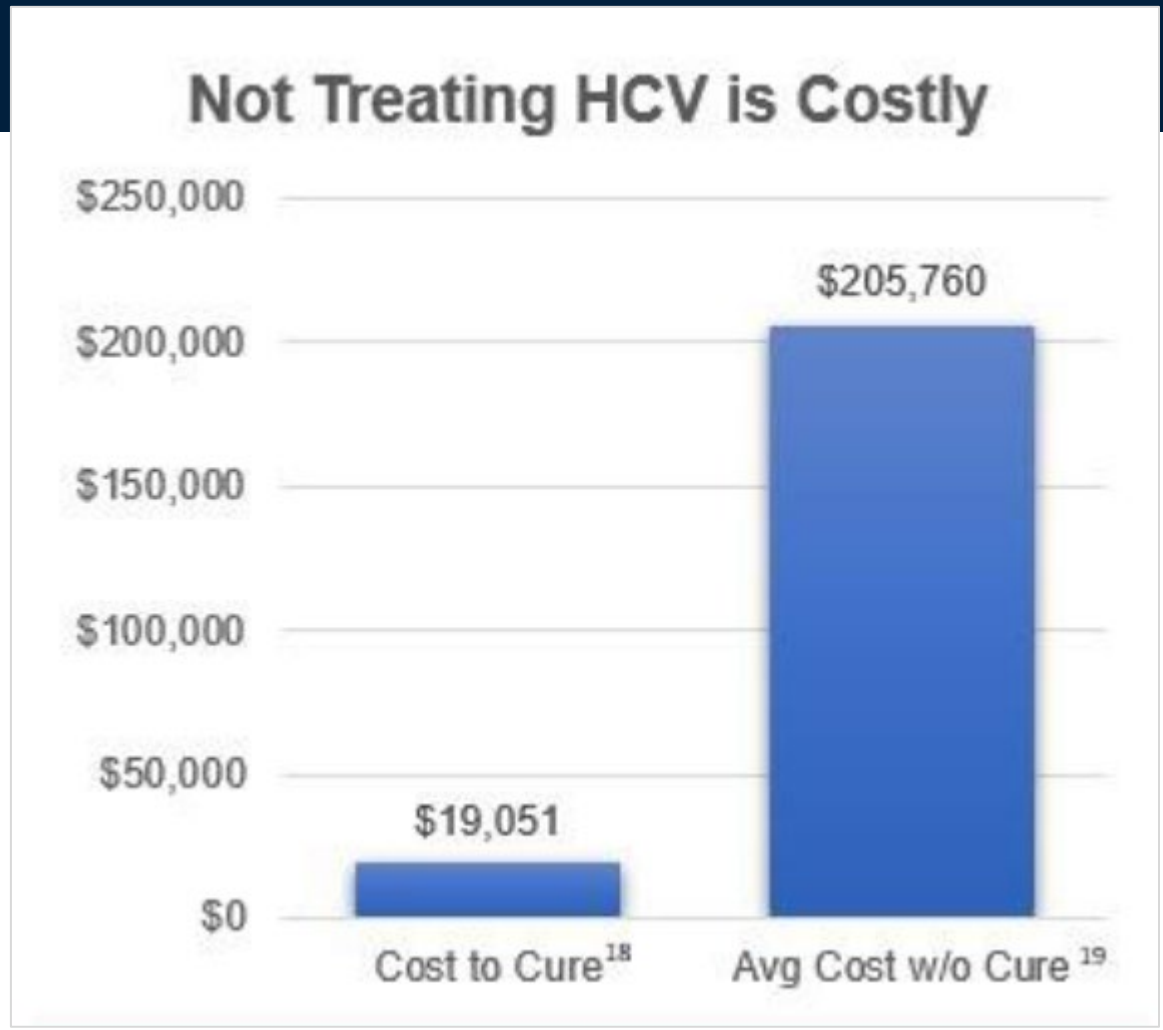
Projected reduction in HCV-related medical costs, per patient

Total costs vs. Savings over 10 years

	2021	2030
Non-Cirrhotic Disease (NCD)	$12,739	($42,755)
Compensated Cirrhosis (CC)	$13,354	($23,201)
End-Stage Liver Disease (ESLD)	$9,479	($185,245)

Source: Milliman White Paper (Projected U.S. national Hepatitis C treatment costs and estimated reduction to medical costs)

Hepatitis C is 'not something you wish on anybody.'| PBS News



Fact Sheet MAY 2021 (aidsinstitute.net)

