

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION**

CARL HOFFER, et al.,

Plaintiffs,

v.

Case No. 4:17cv214-MW/CAS

**JULIE L. JONES, in her official
capacity as Secretary of the
Florida Department of
Corrections,**

Defendant.

_____ /

ORDER ENTERING A PRELIMINARY INJUNCTION

This Court previously granted Plaintiffs' motion for a preliminary injunction as to the treatment being provided by the Florida Department of Corrections ("FDC") to inmates infected with the Hepatitis C virus ("HCV"). ECF No. 153. In doing so, however, this Court noted that it was "only providing overarching guidance of how it believes FDC should address HCV treatment going forward." *Id.* at 31. This Court did that because Defendant specifically requested to "prepare a plan in light of this Court's directions" before this Court entered a preliminary injunction. *Id.*

Since then, Defendant filed her proposed plan. ECF No. 175. This Court noted a number of deficiencies with Defendant's plan and asked the parties to provide comments in light of this Court's findings. ECF No. 178. The parties have now filed their comments. ECF No. 180;¹ ECF No. 181.² Having considered the parties' comments, and in light of this Court's findings in its order granting Plaintiffs' motion for a preliminary injunction, this Court orders Defendant to comply with her plan with some modifications.

¹ Plaintiffs identified several shortcomings with Defendant's plan. Some of those shortcomings need to be fixed, and are accordingly addressed in this injunction. Other alleged shortcomings (such as Plaintiffs' concern for the "vague" standards that make an inmate ineligible for treatment) need not be addressed at this stage. This Court may revisit those issues at the conclusion of the case or upon a motion for modification. Indeed, "[n]othing prevents the plaintiffs from seeking further relief from the district court if [defendant] fail[s] to comply in good faith with the requirements of the injunction and the applicable federal standards." *Ga. Ass'n of Retarded Citizens v. McDaniel*, 716 F.2d 1565, 1581 (11th Cir. 1983), *vacated on other grounds by Bd. of Pub. Educ. for City of Savannah & Cty. of Chatham v. Ga. Ass'n of Retarded Citizens*, 468 U.S. 1213 (1984). Moreover, it should be obvious that FDC may not circumvent this Court's injunction by attempting to do indirectly what it may not do directly. *Cf. Feikema v. Texaco, Inc.*, 16 F.3d 1408, 1419 (4th Cir. 1994) (Murnaghan, J., concurring) ("[W]e would not allow the plaintiffs to gain indirectly . . . what we have expressly prevented them from gaining directly through an injunction . . ."). In other words, this Court does not expect FDC to avoid its obligation to treat inmates by unjustifiably finding inmates ineligible for treatment. This Court and Plaintiffs can be sure of this expectation because Defendant will be filing monthly status reports of FDC's progress. Like President Ronald Reagan, this Court will "trust, but verify."

² Defendant addressed some of this Court's concerns, but not all of them. In fact, Defendant created further concerns by stating that some of the deadlines she had promised to comply with in her plan were "potentially ambitious." ECF No. 181-1, at 5. To be clear, none of the dates in this injunction are "goals"—the dates are adopted as deadlines that must be complied with.

Accordingly,

IT IS ORDERED:

1. Defendant must ensure that FDC, FDC's employees, and FDC's contractors comply with Defendant's Plan of Treatment for Chronic Hepatitis C, ECF No. 175-1, (attached as Exhibit A to this order)³ as modified below:

³ The Federal Rules of Civil Procedure provide that “[e]very order granting an injunction . . . must . . . describe in reasonable detail—and *not by referring to the complaint or other document*—the act or acts restrained or required.” Fed. R. Civ. P. 65(d)(1)(C) (emphasis added). As some have recognized,

[e]ven though the express language of Rule 65(d) appears to prohibit incorporation by reference, it is undesirable to . . . set out long and verbose findings that may be found in another document since the injunction or restraining order should furnish defendant with a direct and succinct statement of the acts that have been enjoined or the conduct that must be undertaken by the defendant.

