

MANAGEMENT OF HEPATITIS C

This guideline describes departmental recommendations for the screening, evaluation, treatment, and monitoring of patients infected with hepatitis C virus (HCV). NOTE: All deadlines within this bulletin are mandatory.

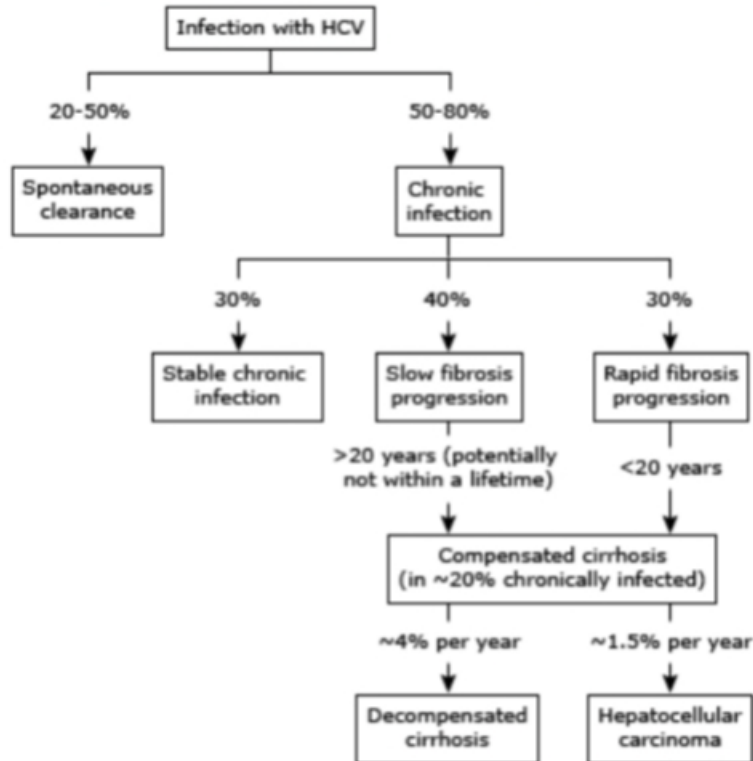
A. GENERAL INFORMATION REGARDING HEPATITIS C

1. Hepatitis C is a liver disease caused by the hepatitis C virus (HCV) which is found in the blood of persons who have this disease. HCV is spread by contact with the blood of an infected person.
2. Risk factors for infection may include, but are not limited to, injection drug use, transfusion with HCV-infected blood or blood products, tattooing, vertical transmission from mother to child, and massive exposure to HCV-infected blood during fighting or other trauma, being born between 1945 and 1965, previous incarceration, and HIV positive.
3. The average incubation period is six to nine weeks, with a range from two weeks to six months. Therefore, acute HCV infection usually is established within 3-6 months of the contact with the infected blood.
4. Those individuals who spontaneously clear hepatitis C usually do so within the first six months of being infected. Many patients have no symptoms of acute hepatitis.
5. Approximately 50-80% of individuals infected with hepatitis C will not spontaneously clear the virus. For them, the infection becomes chronic.
6. Chronic hepatitis C (sometimes abbreviated as “cHCV”) is characterized by the persistent presence of HCV-RNA detectable in blood/serum, i.e., the HCV viral load (HCV-VL). Those patients who are HCV-VL+ in the context of the correctional setting usually have chronic HCV disease.
7. The principal consequence of cHCV is infection of the liver, which causes inflammation that may, in turn, result in scarring of the liver, which is known as “fibrosis.” The amount of liver scarring a patient has is usually measured on the METAVIR scale. On this scale, a person can be classified as F0 (inflammation, but no fibrosis), F1 (mild fibrosis), F2 (moderate fibrosis), F3 (severe fibrosis), or F4 (cirrhosis).
8. Liver scarring can significantly impair liver function, and can place a patient at risk for several serious symptoms/complications, as well as liver failure or liver cancer.

