Medical care standards evolve as knowledge and treatment options expand. ODOC treatment guidelines change accordingly, in keeping with the mandates and mission of medicine in a correctional environment. Since their initiation in ODOC in 1999, medical guidelines for cHCV have been updated multiple times, notably: in 2004 in cooperation with a court appointed expert panel; in 2010 to reflect AASLD Guidelines; in 2012 to incorporate the first generation protease inhibitor drugs; and in 2016 to analyze and provide the correctional perspective complementary to the evidence-based scientific and advocacy driven advice presented in the AASLD/IDSA website www.hcvguidelines.org. This 2017 revised ODOC clinical guideline reflects the growing scientific evidence, which is the basis for expanded eligibility to patients with F2 hepatic fibrosis and above. This will continue to direct the present use of the rapidly expanding group of direct-acting antiviral agents and help patients plan for their future.

BACKGROUND: HCV hepatitis continues to be a common health problem in Oregon prisons, as in all U.S. correctional institutions, and is primarily associated with substance abuse (usually injection drug use [IDU] prior to incarceration). The course of cHCV and the likelihood of progression to advanced liver disease vary greatly among individuals over time and is difficult to predict in its early stages. The goal of HCV evaluation within the ODOC is to identify and prioritize treatment to the patients who need it soonest and will benefit the most.

In the new and expanding world of the direct-acting antiviral agents (DAAs), exponentially increased drug acquisition costs (of which correctional institutions routinely pay more than community averages [ref: www.hcvguidelines.org]) require sound resource allocation management. The American College of Correctional Physicians has stated in a 2014 position statement: “...The treatment of hepatitis C is advancing rapidly with new treatments utilizing medications that are more efficacious but also more expensive. It is the obligation of the correctional physician to use evidence-based criteria to identify those patients who would benefit most from these new medications and to advocate for their treatment. Correctional systems must not prohibit the new medications based solely on price. They must balance the available resources to treat hepatitis C without compromising the delivery of care for other medical conditions.” (http://societyofcorrectionalphysicians.org/resources/position-statements/hepatitis-c-position-statement.)

The positive outcomes of increased survival and improved quality of life associated with successful viral eradication and a sustained viral response (SVR) are also dependent upon sobriety and positive lifestyle change.¹ Likewise, a Scottish study showed that long term survival for patients who successfully reached SVR is compromised most frequently by

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¹ A long term Danish study demonstrated 18.2 fold increased mortality risk among younger patients with chronic HCV, not due to liver disease but due to unnatural death: i.e., mortality associated with untreated mental illness and substance abuse associated suicide, homicide, and trauma. Liver related mortality becomes more prevalent as the population ages. Sobriety is key to overall harms reduction. Clin Gastro and Hepatology 2011; 9:71-78.
substance abuse and overdose. Patients have a responsibility to learn from past behaviors and positively interact with society. Evaluation and treatment of chronic health problems such as cHCV and substance abuse play a crucial role in establishing trust and developing healthy behaviors, thereby reducing rates of substance abuse relapse and correctional recidivism. This supports the Oregon Accountability Model, the ultimate goal of which is to improve public safety, by recognizing and supporting these positive behaviors in a multi-component approach. Successful cHCV treatment also reduces risk of transmission after release. Thus, 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 individual, his/her family, and society.

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2 Excess Patient Deaths As Compared to National Death Rates In Patients with SVR; Scotland 1996-2011 (J Hep 2017, 66:19-27)

![Excess Patient Deaths As Compared to National Death Rates](image)

**Fig. 2.** Absolute contribution (%) to the overall excess for each cause of death. For (A) all SVR patients, and (B) SVR patients without cirrhosis at baseline.

Any patient 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 patients. 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.

Identifying patients who need treatment soonest and would benefit most is a complex task requiring evaluation of multiple and diverse factors. These guidelines have been developed to keep ODOC recommendations consistent statewide and to help physicians evaluate patients, consider treatment options and determine both eligibility and priority for treatment.

**NATURAL HISTORY AND PROGRESSION OF HCV CHRONIC INFECTION (cHCV) AND ESTIMATION OF HEPATIC FIBROSIS**

The figure below, based on the most up to date natural history data, shows that about 30% of cHCV patients progress rapidly to cirrhosis. Alternately, a large proportion (up to 70%) of the 50-80% of patients infected with HCV who develop cHCV are clinically stable. They either do not demonstrate progressive hepatic fibrosis OR if progression is noted it is very slow and natural history studies have not been able to document significant progression to end-stage hepatic fibrosis as yet (published data reflect ~20 yrs of prospective follow-up, consistent with the identification of HCV in 1989 and the availability of widespread testing for HCV-Ab in 1992).