11A CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE & PROCEDURE § 2955 (3d ed. & Apr. 2017 update). “Thus, some courts have looked to the purpose of the rule, which is to assure adequate notice to defendants of the act or acts prohibited, and have interpreted it less restrictively than the literal text of the rule might suggest is appropriate.” *Id.* See also, e.g., *California v. Campbell*, 138 F.3d 772, 783 (9th Cir. 1998); *United States v. Sarcona*, 457 F. App'x 811, 811–12 (11th Cir. 2012) (unpublished). Given that Defendant drafted her own plan, Defendant should have no qualms with this Court's incorporation of that plan. Cf. *Balla v. Idaho Bd. of Corr.*, No. CV81-1165-S-BLW, 2009 WL 1574454, at *5 (D. Idaho May 28, 2009) (“Here, Defendants drafted the plans that would govern their own actions, satisfying the notice requirement.”). If Defendant disagrees, then she is welcome to move this Court for modification and/or clarification of this injunction.

- a. FDC must initiate treatment for all known chronic HCV inmates, who are eligible for treatment, and who have fibrosis stage 3, by December 31, 2018.
- b. FDC must initiate treatment for all known chronic HCV inmates, who are eligible for treatment, and who have fibrosis stage 2, by December 31, 2018.
- c. FDC must evaluate and stage all of the ~7,500 inmates it knows have chronic HCV no later than April 30, 2018. For all other inmates, FDC must evaluate and stage inmates within 60 days of confirming that the inmates have chronic HCV.
- d. Of the ~7,500 inmates FDC knows have chronic HCV, FDC must stage and evaluate the 2,500 inmates who have the lowest albumin levels no later than February 28, 2018.⁴

⁴ This order is consistent with Dr. Dewsnup's recommendation in light of this Court's questioning at the preliminary-injunction hearing. ECF No. 158, at 176–79. Specifically, it will ensure that inmates with the most advanced liver disease are staged and evaluated first. *See id.* FDC might already be employing a similar methodology, but there is no indication (or guarantee) in FDC's plan that FDC is doing so. If Defendant has a different method in mind for identifying the inmates that should be evaluated and staged first, then Defendant is welcome to move this Court for a modification. Either way, evaluating and staging the worst 2,500 inmates (i.e., 1/3 of the ~7,500) by February 28 should not be an onerous task given that FDC already planned to evaluate all 7,500 by April 30.

2. Defendant must ensure that FDC, FDC's employees, and FDC's contractors comply with FDC's HCV-treatment policy, HSB 15.03.09 Supplement #3,⁵ as it is revised.
3. Defendant must ensure that FDC's HCV-treatment policy, HSB 15.03.09 Supplement #3, is modified as follows:
 - a. The policy must make clear that treatment deadlines (e.g., the 0–6 month deadline for priority level 1) begin to run from the date that an inmate is staged at a particular fibrosis level.
 - b. The policy must make clear that FDC must evaluate and stage inmates within 60 days of confirming that the inmates have chronic HCV.⁶
4. Beginning on January 1, 2018, and on the first day of each month thereafter, Defendant shall file with this Court a status report reflecting FDC's progress in complying with this Court's injunction. That status report must detail:

⁵ The most recent version of this document is attached as Exhibit B to this order.

⁶ The other timeframes in this plan trump the policy. *See supra*, at ¶¶ 1(c)-(d).

- a. The total number of inmates in FDC custody who have been screened/tested for HCV.
- b. The total number of inmates in FDC custody who have been identified as having chronic HCV.
- c. The total number of inmates in FDC custody who have been identified as having chronic HCV but have not yet completed evaluation and staging.
- d. The total number of inmates in FDC custody who have been identified as having chronic HCV and have been staged and evaluated. This number must be further broken down by stage (i.e., F0, F1, F2, F3, F4, and decompensated cirrhosis).
- e. The total number of inmates in FDC custody who have begun and/or completed treatment with direct-acting antiviral drugs (“DAAs”).
- f. The total number of inmates in FDC custody who have been deemed (temporarily or permanently) ineligible for treatment with DAAs. For each such inmate, FDC must list, in summary form, the reason for ineligibility.

5. The bond provisions of Rule 65(c) of the Federal Rules of Civil Procedure are waived, and this preliminary injunction shall issue immediately.

SO ORDERED on December 13, 2017.

s/Mark E. Walker
United States District Judge

EXHIBIT A

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION**

**CARL HOFFER, RONALD
MCPHERSON, and ROLAND
MOLINA, individually and on
behalf of a Class of persons
similarly situated,**

Plaintiffs,

vs.