9. For a depiction of the natural history of HCV, see Diagram 1, below.

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Natural history of hepatitis C virus



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B. THE PROGRESSION OF CHRONIC HEPATITIS

1. Progression of cHCV to fibrosis and cirrhosis may take years in some patients and decades in others, or, in some cases, may not occur at all. The rate at which patients progress along the METAVIR scale, and can progress toward serious symptoms/complications differs among the population, and can be influenced by a variety of factors.
2. Patients with cirrhosis may develop decompensated cirrhosis and/or hepatocellular carcinoma over time. Factors associated with rapid progression or death (less than 20 years from infection to cirrhosis) can include, but are not limited to, ALT elevation (especially if ALT>200, or “ALT flare”), active alcohol and drug abuse, grade 3 inflammation (Batts and Ludwig classification) on liver biopsy, presence of bridging fibrosis (Batts and Ludwig S3+/Metavir F3+) on liver biopsy, genotype 3 infection, HIV co-infection, HBV co-infection (those with HIV+HBV +HCV co-infection and detectable viremia of both HIV+HBV are at highest risk), hepatic steatosis and NASH,

diabetes and insulin resistance, obesity, daily use of marijuana, and uncontrolled underlying liver disease. HCV risk behaviors that occur 10 or more years prior to the cHCV diagnosis, the male gender, and whether an individual is age 40 or more at the time of infection, are also associated with a rapid progression, but are less significant in multivariate analysis.

3. The rapid accumulation of data since 2013 regarding hepatic fibrosis and progression to end stage liver disease (decompensated cirrhosis and hepatocellular carcinoma or primary liver cancer) has indicated that the risk for rapid progression within one year begins to be measurable when the patient reaches F2. There is an ~0.5% and ~1.0% one-year risk of progressing to hepatocellular carcinoma and decompensated cirrhosis, respectively, once the patient can be staged as F2 (Whether this is due to underestimation of the actual stage with present staging methods or represents very rapid progression of hepatic fibrosis is unknown). The best data continues to indicate that risks of progression in one year to hepatocellular carcinoma or decompensated cirrhosis in the patient with F3 and F4 fibrosis is 1%, 2% or 1.5-2%, 4%, respectively.
4. On the other hand, the factors associated with non-progression of hepatic fibrosis are not fully understood at this time, and may be less well-studied due to treatment bias. Non progression is more likely in patients with the following characteristics: female sex, age <40yrs, BMI<30, Batts and Ludwig inflammation Grade 0-1, Batts and Ludwig S0-1/Metavir F0-1, IL28B genotype (with C/C and C/T genotypes less likely to be associated with advanced hepatic fibrosis), and normal ALT ($\geq 75\%$ do not have advanced hepatic fibrosis). African-American race (slower progression/histology less severe in black patients), patients whose HCV risk behaviors have happened in the recent past (usually <5-10yrs), and those without an alcohol abuse history also have less risk.
5. The contribution of sobriety/cessation of injection drug use to slowing the progression of hepatic fibrosis is also highly significant in terms of positive lifestyle behaviors associated with improved quality and length of life, especially if the patient achieves a sustained viral response (SVR), which is considered to be a cure. Additionally, statin use has been associated with a lower progression rate, and coffee (caffeinated only) consumption has been demonstrated in both retrospective and prospective trials to be associated with reduced hepatic fibrosis.
6. For a depiction of the progression of cHCV, and priority for treatment, see Diagram 2, below.