*Estimation of Progression of Hepatic Fibrosis: Factors associated with rapid progression or death* (<20yrs to cirrhosis) are many, including but 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 (with HIV+HBV +HCV co-infection and detectable viremia of both HIV+HBV at highest risk), hepatic steatosis and NASH, diabetes and insulin resistance, obesity, daily use of marijuana, and uncontrolled underlying liver disease. HCV risk behaviors >10yr prior to diagnosis, male sex, age >40yrs are also associated, but are less significant in multivariate analysis. Generally, it is wise to assume that patients with more risk factors for progression also have higher risk for more rapid progression. 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 risk for rapid progression within one year begins to be measurable when the patient reaches F2
d. 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. Best data continues

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4 AASLD 2014, Abstract 174
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.

FIGURE 1
©2016 UpToDate

Natural history of hepatitis C virus

The likelihood of chronic infection following acquisition of HCV and the rate of fibrosis progression depend on various host and viral factors. As examples, young women and children are more likely to spontaneously clear HCV infection, and if chronically infected, have relatively slow fibrosis progression rates. Refer to the UpToDate topic on the natural history of HCV infection for further details.

Graphic 99947 Version 1.0
**Estimation of Hepatic Fibrosis: 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 (≥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. The contribution of sobriety/cessation of IDU 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 an SVR. 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.

**Estimation of Hepatic Fibrosis by Predictive Scoring:** Use of predictive scoring uses laboratory surrogate markers to predict the stage of hepatic fibrosis and may help inform the patient’s decision as to whether to proceed. An APRI score (see Definition of Terms in Addenda section) >0.5 or FIB-4 score of >1.45 identify ≥75% of patients with advanced hepatic fibrosis (Lin, et al; Hepatology, March 2011). Generally, however, APRI and FIB-4 scoring lack the power to exclude patients with advanced fibrosis to a statistically significant level (p<0.05). Generally, blood tests have been shown to be “moderately useful for predicting clinically significant fibrosis or cirrhosis in HCV-infected patients”⁵

Proprietary indices that predict hepatic fibrosis stage such as Fibrometer™ or FibroSPECT™ are also available and have improved predictive power at an increased price, with the caveat that they may over-predict hepatic fibrosis in the presence of increased hepatic inflammation. Conversely, they may do a better job of predicting which patients don’t have significant fibrosis (Metavir F0-F1, Batts and Ludwig S0-S1) than the APRI or FIB-4. Proprietary indices are widely utilized in the U.S. correctional system and in some communities in combination with abdominal US imaging to estimate stage of hepatic fibrosis and rule out occult portal hypertension, especially in areas which are resource or access limited, making routine elastography or other advanced fibrosis imaging difficult.

**Estimation of Hepatic Fibrosis by Liver Biopsy, and by Elastography Methods** (using either U/S or MRI) are also critical in the staging process, and are discussed further in later sections of the guideline. Imaging studies may also identify cirrhosis, and not require further staging. A recent review of the use of liver imaging and biopsy in clinical practice⁶ 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.

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⁶ Use of Liver Imaging and Biopsy in Clinical Practice; Tapper EB and S.-F. Lok, NEJM 377:8:756-768
All the present tests for estimation of advanced hepatic fibrosis are limited, and a concordance of clinical exam, history, labs, predictive indices, imaging, and/or liver biopsy should be sought to provide the best answer.

**Extrahepatic complications independent of hepatic fibrosis:** Regardless of the stage of hepatic fibrosis, HCV-associated complications such as DM2, proteinuria, cryoglobulinemia associated kidney disease, B-cell lymphoma, porphyria cutanea tarda, lichen planus, and other diseases may necessitate earlier evaluation and/or treatment of cHCV. These extrahepatic manifestations of cHCV may also cause morbidity and mortality in patients with Batts and Ludwig S0-S2, or Metavir F0-F2 hepatic fibrosis, but at a very low rate if recognized and treated promptly.

Although an imprecise science, usually patients benefit from a thorough discussion of risk for progressive hepatic fibrosis, resulting in an improved therapeutic relationship as they have their choices informed. Helping them understand their options for medical care after release also assists in this process.

