HepC INSIDE

The SILENT killer.

Facts, stats and info on Hepatitis C for prisoners

Dear Reader:

Hepatitis C virus (also called Hep C or HCV for short), is a potentially deadly virus that attacks the human liver and can cause mild to very serious damage. It is an important health problem for everyone around the world, but is especially critical for people in prisons and jails.

HCV is different than many other diseases. Sometimes people wait too long to seek help and it becomes difficult to treat the infection effectively. Sometimes treatment just doesn't work—but the good news is that HCV treatment is improving, and more people can be cured with new treatments.

While some people do not have symptoms, others feel tired, forgetful and depressed. Most people don't develop liver problems for a long time (sometimes over 20 years). Hepatitis C can be cleared, either by a person's own immune system or by medication, but not all cases respond to treatment.

There are over 3 million Hepatitis C infections in the United States — that's more than triple the number of HIV (Human Immunodeficiency Virus) infections — and the rates are growing. Since hepatitis C is found in blood, it is very common among people who have ever shot drugs, hormones or steroids with shared needles, or otherwise been exposed to someone else's blood (like through tattooing). Because HIV is also transmitted through blood, there are a lot of people who have both diseases (called co-infection). Information about HIV/HCV co-infection is included a little later in this booklet.

The staff at the Center for Health Justice who created this booklet (many of us former prisoners ourselves), along with our HCV expert Tracy Swan, want you to have up-to-date information about HCV so you can protect yourself against infection, or get help and treatment if you are already infected.

HCV is harder to transmit sexually than HIV, and certain sexual activities carry more risk than others… but it can happen. Most importantly, you should know that in California, state prisoners have a right to be tested and treated for HCV. That's good news because HCV can sometimes be cleared from the body without treatment unlike HIV). Whether you have HCV or not, or regardless of how much time you are doing in jail or prison, this information is important for you to know. We hope that you will find this booklet helpful and share it with others — inside, and out.


HCV

WHAT'S INSIDE...

FACTS

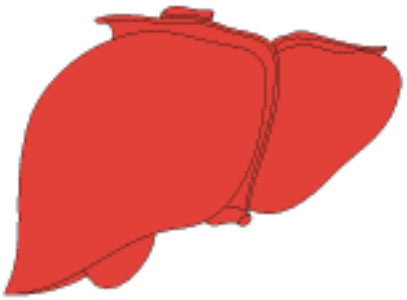
- According to the World Health Organization, more than 170 million people have been infected with the hepatitis C virus (HCV).
- HCV is spread through direct contact with blood from an infected person.
- In the U.S., at least 3.7 million people have been infected with HCV.
- HCV rates are high among people in prisions and jails (31% to 50% of people in prisions have HCV).
- In the U.S., as many as one-third (or at least 300,000) of all HIV-positive people are co-infected with HCV.
- There is no vaccine available to prevent HCV infection.
- HCV can be treated, but treatment doesn't always get rid of the virus.
- There are many new HCV drugs in clinical trials.

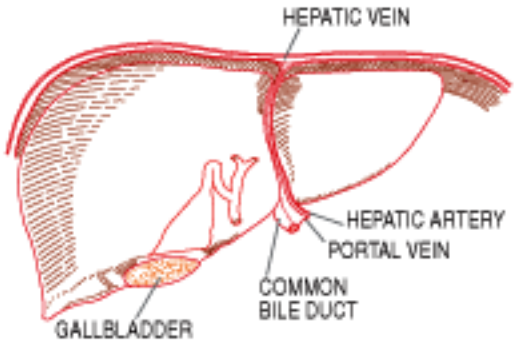
What Is The Liver, And Why Is It Important?

The liver is the body's largest internal organ, on the right side, underneath the ribs. The liver works as the body's filtering system and processing plant. Everything a person eats, drinks, inhales and all drugs (prescription, over-the-counter and illegal), herbs, and vitamins pass through the liver.

The liver:

- Filters toxins and waste from the bloodstream
- Stores vitamins, minerals, and iron
- Converts nutrients from food into energy
- Helps to regulate levels of sugar and hormones
- Produces cholesterol
- Makes bile, which is necessary for digestion
- Produces hormones to make platelets, which help make blood clot.





What is Hepatitis?

Hepatitis is a general term, meaning liver inflammation (swelling): hepat=liver and itis=inflammation. Different things may cause the liver to become inflamed: heavy alcohol intake, inhaling toxic fumes, infections and viruses. Some of these are called viral hepatitis. There are several different hepatitis viruses (A, B, C, D, E, and G). They were named alphabetically in the order that they were discovered. The most common ones that impact people in the United States are A, B, and C (and sometimes D and E). Although this booklet focuses predominantly on Hepatitis C, we also thought it was important to talk about the other hepatitis viruses too. Here are some facts about the other hepatitis viruses:

FACTS: Hepatitis A Virus (HAV), Hepatitis B Virus (HBV), Hepatitis D Virus (HDV), and Hepatitis E virus (HEV)

HAV

- HAV is not a chronic (lifelong) infection.
- HAV is found in feces (stool) of infected people; a person becomes infected when feces from an infected person enters their mouth. HAV is often passed when food or water is contaminated with sewage, or an infected person handles food without washing his or her hands after using the bathroom. A person can get HAV from oral-anal sex with an infected person (also known as rimming) and rarely, from blood transfusions.
- A person can only become infected with HAV once.
- HAV symptoms are: nausea, vomiting, diarrhea, fever, rash, fatigue, jaundice (yellow skin and eyes), liver pain, dark brown urine. Some people don't have any symptoms; older people are more likely to feel sick from HAV.
- Some of the symptoms from HAV can be treated, but there is no treatment that will cure HAV; it goes away by itself, usually within two months.

- HAV is very rarely life-threatening, ***but people with HCV are at risk for liver failure if they become infected with HAV.***
- There is a vaccine to protect against HAV.

