A Comprehensive Guide to Hepatitis C: Infection, Testing, and Treatment

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Purpose

The purpose of this course is to provide you with a comprehensive overview of hepatitis C virus (HCV), from the basics of the virus to current algorithms for treatment.

Increasing your knowledge about HCV will enable you to be an informed provider of care, utilizing evidence-based research.

Learning Objectives

At the end of this course, you will be able to:

1. Explain how hepatitis C virus (HCV) impacts public health.
2. List the modes of HCV transmission.
3. Describe how HCV's molecular structure impacts the pathogenesis of disease.
4. State the current CDC recommended guidelines for HCV testing by risk stratification and age cohort.
5. Explore current and new medications currently under development for the treatment of HCV infection.
6. Select evidence-based algorithms for treatment and monitoring of patients with chronic HCV infection.
7. Utilize a holistic nursing approach to the care of the patient with HCV infection.

Introduction

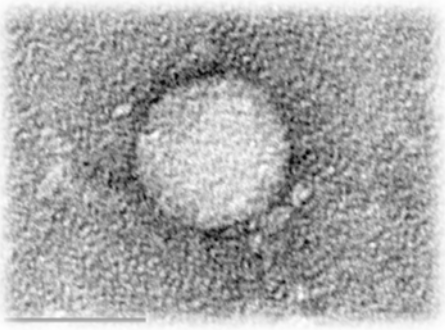
Hepatitis C (also referred to as HCV), can be an overwhelming subject not just for patients, but for health care providers as well. HCV is one of the more complicated types of viral hepatitis because there is no vaccine; there is also no cure, only treatment.

The treatment of HCV is evolving and advancing each day. With early detection and treatment and your holistic approach to care, your patients will live healthier and longer with this disease.

Module I: The Basics of HCV

In the first section of this course, we will review:

- How hepatitis C virus (HCV) impacts public health.
- The modes of HCV transmission.
- How HCV's molecular structure impacts the pathogenesis of disease.



HCV EM. Image courtesy of Wikipedia.org, accessed August 7, 2013. http://en.wikipedia.org/wiki/Hepatitis_C_virus.

The Facts from the CDC

The Centers for Disease Control (CDC) estimates that there are between 2.7-3.9 million people in the United States living with hepatitis C virus (HCV) (CDC, 2013).

Because of the nature of the virus and slow progression of disease, many of these people are not aware they are carrying HCV. If people are infected and not receiving treatment, they are at high risk for liver disease and hepatocellular carcinoma.

Transmission

Unlike other forms of hepatitis, ***HCV has no vaccine***, treatments are long term and for many, the side effects are difficult to manage. This is why it is important to review how the virus is transmitted.

Hepatitis C is a blood borne disease. It can only be transmitted by:

- IV drug use
- Intra-institutional Infection (healthcare workers, e.g., needle stick injuries)
- Transfusions (primarily prior to testing for HCV)
- Hemodialysis
- Sexual contact
- Household contact (when living with infected persons)
- Passage from HCV-infected mother to newborn

Transmission Route	Hepatitis A	Hepatitis B	Hepatitis C	Hepatitis D	Hepatitis E
Food-Borne	X	N/A	N/A	N/A	X
Oral-Fecal	X	N/A	N/A	N/A	X
Water-Borne	X	N/A	N/A	N/A	X
Intra-Institutional	X	X	X	X	Suspected
IV Drug Use	Infrequent	X	X	X	N/A
Transfusion	Infrequent	X	X	X	Infrequent
Sexual	Infrequent	X	Infrequent	X	Infrequent
Household	X	Infrequent	Infrequent	Infrequent	X
Mother-Newborn	Infrequent	X	Infrequent	X	Infrequent

Modified from C. Everett Coop Institute, 2013.

Test Yourself

Hepatitis C is a blood borne pathogen, transmissible by the oral-fecal route.

A. True
B. False

The correct answer is false. Hepatitis C is a blood borne pathogen, however, the virus is transmitted by:

- IV drug use
- Intra-institutional infection (healthcare workers, e.g., needle stick injuries)
- Transfusions (primarily prior to testing for HCV)
- Hemodialysis
- Sexual contact
- Household contact (when living with infected persons)
- Passage from HCV-infected mother to newborn

The Public Health and Fiscal Impact

- Hepatitis C affects 3 1/2 more individuals than hepatitis B.
- Nearly 80% of HCV patients will develop chronic liver disease.
- 15-20% will develop cirrhosis within the first five years of infection.
- Approximately 1% will develop hepatocellular carcinoma within 20 years and the risk increases every year thereafter.
- HCV accounts for a third of all the liver transplants in the US annually.
- Approximately 1,000 liver transplants take place per year at a cost of $280,000 each.
- Total costs annually for transplants in the US due to HCV is upwards of $300,000 million.
- The average lifetime cost for chronic hepatitis C per person is $100,000.

Image courtesy of © Can Stock Photo Inc./Eraxion.

Assuming 3.6 million people are infected, that's a lifetime cost of $360,000 million times a 40 year lifespan = $9 billion US dollars!