**BENCHMARK TIMELINESS STANDARDS FOR EVALUATION AND TREATMENT:**

1. As established in accordance with the court decrees associated with *Anstett v. Oregon Department of Corrections*, in order to consider treatment for cHCV an individual’s total time within ODOC may need to be as long as 18 months. This allows for the establishment of sobriety, initial development of healthy lifestyles reinforced by consistent living, full treatment within the variable treatment regimen timelines currently established, and post-treatment follow-up (including SVR assessment). Patients who received regimens containing RIBAVIRIN may also benefit from medical and mental health stabilization prior to release. *Note: This may be an exceedingly short window of time for a patient to assimilate healthy lifestyle change, sobriety, and become ready for treatment. In the community this evolution usually occurs over years. Providers should make the patient aware of this fact even while encouraging the patient along their accelerated timeline of change. Present data indicate the patient benefits from this process*.7

2. Initiation of evaluation after a minimum of 3 months within ODOC. This allows reasonable time for the individual to stabilize within the incarcerated environment medically, mentally, and socially.

3. The individual needs 6 months without evidence of continuing HCV risk behaviors or uncontrolled mental health problems which would affect adherence. This may include time prior to ODOC in county jails if medical or mental health treatment can be reliably confirmed.

4. Staging by exam, labs, predictive indices, abdominal US, liver elastography, and/or liver biopsy consideration by TLC should be considered by TLC ~ 12 months prior to release.

5. After finishing viral eradication treatment the patient should have at least 3-6 months prior to release. Enough time to document SVR prior to release is essential to monitor the effectiveness of new drugs and evaluate potential system problems in the event of treatment failure.

7[hcvguidelines.org](http://hcvguidelines.org) (2017)
6. Females who receive RIBAVIRIN (RBV) treatment should usually have at least 6 months after treatment completion in order to reduce teratogenicity risk were the patient to become pregnant immediately after release.

INCLUSION/EXCLUSION CRITERIA FOR cHCV TREATMENT:

Prior authorization by the TLC (Therapeutic Level of Care Committee) is required for treatment initiation. The decision to treat will be made on an individual, case by case basis, with evidence-based treatment efficacy, application of the appropriate timeliness standard, and population risk given comprehensive consideration. Exceptions to criteria such as timeliness, inclusion and exclusion criteria, etc., may be warranted due to individual circumstances; these should be brought to TLC, discussed and resolved prior to the treatment decision.

Inclusion/exclusion criteria as follows:

1. HCV genotype testing completed, and cHCV verified by a detectable viral load.
2. Treatment experience documented (either no prior treatment or treatment experienced with the specific regimen recorded in chart)
3. No evidence of HCV risk behavior for at least 6 months prior to treatment initiation
4. The patient agrees to illicit drug screening at the provider’s discretion before and during treatment. Screening positive for illicit substances prior to or during cHCV usually will delay treatment, and may be grounds for stopping treatment.
5. Patient adherence issues have been addressed and resolved to the satisfaction of the TLC committee. Examples of issues which will delay inclusion would be unstable medical or mental health conditions, recent poorly controlled and/or aggressive behavior, or disciplinary issues indicating the patient is not fully capable of treatment adherence.
6. The patient can be expected to attain reasonable benefit from treatment as evidenced by improvement in quality of life (QOL) or lifespan.
7. Patients with ≥ S2 (Metavir F2+) as confirmed by by liver biopsy OR point Shear Wave Elastography (pSWE) of ≥ 1.34 m/sec m/sec or other elastography modalities previously performed prior to incarceration. Within the eligible group, the highest priority for immediate treatment will be given to patients with advanced hepatic fibrosis (bridging fibrosis) corresponding to a Batts and Ludwig Stage of 3-4, or Metavir score of 3 or greater.
8. Alternatively, the following groups of patients will also qualify for immediate treatment:
   a. Patients with any fibrosis score who are at highest risk of cHCV complications, including cryoglobulinemia with end-organ manifestations (vasculitis, decreased eGFR, proteinuria, nephritic syndrome, or membranoproliferative glomerulonephritis), or co-infection with HIV or HBV or other underlying liver disease where rapid progression of hepatic fibrosis can be reasonably predicted.
   b. Rx with documentation of rapidly progressing fibrosis (progression of stage to stage in <5yrs).
   c. Proteinuria or Porphyria Cutanea Tarda (not as common in incarcerated settings where access to alcohol is more restricted).
   d. Clinical, radiologic or laboratory evidence of advanced cirrhosis (ascites, portal hypertension, hepatic encephalopathy, HCCa)
9. Treatment of major medical and underlying liver conditions is optimized and not impeded by patient non-adherence. Examples of these conditions may include, but are not limited to:
   b. Symptomatic CHF, COPD or asthma with frequent exacerbations (indications of either end-stage disease or patient non-adherence).
   c. ASCAD with active angina
   d. Poorly controlled diabetes, A1c>8.0 due to non-adherence with medical regimens