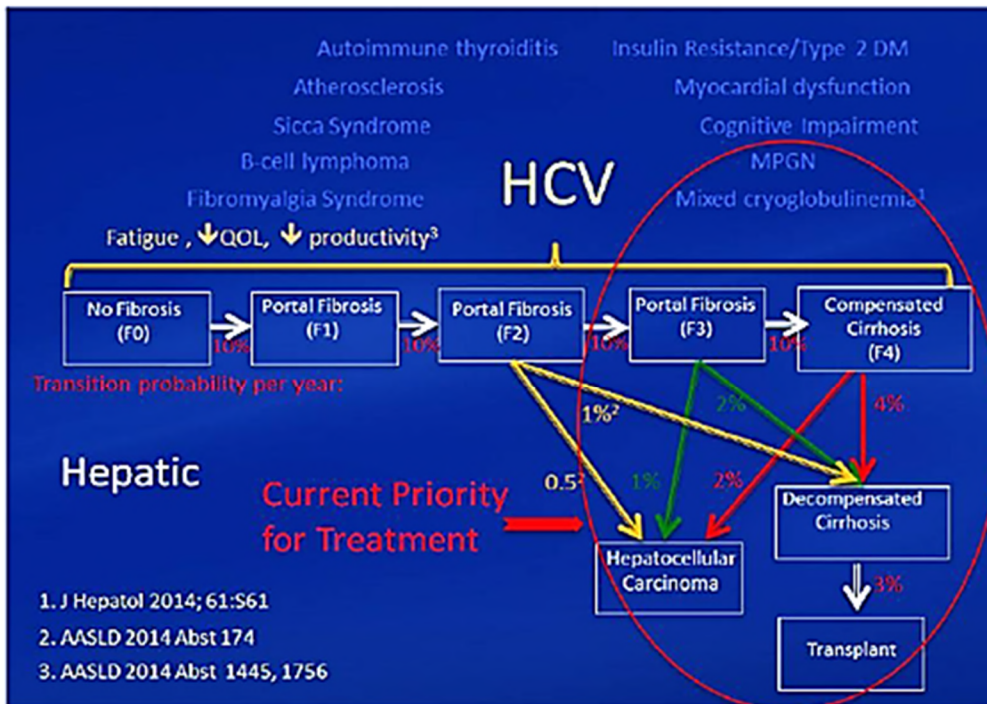


Diagram 2 attribution: Ken Benner, MD/Hepatology, Oregon Clinic, Portland, Oregon.

C. THE NEED FOR COMPREHENSIVE HCV TREATMENT, NOT JUST VIRAL ERADICATION

1. Identifying patients who need treatment sooner than others, and would benefit most, is a complex task requiring evaluation of multiple and diverse factors. The positive outcomes of increased survival and improved quality of life associated with successful viral eradication and a sustained viral response (SVR) are dependent upon sobriety and positive lifestyle change.¹
2. Patients have a responsibility to learn from past behaviors and interact with society positively. Evaluation and treatment of chronic health problems such as chronic HCV and substance abuse play a crucial role in patients establishing trust and developing healthy behaviors, thereby reducing their rates of substance abuse relapse and correctional recidivism.

¹ For example, a long-term Danish study demonstrated an 18.2-fold increased mortality risk among younger patients with chronic HCV that was not due to their liver disease but, instead, was due to unnatural death: i.e., mortality associated with untreated mental illness and substance abuse associated suicide, homicide, and trauma. Liver related mortality only becomes more prevalent as the population ages. Therefore, sobriety is key to an overall harm reduction. (Clin Gastro and Hepatology 2011; 9:71-78).

3. The benefits of evaluation and treatment of cHCV go beyond the immediate goal of viral eradication in the individual. cHCV treatment is one part of a multi-part strategy to promote healthy lifestyles, which in turn benefits the patient, his/her family, and society.
4. Any patients interested in cHCV evaluation should understand that further laboratory testing, liver biopsy, imaging, or another method for staging hepatic fibrosis may be required prior to and during therapy. The risk and side effects of evaluation, the proposed treatment regimen and the need for monitoring must be fully discussed with the patients.
5. If there is reasonable documented concern about a patient's ability to adhere to and benefit from a standardized treatment regimen, and these concerns are not able to be resolved through a cooperative treatment plan, treatment should not be initiated. Patients will be re-evaluated for treatment compliance in accordance with their Gastrointestinal Clinic (GC) scheduling.
6. Behavioral risk reduction and substance abuse counseling is an integral part of cHCV treatment. The use of peer educators has been shown to potentially have the greatest impact in this area. Patients should have pro-sobriety attitudes assessed and documented in the medical record. Patients with high propensity for relapse may need more extended time periods of sobriety prior to treatment as deemed appropriate by the clinical care committee or equivalent. Unfortunately, there is no evidence at this time that institutionally-mandated substance abuse programs improve outcomes over incarceration alone. However, patient-driven substance abuse treatment such as Narcotics Anonymous or Alcoholics Anonymous groups with peer educators and sponsors have demonstrated improved outcomes and decreased substance abuse relapse rates post-release. Patients should be encouraged to participate in these programs.

D. EDUCATION FOR NEWLY INCARCERATED INMATES REGARDING HCV

All newly incarcerated patients should be provided with educational information regarding prevention, transmission, risk factors, and screening of HCV.

