



Hepatitis C

2005 Clinical Guidelines

Summary of the:

New York State Department of Health Clinical Guidelines for the Medical Management of Hepatitis C

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Hepatitis C Virus



The Hidden Epidemic



- 3 million Americans are chronically infected with the Hepatitis C virus (HCV).
- 342,000 New Yorkers are estimated to be infected with HCV.
- A majority of the people infected with HCV do not know they have it.
- Thousands of people go undetected each year—due to inadequate risk assessment, under-screening and confusion about the use of diagnostic tests.

Hepatitis C Virus

- HCV is a blood-borne disease transmitted by blood-to-blood contact.
- Up to 80% of people infected show no symptoms
- HCV can take 10 to 30 years to show any serious health problems.



Sources:
Centers for Disease Control & Prevention-Hepatitis
www.cdc.gov/hepatitis

The Burden of HCV

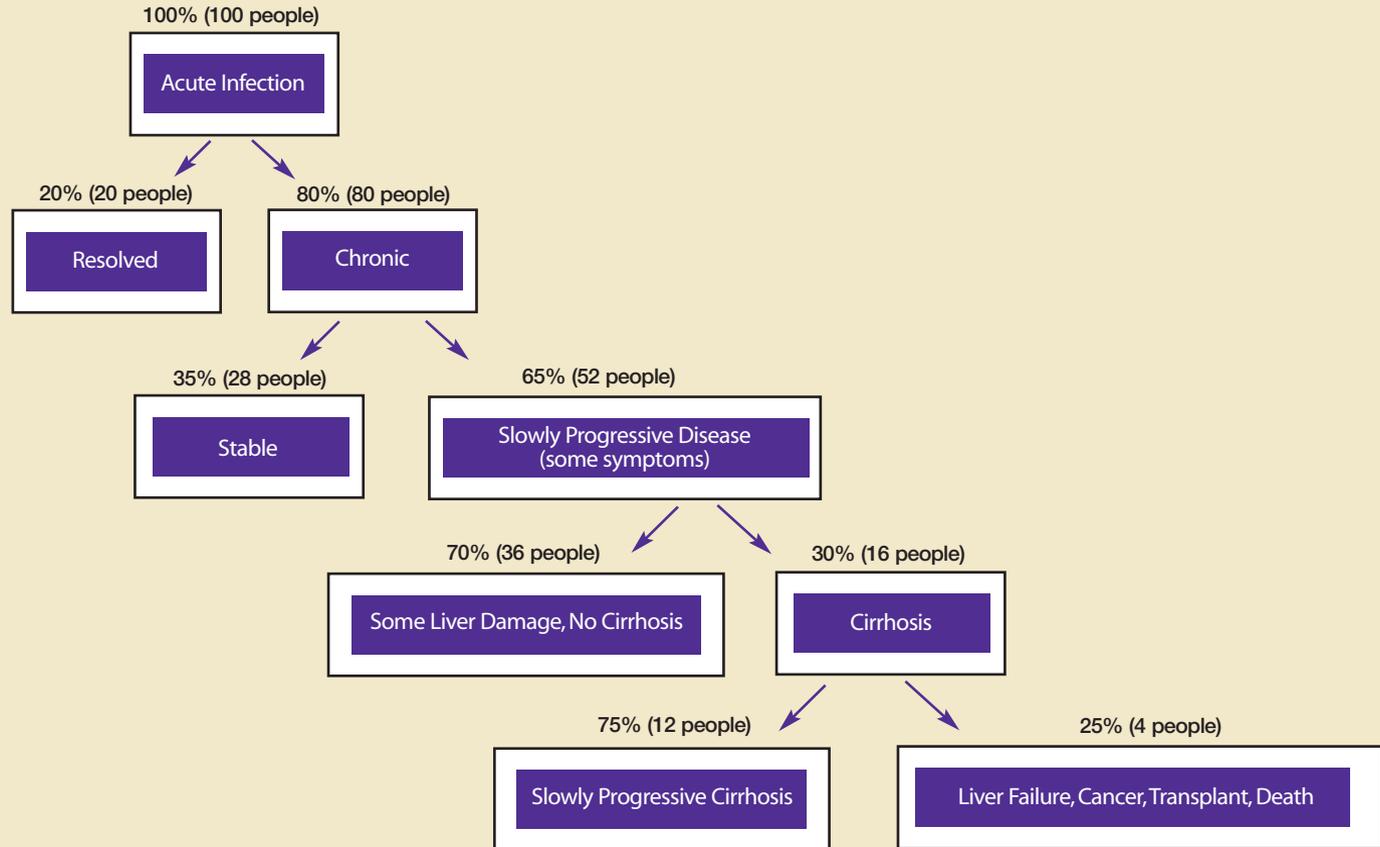
- 8-10,000 deaths a year are caused by HCV.
- HCV is the leading cause for liver transplants and chronic liver disease.
- HCV deaths will increase four-fold to 38,000, by the year 2010.
- Years of life lost to Hepatitis C (2001-2019)
3.1 million years
- Cost of premature disability and death (2010-2109)
\$75.5 billion
- Direct medical costs in absentee losses due to Hepatitis C **\$750 million/ year**
- Total medical expenditures for persons with HCV
\$15 billion/ year

Benefits of Screening for High-Risk Persons

The U.S. Department of Health and Human Services, the National Institutes of Health, and the CDC recommend and support **routine HCV screening for high risk individuals**. Resulting in:

- higher number of persons tested and more cases identified.
- reduction of HCV transmission.
- education and behavioral modification efforts to slow disease progression, and cut cost-intensive medical procedures due to long term complications of chronic HCV.