Importance of Testing

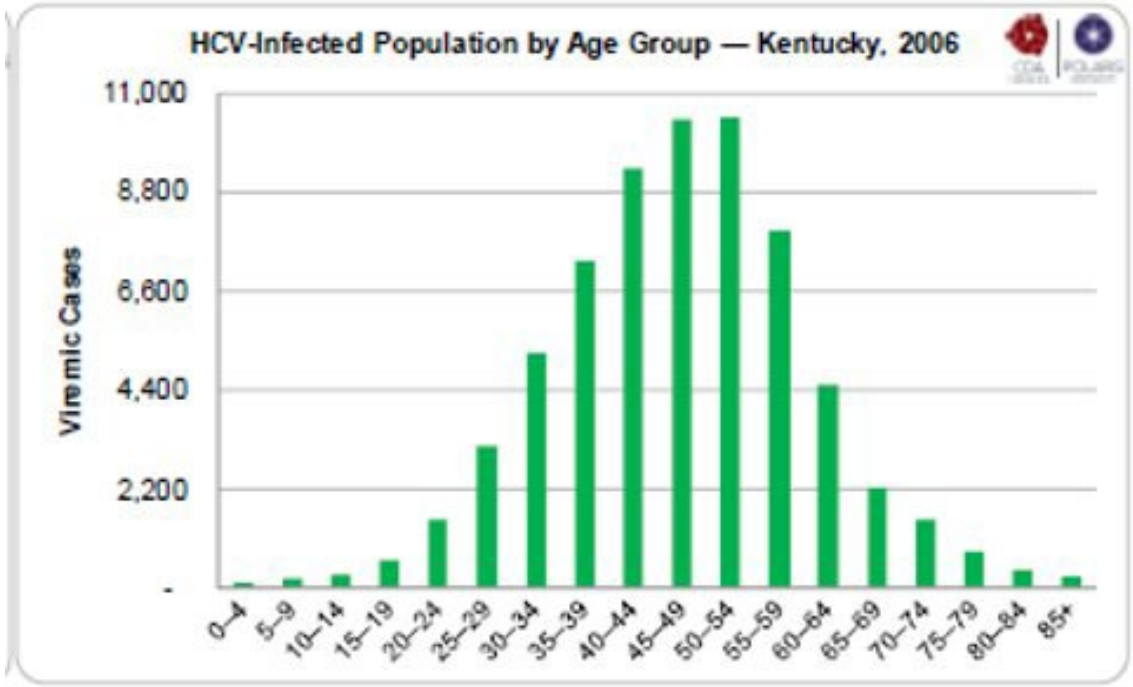
Treatment & cure cannot happen without testing and diagnosis

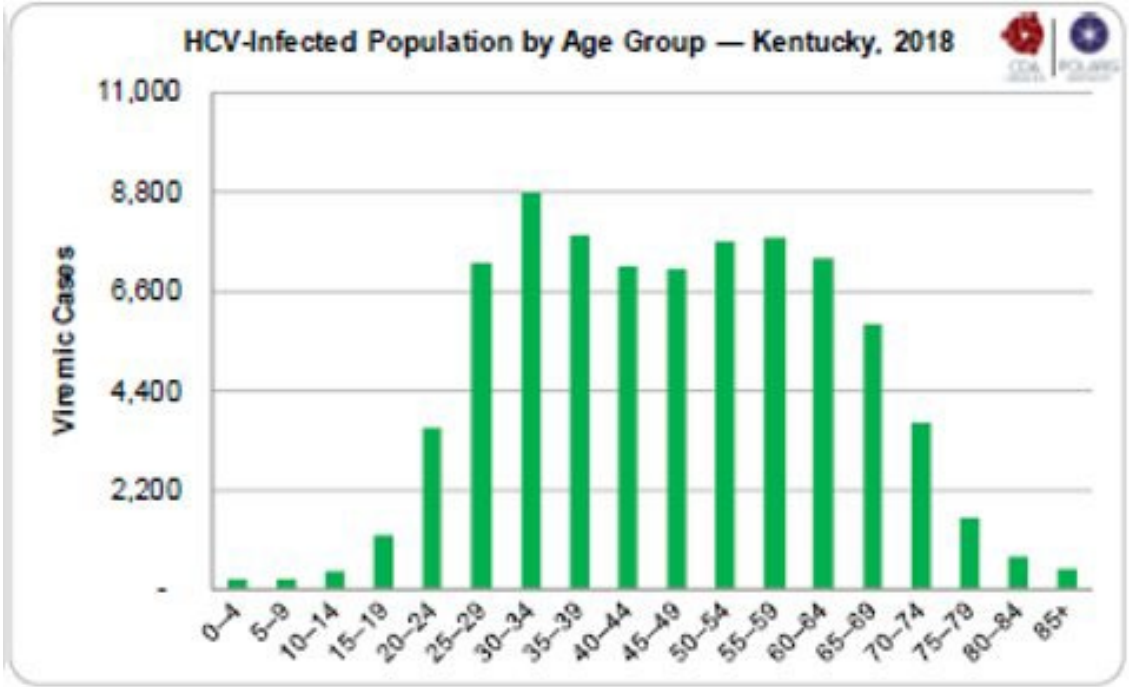
- Around half of people with HCV do not know they have it
- 75-85% of people with HCV don’t have symptoms