E. MONITORING OR TREATMENT FOR ACUTE HEPATITIS

1. HCV-VL shall be monitored at 6 months after the date of first diagnosis. If viremia persists after that time, continue to monitor and manage the case as a chronic infection.
2. In some cases when acute HCV infection superimposes on patients with established cirrhosis or advanced fibrosis, there may be a compelling reason to treat the acute infection as a chronic infection in order to prevent severe complications.

F. SCREENING OF PATIENTS FOR THE PRESENCE OF cHCV, AND THE AMOUNT OF FIBROSIS

Screening for cHCV will be offered to all patients, regardless of risk factors, at multiple opportunities throughout incarceration. Patients may request screening as well. Screening should include the following components:

1. The preferred screening test for HCV infection is an immunoassay that detects the presence of antibodies to HCV antigens (referred to as HCV-Ab, or Anti-HCV).
2. If there is the presence of HCV-Ab, the specimen should be automatically analyzed for HCV-RNA (the HCV viral load, or HCV-VL) to immediately establish the presence or absence of active HCV. Patients must be evaluated and staged within 30 days of confirming they have chronic HCV, using the Fibrosure test.
3. HCV-VL+ patients who have been diagnosed with chronic HCV will be reviewed and a liver/spleen ultrasound provided within 90 days to rule out the presence of portal hypertension (indicative of advanced hepatic fibrosis). If a patient needs to be restaged as a result of an ultrasound, the restaging must take place within 5 business days of receiving the ultrasound results.
4. Elastography may be utilized for additional staging when clinically indicated, and it will be required under the conditions outlined below.
 - a. If a patient is staged F0 or F1 (Priority Level 3) using the Fibrosure Test and the Abdominal Ultrasound report indicates Splenomegaly, the medical provider will evaluate the patient to rule out any other possible cause of Splenomegaly that is not related to the Hepatitis C. If based on the patient's evaluation and provider's clinical judgment there is no other medical condition that could be causing his Splenomegaly but Hepatitis C, the patient will be restaged using Elastography within the following time frames:
 - i. The elastography will be performed within 90 days of receiving the ultrasound report indicating Splenomegaly.
 - ii. Re-staging will occur within 30 days of receiving the elastography report if the results indicate a higher stage.
 - b. Elastography will be used to restage patients whose Fibrosure results indicate F1-F2 who are not ineligible for treatment if they have not already been provided DAA treatment, been approved for DAA treatment, cleared the Hepatitis C virus without treatment, or refused evaluation or treatment for Hepatitis C. Time frames are as follows:

- i. Elastography will be performed within the later of 90 days after receiving the Fibrosure result indicating F1-F2 or 180 days after the date of this HSB revision.
 - ii. Re-staging will occur within 30 days of receiving the elastography report if the results indicate a higher stage.
5. Staff have discretion to restage a patient sooner than scheduled if determined appropriate.
6. Staff must rely on the test, exam, or study indicating the highest fibrosis level for staging.

G. EDUCATION OF PATIENTS WHO ARE FOUND TO BE INFECTED WITH cHCV

Once patients are found to be infected with cHCV, they should be counseled by a clinician during the initial visit regarding the natural history of the infection, measures to assess the progress of cHCV, potential treatment options, and specific measures to prevent transmitting the HCV infection to others.

H. EVALUATION AND MONITORING IN THE GASTROINTESTINAL CLINIC

1. The following patients will be enrolled in the Gastrointestinal Clinic (“GC”) for evaluation and monitoring: (a) those with active cHCV who are not being treated with direct-acting antiviral (DAA) medication, (b) those currently being treated with DAAs (c) those who have had HCV treatment failure, and (d) those who have had a relapse of HCV infection or reinfection.
2. In the GC clinic, the patient will receive the following: (a) a baseline history and physical examination; (b) labs and other tests (see below), including a proprietary predictive index, if not previously provided, and an abdominal ultrasound, if not previously provided; (c) an assessment and discussion with the patient of the results of the proprietary predictive index and abdominal ultrasound; (d) an evaluation and assessment of the need for preventive health interventions such as vaccines and screenings for other conditions; and (e) counseling on cHCV infection.
3. Patients who are fibrosis stage 4 (F4), or stage 3 (F3) shall be seen every six (6) months or sooner, if indicated, shall receive laboratory testing every 3-6 months, and shall receive an abdominal ultrasound for hepatocellular carcinoma (HCC) surveillance every six (6) months.
4. Patients who are fibrosis stage 2 (F2), stage 1 (F1) or stage 0 (F0) shall be seen every six (6) months, and shall receive laboratory testing every six (6) months, and the proprietary predictive indices and/or elastography every twelve (12) months.
5. Each patient’s fibrosis stage will be recorded as F0-F4. If available, the patient’s Child-Turcotte-Pugh score will be recorded as well. In particular, consider the following:

(a) The history and physical examination: Focus on signs and symptoms of liver disease, prior alcohol consumption, and risk behaviors for acquiring HCV infection. Based on this information and the period in which the patient engaged in injection drug use or other risk behaviors, attempt to estimate earliest possible date of infection. Evaluate for other possible causes of liver disease, including alcoholism, non-alcoholic steatohepatitis (NASH), iron overload (hemochromatosis), and auto-immune hepatitis. Inquire about prior treatment for HCV infection, specific medications used, dosages and duration of treatment, and outcomes, if known.

(b) Laboratory and Other tests:

- (1) This will include a complete blood count (CBC); Prothrombin time (PT) with International Normalization Ratio (INR); urinalysis (UA); and a comprehensive metabolic panel (CMP). The initial evaluation of cHCV will also include a HCV genotype.
- (2) Laboratory testing consistent with cirrhosis may include elevated bilirubin, decreased albumin, and prolonged INR, but these tests are only used to quantify cirrhosis. Use of predictive indices uses laboratory markers to predict the state of hepatic fibrosis.
- (3) Elastography methods (using either ultrasound or MRI) may be critical in determining the fibrosis stage. Imaging studies may also identify cirrhosis, and not require further staging.²
- (4) A liver biopsy is no longer required unless otherwise clinically indicated.
- (5) Abdominal imaging studies such as ultrasound or CT scan may identify findings consistent with or suggestive of cirrhosis, portal hypertension or hepatocellular carcinoma (HCC).

CTP calculators are available at: <https://www.hepatitisc.uw.edu/page/clinical-calculators/ctp>

(c) Screening for other conditions: There should be screening for the Hepatitis A antibody (HAV-Ab), and the Hepatitis B surface antigen (HBsAg), unless these were already known from a prior Hepatitis Panel, and also testing for the HIV antibody (HIV- Ab). If risky behavior occurred after previously negative testing, repeat the testing. An anti-nuclear antibody (ANA) and ferritin should be ordered as screening for auto-immune hepatitis and hepatic iron overload.

² A recent review of the use of liver imaging and biopsy in clinical practice (Use of Liver Imaging and Biopsy in Clinical Practice; Tapper EB and S.-F. Lok, NEJM 377:8:756-768) indicates that present non-invasive elastography modalities have been shown to be reliable in detecting advanced hepatic fibrosis, are cheaper, easily repeated for serial monitoring, and thus long-term outcomes may be accurately predicted.

- (d) **Counseling:** Patients should be counseled regarding the progression of cHCV, the staging of treatment with direct acting antiviral medication (DAAs), other potential treatment options, the availability of peer-to-peer counseling, and specific measures to prevent transmitting HCV infection to others.

I. PRIORITIZATION FOR TREATMENT WITH DAAs

1. Although many patients with chronic HCV infection may benefit from treatment with direct-acting antiviral medication (DAAs), certain cases are at higher risk for complications or disease progression and require more urgent consideration.
2. Eligibility for DAA treatment should be established via concordance between laboratory, imaging (abdominal ultrasound, and elastography if available), and predictive scoring (proprietary indices). Resource challenged systems may use the combination of proprietary indices and abdominal ultrasound to assess for the presence of F2-F4 hepatic fibrosis.
3. Within the eligible group of patients, the following priority criteria have been established to ensure that those with the greatest need are treated first.
4. The treatment deadlines outlined below run from the date the patient is staged at a particular fibrosis level.