VIRAL AGENT	HEPATITIS A (HAV)	HEPATITIS B (HBV)	HEPATITIS C (HCV)
Diagnosis and Testing	<ul style="list-style-type: none"> HAV-IgM antibodies - indicate acute infection HAV-IgG antibodies- indicate previous infection or vaccination 	<p>A panel of antigen and antibody tests are used to diagnose infection:</p> <ul style="list-style-type: none"> Hepatitis B surface antigen (HBsAg) present in either acute or chronic infection. IgM antibody to hepatitis B core antigen (IgM anti-HBc) is diagnostic of acute HBV infection. Antibody to HBsAg (anti-HBs) is produced following a resolved infection and is the only HBV marker found following vaccination. HBsAg with a negative test for IgM anti-HBc is indicative of chronic HBV infection. <p>Hepatitis B core antibody (anti-HBc) may indicate either acute, resolved, chronic infection, or, rarely, a false positive result.</p>	<p>HCV Antibody Tests Does not differentiate between acute, chronic or resolved infection.</p> <ul style="list-style-type: none"> Anti-HCV EIA (enzyme immunoassay) - Initial screening test. Anti-HCV RIBA- Antibody test used to confirm positive EIA results. <p>HCV RNA Tests</p> <p>Qualitative HCV RNA: Tests to determine presence of hepatitis C virus</p> <ul style="list-style-type: none"> HCV RNA Transcription Mediated Assay (TMA) <p>Quantitative HCV RNA: Tests that measure the amount of HCV RNA (viral load)</p> <ul style="list-style-type: none"> HCV RNA Quantitative Branched chain DNA (bDNA)
Methods of Transmission	Fecal oral	Contact with infected blood or body fluids (serum, semen, vaginal fluids, saliva).	Contact with infected blood Risk of sexual transmission: unknown
Initial Symptoms and Spectrum of Illness	The incubation period of hepatitis A ranges from 15-50 days with the average being 28-30 days. Individuals infected with HAV generally have an abrupt onset of fever, malaise, anorexia, nausea, abdominal discomfort, dark urine and jaundice.	The incubation period for hepatitis B ranges from 45 to 160 days with an average of 120 days. Approximately 30% of individuals infected will not have symptoms. Children are less likely to have symptoms than adults. Individuals who do have symptoms experience jaundice, fatigue, abdominal pain, loss of appetite, nausea, vomiting and joint pain.	The incubation period for hepatitis C infection ranges from 14-180 days, with an average of 45 days. The majority of individuals infected with hepatitis C do not have symptoms. When symptoms are present, they include jaundice, fatigue, dark urine, abdominal pain, loss of appetite and nausea.
Treatment	There are no specific treatments for HAV infection once the symptoms appear. Persons acutely infected with HAV should avoid alcohol and other hepatotoxic medications until they have fully recovered.	FDA-approved drugs for the treatment of chronic hepatitis B. They include lamivudine, adefovir dipovoxil, interferon alfa-2b, entecavir, and pegylated interferon alpha-2a. These drugs are effective in up to 40% of patients.	FDA-approved treatments for chronic hepatitis C are interferon, alone or in combination with ribavirin, and pegylated interferon, alone or in combination with ribavirin. The standard treatment for chronic HCV infection is pegylated interferon plus ribavirin. Pegylated interferon/ ribavirin combination therapy can effectively eliminate the virus in up to 40% of those infected with genotype, type 1, and up to 80% in those infected with genotypes 2 or 3.
Total new infections/year	180,000	80,000	36,000
Chronic Infections	0	1-1.25 million	3.9 million
Deaths/year	Rare	5,500	8,000 - 10,000



PERSONS	RISK OF INFECTION©	TESTING RECOMMENDED
Current and past injecting drug users	HIGH	YES
Recipients of clotting factors made before 1987	HIGH‡	YES
Hemodialysis patients	HIGH‡	YES
Recipients of blood and/or solid organs before 1992	MODERATE‡	YES
Persons with undiagnosed liver problems	MODERATE‡	YES
Infants born to infected mothers*	MODERATE‡	YES
Persons having high risk sexual activity**	MODERATE‡	YES
Persons having sex with multiple partners	MODERATE‡	YES
Persons requesting to be screened should be tested	LOW	YES
Healthcare/Public Safety workers	LOW	Only after known exposure
People having sex with HCV infected steady partner	LOW	NO
Tattoos, body piercing and acupuncture	UNKNOWN	NO
Sharing toothbrushes, razors, and nail clippers	UNKNOWN	NO

