


Idaho Department of Correction 	Standard Operating Procedure Division of Education Treatment and Reentry Operational Services	Control Number: 401.06.03.077	Version: 3.0	Page Number: 1 of 6
		Title: Hepatitis C		Adopted: 10-30-2002 Reviewed: 07-26-2013

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BOARD OF CORRECTION IDAPA RULE NUMBER 401

Medical Care

POLICY CONTROL NUMBER 401

Clinical Services and Treatment

DEFINITIONS

Standardized Terms and Definitions List

Exposure Control Plan: A plan that describes actions that staff may take to eliminate or minimize exposure to pathogens.

Health Authority: The Idaho Department of Correction (IDOC) employee who is primarily responsible for overseeing or managing the IDOC’s medical services. (The health authority is commonly referred to as the health services director.)

Health Care Provider: Health care practitioners are clinicians trained to diagnose and treat patients.

Hepatitis C Virus (HCV): A blood borne, infectious, viral disease that is caused by the hepatitis C virus. The infection can cause liver inflammation that is often asymptomatic, but ensuing chronic hepatitis can result later in cirrhosis (scarring of the liver) and liver cancer.

Clinical Practice Guideline: A systematically developed, science-based guideline (presented by a national professional organization and accepted by experts in their respective medical field) designed to assist the practitioner and patient with decisions about appropriate healthcare for specific clinical circumstances.

Contract Medical Provider: A private company or other entity that is under contract with the Idaho Department of Correction (IDOC) to provide comprehensive medical, dental, and/or mental health services to the IDOC’s incarcerated offender population.

Medical Director: A physician either employed by the Idaho Department of Correction (IDOC) or contracted through privatized services (i.e., the physician in charge if medical services are privatized).

Mid-level Provider: A physician assistant or nurse practitioner.

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Qualified Health Professional: A physician, physician assistant, nurse practitioner, nurse, dentist, mental health professional, or other health professional who — by virtue of his education, training, credentials, and experience — is permitted by law (within the scope of his professional practice) to educate, train, evaluate, provide services, and care for patients.

Regional Health Manager: The individual (a) assigned as the primary manager, and (b) administratively responsible for the delivery of medical services, if health services are privatized.

Regional Medical Director: An employee of the contract medical provider, the physician assigned with the responsibility of overseeing all clinical aspects of health care in accordance with the terms of the contractual agreement between the contract medical provider and the department.

PURPOSE

The purpose of this standard operating procedure (SOP) is to provide evidence-based guidance to contract medical providers to establish a program to identify, counsel, evaluate and treat patients with hepatitis C, with the goal of preventing disease transmission and progression and fostering improvement in function.

The guidelines for screening, testing, counseling, evaluation and treatment in this SOP are based on the most recent information from the National Institute of Health (NIH), Centers for Disease Control and Prevention (CDC) and other nationally recognized science-based literature.

The Federal Bureau of Prisons (BOP) clinical practice guideline is based upon recommendations of NIH and CDC, as well as current scientific research from a wide variety of sources, and is the standard adopted by the Department for the identification, evaluation and treatment of Hepatitis C. As the BOP clinical practice guideline is updated to reflect new scientific evidence, this SOP will be revised accordingly.

In addition to requiring the contract medical provider to develop protocols consistent with the BOP clinical practice guideline, this SOP provides specific procedures for screening, testing, notification, and counseling offenders with Hepatitis C.

SCOPE

The scope of this SOP includes offenders, contract medical staff, and Idaho Department of Correction (IDOC) staff members involved in the treatment, assessment, or counseling of affected offenders.

RESPONSIBILITY

The department health authority is responsible to oversee the implementation and continued practice of the provisions contained in this SOP.

The contract medical provider is responsible to implement and practice the provisions of this SOP.

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GENERAL REQUIREMENTS

1. Clinical Practice Guidelines and Protocols

The contract medical provider shall establish and utilize clinical protocols for the evaluation and treatment of hepatitis C that are consistent with the Federal Bureau of Prisons Clinical Practice Guidelines for the Evaluation and Treatment of hepatitis C and cirrhosis.

The protocols must be reviewed and approved by the department’s health services director prior to implementation. The protocols shall be submitted to the health services director within 30 days of publication of this SOP.