(C. Everett Coop Institute, 2013)

Test Yourself

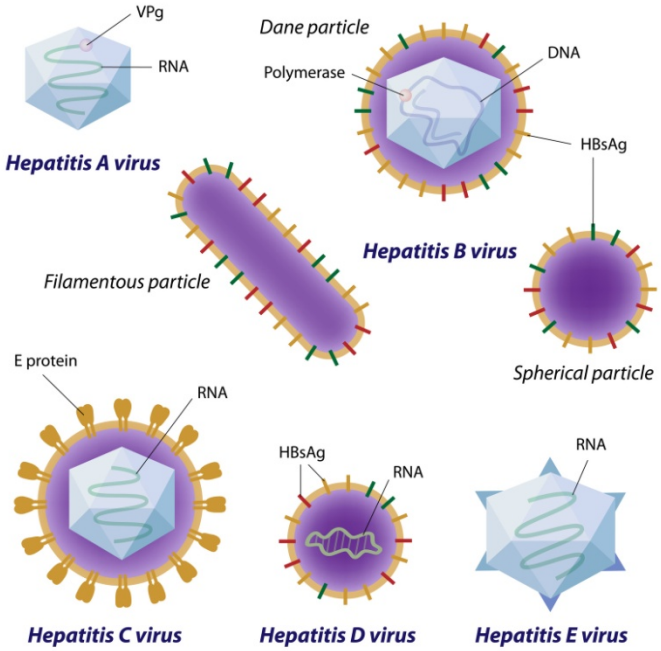
Chronic HCV infection without liver transplant:

A. Affects half as many individuals as hepatitis B and costs $280,000 per person for lifetime treatment.
B. Affects the same number of persons as hepatitis B and costs $100,000 per person annually for treatment.
C. Affects two and a half times as many persons with hepatitis B and costs $360,000 per person for lifetime treatment.
D. Affects three and a half times more persons than those with hepatitis B and costs $100,000 per person for lifetime treatment.

The correct answer is D. Hepatitis C affects three and a half more people than hepatitis B and costs an average of $100,000 for lifetime treatment of chronic HCV without liver transplant.

A Brief Background of the Virus

While there are many forms of viral hepatitis, we have seen that HCV poses the most severe health and financial impacts on the public. This is primarily because of the peculiarities of the HCV virus itself. Let's look at the virus itself for a moment so you can see how it affects transmission, testing and ultimately, treatment.



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The Complex Nature of HCV

HCV is a very small RNA virus – only 50nm in size. RNA is "unstable" as compared to DNA making it an ideal mechanism for reproduction of viral contents. RNA mutates easily and reproduces quickly, making it difficult for the host's immune system to develop effective antibodies against the virus. It was also difficult to detect in an effective laboratory test. For many years, people were unknowingly receiving blood transfusions and organ transplants from infected donors due to an inability to test for HCV.

It was only in 1988 when the technology was available for researchers to identify the elusive, small hepatitis C virus (which was previously referred to as "non-A", "non-B" since 1965). The first test for HCV was then developed and licensed in **1992**. Because there was no way to test for HCV prior to 1992, many people were infected with HCV and donated blood and organs not knowing that they were passing their disease on to others.

(C. Everett Coop Institute, 2013; Huether, 2010)

No Vaccine Available

Why is it that there are vaccines for Hepatitis A and B, but not for type C? On the surface, it would seem logical that a vaccine for HCV would be available soon. After all, the disease is devastating and costly and mass vaccination programs for the other forms of hepatitis are proving successful in worldwide campaigns. Hepatitis C, however, remains elusive.

The size of the virus and the mutagenic nature of an RNA virus versus a DNA virus make creating a vaccine more difficult. But because approximately 15-45% of all acutely infected persons achieve spontaneous viral clearance without remission or progression to chronic HCV, it can be inferred that they have immunity to the disease (Lanford, et al, 2004). This is exactly how a vaccine works to prevent disease. Even those that relapse seem to handle secondary infection better with lower viremia, however, naturally occurring infection and the subsequent antibodies produced do not guarantee immunity from disease (Farci, et al, 1992).

Given this data, how effective would a vaccine be? Would an HCV vaccine eradicate the disease, slow the progression or just lessen the impact of liver disease and hepatocellular carcinoma? In theory, just lessening the impact on liver disease would be a step in the right direction and increase the quality of life for millions of people living with HCV.

Test Yourself

The nurse caring for the patient with chronic HCV understands that the virus is difficult to treat because:

A. DNA mutates easily and reproduces quickly making it difficult for the host's immune system to develop effective antibodies against the virus.
B. RNA mutates easily and reproduces quickly making it difficult for the host's immune system to develop effective antibodies against the virus.
C. Antigens mutate easily and reproduce quickly making it difficult for the host's immune system to develop effective antibodies against the virus.

The correct answer is B. HCV is an RNA virus. RNA is "unstable" as compared to DNA making it an ideal mechanism for reproduction of viral contents. RNA mutates easily making development of antibodies difficult and sometimes ineffective.

If There Was a Vaccine for HCV

The question then becomes, what type of vaccine should be developed and who should be vaccinated? HCV is a blood borne disease, so theoretically the best prevention is abstinence from the behaviors that place a person at risk for contracting the disease. This would mean that infants and children, for example, would not have to be immunized for HCV. Only high risk populations would be recommended to receive a vaccine if it were available. The other option would be to develop a vaccine that prevents progression of acute HCV to chronic HCV, thereby preventing cirrhosis and hepatocellular carcinoma.

One study in Brazil researched the financial impact of a hepatitis C vaccine and determined that if the vaccine were given only to high-risk populations, even at only 80% efficacy with lifelong protection, it would cost $242,667 per death averted (Massad, 2009). This is a significant savings in cost of care and life. Currently, there are HCV vaccines in Stage II and III clinical trials. It remains to be seen if and how they will work and when they will be commercially available for use.