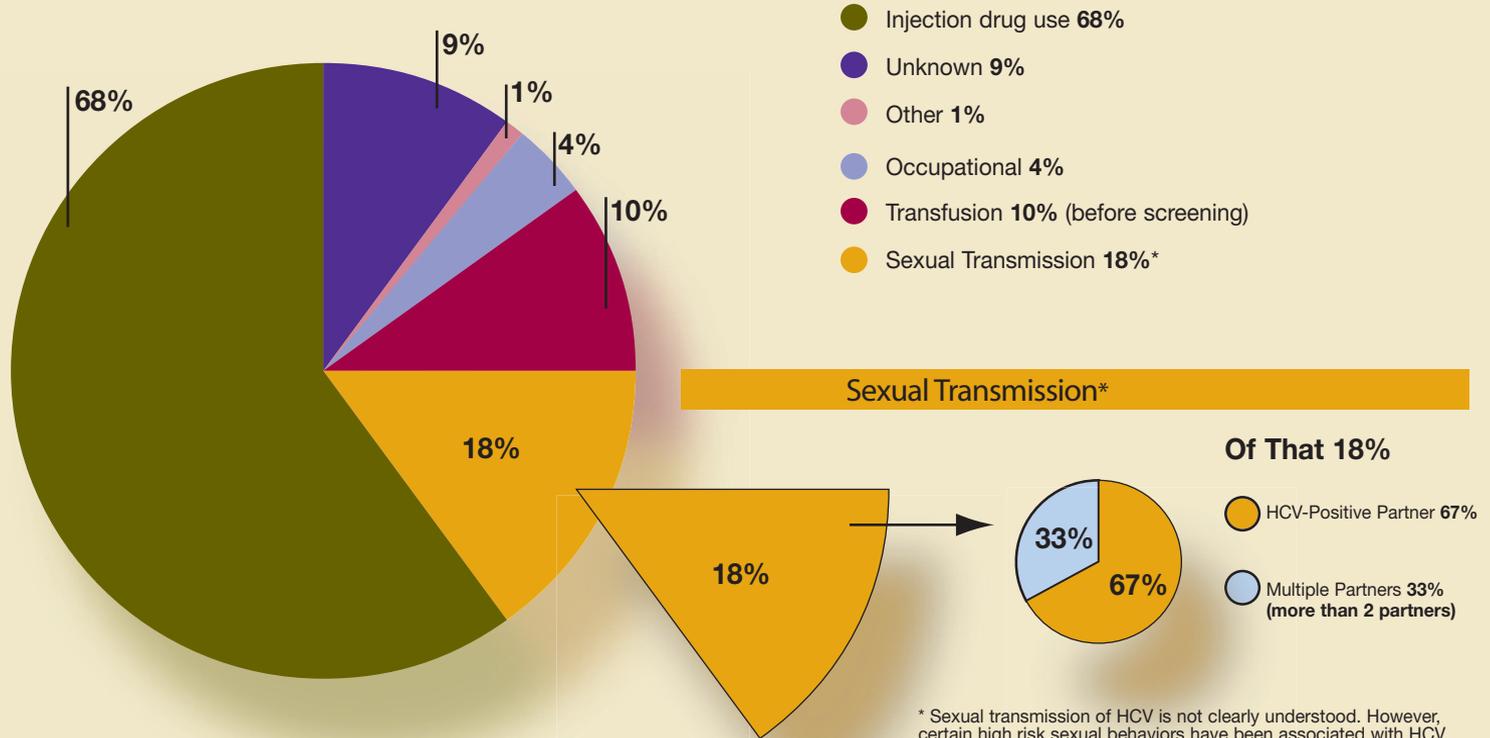
ALL PERSONS REQUESTING TO BE TESTED FOR HEPATITIS C SHOULD BE SCREENED FOR SERUM HCV ANTIBODY (ANTI-HCV), EVEN LOW RISK PATIENTS

*PCR (HCV-RNA) testing on infants born to HCV infected mothers should be performed 1-2 months after birth.

**unprotected sex; any blood-to-blood sexual contact; partners with STDs/HIV; sexual abuse, rape, etc.

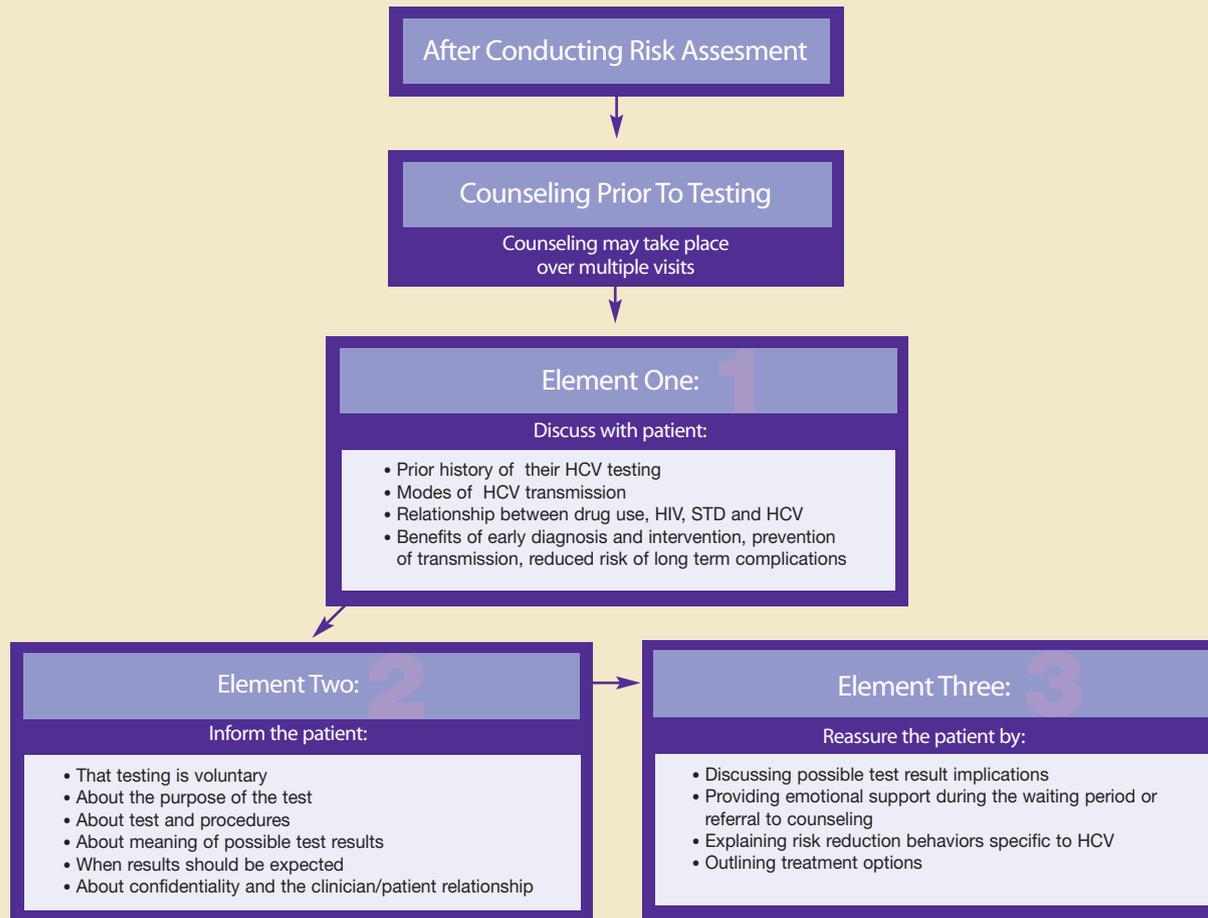
•All patients at risk for infection should be educated for prevention.