The contractor’s regional medical director and the department’s health services director shall review and approve the protocol annually to ensure that the protocol is consistent with the most recent version of the BOP clinical practice guideline. Documentation of the annual review shall be kept on file in each facility’s medical unit.

Any deviation from the established protocols must be approved by a physician, documented in the offender’s medical file, and supported by clinical evidence.

2. Screening

Offenders shall be provided educational information on the transmission, natural history, and medical management of HCV infection. The contract medical provider’s qualified staff will perform this function on intake at the receiving and diagnostic units (RDU).

Identifying persons with chronic HCV infection requires screening asymptomatic persons, since the majority of persons with HCV are not ill. The Centers for Disease Control and Prevention (CDC) recommends screening persons at increased risk of infection, since identifying persons with HCV infection provides an opportunity for patient counseling, medical evaluation and treatment. Candidates for risk-based testing include offenders who have ever:

- injected illegal drugs;
- received a blood transfusion or organ transplant prior to July 1992;
- received a clotting factor transfusion prior to 1987;
- been on long-term hemodialysis;

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received tattoos or body piercings while incarcerated.

Appendix A, Offender Hepatitis Fact Sheet, shall be distributed to all offenders at intake by the contract medical provider's qualified staff at intake in the RDU. Based upon the information provided, the offender may submit a health services request to receive a test to determine the presence of hepatitis infection.

Appendix A, Offender Hepatitis Fact Sheet, shall be made available to all offenders in the medical units. At any time during incarceration, offenders may submit a health services request to receive testing.

3. Testing

In addition to the risk-based testing required in section 2, "Screening," the contract medical provider shall routinely test offenders for HCV infection based on clinical indications, including:

- signs and symptoms of hepatitis;
- elevated ALT levels of unknown etiology;
- concurrent infections with HIV or HBV;
- presence of medical conditions strongly associated with HCV infection such as cryoglobulinemia, membranoproliferative glomerulonephritis, and porphyria cutanea tarda.

Non-infected offenders on chronic hemodialysis should be screened for HCV infection by assaying ALT levels monthly; and anti-HCV by immunoassay semiannually.

Following an exposure to blood or body fluids, IDOC staff shall follow the facility exposure control plan. Offenders shall be tested appropriately following an evaluation by the facility health authority.

Tests for HCV infection should be performed by appropriately accredited laboratories, and ordered and interpreted by appropriately qualified health professionals in accordance with the established protocols, consistent with the BOP clinical practice guideline. The preferred screening test for HCV infection is an immunoassay that measures antibodies to HCV antigens.

4. Notification and Counseling

All HCV-Ab positive patients must be notified and counseled concerning hepatitis C infection. During the course of evaluation via the chronic disease program, further counseling may be indicated and tailored to specific co-morbid conditions associated with the offender's medical status. This counseling may include advice concerning management of depression, alcoholism, weight reduction if obese, control of diabetes, and control of other medical problems.

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Functional Roles and Responsibilities	Step	Tasks CIS steps are in bold
Qualified health professional	1	Learns that an offender has tested positive for HCV-Ab.
	2	Within fourteen (14) days, schedules an appointment with the offender.
	3	Counsel the offender regarding the positive diagnosis.
	4	Give the offender copies of appendix C, Information For Offenders Infected With Hepatitis C.
Offender	5	Read appendix C. (If the offender cannot read or cannot understand the material, the medical professional shall read the material to the offender.)
	6	After reading the material, signs the form and returns it to the medical professional.
Qualified health professional	7	Provide the offender a copy of the signed form, appendix C, and ensures that the form is filed in the offender's medical file.
	8	Documents the counseling in the offender's medical record.
	9	Enrolls the offender in the chronic care clinic where qualified health care professionals will complete follow-up evaluations at intervals to be determined by a physician or licensed mid-level provider and in accordance with the protocol established by the contract medical provider, which must be consistent with the BOP clinical practice guideline.
	10	As necessary, provides further counseling specific to the co-morbid conditions associated with the offender's medical status.

5. Evaluation and Treatment

Evaluation and treatment of hepatitis C shall be conducted in accordance with protocols established by the contract medical provider, consistent with the BOP clinical practice guideline and approved by the department's health services director prior to implementation. Appendix B, Consent for Hepatitis C Evaluation and Treatment, shall be completed prior to initiating treatment with interferon and ribavirin; (Dual Therapy), or with interferon, ribavirin and boceprevir or telaprevir (Triple Therapy). Triple Therapy is used for HCV genotype 1 only.