Case No.: 4:17-cv-214-MW/CAS

JULIE L. JONES,

Defendant.

**DEFENDANT’S PLAN OF
TREATMENT FOR CHRONIC HEPATITIS C**

Defendant Julie L. Jones, sued in her official capacity as Secretary of the Florida Department of Corrections (“FDC”), submits this plan of treatment for inmates with chronic hepatitis C, and in response to this court’s Order Granting Motion for a Preliminary Injunction (“Order”) [D.E. 153]:

A. INTRODUCTION

On November 17, 2017, this court entered an order that granted the Plaintiffs’ motion for a preliminary injunction and required FDC to file a plan that was consistent with the court’s directions, and that included specific timetables [D.E. 153, page 32]. During final argument on November 1, 2017, FDC offered to

submit such a plan, but noted that in participating in the process of plan submission, FDC was not waiving the right to either further contest liability, or to challenge the scope of any court ordered remedy.

B. POLICY REVISIONS

FDC's medical providers are mandated to follow its health services bulletins for the care of inmates who have hepatitis C, specifically HSB 15.03.09, Supplement No. 3 ("Supplement 3"). Prior to the evidentiary hearing on Plaintiffs' motions, Supplement 3 was revised in October 2017. In its order, the Court required the FDC to update Supplement 3 so that there is a clear plan for doctors to follow [D.E. 132, page 21 and 29].

Attached as Exhibit A is FDC's revised Supplement 3.¹ Generally, Supplement 3 now includes specific direction to providers regarding the steps to be taken in screening inmates for both the presence of hepatitis C ("HCV") and the presence of fibrosis (pages 5-6). Additionally, once inmates are found to have chronic hepatitis C ("cHCV"), Supplement 3 contains detailed directions for their evaluation and testing, along with time periods for that (pages 6-8). With respect to treatment with direct-acting antiviral medication ("DAA" or "DAAs"), Supplement 3 now contains two priority levels for treatment with DAAs, as well as

¹ This needs to be reviewed by the Correctional Medical Authority (CMA), pursuant to Sec. 945.603, Florida Statutes.

directions regarding the time periods for DAA treatment (pages 8-9). There is also direction for regular monitoring of the third priority level, those individuals who are at fibrosis stages F1 and FO (page 9). The new, comprehensive descriptions of tests, treatment, and time standards are consistent with the expert testimony of Dr. Dan Dewsnup at the evidentiary hearing, and this court's direction.

Timetable: Complete.

C. MONITORING AND EVALUATION OF INMATES WHO ARE KNOWN TO HAVE CHRONIC HEPATITIS C

FDC has begun the process of evaluating and staging all inmates known to have cHCV, and will complete this process for all current cHCV inmates by April 30, 2018. This process will be ongoing for all newly discovered cHCV inmates. Inmates with cHCV will be enrolled in the Gastrointestinal Clinic ("GC") where their monitoring and evaluation will include an examination every six months, and they will receive proprietary indices and/or elastography every six months, and an abdominal ultrasound every six months if they are at fibrosis stages 2-4 (Supplement 3, pages 6-8). For those who are at fibrosis stages 0-1, they will receive an examination every 6-12 months in the GC, as well as laboratory testing every six months, and the proprietary indices and/or elastography every 12 months (Supplement 3, pages 6-8).

It is important to recognize that, based on existing information, the GC will have a patient load of approximately 7,500 inmates. Hence, FDC is prepared to

significantly surpass the previously suggested evaluation rate of 100 inmates per month that the court found to be deficient [D.E. 132, page 30].

Moreover, all those with cHCV will receive counseling regarding the disease, including the staging of treatment with DAAs, and the availability of peer-to-peer counseling (Supplement 3, page 8).

Timetable: This began in November 2017, and will be complete for currently known cHCV inmates by April 30, 2018. The process will be ongoing for newly discovered cHCV inmates.

D. TREATMENT OF THOSE WHO HAVE DECOMPENSATED CIRRHOSIS WITH DIRECT-ACTING ANTIVIRAL MEDICATION

All cHCV inmates who are known to have decompensated cirrhosis will be offered treatment with DAAs (Supplement 3, page 8).

Timetable: FDC began treating inmates with decompensated cirrhosis in August 2017, and will have initiated treatment for all known cHCV inmates with decompensated cirrhosis by December 31, 2017. This will be ongoing for newly discovered cHCV inmates with decompensated cirrhosis.