10. For patients who will be taking a regimen containing RIBAVIRIN:
   a. Patient is not pregnant
   b. Women of childbearing potential and within 6 months of treatment conclusion agree to use of two forms of effective birth control post-release with male partners. This should usually be accomplished by treatment initiation within 12 months prior to release.

11. Pharmacy and prescribing provider have determined that no significant drug-drug interactions exist with the HCV regimen and the patient’s other medical/psychiatric therapies.

Indications and contraindications Follow-Up: Routine follow up to re-assess indications for treatment should occur at appropriate intervals as clinical evidence suggests. Accordingly, assessment monitoring reveals either compliance with treatment indications or new contraindications the patient should be re-evaluated for treatment. During each evaluation the patient should receive a summary of testing done, reason for treatment contraindication if present, and education regarding the next step to resolve the contraindication if possible.

Uncorrected HCV behavioral risk factors as contraindications for cHCV treatment: Drug or alcohol use/abuse (self report, positive drug screen, possession, rule violation) or a new tattoo (DOC specific) within the prior 6 months is a temporary contraindication to medication treatment for Hepatitis C, but is not necessarily a contraindication for work up or evaluation.

HCV Treatment Contract: The patient must agree to terms of treatment, which may include any/all of the following:
   1. Inmate may be subject to random alcohol and drug testing at ODOC discretion
   2. Evidence of use of alcohol or non-prescribed drugs or a positive random alcohol or drug testing or fresh tattoos or equipment possession should usually result in removal from therapy.

Use of concordance in diagnostic modalities to establish eligibility for treatment: As discussed above, in many cases the liver biopsy may not be the definitive answer for eligibility. Presently, there is no “gold standard” of hepatic fibrosis staging, and eligibility for treatment should be established via concordance between laboratory, imaging (abdominal US to rule out advanced portal hypertension, and elastography), and predictive scoring (proprietary indices, or to a lesser extent, APRI and FIB-4).

HCV TREATMENT PROTOCOLS: Treatment regimens are changing rapidly as new agents become available. Usually 8-12wk regimens are preferred due to improved adherence, lower
toxicity, and cost-effectiveness. The AASLD/IDSA website, hcvguidelines.org, presents reliable summaries of drug treatment data and should be used to direct most treatment. Guidelines may be revised if correctional concerns exist. Expert consultation may be needed in special circumstances.

Clear orders must be written or entered into the computerized order entry system in order to facilitate best management of medication delivery to the patient. Choices are given in the directions box of CIPS as a script is being entered. An example of an HARVONI order would be: “HARVONI 1T PO DAILY x 84 doses, concurrent with (other drugs in regimen if indicated).” In the box for “Days Supply” we presently advise typing “120” in order for delays in treatment initiation to not interrupt the consistent and consecutive delivery of the required 84 doses.

MAJOR DRUG-DRUG INTERACTIONS WITH THE DIRECT-ACTING ANTIVIRALS: Pharmacy input on the patient’s current drug profile should be reviewed prior to dispensing to patient, and appropriate patient education should be given.

SOFOSBUVIR: Mechanism of action-inhibits HCV NS5B RNA-dependent RNA polymerase, essential for viral replication, and acts as a chain terminator. Selected important interactions common to ODOC patients may include (not a comprehensive list):

Amiodarone: SOF may enhance the bradycardic effect of Amiodarone.

OXcarbazepine: May decrease the serum concentration of SOF.

Rifapentine: May decrease the serum concentration of Sofosbuvir. Do not use concurrently.