Clinical Screening and Diagnosis for Hepatitis C | Hepatitis C | CDC

CDC Testing Recommendations

- Old recommendations centered on baby boomers
- After decades of decline in acute hepatitis C incidence, rates began increasing in 2010.
- National surveillance data in 2010s showed new populations; Same for Kentucky





BurdenFinalReportCDAF.pdf (ky.gov)

CDC Testing Recommendations

- 2020: Universal testing for everyone 18 years and older (at least once), all pregnant individuals during every pregnancy, plus regular testing for those with ongoing risk

SOURCES: CDC Recommendations for Hepatitis C Screening, MMWR, April 2020
CDC Vital Signs, April 2020

Any person who requests hepatitis C testing should receive it, regardless of disclosure of risk, because many persons might be reluctant to disclose stigmatizing risks

Testing for Hepatitis C | Hepatitis C | CDC

New Perinatal Testing Guidance

November 2023:

Earlier testing recommended due to ‘loss to follow-up’

- Prior guidance:
  18 months
- New guidance:
  2-6 months

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

Laboratory Markers of HCV

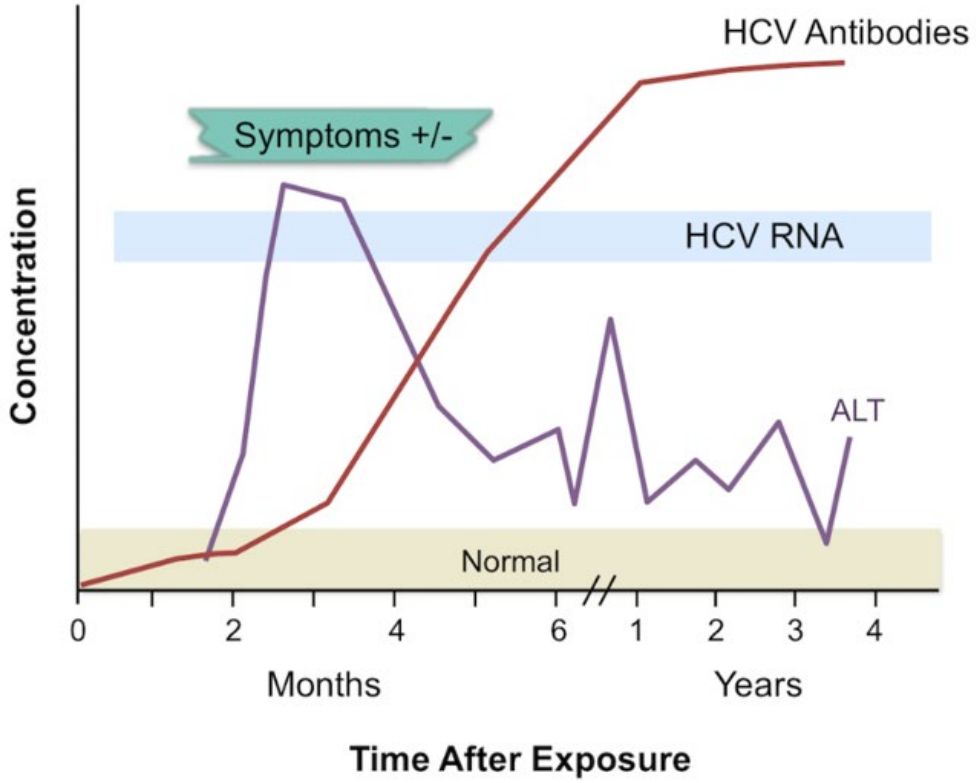
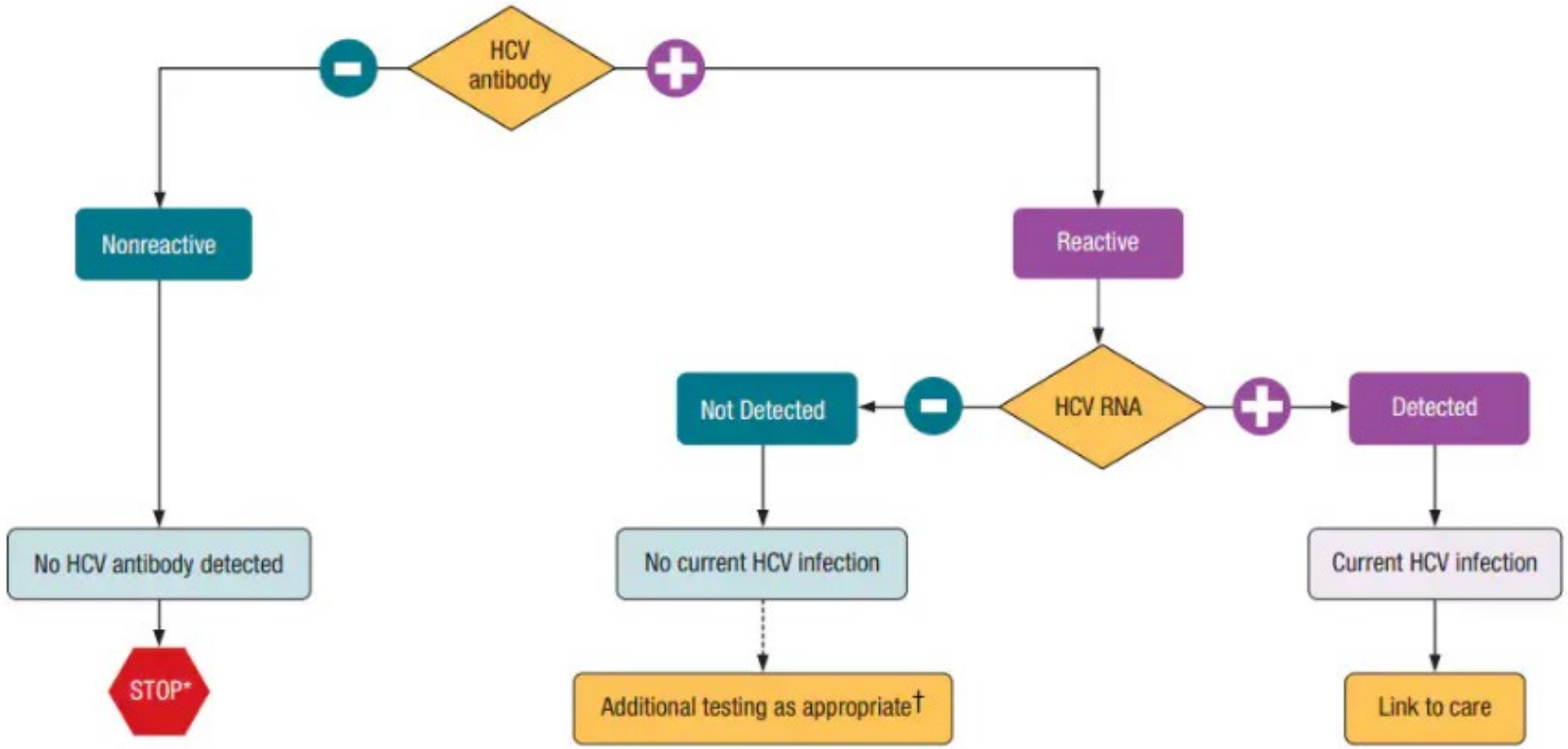