HBV

- Can become a chronic infection in 3 to 6% of adults. HBV is more likely to be chronic in persons infected at birth (90%), children between 1 and 5 years of age (30%) and people with weakened immune systems, including people who are HIV-positive (30 to 90%).
- HBV is found in blood, semen, and vaginal fluid of infected persons. Very small amounts of HBV have been found in breast milk and saliva. HBV can be passed from mother to child, through shared injection or tattooing equipment, unprotected anal, vaginal or oral sex, and from shared personal care implements such as toothbrushes and razors.
- A person can only be infected with HBV once.
- About 70% of people have symptoms, such as nausea, vomiting, appetite loss, fever, fatigue, abdominal and joint pain, liver swelling, and jaundice.
- HBV can be treated (but not cured) with some antiviral drugs and interferon.
- Chronic HBV infection can lead to cirrhosis (serious liver scarring), liver failure and liver cancer; 15 to 25% of chronically infected, untreated people die from liver damage from HBV.
- HBV worsens liver damage from HCV.
- There is a vaccine to protect against HBV.

Hepatitis D Virus (HDV)

- HDV is only infectious to people who have HBV (but a person can get both viruses at the same time; this is called superinfection.
- HDV becomes chronic in about 10 to 20% of cases.
- HDV is found in blood, and can be transmitted by sharing injection or tattooing equipment, unprotected anal, vaginal or oral sex, and from mother to infant.

- Symptoms of acute HDV are the same as HBV, but they may start suddenly and be severe. During acute HDV infection, there is a small risk of liver failure (about 1% for people who got HBV and HDV at the same time, and about 5% in people who already have HBV when they got HDV).
- Some of the treatments for HBV may also be effective against HDV.
- Chronic HDV infection may lead to serious liver damage, including cirrhosis, liver cancer and liver failure; people who have both chronic HBV and HDV are at greater risk of these complications.
- Being vaccinated against HBV will protect a person from getting HDV.

Hepatitis E Virus (HEV)

- Rare in the U.S., HEV is more common in parts of Asia, Africa and in Mexico.
- HEV is similar to HAV in that it is not chronic (except in very rare cases); you can only be infected once; it has the same symptoms, but is not passed from person to person as easily as HAV.
- People usually get HEV from contaminated food or water that has been contaminated by sewage, but it can also be passed from eating raw or undercooked meat from infected animals (such as pigs and deer) or close contact with pigs, deer and monkeys, gorillas, apes and other non-human primates (such as cleaning their waste).
- HEV is usually not serious, but can be life-threatening during pregnancy, especially the third trimester.
- There is no vaccine against HEV.

What is Hepatitis C?

Hepatitis C (also known as HCV) is a small virus that lives in blood. It enters a person's body through the bloodstream, and infects liver cells (called hepatocytes). The hepatitis C virus (HCV) can have different effects on people.

What Happens to People Who Are Infected?

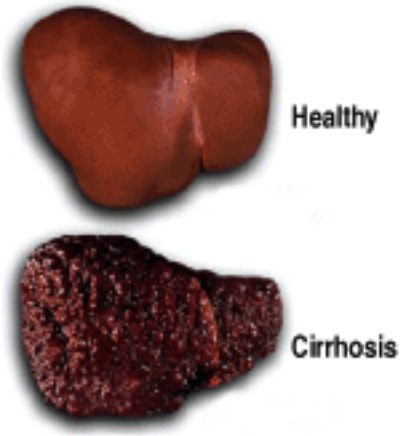
Acute HCV

Most people (80%) do not have any signs or symptoms when they first get infected with HCV (this is called *acute infection*), but when they do, the most common symptoms of acute HCV infection are nausea, fever, feeling tired, and jaundice (yellowing of the eyes and skin).

Some people (between 15% and 25%) will clear HCV— without treatment — usually within a few months after they are infected. This is called *spontaneous viral clearance.* People who have spontaneously cleared HCV remain antibody positive, but they don't have any HCV virus in their blood. Unlike HIV, having HCV antibodies does not mean that a person is chronically infected with HCV (antibodies are proteins produced by the immune system in response to a germ, virus, bacteria or other pathogen that does not belong in the body).

Spontaneous viral clearance is more likely among HIV-negative people, persons under 40, and women. African-Americans are less likely to clear HCV than Whites. Researchers have recently found a genetic difference that helps to explain this, in a gene called IL-28B. Everybody gets one gene from each parent, in this case, a "C" or a "T". This means that a person will have a C/C genotype (most common among people with Asian or white European ancestors), or a C/T genotype, or a T/T genotype (most common among African Americans). People with a T/T genotype are less likely to spontaneously clear hepatitis C, and less likely to respond to interferon, which is used to treat HCV. People with a C/C genotype are most likely to respond to interferon, and people with a C/T fall somewhere in between.

HCV treatment is more effective during the acute stage (the first six months after a person gets infected) of HCV than during chronic infection. Usually experts suggest waiting for about 12 weeks after a person becomes infected with HCV before starting treatment, since some people will spontaneously clear HCV.



Chronic HCV

If HCV is not spontaneously cleared, then it becomes a chronic (lifelong) infection. Although most people who have been infected with HCV have chronic HCV, not all of them will develop serious liver damage. Lifestyle changes — especially avoiding alcohol, or drinking as little as possible — can reduce the risk of developing liver damage.

HCV does not directly damage the liver. It is the immune system's response to the virus that can cause liver damage. The immune system tries to surround and separate HVC-infected liver cells to protect other cells from becoming infected. Over time, this creates liver scarring. Although the liver can regenerate, it cannot reverse scarring. Mild-to-moderate liver scarring is called *fibrosis*. More serious liver scarring, making it difficult for the liver to function, is called *cirrhosis*.

About 20% of people with chronic HCV don't have symptoms, and do not develop liver damage. Others may experience:

- Symptoms (such as fatigue/depression), some liver damage
- Fat in the liver (called steatosis; this can worsen liver damage)
- Liver scarring (fibrosis)
- Serious liver scarring that makes it difficult for the liver to function (cirrhosis).