HARVONI® (SOFOSBUVIR-LEDIPASVIR) or EPCLUSA® (SOFOSBUVIR-VELPATASVIR) action-inhibition of the HCV NS5A protein necessary for viral replication (see above for SOFOSBUVIR information). Additional important interactions:

H2-Antagonists: May decrease the serum concentration of Ledipasvir and to a lesser extent, Velpatasvir. Risk D: Consider therapy modification

Proton Pump Inhibitors: May decrease the serum concentration of Ledipasvir and to a lesser extent, Velpatasvir. Management: At this time PPIs are contraindicated during HARVONI or EPCLUSA treatment. Both classes should be avoided during treatment; use temporary supportive measures for reflux instead, then reinstitute H2 or PPI after cHCV treatment completed.

ELBASVIR-GRAZOPREVIR (Zepatier®): Not used commonly in ODOC at the present time due to multiple drug-drug interactions. Glecapravir-Pibrentasvir (MAVYRET®) may be used if stopping H2Bs or PPIs are clinically contraindicated. If these drugs are used and cirrhosis is present, only patients with Childs-Pugh Class A cirrhosis may be treated, and the cirrhosis class must be recently verified and checked throughout treatment via laboratory testing. Additionally, use of RIBAVIRIN is probably necessary for all S3-4 (F3-4) patients due to resistance concerns with ELBASVIR-GRAZOPREVIR (Zepatier®).
TREATMENT FAILURE FOLLOWING DAA Rx: Treatment failure is defined as a detectable HCV viral load 12 wks following completion of therapy. If the HCV-VL is in the <50 copies/ml or the “non quantifiable” range then the test should be repeated in 4 weeks as this situation usually represents lab error and the repeat testing will be “not detected”. In the case of true failure the chart should be reviewed for non-adherence, system failures in drug dispensing, possible drug-drug interactions, and the patient interviewed for illicit drug use and the ingestion of other acid-lowering medications or supplements. If no interfering risk factors are identified, the possibility of viral mutation causing drug resistance (or resistance associated substitutions [RAS]) should be considered. Further resistance testing and a secondary treatment regimen should be selected according to the principles and treatment recommendations contained in hcvguidelines.org.

TREATMENT GUIDELINE ADDENDA (AS APPLICABLE):

RATIONALE FOR PATIENT EDUCATION: WHO CAN SAFELY WAIT FOR TREATMENT? Or, how do we talk to patients about treatment delays in the present day? (The following discussion is provided to help providers assimilate critical concepts prior to discussing with the patient):

Because www.hcvguidelines.org advocates nearly universal treatment, i.e., viral eradication, of patients with cHCV, some patients will believe that he/she is being discriminated against and not offered what he/she believes they are entitled. This belief may be reinforced by media and advocacy messages without the filter of individual patient responsibility and a more realistic view of the future.

Many patients may not have advanced hepatic fibrosis or otherwise meet present criteria for treatment. This should be presented positively to patients without removing hope for treatment in the future, i.e., “not having bad scarring of the liver is a very good thing! Eventually everyone who wishes to be treated will have that opportunity.” Many factors are increasing the availability of antiviral drugs to a larger segment of the cHCV population in the short term, including market competition lowering the price of medications, expanding state and federal support of Medicaid programs, and expanded funding of public health initiatives supporting treatment of patients with lower fibrosis scores during incarceration. If the patient remains clean and sober and lives a healthy lifestyle it is highly likely that treatment will become available prior to significant progression of their cHCV.

Accordingly, patients should be educated that many factors influence progression of hepatic fibrosis, not just the presence of a VL. They should understand that the height of the VL does NOT impact positively or negatively on fibrosis progression unless they have underlying kidney disease. Also, if their ALT/AST levels have normalized in their clean and sober state, the rate of progression will be very slow, and the large majority of patients may never progress to advanced
fibrotic states. So the outlook for the clean and sober patient is bright even before viral eradication.

This positive prognosis is not possible if they experience substance abuse relapse, and those who do are also at an higher risk of death. **Substance abuse relapse is, was, and continues to be lethal.** It also makes it very difficult for the patient to participate in post-release medical care and keep eligible for treatment when it becomes available.

The evidence for decreased mortality in patients who obtain an SVR (www.hcvguidelines.org) continues to accumulate. Decreased mortality has also been seen in patients who become clean and sober at all ages or stage of disease. SVR is associated with increased probability of sobriety and decreased rates of substance abuse relapse (www.hcvguidelines.org); therefore, sobriety is an as yet unquantified but highly significant component of decreased mortality rates in patients who obtain SVR (in fact, all cHCV drug treatment studies to date have required sobriety prior to study entry). These positive outcomes, i.e., improved survival, sobriety, and SVR, are inextricably inter-related, and correctional treatment programs should assist the patient to understand the inter-relationship and continue to “own” their sobriety as they await cHCV treatment availability. As previously stated, 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-component strategy to promote healthy lifestyles, which in turn benefit the individual, his/her family, and society.