HCV Types

Because HCV is constantly mutating, it is not a self-limiting disease like other viral forms of hepatitis.

HCV also has six genotypes, 15 subtypes and 21 variations in the genotype, further complicating the ability to develop a vaccine or additional treatment options. It also creates a situation where infected individuals that have been treated may become re-infected with other strains as mutations occur.

Treatment of HCV is in part, based on genotype as well as patient clinical status and ability to tolerate treatment. Of the four, the most common genotypes found are:

- Type 1 represents approximately 70% of cases
- Type 2 and 3 represent approximately 25-30% of cases
- Type 4 is rare, and most frequently found in persons of Egyptian descent

Note!	Genotype 1 and 4 are more difficult to eradicate which is a problem since 70% of cases are Type 1.

(C. Everett Coop Institute, 2013; Huether, 2010)

Barriers to Testing

It may seem like hepatitis C is alarming based on the information you've been provided thus far. However, the issue is that risk-based testing has historically been unsuccessful. As many as 17-87% of infected persons have not been tested. It is impossible to determine exactly how many are infected and how many go untested.

<u>Barriers to Testing</u>:

1. 72% of persons with a history of injection-drug use who are infected with HCV remain unaware of their infection status.
2. Many that are infected with HCV have inadequate health insurance coverage and/or limited access to regular healthcare.
3. Even those with access to healthcare remain untested.
4. Primary care providers' knowledge of testing guidelines remains limited further compounding the problem.

(CDC, 2012)

Current CDC Recommendations for HCV Testing

	Persons who ever injected illegal drugs:	Persons who selected medical conditions:	Prior to recipients of transfusions or organ transplants:	Persons with recognized exposures:
Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease	Includes those who injected once or a few times many years ago and do not consider themselves "drug users".	• Received clotting factor concentrates produced before 1987. • Chronic hemodialysis. • Persistently abnormal alanine adminotransferase levels.	• Persons who were notified that they received blood from a donor who later tested positive for HCV infection. • Received a transfusion of blood or blood components before July 1992. • Received an organ transplant before July 1992.	• Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood. • Children born to HCV-positive women.
Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945-1965	Adults born during 1945-1965 should receive one-time testing for HCV without prior ascertainment of HCV risk.	All persons with identified HCV infection should receive a brief alcohol screening and intervention as clinically indicated, followed by referral to appropriate care and treatment of services for HCV infection and related conditions.		
Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents	HIV-infected patients should be tested routinely for evidence of chronic HCV infection.	Initial testing for HCV should be performed using the most sensitive immunoassays licensed for detection of antibody to HCV (anti-HCV) in blood.		

Benefits of Testing the Birth Cohort

After much research, in 2012, CDC added the 1945-1965 birth cohort to testing based on the fact that risk stratification testing for HCV infection (e.g., testing based on high risk behaviors, environments, or potentials for exposure) was inadequate. This means that all persons born between 1945 and 1965 should be tested for HCV regardless of risk factors, behaviors, or potential exposure.

The research revealed that there was a disproportionately high number of infected persons born between the years 1945 and 1965, which account for **nearly 75% of all persons infected with chronic HCV**. CDC added this group as a target for testing in addition to other high risk groups so that early treatment and management can be initiated to halt the progression of chronic disease and the spread of infection to others.

CDC's research also concluded that the benefits of testing far outweighed the risks (actual and perceived). Although waiting for blood tests or a liver biopsy may cause anxiety and even physical pain and bleeding, the studies have shown that detection and effective treatment enhance sustained virologic response (SVR) in persons with HCV infection.

Test Yourself

Who should be screened for HCV?

A. 56 year old man without any prior history of IV drug use.
B. 42 year old woman with hemophilia that received many transfusions during her childhood.
C. 60 year old woman that received a kidney transplant in 1998.

All of the above are correct.

A. This man would have been born in 1957 placing him in the CDC's recommended timeframe for testing for those born between 1945-1965 even though he has no high risk behavior.
B. This woman would have received transfusions as a child before testing of blood products began in 1992 and may have been exposed to HCV.
C. This woman should be tested because of her age (she would have been born around 1953), not because of the year of the kidney transplant.

Module II – Go to the Guidelines!

This section explores the currently used and new medications under development for the treatment of HCV infection.

In this section, the healthcare professional will learn to select evidence-based algorithms for treatment and monitoring of patients with chronic HCV infection.

Current Medications

Before you can learn about the treatment guidelines, you must first review the medications used to treat HCV infection.

The current, FDA-approved medications for the treatment of hepatitis C infection are:

- **Pegylated Interferon**: Long acting interferon-α, also called peginterferon. Interferons are cytokines that literally "interfere" with a virus' ability to replicate. Interferons also stimulate natural killer cells in the body as well as aid in promoting uninfected cells to resist new viral infection. Peginterferon is taken as a once weekly subcutaneous injection.
- **Ribavirin**: A nucleoside inhibitor, this medication that is taken orally and is weight-based, stops viral RNA sythesis. Must be used in combination with peginterferon, never used alone.
- **Boceprevir and Telaprevir**: Protease inhibitors used in combination with the above (known as "triple therapy"). Currently only being used for certain patients with genotype 1 HCV which is difficult to treat and eradicate, but also the most common genotype in the US.