E. TREATMENT OF THOSE WHO HAVE COMPENSATED CIRRHOSIS WITH DIRECT-ACTING ANTIVIRAL MEDICATION

All cHCV inmates who are known to have compensated cirrhosis will be offered treatment with DAAs within three to six months (Supplement 3, page 8).

Timetable: FDC will begin initiating treatment for cHCV inmates with compensated cirrhosis in December 2017, and will have initiated treatment for all current cHCV inmates with compensated cirrhosis by May 2018. This will be ongoing for newly discovered cHCV inmates.

F. TREATMENT OF THOSE WHO HAVE FIBROSIS STAGE 3 WITH DIRECT-ACTING ANTIVIRAL MEDICATION

All cHCV inmates who are known to have fibrosis stage 3 will be offered treatment with DAAs within 12 months (Supplement 3, page 8).

Timetable: FDC will begin initiating treatment for cHCV inmates who have fibrosis stage 3 by no later than April 1, 2018, and will have initiated treatment for all current cHCV inmates who have fibrosis stage 3 by March 31, 2019. This will be ongoing for newly discovered cHCV inmates.

G. TREATMENT OF THOSE WHO HAVE FIBROSIS STAGE 2 WITH DIRECT-ACTING ANTIVIRAL MEDICATION

All cHCV inmates who are known to have fibrosis stage 2 will be offered treatment with DAAs within 24 months (Supplement 3, page 9). The timetable for treatment is directly impacted by the fact that the current number of inmates who are in fibrosis stage 2 is presently unknown. The FDC is actively evaluating the 6,500 inmates referenced in the Order to determine the fibrosis scores of 0, 1, and 2. [D.E. 153, p. 30-31]. Additionally, every year the FDC receives approximately 30,000 newly incarcerated inmates; thus, the number of inmates in fibrosis stage 2

is likely to increase by an unknown magnitude over the court's proposed timetable for treatment.

Timetable: All 6,500 inmates referenced in the Order will be evaluated and staged on or before April 1, 2018. FDC will begin initiating treatment for cHCV inmates who have fibrosis stage 2 by no later than May 1, 2018, and will have initiated treatment for all current cHCV inmates who have fibrosis stage 2 by April 30, 2020. This will be ongoing for newly discovered cHCV inmates.

H. STANDING ORDERS FOR THE ADMINISTRATION OF EPCLUSA, MAVYRET, AND RIBAVIRIN

Dr. Dan Dewsnup has issued standing orders for the administration of Epclusa and Mavyret, which are two commonly used DAAs, along with Ribavirin, which needs to be utilized in conjunction with DAAs in certain circumstances. The current versions of those standing orders are attached hereto as composite Exhibit B. It should be noted that the content of standing orders may need to be adjusted from time-to-time to reflect provider feedback, adjustments in administration, or new information.

Timetable: Ongoing.

I. MONITORING THOSE WHO HAVE FIBROSIS STAGES 0-1

All cHCV inmates who are known to be in fibrosis stages 0-1 will be monitored regularly with both labs and proprietary indices for re-staging at least annually into a higher priority level (Supplement 3, page 9).

Timetable: Ongoing.

J. EXPANSION OF SYSTEM CAPACITY

The FDC's medical contractor, Centurion, will be adding a specialty physician to assist with identification, evaluation, and staging for treatment with DAAs. Also, Centurion will be adding eleven infection control nurses whose duties are anticipated to include ordering tests and coordinating medication administration. In addition, the FDC will hire a specialty physician as a project consultant to assist with oversight and administration of this program. Moreover, existing health services staff from Centurion who are located at prisons will undergo additional HCV training, and shift responsibilities as necessary to participate in the screening, monitoring, testing, and medication administration.

Timetable: By January 31, 2018.

K. TRACKING OF INMATES WHO HAVE CHRONIC HEPATITIS C

FDC has significantly enhanced its ability to identify and track those inmates who have HCV. For example, new computer codes have been created for HCV inmates that will indicate whether they have acute hepatitis or, instead, cHCV, and also indicate whether they have been treated with DAAs, and have achieved cure, i.e., a Sustained Viral Response ("SVR").

Timetable: Complete.