If the offender declines evaluation and/or therapy, a refusal of treatment form should be completed, and signed by the medical provider and the offender. The form should be faxed

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to the department's health services director and the original placed in the offender's medical file.

6. Compliance

Compliance with this SOP and the established department-approved protocols will be monitored via routine and case-specific audits and record reviews conducted by the department's health services director or designee.

REFERENCES

Appendix A, *Offender Hepatitis Fact Sheet*

Appendix B, *Consent For Hepatitis C Evaluation and Treatment*

Appendix C, *Information for Offenders Infected With Hepatitis C*

Appendix D, *Mental Health Review for Hepatitis C Patients on Interferon/Ribavirin Therapy.*

Centers for Disease Control and Prevention, *Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings*, MMWR 2003; 52 (No. RR-1): 1-36

Federal Bureau of Prisons, *Clinical Practice Guidelines for the Prevention and Treatment of Viral Hepatitis*, October 2005.

National Commission on Correctional Health Care, *Standards for Health Services in Prisons, 2003.*

National Institutes of Health Consensus Statement on Management of Hepatitis C: 2002; NIH Consensus and State-of-the-Science Statements, Volume 19, Number 3, June 10-12, 2002

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IDAHO DEPARTMENT OF CORRECTION
OFFENDER HEPATITIS FACT SHEET

Am I at risk of being infected with hepatitis B virus (HBV) or hepatitis C virus (HCV)?

You may be at risk for HBV or HCV infection if you have ever injected drugs or had sex with an infected partner. HBV is more easily transmitted through sex and from a mother to her child compared to HCV. Persons receiving blood transfusions prior to 1992 may be at risk for HCV infection. Talk to a health care provider about the risks of infection that affect you personally.

How can I prevent getting HCV or HBV while I am in prison?

Do not have sex with other offenders, shoot drugs, or get a tattoo or body piercing.

Do not share toothbrushes, razors, nail clipping devices, or other personal items that might have blood on them with other offenders.

Are these infections dangerous to my health?

Most persons infected with HBV or HCV do not develop serious health problems; however, a small but significant number of patients develop serious liver disease. Talk to a health care provider about personal risks for developing liver disease.

Why should I be tested for HBV or HCV infection?

You should be tested if you are at risk so doctors can monitor your infection and assess your need for treatment now or in the future. You should also be tested so that you can better prevent others from getting infected, including your infant if you are pregnant.

How do I get tested for HBV or HCV?

A simple blood test can determine if you are infected.

How can I prevent giving HBV or HCV to others if I am already infected?

First, remember that you can spread these infections even if you feel fine.

Do not shoot drugs or have sex with other offenders.

Do not share personal items that might have your blood on them, such as toothbrushes, dental appliances, nail-clipping equipment or razors.

Cover your cuts and skin sores to keep your blood from contacting other persons.

If you are being released, talk to a health care provider about specific ways you can reduce the risk of spreading HBV or HCV to others.

After reading this information, if you have additional questions or would like to request a test for hepatitis C, please submit a health services request form to the medical staff.