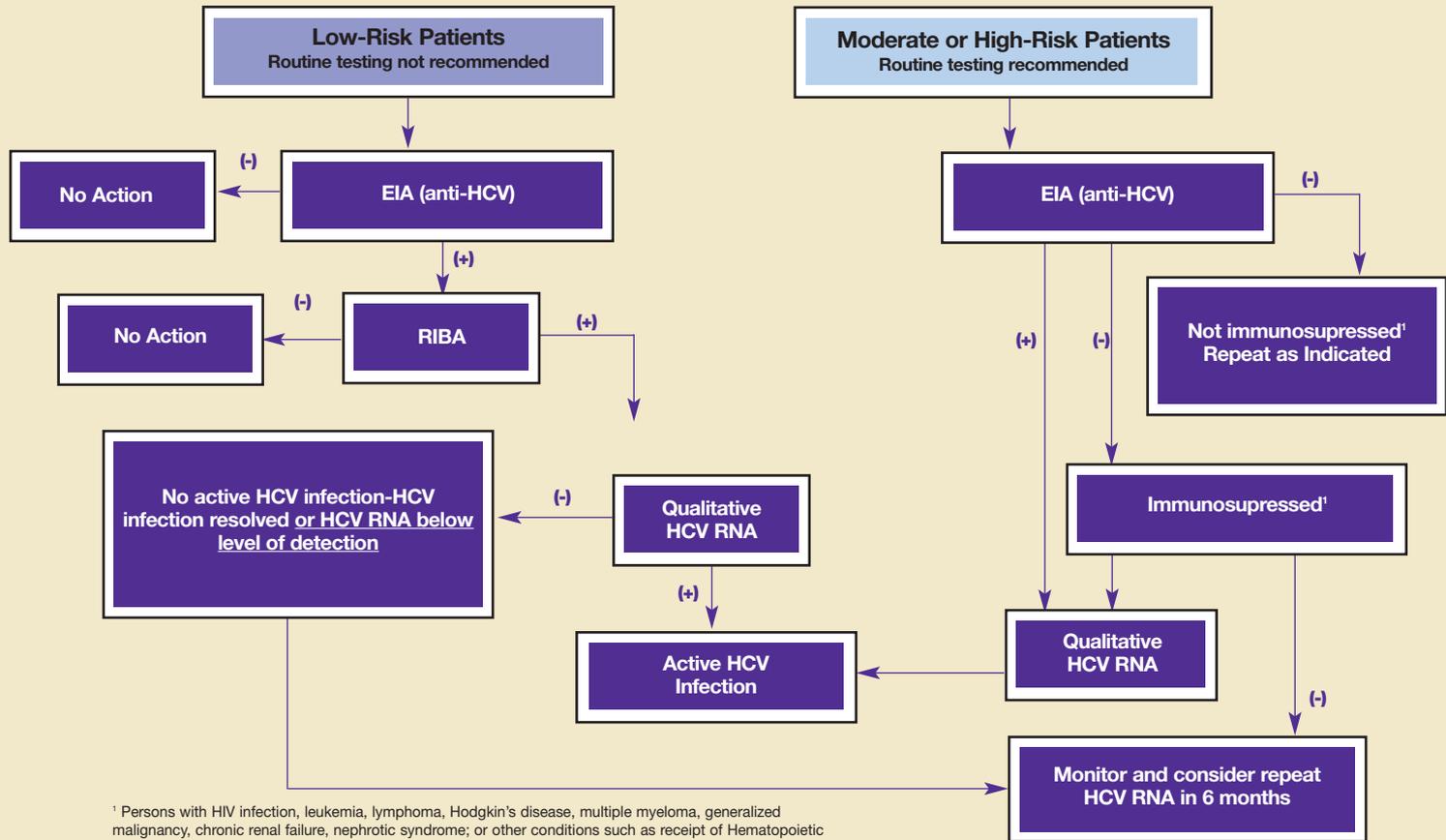
‡ Periodic testing is recommended.