Figure 2 - Laboratory Markers with Acute HCV Infection
Note the temporal appearance of laboratory markers typically observed with acute hepatitis C infection: HCV RNA levels first become detectable, followed by increases in ALT levels, and then detectable HCV antibody.

Source: Centers for Disease Control and Prevention (CDC).

Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention



* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).

Clinical Screening and Diagnosis for Hepatitis C | Hepatitis C | CDC

Rapid Tests

- Detect HCV antibodies

Laboratory and Confirmatory Tests

Clinicians should use an FDA-approved HCV antibody test followed by a NAT for HCV RNA test when antibody is positive/reactive. Tests include:

- HCV antibody test (anti-HCV) (e.g., enzyme immunoassay [EIA]).
- Nucleic acid test (NAT) to detect presence of HCV RNA (qualitative RNA test).
- NAT to detect levels of HCV RNA (quantitative RNA test).

A reactive HCV antibody test result indicates a history of past or current HCV infection. A detectable HCV RNA test result indicates current infection.

NAT for detection of HCV RNA should be used among people with suspected HCV exposure within the past 6 months.

Clinical Screening and Diagnosis for Hepatitis C | Hepatitis C | CDC

Potentially available soon…

Point of Care (POC) Confirmatory Testing

FDA NEWS RELEASE

FDA Permits Marketing of First Point-of-Care Hepatitis C RNA Test

Test Enables Single-Visit Testing and Treatment for Hepatitis C

For Immediate Release:

June 27, 2024

Today, the U.S. Food and Drug Administration granted marketing authorization to Cepheid for the Xpert HCV test and GeneXpert Xpress System, the first hepatitis C virus (HCV) test that can be used to bring diagnosis to appropriately certified point-of-care settings for individuals at risk for hepatitis C. The test may be performed in settings operating under a CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver, such as certain substance use disorder treatment facilities, correctional facilities, syringe service programs, doctor's offices, emergency departments and urgent care clinics. Rather than requiring a sample to be sent to a central lab for testing, the test detects HCV RNA and delivers results in about an hour using a blood sample from the fingertip.