IDAHO DEPARTMENT OF CORRECTION
Consent for Hepatitis C Evaluation and Treatment

Offender Name _____ Number _____ Facility _____

1. I understand that I have hepatitis C infection and that blood tests have suggested that there is active injury to my liver. I agree to proceed with further evaluation of my liver with a liver biopsy, ultrasound (sound wave) test, and further blood tests. I understand that there are certain risks associated with the liver biopsy that include possible allergic reaction to the local anesthetic used to numb my skin, pain at the area where the needle is inserted, possible severe bleeding, and possible injury to my gallbladder or other internal organs. However, I understand that the biopsy will be performed by personnel trained in this procedure, that the biopsy will be performed only if I have normal blood clotting and no fluid accumulation in my abdominal cavity (ascites), and that I will be observed for at least two (2) hours after the biopsy and then be relieved of any work and not do any strenuous activity for the rest of that day and the next.
2. I understand that if I have significant active damage and scar tissue formation revealed by my liver biopsy, I would be a candidate for receiving Interferon and Ribavirin treatment. I understand that the biopsy might show only a small amount of damage, in which case I would not be offered Interferon and Ribavirin therapy.
3. I understand that this is a complicated and complex treatment that must be monitored closely, and due to the significant toxicities of the interferon and ribavirin, treatment should not begin unless it can be completed prior to my release from custody, unless continuity of care can be assured upon transition to the community. The time required for evaluation, treatment, and follow-up testing will be determined by the treating physician and will depend upon multiple clinical variables. I will be housed in a single IDOC facility for the duration of evaluation, treatment, and follow-up testing.
4. I understand that there are many side effects of receiving Interferon and Ribavirin. Interferon will be injected under my skin either three (3) times a week or weekly and can cause fatigue, aching, headache, loss of appetite, weight loss, difficulty sleeping, anxiety, irritability, and severe depression which may cause me to become suicidal. Interferon can also lower my white blood cells and platelets and also cause thyroid problems. Ribavirin pills will be taken twice a day and this medication can cause breakdown of my red blood cells with a resulting anemia. It can also cause a skin rash, itching, shortness of breath, cough, sore throat, nasal congestion, stomach pain and loss of appetite. These side effects of Interferon and Ribavirin can be severe and can cause death. I understand that I will need to make frequent visits to the prison medical unit to have blood tests and that the Interferon and Ribavirin doses may have to be adjusted or discontinued.
5. I understand that no promises or guarantees have been made to me that I will receive the Interferon and Ribavirin after the liver biopsy and that if I do receive these medications, I understand that this therapy may not eliminate the hepatitis C virus or prevent cirrhosis of the liver or prevent the development of liver cancer.
6. I understand that if I have a history of drug and alcohol abuse, I may be referred to a substance abuse program. I understand that I may be randomly tested during therapy for

illegal drugs and alcohol. I understand that if I continue to use alcohol or illicit drugs during treatment for hepatitis C, or otherwise demonstrate noncompliance with the prescribed treatment regimen, therapy may be discontinued.

7. I understand that Ribavirin can cause birth defects. If I am a woman, I must not become pregnant while on Ribavirin and for six (6) months after I stop taking it. If I am a man, I must not impregnate any woman for the time I am on Ribavirin and for six (6) months after I stop taking it.
8. I have discussed with my physician the following risks or issues in addition to those mentioned above concerning my medical condition and the evaluation and treatment of my hepatitis C:

9. I have discussed with my doctor the risks/benefits of having a liver biopsy and receiving Interferon and Ribavirin. All my questions have been answered in the terms and language that I understand.

I agree to have further evaluation of my hepatitis C with a liver biopsy, ultrasound test and more laboratory studies. If indicated, I agree to receive Interferon and Ribavirin for treatment of my hepatitis C.

I decline further evaluation of my hepatitis C and do not wish to have a liver biopsy and understand that I will not receive Interferon and Ribavirin treatment.

Offender's Signature _____ Date _____

Physician's Signature _____ Date _____



IDAHO DEPARTMENT OF CORRECTION INFORMATION FOR OFFENDERS INFECTED WITH HEPATITIS C

A recent blood test showed that you have an infection with the hepatitis C virus (HCV). This is a virus, which could seriously hurt your liver. You may have had HCV for a long time. You may have gotten the virus from being given contaminated blood or blood products before 1992 when the virus could not be detected. You may have gotten the virus from contaminated needles abusing intravenous drugs. Even if you abused drugs only a few times many years ago, you may have gotten HCV back then and never knew it. Frequent high-risk sexual contact is also thought to spread the virus. Tattoos and body piercing could also have been the source of the infection.

Fortunately, the majority of HCV infected people do not develop serious liver damage and the virus is not easily transmitted to others, even with close contact. However, it is important that we find out whether you are one of the people who have serious liver damage from HCV and find out if we can slow damage being done to your liver. Although there is FDA-approved therapy to try to reduce or eliminate the virus, the currently approved Interferon and Ribavirin treatment is not always successful and the treatment (shots and pills) is hard to tolerate with serious side-effects. A liver biopsy is usually required to determine if this therapy is indicated. For those who develop liver damage from HCV (cirrhosis of the liver and liver failure), it usually takes many years to develop significant liver damage. Although that sounds like a lot of time, if you were infected many years ago and did not know it, you may have more damage than you think.