About 20 to 30% of people with chronic HCV develop cirrhosis. Often, people don't feel sick until they have serious liver damage. It usually

takes a long time for this damage to occur – around 15 to 40 years after becoming infected. The signs and symptoms of cirrhosis include:

- Nausea
- Appetite and weight loss
- Swollen abdomen
- Enlarged liver and spleen
- Edema (fluid retention, causing swollen ankles and legs)
- Ascites (abnormal build up of fluid in the abdomen)
- Dark, cola-colored urine
- Jaundice (yellowing of the skin)
- Muscle weakness
- Itchiness
- More frequent bruising
- Loss of sexual desire
- Irregular menstruation
- Impotence
- Breast enlargement in males
- Visible, spider-like blood vessels

Sometimes, a cirrhotic liver is not too damaged to function; this is called *compensated cirrhosis*. When the liver does become too damaged to function (this is called *decompensated cirrhosis*), a liver transplant is necessary. In the United States, HCV-related liver damage is the most common reason for liver transplants. In addition, each year, 1% to 5% of people with HCV cirrhosis develop liver cancer.

Sometimes, people with HCV will develop liver cancer even though they do not have cirrhosis, although this is rate. Overall, between 8,000 and 12,000 deaths occur each year from complications of HCV.

Co-Factors: What Can Worsen HCV Infection?

HCV does not progress at the same rate in every person. Certain co-factors increase the risk for serious liver damage. These include:

- Co-infection with HIV
- Drinking alcohol, especially more than four drinks (glasses of wine, beer, shots or cocktails) per day. No one knows if there's a "safe" amount of alcohol for people with HCV
- Co-infection with chronic HBV
- Aging — HCV progresses more rapidly in people who are over 40
- Duration of infection: this may be related to aging, but the longer a person has had HCV, the more likely that he/she will develop liver damage
- Being male
- Being overweight may increase the risk for steatosis (fat in the liver), which worsens liver damage from HCV.

How is HCV Transmitted?

HCV is transmitted by blood-to-blood contact: blood from a person who has HCV must directly enter another person's bloodstream for them to become infected with the virus.

Before mid-1992, many people got HCV from blood transfusions and blood products, but since then, the blood supply has been thoroughly screened for HCV. The risk of getting HCV from a transfusion or blood products in the U.S. is now almost nonexistent. Before 1987 — when the risk was pretty much eliminated through viral inactivation procedures — many people with hereditary blood clotting disorders such as hemophilia got HCV (and HIV) from their treatment with blood clotting factors.

Most new HCV infections result from injecting drugs, hormones, or steroids with shared, unsterilized equipment. HCV is ten times easier to get from shared needles than HIV. This is because HCV is a much smaller virus, and there is much more of it in a drop of blood. HCV is hard to kill: for example, although bleach kills HIV, it is not as effective

against HCV. Injectors who don't usually share syringes have become infected with HCV by sharing cookers, cotton, measuring syringes, and water with other users.

HCV can be transmitted sexually, but this happens far less often than with HIV. Tiny amounts of blood may be present in semen and vaginal fluid. Blood can be passed between sex partners, especially during rough anal or vaginal sex, or sex with a woman during her period. Condom use for anal and vaginal sex reduces the risk of HCV infection.

Hepatitis C is more common in HIV-positive men who have sex with other men (MSM). During the last decade, cases of sexually-transmitted HCV have been reported among HIV-positive MSM in the U.S., Australia and Europe. HIV can increase the levels of HCV in blood and semen, so it is a risk factor for sexually transmitted hepatitis C — this is one reason for higher rates of sexual transmission in HIV positive men who have sex with men. Other risk factors may be involved, such as group sex, fisting, rough sex (also called "traumatic sex" because tissues in the body can tear), sharing sex toys, and non-injection drug use.

HCV is more common among MSM, people who have more than one sex partner, people who have another sexually transmitted disease (such as genital herpes or syphilis), and sex workers, than the general public.

HCV is also more common among non-injection drug users than the general public. Some experts think that sharing a straw to snort drugs puts people at risk for HCV, because tiny amounts of blood may be on the inside or outside of the straw, and because the membranes in the nose are very fragile. Others think that sharing a crack pipe may be a risk for HCV because people may have blisters, burns, and sores on their lips from smoking (and these may bleed). **A person can lower his or her risk for HCV by not sharing any drug paraphernalia (syringe, cooker, cotton, measuring syringe, water, tie, straw or crack pipe).**

Tattooing with shared, unsterilized equipment — including ink and inkwells — can be a risk for HCV infection, as is shared, unsterilized piercing equipment. Sharing manicuring equipment, toothbrushes and razors also may be a risk for HCV, because there may be tiny amounts of blood on these personal care implements. Therefore, it is important that people in prisons and jails do not share any personal items. It is safer to wait until you are released to get that tattoo. Tattoo and piercing shops on the street have safety procedures that they must follow to protect their

customers. We can't say the same thing about jail tattoo and piercing equipment.

HCV can be passed from a mother to her infant. Unfortunately, HCV treatment cannot be used during pregnancy because ribavirin causes birth defects.

By the way, HCV ***cannot*** be transmitted from sharing silverware, plates, or glasses, sharing a bathroom with a person who has HCV, or by eating food prepared by a person who has HCV.

Who Has HCV?

Most people who have HCV got it from sharing needles. As many as 90% of people who have *ever* injected drugs — even once — have been infected with HCV.

A nationwide sample reported that 1.6% of the U.S. population (almost 4 million people) have been infected with HCV. HCV is most common among:

- African-American men between 50 and 59 years old (13.6%)
- Prisoners (one study found that 34.3% of prisoners in California correctional facilities had HCV)
- Homeless persons (30% to 40%).
- Current or former injection drug users (up to 90%).

Liver Health

There are many things that a person who has HCV can do to support liver health:

- Get vaccinated against hepatitis A (HAV) and hepatitis B (HBV). HAV can be life-threatening for people with HCV, and HBV makes HCV progress more quickly.
- Drink less, or stop drinking alcohol — the less you drink, the better it is for your liver. Alcohol speeds up HCV disease progression. Sometimes drinking less — or not at all — is more important than treating HCV!
- Drink lots of water, it helps your liver to filter out waste and toxins.

- When possible, eat less fatty, salty, sugary foods (these are hard on the liver).
- Ask questions and get support — talk to other people who are living with HCV.
- Avoid inhaling fumes from paint and chemicals.
- Obtain more information on HCV by calling the Center for Health Justice Hotline collect at 213-229-0979.