FDA Permits Marketing of First Point-of-Care Hepatitis C RNA Test | FDA

What to do after diagnosing…

- Educate
- Treat/Refer to treatment
- Report

Patient Education

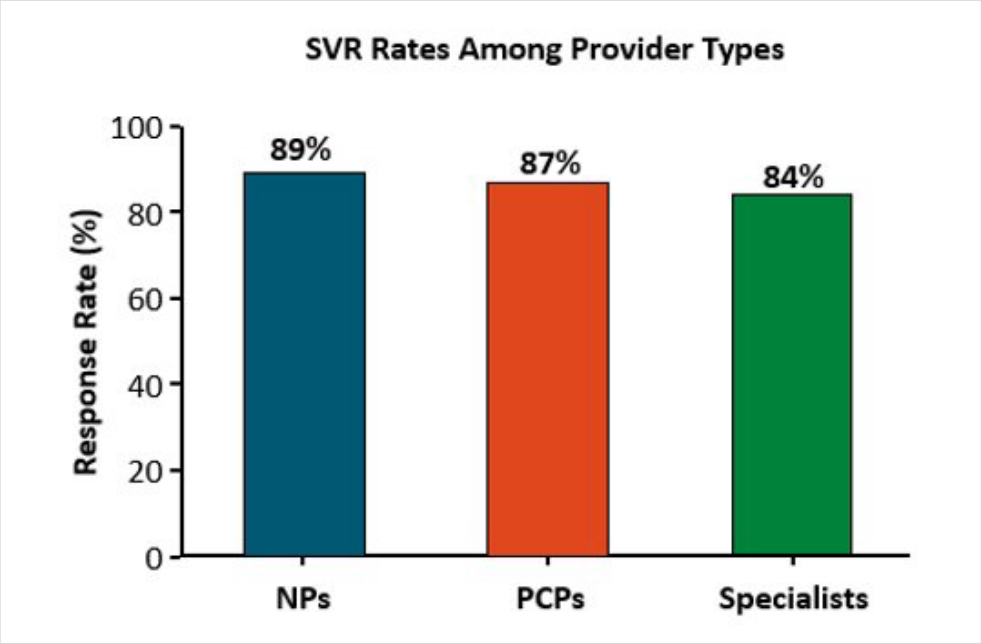
- Transmission & Risk factors
  - Where did this come from? How to avoid giving it to others..
  - Can survive on dry surfaces and equipment for up to 6 weeks
- Treatment- it's curable! (don't assume everyone knows this now)
  - Long-term consequences of not treating
- Re-infection risk and prevention: important!!
  - Re-treatment restrictions
  - Harm reduction

Viral Hepatitis Surveillance and Case Management - Hepatitis C | CDC

Treatment

- Minimal Medicaid restrictions
- Simplified treatment and minimal monitoring for many patients

- Who can treat? Any provider!
  - In fact, some studies show better cures rates for APPs rather than MDs and specialists
- Encourage local providers to get trained, especially primary care and safety net providers (FQHCs)



Kattakuzhy. Ann Intern Med. 2017;167:311 Clinicalcareoptions.com

Provider Resources

KHAMP

Kentucky Hepatitis Academic Mentorship Program

https://kyrha.org/khamp

Goal: Increase the number of people with hepatitis C infection linked to care and CURED in high-risk, low resource settings

HEP C:

KNOW

MORE

Kentucky's Training Program

Free training and mentoring program for healthcare providers:
Education on Hepatitis C Virus, epidemiology, diagnosis, management, treatment, prevention and after cure planning

Kentucky Rural Health Association - KHAMP (kyrha.org)

CDC Hepatitis C Treatment Finder

Treatment of Hepatitis C | Hepatitis C | CDC

https://www.cdc.gov/hepatitis-c/treatment/index.html

Reporting Requirements

902 KAR 2:020

- Acute cases
- Perinatal: Newborns & children ≤5 years old**
- People who are confirmed to be pregnant
  - Chronic or acute cases

**changing to align with CDC definition (36 months of age)

Title 902 Chapter 2 Regulation 020 • Kentucky Administrative Regulations • Legislative Research Commission

Transition to Electronic Reporting

- Instead of paper or PDF (EPID) forms for reporting: shift to online reporting (Direct Data Entry (DDE) - KHIE)
- Part of Data Modernization Initiative
- This is to increase efficiency, minimize time and effort needed by multiple parties for manual data entry, and decrease errors made during data entry.
- Transition is happening for many reportable diseases. If you haven't seen it yet, you will soon.
- EPID forms are **not** obsolete, and there is currently no timeline and when and if they will be.