If you are interested in being evaluated for your HCV infection, you will be asked to have more blood tests. However, due to the significant toxicities of the interferon and ribavirin, treatment shall not begin unless it can be completed prior to your release from custody, unless continuity of care can be assured upon transition to the community. The time required for evaluation, treatment, and follow-up testing will be determined by the treating physician and will depend upon multiple clinical variables. You must also not have any risks that would make Interferon and Ribavirin therapy dangerous for you. Then, if your blood tests show persistent active liver damage, you will be advised to have a liver biopsy.

If your biopsy shows that you would benefit from therapy with Interferon and Ribavirin, then this therapy will be offered to you in hopes of clearing the virus and stopping further liver damage.

Following are some "Frequently Asked Questions" and answers taken from the Centers for Disease Control (CDC):

Q. What is hepatitis C?

Hepatitis C is a virus (HCV) that can cause liver disease. The virus is found in the blood and liver of infected people and lives in the liver for many years. Most people who have HCV do not get serious liver disease. About fifteen percent (15%) to twenty percent (20%) of infected people develop cirrhosis and liver failure after several decades of infection.

Q. How could a person have gotten hepatitis C?

HCV is spread primarily by direct contact with human blood. For example, you may have gotten infected with HCV if:

You had a blood transfusion prior to 1992;

You once injected street drugs, and the needle and/or other drug paraphernalia used to prepare or inject drugs had someone else's blood that contained HCV on them;
If you have ever had sex with a person infected with HCV; or
You lived with someone who was infected with HCV and shared items such as razors or toothbrushes that might have had his blood on them.

Q. How can persons infected with HCV prevent spreading HCV to others?

Do not share personal items that might have your blood on them such as toothbrushes, dental appliances, nail clippers, or razors;
Cover your cuts and skin sores to keep from spreading HCV;
Do not have unprotected sex; and
Do not share needles, tattoo or body piercing equipment.

Q. How can people protect themselves from getting hepatitis C and other diseases spread by contact with human blood and body fluids?

Do not inject drugs;
If you inject drugs, stop and get into a substance abuse program. Never reuse or share syringes, water (used for injections) or drug paraphernalia;
Do not get a tattoo or any body piercing; and
Remember HCV can be spread by sexual activity, but at a very low rate.

Q. What can persons with HCV infection do to protect their liver?

Stop using all alcohol;
Stop using all street drugs;
Do not take over-the-counter, herbal, or other medications without your doctor's knowledge;
Avoid being overweight; and
Consider other measures your doctor may recommend (iron reduction and Vitamin E).

Q. What other information should you be aware of?

HCV is not spread by sneezing, coughing, food or water, sharing eating utensils or drinking glasses, or by casual contact;
A person can be re-infected, as prior infection does not give protection against a different strain; and
Your doctor will make medical decisions based on your medical status and evaluation.

Offender's Name (printed): _____ IDOC Number: _____

Offender's Signature: _____ Date _____

Physician's Signature: _____ Date _____



IDAHO DEPARTMENT OF CORRECTION
MENTAL HEALTH REVIEW FOR HEPATITIS C PATIENTS ON
INTERFERON/RIBAVIRIN THERAPY

Offender Name _____ Number _____ Facility _____

Severe depression and other psychiatric disorders can occur as a side effect of Interferon therapy. Some hepatitis C patients should be started on antidepressant medications before Interferon and Ribavirin therapy is begun. The following questions should be asked at each medical follow-up appointment. If there are any affirmative responses, a referral to correction outpatient psychiatric services should be made.

Date Interferon Started _____

Week of Interferon/ Ribavirin Therapy: (Circle "Y" for Yes or "N" for No, for each visit)

1	2	4	8	12	16	20	24	Questions:
Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Have you had any serious suicidal thoughts, developed a plan for suicide or had a suicide attempt within the past four (4) weeks?
Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Have you experienced hearing voices or seeing things that those around you have not, more than once within the past four (4) weeks?
Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Have you experienced a significant change in your mood that has lasted at least two (2) weeks?
Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	In the past two (2) weeks, have you experienced crying episodes or feelings of uncontrollable rage that were not in response to bad news or another serious event?
Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	In the past two (2) weeks, have you felt that you possess special powers, such as the ability to read people's minds, communicate with spirits or control others?

If offender answers "Yes" at any time to any question, hold Interferon and Ribavirin Rx and make referral to the Medical Director.

Mental Health Professional Signature _____ Date of Referral: _____