New Medications

What are the newest drug being tested?

1. HCV NS3/4 Protease Inhibitors
2. Nucleos(t)ide HCV NS5B Polymerase Inhibitors
3. Non-nucleos(t)ide HCV NS5B Polymerase Inhibitors
4. HCV NS5A Inhibitors

All of the above drugs are direct acting antivirals or DAAs. Eventually, they will be used in combination with interferon-α, pegylated interferon or ribavirin, although there is no indication what combinations will be used and how. Until clinical trials and testing are complete, patients will have to wait and see how the newest treatment regimens will be prescribed.

(USVA, 2013)

Testing for HCV

The first step in treating HCV is confirming presence of HCV infection. Further tests will determine if there is liver impairment or not and if there are other comorbidities such as HIV. Once the PCR test is run, the results may vary. Review the table below to see the four possible outcomes from the hepatitis screening highly sensitive PCR test.

Anti HCV	HCV RNA	Interpretation
Positive	Positive	Acute or chronic HCV – depends on the patient/presenting clinical context and condition
Positive	Negative	Resolution of HCV; or acute HCV during period of low-level viremia
Negative	Positive	Early acute HCV infection; chronic HCV in setting of immunosuppressed state; or false positive HCV RNA test
Negative	Negative	Patient not infected with HCV

To Treat or Not to Treat?

Now that a patient has been tested for HCV, many questions may arise about being treated or not and what's right for them. Patients may ask/state:

1. What do the results mean?
2. What's the difference between acute and chronic? Which one am I?
3. But I'm asymptomatic. Is it worth it to put me through weekly injections and side effects?
4. Do I have a choice? Will I die if I don't?
5. What are my chances of the hepatitis being cured?
6. Will the treatment work?
7. Will my family and spouse be hurt or exposed if I don't treat myself now?
8. I know people who've had the treatment – it was bad and it didn't work. Why should I do this?

9. I don't care that I'm not symptomatic now; I want to be treated immediately. I don't want to be sick and die.

Begin with the Test Results

The previous patient questions are valid and unfortunately, there are no easy answers. Each patient is different. Depending on the results of each individual's lab work, testing and situation, treatment may be initiated immediately, or deferred.

For example, if a patient wishes to get pregnant in the next year, she cannot start peginterferon treatment now or for six months after giving birth. After discussing this with her hepatologist, her family and the healthcare team may then decide it is safe for her to defer treatment until after pregnancy and delivery.

However, if her liver condition is decompensated, her physician may decide that treatment now is advisable, as she may not be healthy enough to be pregnant later if she is advancing towards liver failure. This is why there are no clear cut answers regarding when to treat HCV. It must be on an individualized basis.

Acute HCV vs. Chronic Infection

Once HCV presence has been established, the patient's history and physical in addition to other lab work and physical presentation will help determine if the infection is acute or chronic.

Acute infections last approximately 12 weeks and may resolve without treatment. However, if the HCV has not cleared after 12 weeks, monotherapy with peginterferon for 24 weeks is recommended and has a success rate of 80-100%. Remember that up to 85% of acute infections last longer than six months and become chronic.

In either case, whether acute or chronic, after the PCR test has confirmed the presence of HCV infection, he or she should also be tested for other forms of hepatitis co-infection such as hepatitis A and B.

Now let's review two basic treatment algorithms and apply them to two patients.

(Ghany, et al., 2009)

Multiple Pathways

There are many complex, branching pathways to treat patients with chronic HCV. The algorithm may change based on the considerations/examples listed below:

- Genotype 1 or 4
- HIV status
- Child-Pugh score
- Decompensated cirrhosis
- Relapse/failure to respond to initial treatment
- Persistently normal ALT
- Current alcohol abuse
- Age >65 years
- Renal disease
- History of solid organ transplant

To simplify the process, you will be provided with only two of the more basic pathways and apply them to two case studies.

(Ghany, et al., 2009)

Two Patients, Two Pathways

Rachel:
Meet Rachel. She is 54 years old and works full time as a social worker in a free clinic. She was recently hospitalized when she went to the ER after a syncopal episode and fall at work.

Routine blood work at that time showed elevated AST and ALT. She was kept for observation and further tests when she informed the ER doctor she had hepatitis C in the past and was treated for two years with interferon injections with a good result about ten years ago. Her last visit to the hepatologist about three years ago showed no detectable virus in her blood work.

Rachel's Additional Labs and Evaluation:

- HCV viral load: 650,000
- Serum HBsAg, Anti-HBc, anti-HBs, anti-HAV: All negative
- Albumin: 3.0
- Bilirubin: 2.8
- INR: 2.2
- Creatinine: 1.0
- Platelets: 145
- H&H: 12.2/35.4
- HCV Genotype: 1
- HIV: Negative
- Splenomegaly: Negative
- Encephalopathy: Negative
- Ascites: Negative
- Liver biopsy: Reveals minimal fibrosis and early stage 1 cirrhosis
- EKG: Normal sinus rhythm, no ectopy rate 72
- BP: 144/78

Rachel's continued history and physical show that she was treated ten years ago with interferon-α (monotherapy) and at the time had a sustained viral response (SVR). It is believed she may have been exposed to HCV after a blood transfusion in 1989 due to a traumatic birth and c-section with her youngest son that resulted in a total hysterectomy.