Source: Centers for Disease Control & Prevention

* Sexual transmission of HCV is not clearly understood. However, certain high risk sexual behaviors have been associated with HCV transmission such as anal sex, sex with trauma, sex in the presence of a sexually transmitted disease (STD), and sex without a condom.





¹ Persons with HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome; or other conditions such as receipt of Hematopoietic Stem Cell Transplant (HSCT), solid organ transplant, chemotherapy, long term systemic corticosteroids, or other immunosuppressive agents

TYPE	TEST		APPLICATION	DETERMINATION	INTERPRETATIONS
Serological Assay	EIA (enzyme immunoassay) or ELISA (enzyme immunosorbent assay)		<ul style="list-style-type: none"> • Detects anti-HCV • Indicates past or present infection** • All positive EIA results should be verified with a supplemental assay (RIBA or qualitative HCV RNA) 	Exposure to virus	<p>Reactive:</p> <ul style="list-style-type: none"> • Past exposure to HCV with resolution of infection**, or • False positive (rare) <p>Non-reactive:</p> <ul style="list-style-type: none"> • No present or resolved past infection or • Acute or chronic infection in HIV+ or other immunosuppressive illness
	RIBA (recombinant immunoblot assay)		<ul style="list-style-type: none"> • Detects anti-HCV • Indicates past or present infection** • Confirms positive EIA in low risk populations 	Exposure to virus	<p>Positive:</p> <ul style="list-style-type: none"> • Ongoing acute or chronic infection • Past exposure to HCV with resolution of infection <p>Negative:</p> <ul style="list-style-type: none"> • No present or past infection, or • Acute or chronic HCV infection in HIV+ or other immunosuppressive illness, or • False positive EIA <p>Indeterminate:</p> <ul style="list-style-type: none"> • Probable false positive if no risk factors
Molecular Assay (nucleic acid detection)	Qualitative	RT-PCR (reverse transcription polymerase chain reaction)	<ul style="list-style-type: none"> • Detects very low levels of HCV RNA (viremia) 	Presence of circulating HCV RNA	<p>Positive:</p> <ul style="list-style-type: none"> • Active HCV infection (but does not indicate acute or chronic) <p>Negative:</p> <ul style="list-style-type: none"> • Not infected • Past exposure with resolution of infection
		TMA (Transcription Mediated Assay)			
	Quantitative	RT-PCR	Measures amount of HCV RNA (viral load)	<ol style="list-style-type: none"> 1. Predicts likelihood of treatment response <ul style="list-style-type: none"> • > 2 million copies/ml. or >800,000 IU/ ml = less likely to respond 2. Determines response to treatment <ul style="list-style-type: none"> • Done prior to treatment, and every 12 weeks thereafter 	<p>SVR (sustained virologic response):</p> <ul style="list-style-type: none"> • HCV-RNA is undetectable (after 6 months of treatment) <p>EVR (early virologic response):</p> <ul style="list-style-type: none"> • Predicts SVR (after 12 weeks of treatment) <p>Relapse: HCV RNA rebounds after treatment ends</p> <p>Non-responder: HCV RNA remains unchanged during treatment</p>
		bDNA (branched chain DNA)	Measures amount of HCV RNA		
Genotype	Standardized sequence based assay		<ul style="list-style-type: none"> • Determines the genetic character of the hepatitis C viruses • Currently there are six known hepatitis C genotypes 	Determines length of therapy and likelihood of response to therapy.	<p>Genotypes 1 & 4:</p> <ul style="list-style-type: none"> • Require 48 weeks of therapy in the HCV monoinfected patient. • Respond less favorably (50%) to therapy. <p>Genotypes 2 & 3:</p> <ul style="list-style-type: none"> • Require 24 weeks of therapy in the HCV monoinfected patient. • Respond more favorably to therapy (80%).
	Reverse hybridization analysis				