Patients and providers have also heard a lot about re-infection in patients who relapse into substance abuse. The following facts regarding re-infection may be discussed for patient consideration: The primary incidence of HCV re-infection in a community meta-analysis population was 6-30/100 person.yrs. (Aspinal, et al; *Clin Infect Diseases* 2013; 57:S80-S89); although may be higher among previously incarcerated persons. Expert interpretation of the available data indicates that chances for re-infection are relatively low but present, and “…engaging with healthcare and going through the treatment process often has very positive outcomes among injectors, as far as reduction in risk behavior and increasing access to healthcare after treatment.”

Regardless of viral eradication status, patients should be thinking positively about sobriety and establishing care with a medical provider post-release. Further resource allocation within the ODOC will likely assist the process of post-release medical follow-up in the future.

The treatment of cHCV is multifactorial, and should include a major emphasis on healthy lifestyle. The maintenance of a healthy weight will prevent or delay the onset of HCV-associated DM2, and early use of statins in patients with cardiovascular risk also has the potential of moderating the effect of hepatic steatosis. Even concurrent control of hypertension, especially with ARBs, has the potential of decreasing hepatic inflammation. Although studies of and interventions for the reduction of hepatic inflammation are still ongoing, “getting the fat out of
your liver” is always a healthy goal. To this end, aerobic exercise and conditioning, with a decreased emphasis on weight training, is very appropriate.
### Chronic HCV Hepatitis Evaluation Worksheet

#### SECTION 1  Initial Screening Information

<table>
<thead>
<tr>
<th>Date</th>
<th>HCV-Ab positive?</th>
<th>HCV-VL (&lt;1yr old titer needed for Rx)</th>
<th>Yes</th>
<th>No</th>
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<td></td>
<td>Yes</td>
<td>No</td>
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<table>
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<tr>
<th>Hepatitis C Genotype</th>
<th>Date</th>
<th>ALT</th>
<th>AST</th>
<th>PLT</th>
<th>TBIL</th>
<th>ALB</th>
<th>INR</th>
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Other pertinent lab: ________(ferritin, ANA, TSH, sCr if abnormal)

APRI and/or FIB-4 ([http://www.hepatitisc.uw.edu/page/clinical-calculators/apri.](http://www.hepatitisc.uw.edu/page/clinical-calculators/apri.))

<table>
<thead>
<tr>
<th>Date</th>
<th>Hepatitis B surface Ag positive?</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>(If yes, consider specialty consult/TLC.)</td>
<td>Yes</td>
<td>No</td>
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<table>
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<tr>
<th>Date</th>
<th>HIV positive?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(If yes, refer for specialty consult/TLC.)</td>
<td>Yes</td>
<td>No</td>
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<table>
<thead>
<tr>
<th>Date</th>
<th>Prior HCV treatment?</th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>When/What</td>
<td>Yes</td>
<td>No</td>
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<table>
<thead>
<tr>
<th>Date</th>
<th>Has been in ODOC &gt; 3 months and has greater than 12 months left?</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td></td>
<td>Admit date ______ Release date ______</td>
<td>Yes</td>
<td>No</td>
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<tr>
<th>Date</th>
<th>TLC request for abdominal U/S and elastography?</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td></td>
<td>(If patient has been previously staged and/or has cirrhosis, are we referring to TLC for Rx?)</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

#### SECTION 2  Further Medical Evaluation

<table>
<thead>
<tr>
<th>Date</th>
<th>Evidence of cirrhosis or decompensated liver disease, e.g., ascites, history of hepatic encephalopathy, history of esophageal varices with bleed, etc; or HCV-associated disease (rashes, arthritis)?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If evidence of cirrhosis: refer to Cirrhosis Chronic Disease Monitoring/Cirrhosis SNR (EGD referral, ABD U/S for HCCa surveillance, etc.)