She admits to drinking alcohol more often for the past two years since her divorce and stressful days at work. She consumes 3-4 alcoholic beverages per night and is a non-smoker. She takes no daily medications and reports no illicit drug use present or past. She lives at home with her youngest son. Her older son is married and lives close by. Rachel's hepatologist is called and he determines that her hepatitis C has now relapsed and she has mild stage 1 cirrhosis.

Two Patients, Two Pathways

Kevin:

Meet Kevin. He is 40 years old, teaches high school Environmental Science and is a father of three children. He is also the music teacher at the school and plays in a band on the weekends.

Kevin's wife was bothering him about going to the doctor for a "check up" since he turned 40. After his exam, his provider called to tell him his liver enzymes were slightly "elevated" and he wanted him to come in for additional blood work and follow up.

Kevin returned two days later and had a frank discussion with his physician and agreed to be screened for hepatitis based on his history on risk factors in the past.

Kevin's Additional Labs and Evaluation:

- Anti-HCV: Positive
- HCV-RNA: Positive
- Viral load: 500,000
- Serum HBsAg, anti-HBc, anti-HBs, anti-HAV: All negative
- Albumin: 5.1
- Bilirubin: 1.6
- INR: 1.3
- Creatinine: 0.9
- Platelets: 353
- H&H: 15.5/43.1
- HCV Genotype: 1
- HIV: Negative
- Splenomegaly: Negative
- Encephalopathy: Negative
- Ascites: Negative
- EKG: Normal sinus rhythm, no ectopy rate 81
- BP: 136/72
- Liver biopsy: Deferred, no clinical indication of cirrhosis

Kevin's history and physical revealed that while he was a teenager, he experimented with IV drugs; although, he never considered himself an "addict" and was more of a "recreational user" while touring with his band after high school. His IV drug use stopped at age 19 when he enrolled in college and began his education to become a teacher.

Kevin does not drink alcohol and does not smoke. He takes ibuprofen occasionally for headaches and has no pertinent medical or surgical history. His primary care provider refers him to a hepatologist for HCV infection and evaluation for treatment.

Side-by-Side Comparison

Both Rachel and Kevin have chronic hepatitis C, however, they have very different presentations. Let's look at them side by side and compare. Ask yourself what are the similarities or differences between these two patients? Do you think their treatments will be the same?

	Rachel	Kevin
Anti-HCV	Positive	Positive
HCV-RNA	Positive	Positive
Viral Load	650,000	500,000
Serum HBsAg, Anti-HBc, Anti-HAV	All negative	All negative
Albumin	3.0	5.1
Bilirubin	2.8	1.6
INR	2.2	1.3
Creatinine	1.0	0.9
Platelets	145	353
H&H	12.2/35.4	15.5/43.1
HCV Genotype	1	1
HIV	Negative	Negative
Splenomegaly	Negative	Negative
Encephalopathy	Negative	Negative
Ascites	Negative	Negative
Liver Biopsy	Reveals minimal fibrosis and early stage 1 cirrhosis	Deferred, no clinical indication of cirrhosis
EKG	Normal sinus rhythm, no ectopy rate 72	Normal sinus rhythm, no ectopy rate 81
BP	144/78	136/72

Child-Turcott Pugh Score Chart

There is one more value you must determine before proceeding with treatment. The Child-Pugh Score as it is more commonly known, is used to help determine prognosis of chronic liver disease and if a patient is a candidate for HCV treatment. The higher the score, the sicker the patient is and the less likely it will be that the patient can be treated at this time.

The **score** is obtained by adding the number for each parameter. A class or grade is determined by the total score. Generally, class A patients are immediately treatable, class B patients are treated on a case-by-case basis and class C are not candidates for HCV treatment and must be referred out for management of cirrhosis before the HCV infection can be addressed.

- Class A = 5-6 points
- Class B = 7-9 points
- Class C = 10-15 points

	Points*		
	1	2	3
Encephalopathy	None	Grade 1-2 (or precipitant-induced)	Grade 3-4 (or chronic)
Ascites	None	Mild/moderate (diuretic-responsive)	Severe (diuretic-refractory)
Bilirubin (mg/dL)	<2	2-3	>3
Albumin (g/dL)	>3.5	2.8-3.5	<2.8
PT (sec prolonged) or INR	<4 <1.7	4-6 1.7-2.3	>6 >2.3

(USVA, 2012)