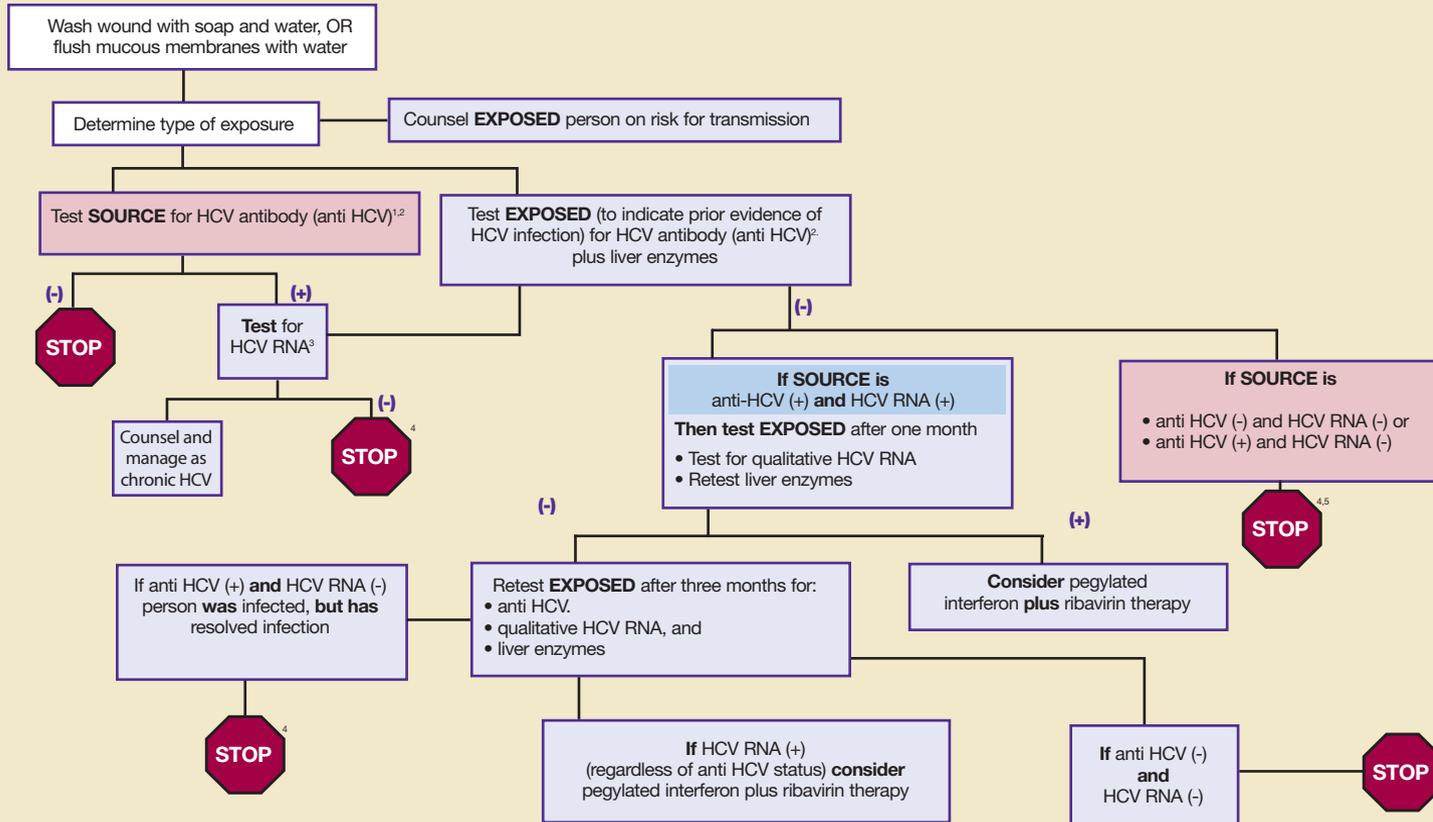
* No single lab test distinguishes between active and resolved infection
 ** Positive antibody test does not differentiate between active and chronic infection

IF YOUR HCV TEST RESULT IS:			INTERPRETATION		ACTION
Anti-HCV Screening Test*	Anti-HCV Supplemental Tests		Prior HCV Exposure	Active HCV Infection	Additional Testing or Evaluation
	RIBA†	or HCV RNA			
Negative	Not Needed	Not Needed	No	No	No
Positive	Not Done	Not Done	Not Known	Not Known	Supplemental Anti-HCV (RIBA) or HCV RNA
Positive	Not Done	Negative	Not Known	Not Known*	Supplemental Anti-HCV (RIBA)
Positive	Negative	Not Needed	No	No	No
Positive	Positive	Not Done	Yes	Not Known	Evaluate for chronic infection and liver disease
Positive	Positive	Negative	Yes	Not Known	Repeat HCV RNA
Positive	Positive/not done	Positive	Yes	Yes	Evaluate for chronic infection and liver disease
Positive	Intermediate	Not Done	Uncertain	Not Known	Test for HCV RNA or repeat Anti-HCV testing
Positive	Intermediate	Positive	Uncertain	Yes	Evaluate for chronic infection and liver disease
Positive	Intermediate	Negative	No	No	No

* EIA - enzyme immunoassay or CIA - enhanced chemiluminescence immunoassay

† Recombinant immunoblot assay, a more specific anti-HCV assay

• Single negative HCV RNA result cannot determine infection status as persons might have intermittent viremia



¹ If source is unavailable or refuses testing, treat exposed as if source was anti-HCV (+) and HCV RNA (+)

² Since immunosuppressed persons can be negative for hepatitis C antibody despite viremia, qualitative HCV RNA testing should be performed

³ Qualitative HCV RNA by PCR or TMA

⁴ Person was HCV-infected at one time and spontaneous cleared the virus. Person is NOT able to transmit HCV at that time.

⁵ Advise and counsel EXPOSED person if SOURCE person is anti-HCV (+) only.

Counseling After Testing

Patient with NEGATIVE results and absence of evidence for HCV infection

Discuss with patient:

- Meaning of the test results
- Negative test results do not imply immunity to future infection
- Possibility of HCV exposure during the past three months and the need for repeat testing if risk factors are significant
- Not to share:
 - Needles,
 - Ink or needles for tattooing or
 - Needles for body piercing, or
 - Razors, toothbrushes, nail clips or other personal items that could have blood or secretions on them

Patient with POSITIVE HCV test results

Patient with POSITIVE HCV antibody test results

Discuss:

- Meaning of test result
- Possible risk factors for infection
- Need for follow-up testing with a HCV RNA Qualitative test

Patient with POSITIVE HCV antibody test and NEGATIVE HCV RNA Qualitative test results

Emphasize:

- Meaning of test result
- Positive antibody test does not confer immunity from future hepatitis C infections and risk reduction is still important
- Need for repeat HCV RNA testing in several months, if there are significant risk factors present, because viral load can fluctuate
- Possibility of past acute infection that may have resolved spontaneously