HCV Antibody Testing

An HCV antibody test can show whether someone has been infected with HCV (remember, anitbodies are little proteins created by the immune system). A positive antibody test does ***not*** mean that a person has *chronic* HCV — it means that they were infected with HCV at one time. People who clear HCV without treatment will still have HCV antibodies in their blood. A different test that looks for the actual hepatitis C virus in a person's blood (called HCV viral load or HCV RNA) is needed to confirm or rule out chronic HCV.

HCV Viral Load (RNA) Testing

The amount of HCV in a person's blood is not related to the condition of the liver, and it does not predict whether or not HCV will worsen over time.

HCV viral load testing is used to:

- Confirm or rule out chronic HCV,
- Help predict the response to HCV treatment,
- Measure response to HCV treatment, during treatment and six months after completion of treatment.

HCV treatment is more likely to work for people with a low HCV viral load. (A **low** HCV viral load is less than 400,000 international units (written as IU/mL) per milliliter of blood — which is about a teaspoon).

Once it has been determined that a person is chronically infected with HCV (that is, has a detectable HCV viral load), there is no reason to continue to measure a viral load unless treatment is started.

How is HCV Diagnosed and Monitored?

HCV Antibody Testing is recommended for:

- Anyone who has ever injected drugs (even once)
- Anyone treated with blood products before 1987
- People with any signs or symptoms of liver disease, such as jaundice or elevated liver enzyme levels
- Anyone who got a blood transfusion or donor organ before July of 1992
- Anyone who is HIV positive
- People on kidney dialysis
- Anyone who has gotten tattooed with shared equipment, including ink and inkwells (especially prisoners)

Note: The HCV antibody usually shows up within 12 weeks after infection.

IF POSITIVE:

HCV viral load testing (HCV RNA): if the viral load test result is "detectable", it means that HCV infection was found in your blood, and that your HCV infection is chronic. If the test does not find any hepatitis C virus in your blood (called "undetectable"), repeat the test again in six months. Both tests must be undetectable to rule out chronic HCV infection.

Note: HCV RNA is usually detectable within two weeks after infection.

IF NEGATIVE:

Retest again in six months and reduce or eliminate all risky activities.

Liver Enzyme Levels

The liver panel is a group of blood tests that are part of a routine physical exam.

Measuring the amount of two different liver enzymes — ALT (short for alanine aminotransferase) and AST (short for asparte aminotransferase) — are part of the liver panel.

Liver enzymes seep into the bloodstream when liver cells are damaged or dying. Liver enzyme levels can be higher than normal in people who are taking certain medications (including some HIV drugs), in heavy drinkers, people with viral hepatitis infection, during detox, and in other situations. Often, liver enzymes will "seesaw" in people with HCV. Liver enzyme levels do not reflect liver damage, or predict HCV progression in people with HCV, although a pattern of abnormally high liver enzymes over time can be a sign of liver damage. One in three people with HCV have persistently normal liver enzyme levels, but some of them do have liver damage.

HCV Genotype (or Viral Genotype)

A blood test can identify the viral strain (called genotype) of HCV that a person has. There are at least six different HCV genotypes (listed in the order that researchers discovered them), such as 1a, 1b, 2a, 2b. HCV genotype does not affect the rate of HCV disease progression or the amount of liver damage a person has, but the genotype is one of the most important factors in predicting the response to HCV treatment (regardless of HIV status). In the U.S., most people have genotype 1, which does not respond as well to treatment as genotype 2 or genotype 3. The good news is that most of the new drugs were made to work against HCV genotype 1, and it may be easier to cure in the future.

Some people are infected with more than one genotype of HCV; this is called a mixed infection. A person can become reinfected with HCV. People who are already infected with HCV may become infected with a different genotype, which may make their HCV harder to cure.

IL-28 B Genotype (or Host Genotype)

A blood test can determine whether a person has the IL28 B C/C, C/T or T/T genotype. While it is clear that people with a C/C genotype are most likely to respond to treatment with pegylated interferon and ribavirin, what happens when a person tries HCV treatment is also very important—if a person is responding to treatment at 4 weeks (measured by an undetectable hepatitis C viral load), it is likely to work even if he or she has a C/T or T/T genotype. Nobody knows what the relationship between host genotype and response to the new HCV drugs is yet, but researchers are working hard to find out. This test is still a research tool, and is not generally used in the treatment of patients. This may change as more is learned about it.

Assessing Liver Damage

A liver biopsy is the **only** test that reveals the grade (amount of inflammation in liver tissue) and stage (amount of scarring and damage) of liver disease. During a liver biopsy, a needle is quickly inserted into the liver, and it draws out a sample of liver tissue. Usually, people spend a few hours in the hospital after a liver biopsy because there is a small risk of internal bleeding and complications. A liver biopsy can be painful; it's a good idea to discuss options for pain medication and talk to people who have had one.

Although a biopsy is considered the best way to check the condition of a person's liver, it is not perfect. Sometimes the sample of liver tissue is too small, sometimes it is taken from a part of the liver that is less or more scarred than the rest, and sometimes the person looking at the sample (called a pathologist) can make an error.

More and more, doctors are using other tests, either in addition to, or instead of a liver biopsy to check for liver damage. These do not provide as much information as a biopsy, and they are not good at identifying mild-to moderate liver damage — they are better for detecting cirrhosis. Some of these tests are not yet available for use in the United States.

Although these tests do not provide as much information as a biopsy, they are less invasive, cheaper, and less painful. These tests either use ultrasound technology to see how stiff a person's liver is, or they are a combination of different blood tests.

Results from a liver biopsy are sometimes used to make HCV treatment decisions, although some providers will treat people who have not had a biopsy, especially if they have genotype 2 or 3.

Who Needs HCV Treatment?

People who have mild liver damage may not need to treat HCV right away and may not ever need treatment. For people with HCV alone, experts recommend a biopsy every five years to monitor HCV progression and to see if treatment is necessary. But many people may feel depressed and tired, or have other symptoms that lower their quality of life; some may decide to treat their hepatitis C before they have serious liver damage, especially when new drugs will make it easier to cure HCV. Patients who are co-infected with HIV have special issues; see the section entitled "What About HCV/HIV Co-Infection?" later is this booklet.