L. TRACKING OF MEDICATION ADMINISTRATION

FDC has begun to produce weekly pharmacy reports that would indicate the inmates who are receiving DAA medication. Medical administration of DAAs will also be tracked at the patient level by virtue of Medication Administration Records (MARs).

Timetable: Ongoing.

M. REFERRAL FOR LIVER TRANSPLANTS

In accordance with Supplement 3, the FDC will determine the MELD score for all patients with decompensated cirrhosis. If the score meets the listing/eligibility criteria maintained by the liver transplant centers in Florida, the patient will be referred to the transplant center. Thereafter, co-management as directed by the transplant center will be instituted if the patient is listed for transplant. (Supplement 3, page 12).

Timetable: January 31, 2018, while referrals are ongoing.

Respectfully submitted,

PAMELA JO BONDI
ATTORNEY GENERAL

EXHIBIT B

MANAGEMENT OF HEPATITIS C

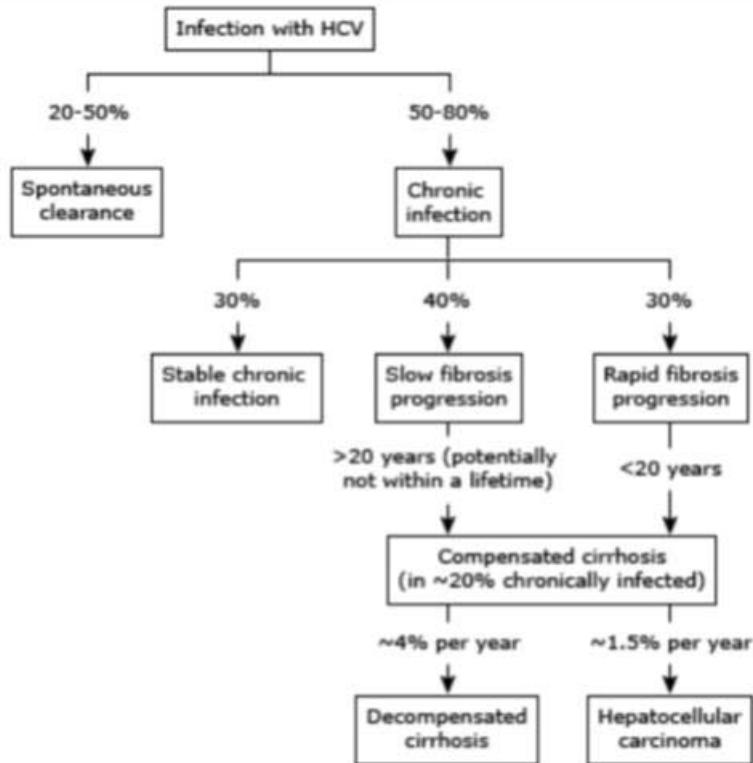
This guideline describes departmental recommendations for the screening, evaluation, treatment, and monitoring of patients infected with hepatitis C virus (HCV).

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.
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.