Calculate the Child Pugh Score

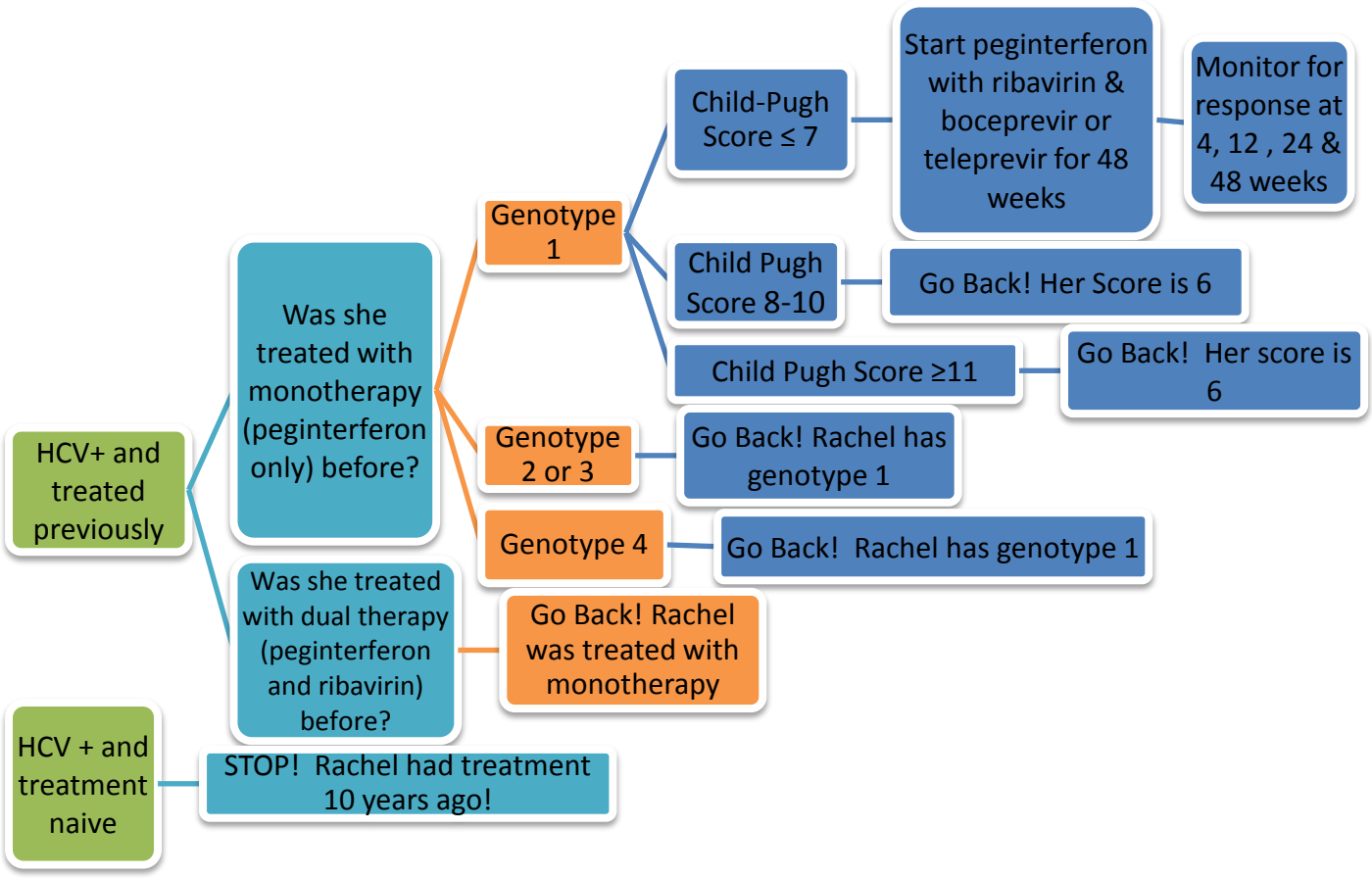
Refer back to Rachel and Kevin's labs and physical assessment in order to calculate the Child Pugh scores for both.

	Points*				
	1	2	3	**Rachel**	**Kevin**
Encephalopathy	None	Grade 1-2 (or precipitant-induced)	Grade 3-4 (or chronic)	0	0
Ascites	None	Mild/moderate (diuretic-responsive)	Severe (diuretic-refractory)	0	0
Bilirubin (mg/dL)	<2	2-3	>3	2	1
Albumin (g/dL)	>3.5	2.8-3.5	<2.8	2	1
PT (sec prolonged) or INR	<4 <1.7	4-6 1.7-2.3	>6 >2.3	2	1
			Totals	**6**	**3**