(a) **PRIORITY LEVEL 1 - Highest Priority for Evaluation and Treatment**
The following individuals should receive DAA treatment within 0-6 months
(subject to paragraph J, below):

- (1) Fibrosis Stage 4, decompensated cirrhosis, including both symptomatic patients (e.g., with ascites, hepatic encephalopathy, esophageal varices, etc.) and asymptomatic patients with CTP scores greater than or equal to 7.
- (2) Fibrosis Stage 4, compensated cirrhosis, with CTP scores greater than 5 and less than 7.
- (3) Fibrosure results indicating F3-F4.
- (4) Liver transplant candidates or recipients in consultation with and co-managed by a transplant hepatologist.
- (5) Hepatocellular carcinoma in consultation with a hepatologist for correct timing.
- (6) Comorbid medical conditions associated with HCV, including cryoglobulinemia with renal disease or vasculitis, certain types of lymphomas, hematologic malignancies or metabolic abnormalities.

- (7) Continuity of care for those entering custody already on treatment.
- (8) Patients taking immunosuppressant medications for a comorbid medical condition which may cause rapid progression of hepatic fibrosis.
- (9) HIV co-infection.
- (10) HBV co-infection.

**(b) PRIORITY LEVEL 2 - Intermediate Priority for Evaluation and Treatment
The following individuals should receive DAA treatment within 12 months
(subject to paragraph J, below):**

- (1) Fibrosis stage 3 (F3)
- (2) Fibrosis stage 2 (F2).
- (3) Comorbid liver disease (e.g., autoimmune hepatitis, hemochromatosis, steatohepatitis).
- (4) Chronic Kidney Disease with proteinuria.
- (5) Diabetes Mellitus
- (6) Patients previously staged as F0, but who advanced in staging to F1 within 1-4 years are considered to have progressive hepatic fibrosis, and should be treated in this priority group.

(c) PRIORITY LEVEL 3 – Active Monitoring for DAA Treatment

The following individuals should be monitored regularly with labs and proprietary predictive indices for re-staging at least annually into a higher priority level:

- (1) Fibrosis stage 1 (F1).
- (2) Fibrosis stage 0 (F0).

J. OTHER CRITERIA TO BE CONSIDERED BEFORE TREATMENT WITH DIRECT-ACTING ANTIVIRAL MEDICATION

- 1. In addition to meeting the above criteria for Priority Level 1 and Priority Level 2, patients being considered for treatment of cHCV infection should 1) have no

contraindications to, or significant drug interactions with, any component of the treatment regimen, 2) have sufficient time remaining on their sentence in the Department of Corrections to complete a course of treatment (lasting between 8-24 weeks), 3) have a life expectancy sufficient to achieve benefit from HCV viral eradication, and 4) demonstrate willingness and an ability to adhere to a rigorous treatment regimen and to abstain from high risk behaviors while incarcerated.

2. A cHCV patient's attitude, functional ability to thrive within the system, and optimal treatment of mental health issues are critical for good outcomes. Patients who have chronic disciplinary issues within the system have very high substance abuse relapse rates upon release, with newer evidence indicating higher re-infection rates. Patients should be counseled and observed on a case-by-case basis, and involvement of mental health professionals is critical. It is also critical to remember that patients who have chronic behavioral management issues, common in jails/prisons, are rarely able to establish and maintain a therapeutic provider-patient relationship which results in completion of treatment. Chronic disciplinary issues in and of themselves are not sufficient to render an inmate ineligible for treatment; rather, treatment may only be delayed for medical issues. High risk behaviors only warrant a delay if there is a medical reason to delay treatment with corroborating documentation filed in the medical record. This delay will be a temporary ineligibility, not a permanent exclusion.

K. RECOMMENDED TREATMENT REGIMENS

1. Recommendations for HCV treatment regimens continue to evolve, and are changing rapidly as new agents become available and as evidence of the most effective ways to utilize the DAAs accumulates. Usually 8-12 week regimens are preferred due to improved adherence, lower toxicity, and cost-effectiveness.
2. The AASLD/IDSA/IAS³ website, which is found at hcvguidelines.org, presents reliable summaries of drug treatment data and should be used to direct most treatment.
3. Expert consultation is required in patients eligible for liver transplantation.
4. Treatment of chronic HCV during pregnancy is presently not recommended due to the lack of safety data.