Patient with POSITIVE HCV RNA Qualitative test results

PATIENT CARE

- Provide counseling for positive test results
- Provide / refer for HCV medical treatment
- Discuss availability of specialized treatment options
- Provide / refer for treatment of co-morbid conditions
- Discuss that all medications (prescription, herbal, over-the-counter) need to be disclosed to the treating physician, as to the effects they can have on the liver and/or the interactions with pegylated interferon/ribavirin
- Discuss harmful effects of alcohol and drug use on HCV
- Refer psychiatric treatment, if needed
- Refer patient to support groups for counseling
- Refer to case management for patient navigation

PREVENTION STRATEGY

- Recommend partner/spousal notification through self-notification or clinician-assisted
- Refer needle-sharing partners for HCV testing
- Inform patient to reduce transmission to others by clarifying NOT TO:
 - ◆ donate blood, tissue or semen
 - ◆ share toothbrushes, razors, nail clippers, drug paraphernalia
- Encourage vaccination of Hepatitis A and B if susceptible
- Inform patient to cover all open sores to prevent possible spread of infectious secretions
- Emphasize barrier protection during sexual activity
- Discuss risk reduction behaviors
- Refer children of chronically infected women for HCV testing
- FOR PREGNANT WOMEN, only infected with HCV
 - ◆ Do not discourage breast-feeding unless nipples are bleeding or cracked

HIV/HCV Co-Infected

Therapy: Pegylated interferon plus ribavirin, unless contraindicated.

DECIDING TO TREAT

Who to treat: all patients with detectable HCV RNA and abnormal liver biopsy.
Evaluate: HCV-RNA, HCV genotype, liver enzymes, and liver biopsy unless contraindicated.
Consider: severity of liver disease, co-morbidities, side effects and likelihood of response.
Assess: Environmental support (living conditions, family/social structure, financial).

SPECIAL CONSIDERATIONS

Patients on methadone, active IDUs, history of well controlled psychiatric disorders should be considered for treatment. Those with uncontrolled psychiatric disorders and unstable substance use- REFER to MEDICAL MANAGEMENT ALGORITHM.

CONTRAINDICATIONS

- Hypersensitivity to pegylated interferon +/- ribavirin
- Auto immune hepatitis
- Decompensated liver disease
- Pregnant women
- Men whose female partners are pregnant or trying to get pregnant
- Hemoglobinopathies

INITIATING TREATMENT

Diagnostic test prior to treatment: CBC, chemistries including AST/ ALT, serum creatinine, TSH, pregnancy, HIV antibody.
Counseling: Side effects, contraceptive
Evaluate: Depression screening

TREATMENT OF CHOICE

Pegylated interferon plus ribavirin
 Duration: Genotype 1 & 4: 48 weeks; Genotype 2 & 3: 24 weeks.

NOTE:

If patient becomes anemic or neutropenic consider Erythropoetin alfa or G-CSF.

TYPE OF MONITORING WHILE ON TREATMENT

Type of Monitoring While on Treatment
Week 2: CBC, chemistries including AST/ ALT.
Week 12: HCV-RNA Quantitative Check for 2 log decrease. If no 2 log decrease, consider discontinuation of treatment.
Q 4-6 weeks: CBC, chemistries, and pregnancy.
End of treatment: HCV-RNA Quantitative.
Week 24 after end of treatment of patients with end of treatment viral response: HCV RNA Quantitative.

NOTE:

Continually monitor and counsel patient for treatment-related side-effects.

Re-treatment of Patients previously treated for HCV

Inadequately treated patients

Non-responders or relapsers to anti-virals other than pegylated interferon plus ribavirin.

Therapy: CONSIDER Pegylated interferon plus ribavirin.