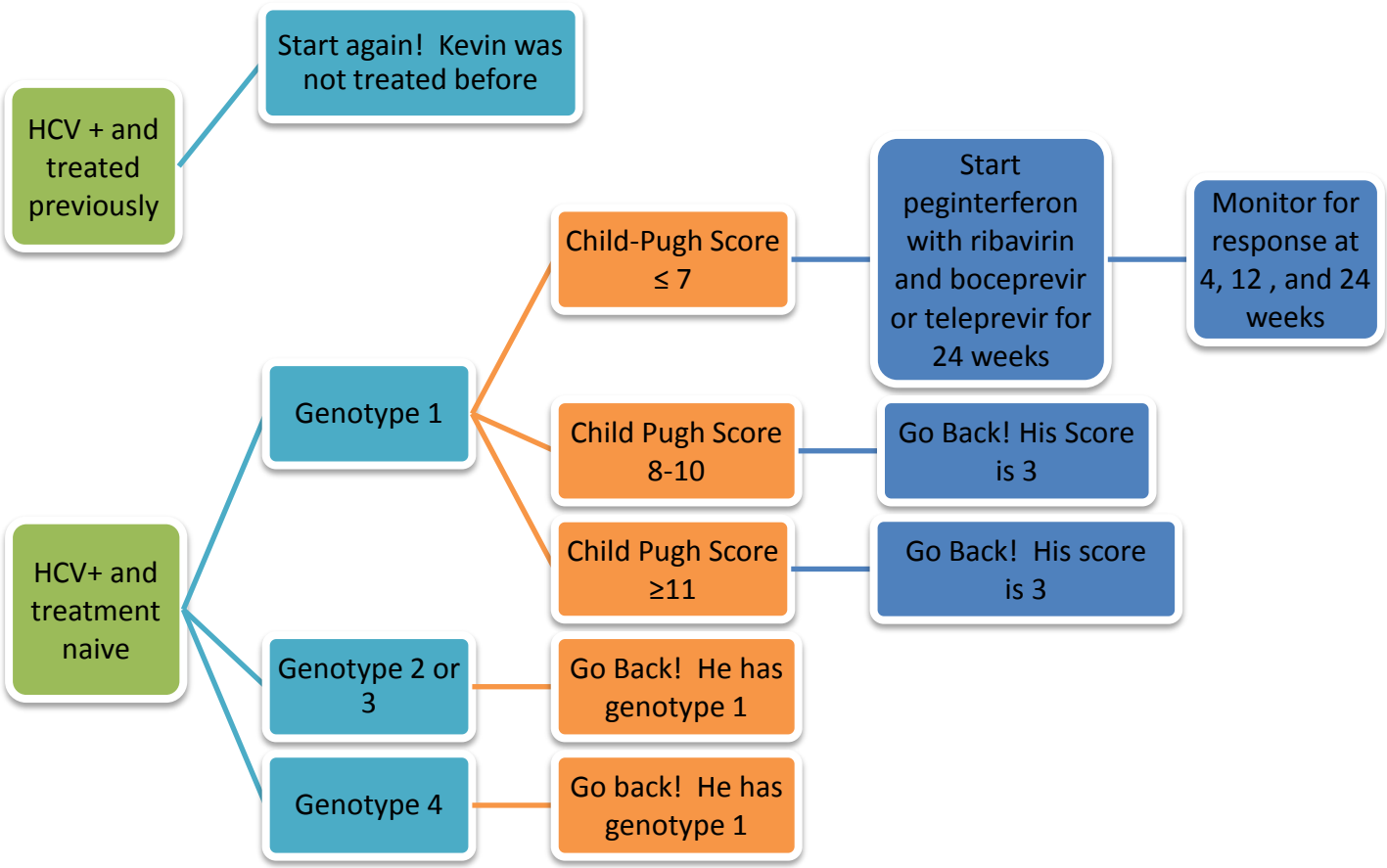
You have determined that Rachel's score is 6 and Kevin's score is 3. Remember these numbers in the next exercise when you are working through the treatment algorithms.

Now you are ready to begin. As you work through each algorithm, make decisions about where to go next as you read each step in the process based on what you know about each patient.

Algorithm for Rachel



Algorithm for Kevin



Differences in Treatment

At first glance, Rachel is obviously "sicker" than Kevin, however the treatment is essentially the same but for different durations. They both have genotype 1 which qualifies each of them for triple therapy. The key difference in Rachel's treatment is that initially she received **monotherapy or duel therapy only in which she was a responder.** If she was a null responder during her first treatment with triple therapy before, she would not be able to be treated again. A null responder is a patient that was treated but whose viral load remained elevated during therapy. Not all patients respond to treatment.

In Kevin's case, however, peginterferon, ribavirin and either boceprevir or teleprevir is the optimal combination for a treatment naïve patient with genotype 1 and currently endorsed by the AASLD. If either patient had a different genotype, only duel therapy would be initiated.

Treatment duration is also a factor. Kevin's recommended duration is 24 weeks if he has a rapid viral response (RVR) at the fourth week of treatment. If he does not have an RVR but does respond with lower viral load after the fourth week, his treatment may extend to 48 weeks.

In Rachel's case, her duration is initially placed at 48 weeks, but also looking for RVR. If the virus is still detectable at 24 weeks, however, treatment will be stopped and she will be considered a null-responder.

Treat Now?

Early treatment means higher SVR rates

Current triple therapy rates of SVR are excellent

Patients with decompensated cirrhosis may advance to stage IV or HCC

New drugs in the pipeline may not be available in time to be used by patients waiting for the FDA to approve them

Defer Treatment?

Current treatments are complex and pose a burden on many patients – adherence is an issue

New/future treatments may have a better risk/benefit profile

New/future treatments may have lesser adverse events profile

Patients that have contraindications to interferon have the potential for an interferon-free regimen in the future

Test Yourself

"Triple therapy" is the combination of ribavirin, boceprevir, and teleprevir, for treatment naïve patients with genotype 2 HCV infection.

A. True
B. False

The correct answer is false. Triple therapy is the combination of peginterferon, ribavirin, and either boceprevir or teleprevir. This treatment is only used for genotype 1.

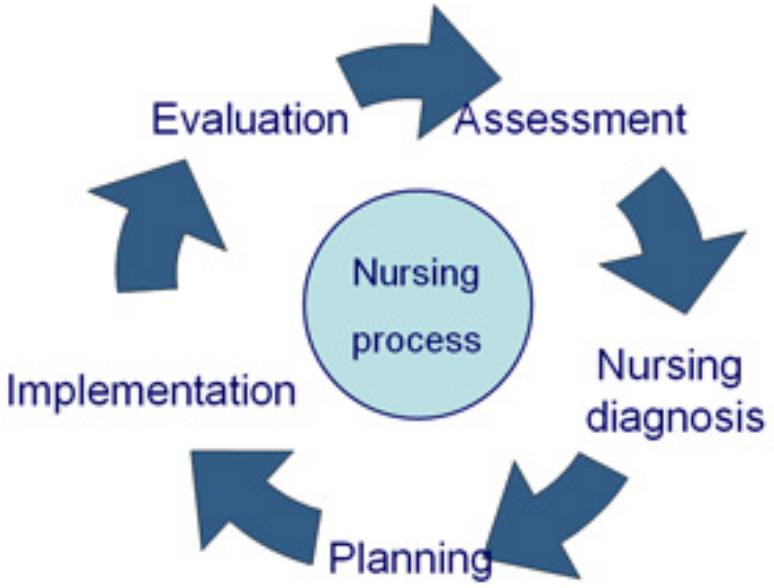
Module III: Nursing Implications

- Utilize a holistic nursing approach to the care of the patient with HCV infection.