L. TREATMENT FAILURE FOLLOWING DAA TREATMENT

³ AASLD (American Association for the Study of Liver Diseases); IDSA (Infectious Diseases Society of America); IAS (International Aids Society)

1. Treatment failure is defined as a detectable HCV-VL 12 weeks following completion of therapy.
2. If the HCV-VL is <50 copies/ml or in the “non-quantifiable” range then the test should be repeated in 4 weeks as this situation usually represents lab error or very slow clearance of virus; the repeat testing will usually be “not detected.”
3. In the case of true failure, the medical record should be reviewed for non-adherence, system failure in drug administration (e.g., omissions in directly observed therapy, not providing refills on time, etc.), possible drug-drug interactions, and the patient should be interviewed for illicit drug use and the ingestion of other acid-lowering medications or supplements.
4. If no interfering risk factors are identified, the possibility of viral mutation causing drug resistance (Resistance-Associated Substitutions) should be considered.
5. Further resistance testing and a secondary treatment regimen should be selected according to the principle and treatment recommendations contained in hcvguidelines.org.

M. TREATMENT MONITORING

1. The patient will have an outpatient clinic visit at 2-4 weeks after starting therapy in order to establish adherence to the prescribed regimen, and assess for side effects and the need for treatment modification. DAA regimens usually do not require routine lab monitoring, unless clinical symptoms of increased fatigue or other side effects occur.
2. A CBC and comprehensive metabolic panel (CMP) equivalent may be drawn at 4 weeks to rule out transaminase elevation due to autoimmune hepatitis or HBV reactivation. The CMP may also be used to reassure the patient that there is evidence of efficacy and encourage further adherence and program compliance.
3. Progressive increases in the ALT may require more frequent monitoring or early discontinuation.
4. For regimens containing RIBAVIRIN: a CBC and CMP should also be drawn 2 weeks after starting therapy, then at 4 weeks, then monthly or more frequently as clinically indicated. A Ribavirin dosage adjustment may be required. Mild (1-3x upper limit of normal) elevation of the total bilirubin may be expected as a consequence of Ribavirin-induced oxidative stress and RBC Lysis. Pregnancy testing is required prior to treatment with ribavirin-containing regimen, and thereafter as risk behavior for pregnancy occurs.

N. POST-TREATMENT MONITORING

1. A post-treatment quantitative HCV-VL assessment will be drawn no earlier than 12 weeks after completion of treatment; and if HCV is undetectable, that defines a sustained viral response (SVR).
2. The following patients who sustain an SVR will remain in the Gastrointestinal Clinic (GC) in order to monitor for cirrhosis, complications or related comorbidities (based on highest pre-treatment F-score): F4 and F3 for continued monitoring of cirrhosis and HCCA surveillance; F2 with co-morbid medical conditions associated with HCV, including cryoglobulinemia with renal disease or vasculitis, certain types of lymphomas, hematologic malignancies or metabolic abnormalities. Co-HIV infection or co-HBV infection.

O. OTHER HEALTH CARE INTERVENTION RECOMMENDED FOR CIRRHOSIS

1. All patients with cirrhosis shall have additional consultative co-management as follows:
 - (a) At first identification of a F4 diagnosis the Platelet/Spleen diameter ratio shall be computed (example: $112,000/131 \text{ (mm)} = 855$). All patients with values <905 shall be referred for EGD for diagnosis of esophageal varices. If varices are present, non-selective beta-blockers to prevent variceal bleeding shall be initiated if not contraindicated. Alternatively, some selected patients may require banding of varices; however, beta-blocker prophylaxis is preferred and recommended in accordance with AASLD recommendations.
 - (b) Patients with decompensated cirrhosis shall be co-managed by a gastroenterologist or hepatologist. Decisions for co-management including ongoing variceal surveillance, antibiotic prophylaxis if risk factors are present for spontaneous bacterial peritonitis, optimized diuretic therapy for ascites, and optimized therapy for hepatic encephalopathy shall be addressed during the consultation.
2. In general, aspirin and NSAIDs should be avoided in advanced liver disease/cirrhosis and METFORMIN should be avoided in decompensated cirrhosis. Other resources should be consulted for more specific recommendations related to management of cirrhosis.