According to the National Institutes of Health, HCV treatment is recommended for "Patients with an increased risk of developing cirrhosis." This means people who already have some liver damage from HCV (fibrosis and cirrhosis). Although some experts think HCV treatment should be started earlier. Unfortunately, if liver damage is too advanced, HCV treatment can be dangerous. In such cases, a liver transplant is the only intervention for people with severe cirrhosis.

What is HCV Treatment?

As of 2010, HCV is treated with combination therapy: once- weekly injections of pegylated interferon (PEG-IFN) plus twice-daily ribavirin (RBV) pills or capsules. Interferon is an anti-viral and immune stimulant, produced naturally in the body in much smaller amounts than what is used to treat HCV. The types of interferon used to treat HCV are man-made, not produced by the human body. Pegylation is the name of a process — it means that a molecule has been attached to interferon to keep it active in the body for a longer time. Pegylated interferon is more effective than interferon, and is only one shot per week, vs. three shots of interferon.

Ribavirin is an nucleoside reverse transcriptase analog (NRTI), from the same family of drugs used as part of HIV treatment, but ribavirin doesn't work against HIV. By itself, ribavirin is not effective against HCV, but it makes interferon more effective.

But soon there will be new treatments for HCV. The first new oral drugs are hepatitis C protease inhibitors , which are made to stop hepatitis C from being able to make more copies of itself (they target the same enzyme as HIV protease inhibitors, but are made to work against hepatitis C instead of HIV). The first hepatitis C protease inhibitors are called boceprevir and telaprevir. As of early 2011, these drugs have not been approved by the FDA but approval is expected by mid-2011. One of these drugs—either boceprevir or telaprevir — can be used with pegylated interferon and ribavirin, to make HCV treatment more effective for people with hepatitis C genotype 1.

About New HCV Drugs and Drug Resistance

New drugs will increase cure rates for people with hepatitis C, but they do not always work. One reason for this is something called drug resistance. Hepatitis C makes billions of copies of itself each day. Some of these will have mistakes (called mutations), so they do not look exactly like the original virus (called wild-type). Since HCV makes so many copies of itself each day, most people already have certain mutations that can make the new HCV drugs less effective (called drug resistance).

For example, the hepatitis C protease enzyme works like a pair of scissors to cut up long strands of HCV so it can reassemble (hepatitis C has to do this to make more copies of itself). An HCV protease inhibitor will bind to the enzyme (like putting a bar between the blades of a pair of scissors). But if a mutation causes a structural change the hepatitis C protease the drug may not be able to bind to the protease because it won't fit anymore.

This is why an HCV protease inhibitor is used with pegylated interferon and ribavirin instead of by itself—to help make sure that infected cells are killed and the virus cannot make more copies of itself.

The point of HCV treatment is to get rid of the virus, by bringing it-and keeping it—at undetectable levels in a person's bloodstream.

So here's the deal with adding a new antiviral drug to pegylated interferon and ribavirin:

1. Pegylated interferon and ribavirin may not completely stop hepatitis C from reproducing
2. A new antiviral drug can "mop up" the leftover virus that pegylated interferon and ribavirin miss

3. In turn, pegylated interferon and ribavirin can work against hepatitis C virus that is resistant to an antiviral drug

BUT: if a person misses doses of their antiviral drug, hepatitis C can still reproduce, and it may make copies that are resistant to the antiviral drug. Pegylated interferon and ribavirin may not kill all of these copies. Then, when the person starts taking their antiviral drug again, it won't work as well—because it is not killing the resistant virus, and pegylated interferon and ribavirin may not be enough to stop all the virus there is from reproducing. The hepatitis C virus will come back (called "breakthrough") or simply never become undetectable. This is why a doctor will check your hepatitis C viral load while you are on treatment. Experts recommend stopping HCV protease inhibitors if they are not working.

Goals of HCV Treatment

The main goal of HCV treatment is to get rid of HCV from the bloodstream and keep it undetectable so it does not come back. People who do not have any detectable virus in their blood six months after completing treatment are called *sustained virological responders*. More than 98% of sustained virological responders have stayed undetectable for years after they finished HCV treatment. Most experts refer to a sustained virological response (SVR) as a cure.

There are other benefits to treating HCV. Sometimes HCV treatment can improve the condition of the liver, even for people who did not have an SVR (sustained virological response), although no one is sure how long the improvement will last—and sometimes the liver condition can worsen after interferon.

How Does HCV Genotype Impact the Response to Treatment?

Overall, about 50% of people with HCV get a sustained virological response after finishing HCV treatment with pegylated interferon and ribavirin. People with genotype 1, people who have cirrhosis, African Americans, Latinos and Latinas, and people with high HCV RNA are less likely to respond to pegylated interferon and ribavirin, but the new

drugs improve cure rates for all of these groups. The numbers below represent data from two large clinical trials looking at HCV treatment of people with different genotypes.

	% SVR
Overall	**54% to 56%**
HCV genotype 1	**42% to 44%**
HCV genotype 2 and 3	**70% to 82%**

What Can Help Predict Response to HCV Treatment In People Who Have Never Treated Their HCV (Called Treatment Naïve?

HCV treatment has been found to be more effective for:

- People with genotype 2 or 3
- People who respond well during the first four weeks of HCV treatment
- People with an IL-28 B "C/C" genotype
- People with a low HCV viral load (less than 400,000 copies)
- People who do not have cirrhosis

HCV treatment is *less* effective for:

- HIV-positive people
- People who have detectable HCV RNA after four weeks of treatment
- People who have an IL-28B "C/T" genotype or a "T/T" genotype
- People with genotype 1 or 4
- African-Americans
- People with a high HCV viral load (more than 400,000 copies)
- People with cirrhosis
- People who are obese
- People with insulin resistance. Insulin resistance decreases the chances of responding to HCV therapy. Insulin resistance occurs when the pancreas produces and releases insulin after a meal so that cells can absorb and convert glucose (carbs/sugar) into energy. In an individual with insulin resistance the normal levels of insulin do not trigger the

absorption of glucose into cells, leading to an excess of glucose in the bloodstream. It is further complicated as the pancreas makes and releases more insulin in response to the elevated glucose levels.