Treat the Whole Person

Patients undergoing treatment for HCV will need support in all aspects of their lives. As a nurse, your approach to care should always be holistic – treat the whole person, not just the disease. Here are some strategies to help you provide holistic care to the patient being treated for chronic HCV.

First, use your nursing process to assess your patient…



Possible Side Effects of Treatment

Side Effect	Holistic Interventions/Suggestions
Flu-like symptoms (muscle aches, joint pain, nausea)	Regular exercise (low impact), massage therapy, ginger tea, peppermint oil, take injection at night before sleep
Anorexia	Small frequent meals, protein shakes
Insomnia	Warm drink at bedtime, no caffeine, light stretching before bed, warm bath or shower, no alcoholic beverages
Depression/irritability	Engage in hobbies and activities daily, exercise daily, join a hep C support group, start a meditation practice, no alcoholic beverages
Diarrhea	Avoid milk and dairy products, increase fluid intake
Fatigue	Assess patient's rest/wake patterns, encourage good nutrition with proper periods of rest with exercise (as tolerated)

Balance Your Care

After having your patient implement your suggested interventions, remember to continue to monitor for effect and evaluate his or her response(s).

Keep in mind that if side effects become severe, treatment may need to be adjusted (e.g., titrating dosages of medications, etc.). Patients have also required hospitalization secondary to side effects such as electrolyte imbalances due to diarrhea and subsequent dehydration.

For example, if diarrhea became severe and continuous, the patient must be monitored for dehydration. Teach the patient the signs and symptoms of dehydration and how to manage

fluid replacement with electrolyte-infused drinks and adequate nutrition. Know when to tell the patient to come in to the office to be assessed or to go to the emergency department to be further evaluated.

Resources for Living

If you have a patient that is recently diagnosed with HCV, there are many resources that he or she can access for information and support.

The CDC's website is packed with the most up to date information on all forms of viral hepatitis. There are videos, downloadable brochures and fact sheets, articles and research papers filled with easy to read information in different languages that you can refer your patient(s) to: http://www.cdc.gov/hepatitis/C/index.htm

For those patients wondering about their current risk for exposure to HCV, the CDC has an online tool that assesses a person's risk for contracting HCV and when to be screened for the virus:
http://www.cdc.gov/hepatitis/RiskAssessment/

Other Helpful Sites

Additional online resources that you may direct your patients to are:

- The American Liver Foundation: http://www.liverfoundation.org/
- The HCV Advocate: http://www.hcvadvocate.org/
- The Center for the Study of Hepatitis C (collaborative between the Rockefeller Foundation, Weill Cornell Medical College, and NY Presbyterian): http://www.hepccenter.org/
- Chronic Liver Disease Foundation: http://www.chronicliverdisease.org/
- Department of Veterans Affairs Hepatitis C Program: http://www.hepatitis.va.gov/

If you have a patient that is a candidate for a clinical trial or is interested in participating in a clinical trial or following studies currently under way, clinicaltrials.gov is an excellent resource categorized by disease. The link for hepatitis C is:
http://www.clinicaltrials.gov/ct2/results?cond=%22Hepatitis+C%22

Please note, these are high quality sites with medical-grade information intended for support and information only. Please tell your patients to be careful of general internet searches of random websites concerning his or her medical condition. Your patients should be aware that

they should never change their treatments or medications based on information "found online", and they should always check in with his or her medical provider with questions about care!

Test Yourself

Kristin started triple therapy four weeks ago. She is feeling very exhausted and short-tempered at home. At her visit today, she explains that she's been fighting with her fiancé a lot and she's not sleeping. What would you suggest at this point?

A. Recommend she stop treatment. She is obviously not tolerating the side effects of the medications.
B. Recommend to the hepatologist that the dosage be reduced to minimize her obvious side effects.
C. Recommend to her fiancé to be more tolerant. She's the sick one, not him.
D. Recommend she start a sleep journal and have her fiancé and herself start going for walks in the evening to wind down from the day and talk before going to bed.

The correct answer is D. Kristin is having a rough time, but if she starts monitoring her sleep and starts walking as an exercise program, it may help. Also engaging her finance in the activity will give her support and time for them to talk about how they're feeling. Stopping or changing treatment would not be advisable and may hinder her progress and prevent SVR.

Time to Review

You are now ready to face hepatitis C with the latest evidence-based research and knowledge available. To recap, you are now able to:

1. Explain how hepatitis C virus (HCV) impacts public health.
2. List the modes of HCV transmission.
3. Describe how HCV's molecular structure impacts the pathogenesis of disease.
4. State the current CDC recommended guidelines for HCV testing by risk stratification and age cohort.
5. Explore current and new medications currently under development for the treatment of HCV infection.

6. Select evidence-based algorithms for treatment and monitoring of patients with chronic HCV infection.
7. Utilize a holistic nursing approach to the care of the patient with HCV infection.

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