P. REFERRAL FOR LIVER TRANSPLANTS FOR PATIENTS WITH DECOMPENSATED CIRRHOSIS

1. All patients with decompensated cirrhosis who have any of the following triggering events will be referred to a Florida liver transplant center for evaluation in accordance with that center's criteria and procedures.
 - a. A MELD score of 15 or higher
 - b. A diagnosis of hepatocellular carcinoma (HCC)
 - c. Decompensation, defined as the presence of encephalopathy, ascites, esophageal varices, or jaundice.

2. Referrals must be initiated within 30 days of any one of the triggering events.
3. Thereafter, co-management as directed by the transplant center will be instituted if the patient is listed for transplant. The Department must promptly comply with the transplant center's request for records and other information and promptly transport an inmate to and from the transplant center.
4. Patients have been staged to receive DAA medication, are currently receiving DAA treatment, or who have finished DAA treatment, a referral must be made only if the post-treatment MELD score is over 15.

Q. HCV TREATMENT APPROVAL PROCESS

Treatment of all genotypes will be coordinated through the Regional Medical Director and if applicable, the Hepatitis C Program Director in order to determine site and mode of therapy. Patients previously unsuccessfully treated may be considered for treatment on a case by case basis.

R. REQUIRED DOCUMENTATION AND DATA ENTRY

In accordance with HSB [15.03.05 Appendix #8](#), patients with chronic liver disease should be enrolled in Gastrointestinal Clinic (GC) with baseline information completed prior to start of treatment using [DC4-770GG](#) *Gastrointestinal Baseline History and Procedures*.

Documentation of evaluation of treatment should be entered on form [DC4-701F](#) *Chronic Illness Clinic*. The encounter should be entered in the OFFENDER-BASED INFORMATION SYSTEM (OBIS) as a GC appointment using the appropriate diagnosis code as shown below.

1. GH08 – Front Page. Add the following codes as determined:
 - (a) **For Acute Hepatitis C** - use ICD-10-CM Diagnosis Code **B17.1**
(**Note:** Per Section E.1. above, if viremia persists at 6 months after the date of first diagnosis, continue to monitor and manage the case as a chronic infection. This requires a change in OBIS code in accordance with R.1.b. If viremia does not persist at 6 months, remove code B17.1, but continue to monitor for other health issues.)
 - (b) **For Chronic viral Hepatitis C** – use ICD-10-CM Diagnosis Code **B18.2**
2. GH08 – back page. Add the following action codes on the GH08 Back page (contact screen):

- (a) **DAA** = HepC Tx Started
 - 1. Enter start date – Required Field
- (b) **DAAx** = HepC Tx Discontinued
 - 1. Enter end date – Required Field **AND**
 - 2. Requires remarks (i.e., 12 weeks completed; inmate non-compliant, inmate refused, etc.)
- (c) **SVR** = Sustained Virologic Response Achieved
 - 1. Enter date – Required Field

S. EDUCATION FOR PATIENTS WHO REFUSE STAGING, TREATMENT, OR ARE NON-COMPLIANT WITH TREATMENT

Any patient who refuses Hepatitis C related treatment including but not limited to diagnostic testing, staging, medication, or monitoring will be required to sign a DC4-711A, Refusal of Health Care Services form. The patient will receive counseling on the following prior to signing the form:

- Risk factors for contracting Hepatitis C
- Symptoms of Hepatitis C
- Methods of diagnosing Hepatitis C
- Complications and consequences of Hepatitis C
- Treatment, availability, lack of side effects, and efficacy of new of Hepatitis C medications
- Whether and when they could receive treatment if they did not refuse.
- Factors considered in decision to treat and the staging process for Hepatitis C

Patients who refuse medication that has already been started will be counseled by the regional infectious disease case manager or clinician. Patients will be counseled on the next business day after missing 2 consecutive doses or 5 total doses over the course of one month and Clinicians will determine if treatment will continue after patient counselling.

Patients who refuse initial diagnostic testing will be counseled at subsequent routine periodic screening (PE) encounters and chronic illness clinics, if indicated. Patients who refuse treatment after the confirmation of diagnosis will be counseled at all Gastro Clinic visits. This education will be documented on the applicable form for the visit.