What About People Who Were Already Treated Unsuccessfully (Called Treatment Experienced)

For treatment experienced people with HCV genotype 1, the new drugs offer hope for a cure. They are most likely to work for:

- People who relapsed (meaning they were undetectable during HCV treatment but the virus came back after they stopped the drugs).
- People who respond early (meaning their hepatitis C virus becomes undetectable after 4 to 8 weeks of HCV treatment, and stays that way).

New drugs are less likely to work for people who:

- Did not respond to HCV treatment with pegylated interferon and ribavirin (meaning that their hepatitis C viral load did not get much lower after 12 weeks of treatment, or was still detectable after 24 weeks of HCV treatment).

Duration of HCV Treatment

For people with HCV alone, the length of HCV treatment depends upon the genotype being treated: Most people who have genotype 1 and 4 need 48 weeks of treatment, but when people respond early (no detectable virus after 4 weeks of treatment, also called a "rapid viral response" or RVR for short), the duration of treatment may be able to be shortened. New oral HCV medications, once available, may shorten the duration of treatment needed.

Most treatment experienced people with HCV genotype 1 will need 36-48 weeks of re-treatment when they are using a new drug with pegylated interferon and ribavirin.

Since the first of the new HCV drugs are made to treat people with genotype 1, people who have genotype 2 and 3 will still be treated with pegylated interferon and ribavirin only, usually for 24 weeks.

The Early Stopping Rule

If a person does not have either a 99% drop in their HCV viral load or an undetectable HCV viral load after 12 weeks of treatment (called an *early virological response*, or EVR), the odds that they will be a sustained virological responder are very, very low. Usually, people discontinue HCV treatment if they do not have an EVR. But the new drugs will change this for some people. In clinical trials, boceprevir and telaprevir were used for different lengths of time, and each has its own stopping rule.

HCV RNA is also measured at different timepoints during HCV treatment (when a new drug is also used with pegylated interferon and ribavirin) to see if treatment is working. At the end of treatment, people with an undetectable HCV RNA are said to have an *end of treatment response*, or ETR. Unfortunately, not everyone with an ETR will also have an SVR; some people will have a relapse (when HCV is detectable in the blood after they have finished treatment).

Side Effects and Strategies for Managing Them

The side effects from HCV treatment can be pretty tough for many people. The good news is there are ways to lessen some of these side effects. It can be very helpful to talk with people who have been on HCV treatment. With the right planning and support, side effects can be managed. Center for Health Justice staff can offer advice on side effect management. Call the hotline collect at 213-229-0979.

Depression, Anxiety, And Other Psychiatric Side Effects

Depression and anxiety are common side effects from interferon. In rare cares, people on interferon report that they have felt like taking their own lives and a few people have committed suicide during their HCV treatment. It's important to have your mental health evaluated before starting treatment and to have access to on-going mental health care so that depression and anxiety can be treated if they become a problem.

Some experts think that starting an anti-depressant before going on HCV treatment can help to prevent depression from interferon, while others think it is better to provide anti-depressants if and when people need

them. Irritability, insomnia, mania and mood swings are also possible side effects of interferon. These side effects can be treated with mood stabilizers and sleeping aids. Support from peers, friends, and family before and during HCV treatment plays a key role in coping with these side effects.

Flu-Like Symptoms

Flu-like symptoms (fever, aches and pains, headache, chills, nausea) are common side effects of interferon. Taking the pegylated interferon shot in the evening helps, as does a low dose of a common pain reliever and an anti-nausea medication. Drinking lots of water helps too.

Weight loss often happens during HCV treatment, because people may lose their appetite. If possible, eating many small, light meals may help. Fatigue is also common; napping and regular exercise, when possible, can help.

Anemia, Neutropenia and Thrombocytopenia

Anemia (an abnormally low red blood cell count) is a common side effect of ribavirin — and pegylated interferon can also cause anemia because it suppresses the growth of bone marrow, where blood cells develop). Hepatitic C protease inhibitors also cause anemia. If anemia develops, people often feel very tired. Anemia can be dangerous if untreated.

There are two ways to treat the anemia that ribavirin causes. One strategy is to lower the dose of ribavirin, but HCV treatment may not work as well with a lower dose of ribavirin. The other is to treat anemia with injections of a red cell growth factor called epogen. Unfortunately, epogen is expensive and also has its own sometimes serious side effects.

Severe anemia is treated by blood transfusions, but this can be avoided if people are monitored and either reduce their dose or start red cell growth factor if anemia develops during HCV treatment.

Neutropenia is an abnormally low amount of white blood cells called neutrophils that fight bacterial infections. Pegylated interferon can cause neutropenia. The risk of developing bacterial infections is increased in people with neutropeina. If the neutrophil count drops too low during HCV treatment, the dose of pegylated interferon is reduced, or neutropenia

is treated with injections of white cell growth factor called neupogen. Neupogen is expensive and causes additional side effects.

Thrombocytes are platelets that help stop bleeding by clotting blood. Thormbocytopenia, or low platelet count, can be caused by serious liver damage (because platelets are made in the liver). It can also be caused by other medical conditions, and by pegylated interferon.

Severe thrombocytopenia can be life-threatening. If thrombocytopenia develops during HCV treatment, treatment is usually discontinued.

Rash

Ribavirin can cause rash and itchy skin, as can telaprevir, one of the new HCV protease inhibitors. Your doctor can recommend the best way to manage this side effect, depending on how serious it is and which drug or drugs you are using.

Balancing Pros And Cons Of Treating HCV

Making a HCV treatment decision can be complicated. There are many factors to take into account:

- Quality of life improves in people who have been cured, but may go down during HCV treatment
- Not everyone needs to be treated for their HCV infection
- Side effects may be intense
- HCV treatment doesn't have the same level of success for everyone
- Newer therapies are in currently in development, and HCV treatment will continue to improve

However, some people really need HCV treatment ***now***. It may be a bridge until better treatments are available.

Concerns for People in Recovery

Many people fear that they will relapse into active drug use because of the way HCV treament makes them feel. The risk of relapse is lower when

side effects are managed and people get good counseling and support from peers and medical and mental health providers. Unfortunately, this support may not always be available in prison or jail. Try to find a buddy who can provide support inside.