<table>
<thead>
<tr>
<th>Date</th>
<th>Major Medical Illness poorly controlled, e.g. Diabetes, ASCVD, Angina, COPD, Mental Health Issues, Cancer, Autoimmune Disorder, etc. Explain.</th>
<th>Yes</th>
<th>No</th>
</tr>
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<table>
<thead>
<tr>
<th>Date</th>
<th>Age of patient at first IDU or other risk behavior</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td></td>
<td>Hx alcohol abuse: _<strong><strong><strong>; if YES: have patient estimate years of alcohol abuse</strong></strong></strong></td>
<td>Yes</td>
<td>No</td>
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</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Medications causing possible Drug-Drug interactions with HCV Rx? (e.g., PPI for DAAs)</th>
<th>Yes</th>
<th>No</th>
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</table>

#### SECTION 3  Mental Health Considerations

<table>
<thead>
<tr>
<th>Date</th>
<th>Unstable MH conditions which could affect adherence or completion of a treatment program?</th>
<th>Yes</th>
<th>No</th>
</tr>
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<tr>
<th>Date</th>
<th>If clean/sober, how long? ______; If sobriety occurred at entry into incarceration, what steps have they taken to show motivation for ongoing sobriety?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>
### SECTION 4  Other Concerns

<table>
<thead>
<tr>
<th>Evidence of ongoing HCV risk behaviors?</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evidence of non-compliance with other treatments or evaluations?</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient refused to sign contract if contract offered?</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If female, pregnancy ruled out?</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is patient willing to use 2 methods of contraception if released within 6 months after completion of RIBAVIRIN containing regimens?</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

### SECTION 5  Clinical Decision making

<table>
<thead>
<tr>
<th>Is patient an appropriate candidate for treatment for viral eradication by ODOC guidelines?</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

If yes, proceed to Section 6—Biopsy and Treatment

<table>
<thead>
<tr>
<th>Treatment approved by TLC? If yes, proceed to treatment.</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>No, proceed to “Hepatitis C Monitoring”</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Signature ________________________________ Date ________________

Name ________________________________

SID# ________________________________
DEFINITION OF TERMS:

HCV-RNA: HCV viral load, or HCV-VL, or VL
RBV: Ribavirin
TW: Treatment Week
SVR: sustained viral response
HCV-1, HCV-2, HCV-3, HCV-4: HCV genotypes presented numerically.
PEGaIFN2a/PEGASYS®: fixed dose aIFN, 180mcg/wk (ODOC formulary choice)
APRI score: AST/PLT ratio index
PEGaIFN2a/PEGASYS®: fixed dose aIFN, 180mcg/wk (ODOC formulary choice)
FIB-4 score: (http://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4.)

ADVERSE EVENTS DURING TREATMENT CAUSED BY RBV:

1. Hemolytic anemia; especially in patients who have reduced GFR due to renal disease.
2. Hyperuricemia induced by RBV is usually asymptomatic, but may induce exacerbation of pre-existing gouty arthritis.
3. Pruritis: alleviated with usual symptomatic therapy.
4. Cough, nasal stuffiness; unknown mechanism
5. Tetratogenicity: up to 6 months post therapy.
6. Hyperbilirubinemia: seen usually in patients with decompensated cirrhosis or moderate to severe hemolytic anemia.

MONITORING: Regular laboratory and clinical evaluation must take place after initiation of RBV therapy, and should be guided by the “Hepatitis C Viral Eradication Treatment Monitoring” worksheet (see attached). At a minimum, this should include a CBC and ALT @ 2 and 4wks, and q monthly thereafter until 1 month after end of treatment. An hTSH assay prior to 3m of treatment, and at end of treatment is also indicated.

Sustained Viral Response (SVR; i.e. “cure”) is established if the viral load is not detectable at the end of 12 weeks post-treatment. All patients should have the 12wk post treatment HCV-VL to document SVR.

TABLE 3: Laboratory Monitoring when applicable in patients receiving aIFN and/or RBV

<table>
<thead>
<tr>
<th>LAB TEST</th>
<th>Indications for Monitoring</th>
<th>Recommended Monitoring Intervals</th>
<th>Recommended Actions</th>
</tr>
</thead>
</table>
| CBC, CMP | Rx-induced anemia, thrombocytopenia, ALT elevations or reductions, etc. | CBC and CMP q2wks for 4 weeks then monthly if stable. | ALT: If over 2 times baseline, consider autoimmune hepatitis
|          |                           |                                  | Hgb >10: No intervention
|          |                           |                                  | Hgb <10.0: stop RBV |
EXAM: Do a directed physical exam at each visit. If SOB/DOE present, consider SpO2 monitoring*;

Mental Health: Evaluate for depression, aggression, drug abuse at each visit and consult CTS as needed.*