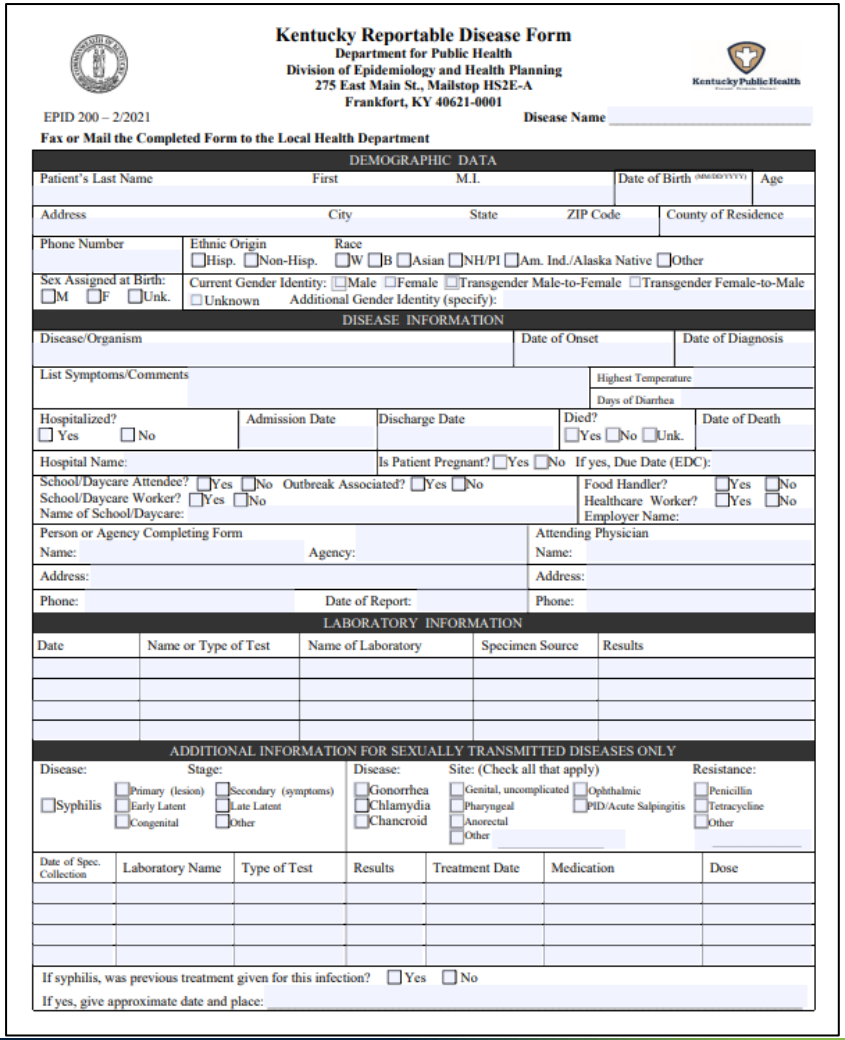
Transition to Electronic Reporting

Hepatitis Adult Acute (A, B, C)

- Currently paper or PDF Form: EPID 200
- NEW: DDE (Direct Data Entry) Form via KHIE

Email KHIEsupport@ky.gov to be onboarded for DDE if your facility does not currently use it.

See website for more information: Direct Data Entry (DDE) - KHIE



Kentucky Reportable Disease Form
Department for Public Health
Division of Epidemiology and Health Planning
275 East Main St., Mailstop HS2E-A
Frankfort, KY 40621-0001

EPID 200 – 2/2021 Disease Name

Fax or Mail the Completed Form to the Local Health Department

DEMOGRAPHIC DATA

Patient's Last Name | First | M.I. | Date of Birth (MM/DD/YYYY) | Age

Address | City | State | ZIP Code | County of Residence

Phone Number | Ethnic Origin ☐Hisp. ☐Non-Hisp. | Race ☐W ☐B ☐Asian ☐NH/PI ☐Am. Ind./Alaska Native ☐Other

Sex Assigned at Birth: ☐M ☐F ☐Unk. | Current Gender Identity: ☐Male ☐Female ☐Transgender Male-to-Female ☐Transgender Female-to-Male ☐Unknown Additional Gender Identity (specify):

DISEASE INFORMATION

Disease/Organism | Date of Onset | Date of Diagnosis

List Symptoms/Comments | Highest Temperature | Days of Diarrhea

Hospitalized? ☐Yes ☐No | Admission Date | Discharge Date | Died? ☐Yes ☐No ☐Unk. | Date of Death

Hospital Name: | Is Patient Pregnant? ☐Yes ☐No If yes, Due Date (EDC):

School/Daycare Attendee? ☐Yes ☐No Outbreak Associated? ☐Yes ☐No
School/Daycare Worker? ☐Yes ☐No
Name of School/Daycare:
Food Handler? ☐Yes ☐No
Healthcare Worker? ☐Yes ☐No
Employer Name:

Person or Agency Completing Form
Name: Agency:
Address:
Phone: Date of Report:

Attending Physician
Name:
Address:
Phone:

LABORATORY INFORMATION

Date	Name or Type of Test	Name of Laboratory	Specimen Source	Results

ADDITIONAL INFORMATION FOR SEXUALLY TRANSMITTED DISEASES ONLY

Disease: ☐Syphilis
Stage: ☐Primary (lesion) ☐Secondary (symptoms) ☐Early Latent ☐Late Latent ☐Congenital ☐Other
Disease: ☐Gonorrhea ☐Chlamydia ☐Chancroid
Site: (Check all that apply) ☐Genital, uncomplicated ☐Ophthalmic ☐Pharyngeal ☐PID/Acute Salpingitis ☐Anorectal ☐Other
Resistance: ☐Penicillin ☐Tetracycline ☐Other

Date of Spec. Collection	Laboratory Name	Type of Test	Results	Treatment Date	Medication	Dose

If syphilis, was previous treatment given for this infection? ☐Yes ☐No
If yes, give approximate date and place:

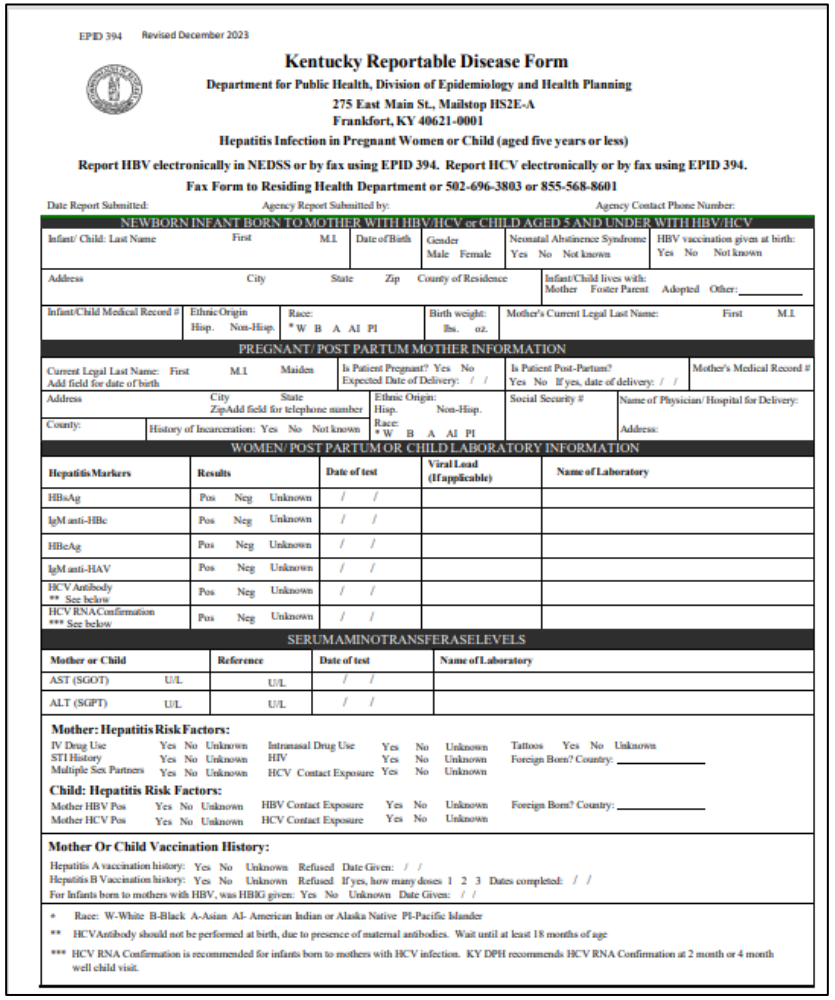
Transition to Electronic Reporting

Reporting pregnant women and infants born to HCV positive women

- Currently paper or PDF Form: EPID 394
- NEW: DDE (Direct Data Entry) Form via KHIE
  - Positive Pregnant Female
  - Perinatal Hepatitis C (child)

Email KHIEsupport@ky.gov to be onboarded for DDE if your facility does not currently use it.