New Drugs for HCV

Many new treatments for HCV are being researched and some may be available by the middle of 2011. Many others are in development. Researchers are trying to cure hepatitis C without interferon, but nobody knows if this will work yet, since it takes several years for many new treatments to be tested. For now, the new HCV drugs will probably need to be used as part of combination therapy, including interferon and perhaps ribavirin. So, pegylated interferon will continue to be part of HCV treatment for years to come, but new, more effective therapies are in development, and these may shorten the length of hepatitis C treatment and increase cure rates. Waiting for better treatments may be a good option for people who don't need treatment now.

HCV Treatment and Pregnancy

Interferon therapy should be discontinued during pregnancy since the effect on the fetus is unknown. There have not been sufficient studies or information to determine the risk to the baby.

Women should not become pregnant while on Rebetron (interferon and ribavirin combination therapy). It is recommended by the manufacturer that a woman of childbearing age use effective contraception during treatment and for 6 months after treatment ends, because of the high risk for birth defects in the fetus. Mothers taking Rebetron medication should not breast feed because of the potential for an adverse reaction from the drug in their infant.

What About HCV/HIV Co-Infection?

HIV and HCV

When someone is infected with both HIV (Human Immunodeficiency Virus) and HCV, this is called co-infection. HCV is considered to be an

opportunistic infection of HIV disease, and HCV is known to progress more rapidly in people co-infected with HIV than in those with HCV alone.

Overall, about 25 to 30% of HIV-positive people in the U.S. are co-infected with HCV. HCV is more common among people who got HIV from injection drug use; 50 to 90% are co-infected with HIV and HCV. HIV/HCV coinfection is also very common among people with a blood clotting disorder called hemophilia who were treated with blood clotting factors before 1987.

Co-infected people with a CD4 T cell count below 200 are at greater risk for serious liver damage than people with higher CD4 counts. End-stage liver disease from HCV is now a leading cause of death among HIV-positive people in the U.S. This is partly because people are now living longer because of HIV treatment. Before highly-active antiretroviral therapy (HAART), most HIV-positive people did not live long enough to develop serious liver damage. However, it is possible to treat HCV in both HIV-negative and HIV-positive people.

HIV medications may help keep the liver in good condition by keeping the immune system strong. But a damaged liver may be less able to break down medications and most HIV meds are processed and broken down by the liver. Co-infected people are at higher risk for hepatotoxicity (liver toxicity) from HIV meds than people with HIV alone. Sometimes HIV drugs need to be switched or stopped. However, many studies in HIV/HCV co-infected people have shown that the benefits of HIV treatment outweigh the risks.

HCV Antibody Testing in HIV-Positive People

Some HIV-positive people with weak immune systems may not be able to make HCV antibodies, even though they have chronic HCV. So, HCV RNA testing is recommended for HIV-positive people, even if their HCV antibody test is negative. And when:

- They have been at risk for HCV
- They have signs (elevated liver enzymes) and/or hepatitis symptoms
- They have had a recent exposure to HCV

HIV/HCV Coinfection and HCV Viral Load

The HCV viral load is ***different*** than HIV viral load — since HCV is a smaller virus than HIV, and it reproduces more quickly, there is more of it in the bloodstream. Co-infected people usually have higher HCV viral loads than people with HCV alone. The HCV viral load does not predict liver disease progression, nor is it related to the amount of liver damage a person has, regardless of his/her HIV status.

Unlike HIV, a high HCV viral load does not necessarily mean that someone needs HCV treatment — but it does mean that HCV treatment is less likely to clear the virus.

HIV/HCV Coinfection, Liver Enzyme Levels and HCV Viral Load

HCV viral load test results and liver enzyme levels can be confusing, especially for HIV-positive people, since they are used to using CD4 T cell counts and HIV viral load test results to predict and monitor HIV progression. Sometimes HIV/HCV co-infected people have normal liver enzyme levels, but they may still have liver damage. Neither of these two tests can tell a person how much liver damage he or she may have, or what the risk of developing serious liver damage in the future is.

Many HIV+ people who are on treatment have elevated liver enzyme levels, from their HIV drugs. Regular monitoring of liver enzyme levels is important for co-infected people taking HIV meds.

HIV/HCV Coinfection and HCV Treatment

- HCV treatment is less effective for co-infected people than those with HCV alone.
- Co-infected people who have genotype 1 and a high HCV viral load are less likely to respond to HCV treatment.
- Co-infected people are usually treated for 48 weeks, regardless of genotype.
- HCV treatment can be effective for people with less than 200 CD4 cells, if they are on stable HIV therapy, although the side effects may be worse.

Response to HCV Treatment, By Genotype (Data from Three Clinical Trials)

	% SVR
Overall	27% to 40%
HCV genotype 1	14% to 29%
HCV genotype 2 and 3	Up to 73%

HCV treatment has improved the condition of the liver in some co-infected people, even those who did not get rid of the virus after treatment. Treating HCV may make it easier for co-infected people to tolerate their HIV meds.

The good news is that both new HCV drugs, boceprevir and telaprevir, are being studied in clinical trials with HIV/HCV coinfected people. Trials of other new HCV drugs should be underway soon in coinfected people.

The new HCV drugs may have interactions with HIV drugs, meaning that some cannot be used together. This is being studied in clinical trials. Since there are now many different HIV drugs to choose from, it is possible to put together a combination of HIV drugs that people can use while they are treating their HCV, although some people may need to switch their HIV meds.

Anemia, Neutropenia, Thrombocytopenia and HIV

HIV-positive people may have low white and/or red blood cell counts before starting HCV treatment, since neutropenia, anemia, and thrombocytopenia sometimes develop in persons with advanced HIV disease. Careful monitoring of white and red blood cell counts during HCV treatment is especially important for co-infected people.

HCV Treatment: Special Issues for HIV/HCV Co-Infected People

Two key issues for co-infected people are tolerating HCV therapy, and whether or not they can clear the virus. Side effects of HCV treatment are usually worse for co-infected people, and HCV treatment is less effective. But side effects can be managed, and HCV treatment may improve, stabilize or even slow down liver damage even in people who don't get rid of the virus, regardless of their HIV status.