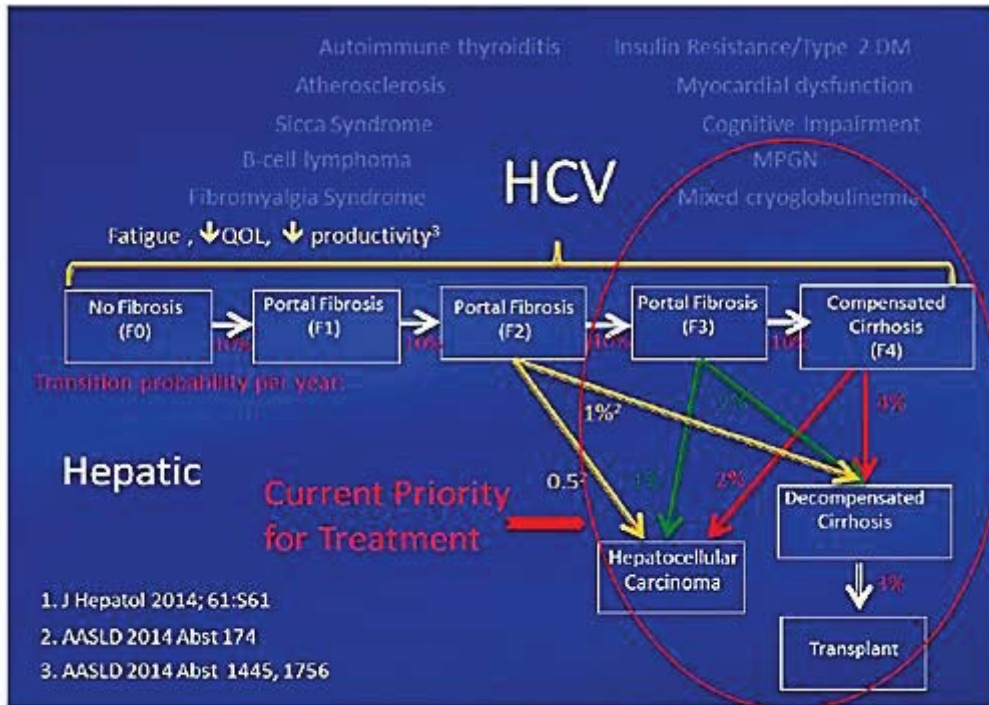


Diagram 2 attribution: Ken Benner, MD/Hepatology, Oregon Clinic, Portland, Oregon.

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. The form for this should include peer-to-peer education.

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 chronic HCV.
3. In patients with a detectable viral load (HCV-VL), the specimen will also then be analyzed by a proprietary predictive index (e.g. FibroSURE), to initially assess the amount of fibrosis (liver scarring). Note: Proprietary indices that predict hepatic fibrosis stage such as FibroSURE, Fibrometer™ or FibroSPECT™ utilize a combination of age, sex, and a battery of laboratory parameters to predict the fibrosis score (F0-F4). Proprietary indices are widely utilized in the U.S. correctional system and in some communities in combination with ultrasound liver imaging to estimate the stage of hepatic fibrosis, especially in areas which are resource or access challenged, which would make routine elastography or other imaging very difficult.
4. HCV-VL+ patients who have been diagnosed to have F2, F3, or F4 will be reviewed and an abdominal ultrasound ordered to rule out the presence of portal hypertension (indicative of advanced hepatic fibrosis).

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

Once patients are found to be infected with chronic HCV, 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 medication, (b) those who have had HCV treatment failure, and (c) 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 (HCCa) 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 autoimmune 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); and a comprehensive metabolic panel (CMP).
- (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

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.

- (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: <http://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.
- (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.

(a) **PRIORITY LEVEL 1 - Highest Priority for Evaluation and Treatment**
The following individuals should receive DAA treatment within 0-6 months (subject to paragraph K, 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) Liver transplant candidates or recipients in consultation with and co-managed by a transplant hepatologist.
 - (4) Hepatocellular carcinoma in consultation with a hepatologist for correct timing.
 - (5) Comorbid medical conditions associated with HCV, including cryoglobulinemia with renal disease or vasculitis, certain types of lymphomas, hematologic malignancies or metabolic abnormalities.
 - (6) Continuity of care for those entering custody already on treatment.
 - (7) Patients taking immunosuppressant medications for a comorbid medical condition which may cause rapid progression of hepatic fibrosis.
 - (8) HIV co-infection.
 - (9) 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 pre-treatment evaluation, a course of treatment, and post treatment SVR assessment at 8-24 weeks, in order for patient education and system efficiencies to be evaluated (generally, this requires approximately 12-18 months), 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 and an SVR.
3. Patients who are Priority Level 1 or Priority Level 2, but who (1) are unable to demonstrate a willingness and an ability to adhere to a rigorous treatment regimen, (2) do not abstain from high risk behaviors while incarcerated, (3) have chronic disciplinary issues, or (4) have chronic behavioral management issues may not be eligible for treatment until those issues are considered to be resolved. A patient should be willing to participate in any available counseling or treatment in order to achieve the sobriety/behavior change before treatment with DAAs is initiated.

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

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

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 at 12 weeks after completion of treatment; and if HCV is undetectable, that defines a sustained viral response (SVR).
2. A patient who sustains SVR may be removed from the Gastrointestinal Clinic (GC), so long as the patient has no cirrhosis, complications, or related comorbidities.

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. 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, 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

A determination of the UNOS MELD score will be made for all patients with decompensated cirrhosis. If the score meets the listing/eligibility criteria maintained by the liver transplant centers in Florida, the patient will be referred to the transplant center. Thereafter, co-management as directed by the transplant center will be instituted if the patient is listed for transplant.

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