Treatment of Special Populations Children/ Acute Hepatitis C

CHILDREN

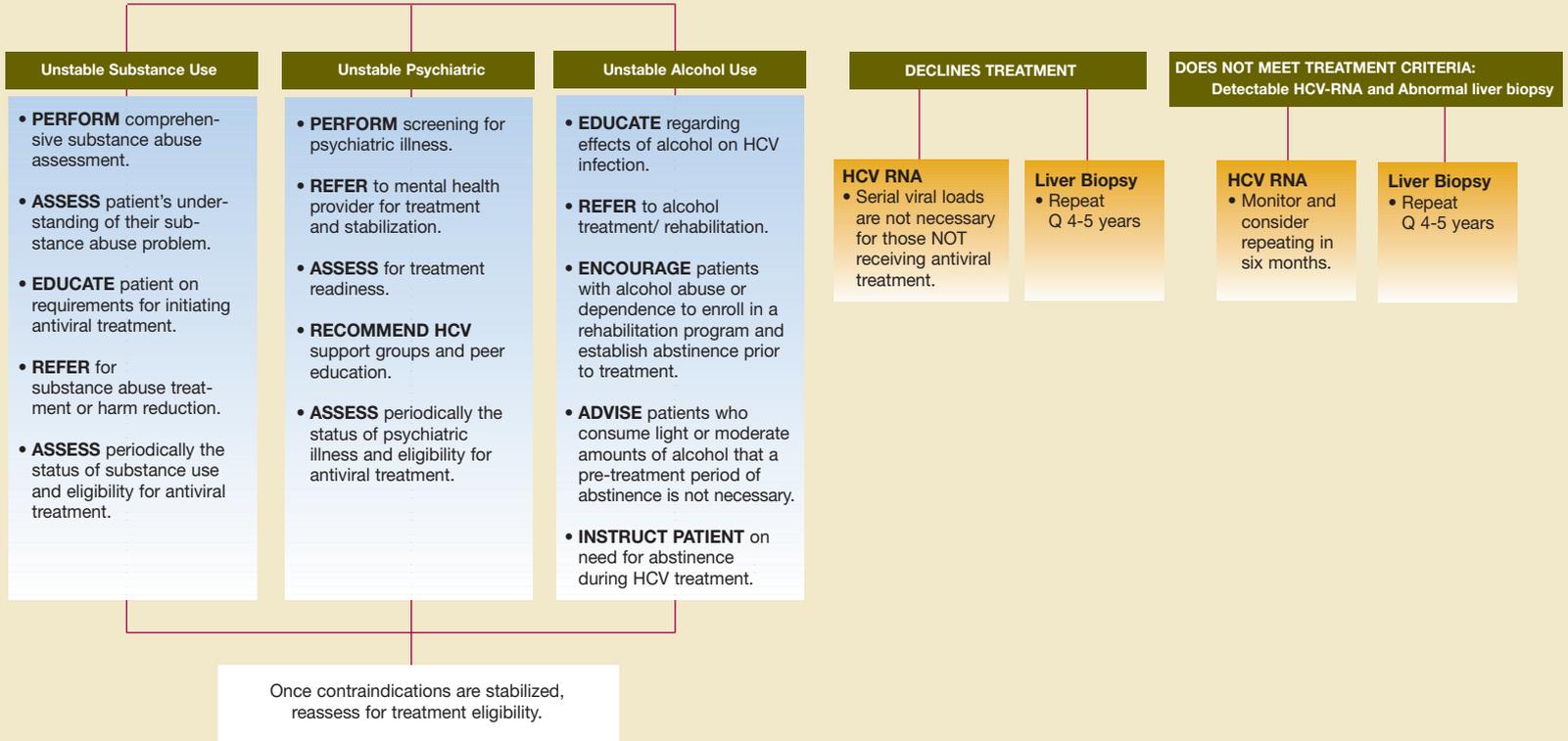
Evaluate: Presence of and severity of HCV, including liver biopsy.
Therapy: Interferon plus ribavirin to children aged 3-17 years. Antiviral therapy should not be administered to children under 3.

Acute HCV

Goal: PREVENT DEVELOPMENT OF CHRONIC HCV
Recommend: Defer treatment decision until 12 weeks after exposure. If patient does not become anti-HCV negative, therapy recommended.
Therapy: Pegylated interferon monotherapy. Duration of therapy unknown. Decisions to treat should be made on a case-by-case basis, in consultation with a Hepatologist, Gastroenterologist, or infectious disease provider.

HCV + With Contraindications

HCV + Without Contraindications



Unstable Substance Use

- **PERFORM** comprehensive substance abuse assessment.
- **ASSESS** patient's understanding of their substance abuse problem.
- **EDUCATE** patient on requirements for initiating antiviral treatment.
- **REFER** for substance abuse treatment or harm reduction.
- **ASSESS** periodically the status of substance use and eligibility for antiviral treatment.

Unstable Psychiatric

- **PERFORM** screening for psychiatric illness.
- **REFER** to mental health provider for treatment and stabilization.
- **ASSESS** for treatment readiness.
- **RECOMMEND HCV** support groups and peer education.
- **ASSESS** periodically the status of psychiatric illness and eligibility for antiviral treatment.

Unstable Alcohol Use

- **EDUCATE** regarding effects of alcohol on HCV infection.
- **REFER** to alcohol treatment/ rehabilitation.
- **ENCOURAGE** patients with alcohol abuse or dependence to enroll in a rehabilitation program and establish abstinence prior to treatment.
- **ADVISE** patients who consume light or moderate amounts of alcohol that a pre-treatment period of abstinence is not necessary.
- **INSTRUCT PATIENT** on need for abstinence during HCV treatment.

DECLINES TREATMENT

- **HCV RNA**
 - Serial viral loads are not necessary for those NOT receiving antiviral treatment.
- **Liver Biopsy**
 - Repeat Q 4-5 years

DOES NOT MEET TREATMENT CRITERIA: Detectable HCV-RNA and Abnormal liver biopsy

- **HCV RNA**
 - Monitor and consider repeating in six months.
- **Liver Biopsy**
 - Repeat Q 4-5 years

Once contraindications are stabilized, reassess for treatment eligibility.

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Internet Resources

- American Gastroenterological Association**
www.gastro.org
- American Liver Foundation**
www.liverfoundation.org
- Centers for Disease Control & Prevention-Hepatitis**
www.cdc.gov/hepatitis
- Clinical Trials: Hepatitis**
www.centerwatch.com/studies/cat79.html
- Immunization Action Coalition**
www.immunize.org
- HCV Advocate**
www.hcvadvocate.org
- Hep C Connection**
www.hepc-connection.org
- HIV and Hepatitis.com**
www.hivandhepatitis.com
- The Liver Transplant Support Forum-NIH**
www.nih.gov
- National Commission on Correctional Healthcare**
www.ncchn.org
- National Digestive Diseases Information Clearinghouse**
www.niddk.nih.gov
- National Hemophilia Foundation**
www.hemophilia.org
- National Institute of Allergy and Infectious Diseases/-NIH**
www.niaid.nih.gov
- New York City Department of Health and Mental Hygiene**
www.nyc.gov/html/doh
- New York State Department of Health Hepatitis Website**
www.health.state.ny.us/diseases/communicable/hepatitis
- Medical Society of the State of New York**
www.mssny.org
- World Health Organization (WHO)**
www.who.int
- Veterans Administration**
www.va.gov/hepatitisc/mission



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