HCV Treatment and CD4 Cell Count

During HCV treatment, the CD4 cell count — but not the percentage of CD4 cells — usually drops, even when people are on HIV meds. This is a known side effect of interferon. Clinical trials of HCV treatment in co-infected people did not report an increased risk of opportunistic infections during HCV treatment, and they found that CD4 cell counts usually returned to pre-treatment levels six months after stopping HCV treatment.

Drug Interactions: HIV Meds and HCV Treatment

Videx (ddI, didanosine), an HIV drug, should **NOT** be used by people on HCV treatment, because of a dangerous interaction with ribavirin. This combination can cause damage to the power plants inside of cells (called mitochondria). Damage to mitochondria can lead to a condition called lactic acidosis. Lactic acidosis happens when lactic acid builds up in the bloodstream to abnormally high levels. Although it can be treated if it is caught early, lactic acidosis can be fatal. Videx and ribavirin can also increase the risk for pancreatitis, and the risk of liver failure in people with advanced cirrhosis.

Anemia is a common problem among people living with HIV. AZT, an HIV medication, can also cause anemia. If possible, co-infected people should avoid taking retrovir (AZT) and ribavirin: both can cause anemia and combining them increases the risk. Combivir and trizivir both contain AZT.

If possible, avoid taking Zerit (stavudine; d4T) and ribavirin: some studies have found that this combination increases the risk of significant weight loss and lipoatrophy (an abnormal loss of fat).

Treatment Strategies

Which virus should be treated first, HIV or HCV? This depends on many factors, most importantly **willingness and readiness to treat one or both viruses.**

Also, new drugs are being developed that may make treatment more effective, and people may not need to stay on it for as long. This will figure into treatment decisions in the future.

Other things to consider include:

- The CD4 T cell count: if it is less than 200, treat HIV first; if already on HIV meds and HCV treatment is necessary, consider treating both.
- The condition of the liver: if damage is mild, plan to monitor it with a biopsy (for people with HCV alone, every 5 years, for HIV/HCV co-infected people, every 2-3 years). If liver damage is moderate or serious, consider HCV treatment.

Access to HCV education, testing, care and treatment is a problem for many co-infected people, even on the outside. Often, co-infected prisoners must wait until they have been released to begin HCV treatment, but hopefully this is beginning to change.

There are resources for co-infected people after their release. Medicaid programs and some State AIDS Drug Assistance Programs (ADAPs) cover HCV treatment, and some help is available through Patient Assistance Programs.

HIV, HCV and Pregnancy

The risk of mother-to-infant transmission of HCV is approximately 20% among co-infected mothers. Reducing the rate of mother-to-child transmission of HIV by treating pregnant women with antiviral therapy also reduces the risk of HCV transmission. Women who are pregnant should delay treatment of HCV until after delivery, as ribavirin can cause birth defects.

Information on Getting HCV Testing and Treatment

Across the U.S. and in other countries, advocates are fighting for access to HCV care and treatment in correctional facilities. Research has proven that HCV treatment is possible and effective for prisoners, but lack of access is still a major problem for prisoners with HCV and those who are co-infected.

Under recent changes in the law (California Penal Code Section 5008.2), you have the right to a ***free and confidential HCV test*** while you are incarcerated. This means that you can't be charged a co-pay (in prison)

if you ask for a HCV test. Your results will be kept private; only the medical staff and you should know if you're positive or negative with HCV. Take advantage of this opportunity! Knowing whether or not you have HCV is important. If you have trouble accessing HCV testing in prison, call Center for Health Justice. We can help.

While prisoners and advocates work towards access to HCV care and treatment, the focus must remain on the quality of care as well. Making treatment available without education, support, and management of side effects is not enough! If you are starting HCV treatment, or have questions about the material in this booklet, please contact Center for Health Justice staff, or write to one of the resources in the next section.

Resource Listing:

Center for Health Justice
900 Avila St. #301
Los Angeles, CA 90012
Hot line: 213-229-0979
(accepts collect calls from prisoners anywhere in the country)

Prisoners' Rights Project — The Legal Aid Society
Milton Zellermyer
199 Water Street
New York, NY 10038
Tel: 212-577-3530
Fax: 212-509-8433

Hepatitis C Support Project
PO Box 427037
San Francisco, CA 94142
Tel: 415-587-8908

Alliance For Inmates With AIDS
24 W. 25th St. 9th floor
New York, New York 10010
Tel: 212-675-3288
Fax: 212-675-3466

Hepatitis Prison Coalition
Michael Ninburg
911 Western Ave. #302
Seattle, WA 98104
Tel: 206-732-0311
Fax: 206-732-0312

National AIDS Treatment Advocacy Project (NATAP)
580 Broadway Suite 1010
New York, NY 10012
Tel: 212-219-0106
Tel: 888-26-NATAP (62827)
Fax: 212-219-8473

ACLU National Prison Project
Jackie Walker
915 15th St. Northwest
Washington, DC 20005
Tel: 202-393-4930

About Center for Health Justice

The mission of Center for Health Justice (CHJ) is to primarily advocate for HIV infected inmates, reduce the spread of diseases like HIV and HCV in prisons and jails, and reduce the recidivism rate for individuals infected or affected by these diseases. As a result of our work in HIV, we have identified that HCV is another important issue that needs to be addressed among the incarcerated and post-incarcerated populations we serve. CHJ was founded in 2000 to serve the unmet needs of California prisoners for HIV prevention information and treatment advocacy. CHJ currently offers a variety of programs to incarcerated persons including: HIV and HCV Treatment Education (both inside the L.A. County Jails, as well as for prisoners across the state via our inmate telephone hot line), Harm Reduction counseling and support, womens programs, peer educator training, re-entry assistance, and condom distribution inside L.A. County Men's Central Jail. A large portion of our staff at CHJ are persons who have been previously incarcerated in the past, and several are living with the diseases we talk about. It is our intention that prisoners in both county jail, state and Federal facilities will receive the treatment they deserve and return to their communities healthier, with greater knowledge of HIV (and HCV) treatment, prevention and risk-reduction.

For full information visit our web site at www.healthjustice.net.

Credits

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