See website for more information: Direct Data Entry (DDE) - KHIE



EPID 394 Revised December 2023

Kentucky Reportable Disease Form

Department for Public Health, Division of Epidemiology and Health Planning
275 East Main St., Mailstop HS2E-A
Frankfort, KY 40621-0001

Hepatitis Infection in Pregnant Women or Child (aged five years or less)

Report HBV electronically in NEDSS or by fax using EPID 394. Report HCV electronically or by fax using EPID 394.
Fax Form to Residing Health Department or 502-696-3803 or 855-568-8601

Date Report Submitted: Agency Report Submitted by: Agency Contact Phone Number:

NEWBORN INFANT BORN TO MOTHER WITH HBV/HCV or CHILD AGED 5 AND UNDER WITH HBV/HCV

Infant/ Child: Last Name First M.I. Date of Birth | Gender Male Female | Neonatal Abstinence Syndrome Yes No Not known | HBV vaccination given at birth: Yes No Not known

Address City State Zip County of Residence | Infant/Child lives with: Mother Foster Parent Adopted Other:_____

Infant/Child Medical Record # | Ethnic Origin Hisp. Non-Hisp. | Race: * W B A AI PI | Birth weight: lbs. oz. | Mother's Current Legal Last Name: First M.I.

PREGNANT/ POST PARTUM MOTHER INFORMATION

Current Legal Last Name: First M.I. Maiden Add field for date of birth | Is Patient Pregnant? Yes No Expected Date of Delivery: / / | Is Patient Post-Partum? Yes No If yes, date of delivery: / / | Mother's Medical Record #

Address City State Zip Add field for telephone number | Ethnic Origin: Hisp. Non-Hisp. | Social Security # | Name of Physician/ Hospital for Delivery:

County: | History of Incarceration: Yes No Not known | Race: * W B A AI PI | Address:

WOMEN/ POST PARTUM OR CHILD LABORATORY INFORMATION

Hepatitis Markers	Results	Date of test	Viral Load (If applicable)	Name of Laboratory
HBsAg	Pos Neg Unknown	/ /		
IgM anti-HBc	Pos Neg Unknown	/ /		
HBeAg	Pos Neg Unknown	/ /		
IgM anti-HAV	Pos Neg Unknown	/ /		
HCV Antibody ** See below	Pos Neg Unknown	/ /		
HCV RNA Confirmation *** See below	Pos Neg Unknown	/ /		

SERUM AMINOTRANSFERASE LEVELS

Mother or Child	Reference	Date of test	Name of Laboratory
AST (SGOT) U/L	U/L	/ /	
ALT (SGPT) U/L	U/L	/ /	

Mother: Hepatitis Risk Factors:
IV Drug Use Yes No Unknown | Intranasal Drug Use Yes No Unknown | Tattoos Yes No Unknown
STI History Yes No Unknown | HIV Yes No Unknown | Foreign Born? Country: _____
Multiple Sex Partners Yes No Unknown | HCV Contact Exposure Yes No Unknown

Child: Hepatitis Risk Factors:
Mother HBV Pos Yes No Unknown | HBV Contact Exposure Yes No Unknown | Foreign Born? Country: _____
Mother HCV Pos Yes No Unknown | HCV Contact Exposure Yes No Unknown

Mother Or Child Vaccination History:
Hepatitis A vaccination history: Yes No Unknown Refused Date Given: / /
Hepatitis B Vaccination history: Yes No Unknown Refused If yes, how many doses 1 2 3 Dates completed: / /
For Infants born to mothers with HBV, was HBIG given: Yes No Unknown Date Given: / /

* Race: W-White B-Black A-Asian AI- American Indian or Alaska Native PI-Pacific Islander

** HCV Antibody should not be performed at birth, due to presence of maternal antibodies. Wait until at least 18 months of age

*** HCV RNA Confirmation is recommended for infants born to mothers with HCV infection. KY DPH recommends HCV RNA Confirmation at 2 month or 4 month well child visit.

Case Definitions

- Acute Hepatitis C
  - >36 months of age, not exposed perinatally
  - Positive Nucleic Acid Test (NAT) for HCV RNA
  - Reportable in Kentucky & CDC.
- Chronic Hepatitis C
  - 2 positive RNA or genotype labs ≥365 days apart with no negative in between.
  - Patient considered ‘chronic’ in the year in which their second test takes place.
  - To be considered ‘cleared/cured’, negative result must take place 12 weeks after second positive.
  - Not reportable in Kentucky.
- Perinatal Hepatitis C
  - Infant/ Child exposed during the perinatal period or at birth.
  - Confirmatory Positive Nucleic Acid Test (NAT) for HCV RNA
  - Reportable in Kentucky & CDC.

Thank You!!

- **Program Staff:**
  - Program Lead: Dia Obonyo dia.obonyo@ky.gov
  - Epidemiologist III: Claire Holladay claire.holladay@ky.gov
  - Epidemiologist II: Christina D'Agostino christina.dagostino@ky.gov
  - Perinatal Coordinator/Epidemiologist: Jordan Murphy Jordan.murphy@ky.gov

- **Program Email:** VHP@ky.gov
- **Program Website:**
  - https://www.chfs.ky.gov/agencies/dph/dehp/idb/Pages/vhp.aspx