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Foreword

The purpose of the Hepatitis C Resource Center program is to enhance the capacity of VA Medical Centers to provide high quality care for patients with hepatitis C. The centers will provide clinical leadership, services, products and programs to assist practitioners in caring for these patients. The centers will also serve as field-based laboratories for developing and evaluating new clinical strategies related to hepatitis C. This manual represents current recommendations based on available evidence and expert consensus, and is designed to help VA practitioners to effectively diagnose, monitor and initiate treatment for the psychiatric and substance use disorders they encounter in hepatitis C patients. We are all continuing to learn how to improve our practice, and would like your help. Please take a few minutes to fill out the evaluation form at the end of this manual, and then fax or mail it to us, so that we may continue to improve these recommendations.

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Introduction

Current estimates indicate that as many as 6.6% of veterans served by Veterans Affairs Medical Centers test positive for the hepatitis C antibody (1). Further studies indicated that psychiatric and substance use disorders are frequently encountered in patients with hepatitis C (2-5). Moreover, psychiatric and substance use disorders are often cited as contraindications to antiviral therapy. Common reasons cited for refusal of therapy include "active psychiatric disease", or "active substance use", or "noncompliance with therapy"; however, these often are initial and perhaps subjective reasons given by the providers, without the help of specific guidelines or access to psychiatric consultation.

Psychiatric and substance use disorders may also complicate the tolerance of or adherence to interferon-based antiviral treatments (9). Recently, we found that patients with psychiatric disorders, including active depression, were able to successfully complete interferon alfa and ribavirin treatment when monitored with a protocol using objective depression scales and treated appropriately with anti-depressants (10). Further, the 2002 NIH Consensus Conference Statement on Management of Hepatitis C states that efforts should be made to increase the availability of the best current treatments to patients with psychiatric, substance use, and medical and neuropsychiatric co morbidities (11). In addition, Sylvestre et al, have shown that patients in a methadone clinic can be successfully treated for hepatitis C when provided with coordinated care (12). These data suggest that a team approach to hepatitis C management is likely to be most effective for evaluation and providing antiviral therapy. This team would involve hepatitis C clinicians, psychiatric or mental health specialists, and clinicians familiar with treating substance abuse.

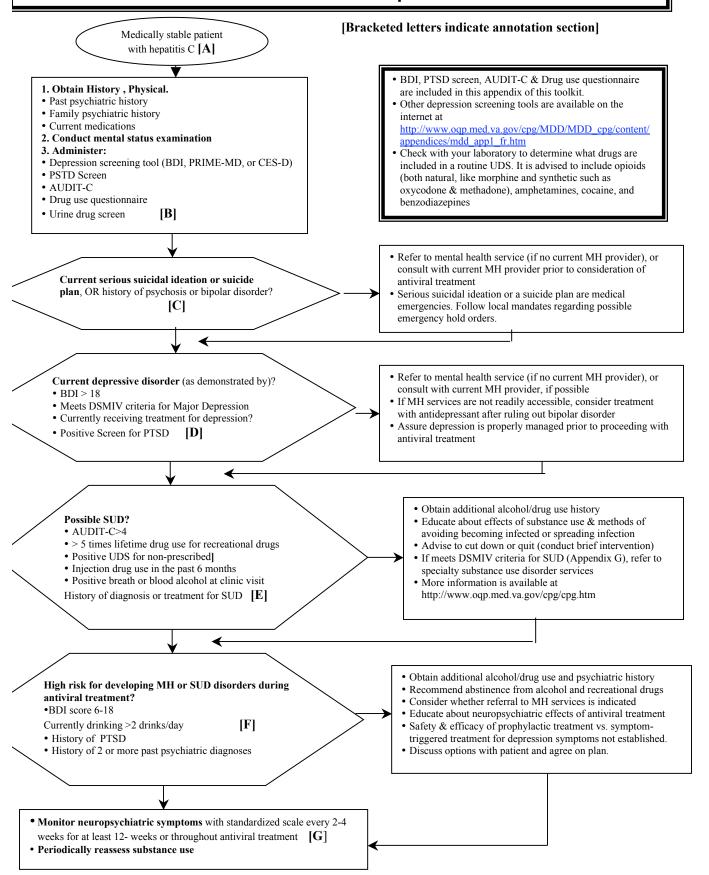
Hepatitis C practitioners will frequently need to consult with or refer patients to mental health service providers. Hepatitis C providers will need to identify psychiatric and addiction treatment providers and collectively agree upon the specific goals of their collaboration. Those goals should include how consultations are obtained, when and where patients are seen, and what each provider's responsibilities are, prior to and during antiviral therapy. One goal of collaborative care should be to develop a shared treatment philosophy. This exchange of knowledge leads to greater expertise in hepatitis C care by mental health providers as well as increased understanding of psychiatric and substance use care by hepatitis C providers. (Note: in this manual, use of the term "mental health providers" refers to psychiatric and addiction treatment providers, psychologists, and social workers). Numerous models of integration exist and are likely to vary due to resources and other site-specific factors. The central feature of integrated care is the development, by collaborators, of policies and procedures that take into account clinic resources and address the unique qualities of the patients treated. Collaborative care has been shown to improve outcomes and be cost effective in a variety of clinical settings (13, 14). Although this has not yet been



shown to be true in caring for hepatitis C patients, it is hard to argue with the logic of integrating services for patients with complex co-existing disorders. Of greatest import is the quality of coordination and communication among providers, and the spirit of collaboration.

This manual outlines one approach to caring for this complex population and is designed to provide a framework for clinicians working as part of a hepatitis C care team. Progress in hepatitis C treatment has been rapid and consequently has outpaced empirical evidence concerning best practices. This is especially so for patients with complex, coexisting conditions. As far as possible, this manual is based upon the best available evidence, but clinical consensus and experience forms the basis for much of what follows. When considering these recommendations, clinicians should always use their clinical judgment in making decisions regarding individual patients.

Screening for mental health and substance use disorders in the treatment of hepatitis C





ANNOTATIONS

A. Medically stable patient with hepatitis C

Definition

Individual with hepatitis C who is potentially eligible for antiviral therapy

B. Obtain psychiatric history and screen for Mental Health and Substance Use Disorders

Objective

Obtain comprehensive clinical background information on the patient

Annotation

- 1. Obtain the patients psychiatric history, as well as the psychiatric history of their family.
- 2. Review medications the patient is currently taking.
- 3. Conduct mental status exam
- 4. Assess MH and SUD status administering:
 - a. Depression screening tool (BDI, PRIME-D, or CES-D) (Note response to question 9 regarding suicidal ideation)
 - b. PTSD Screen
 - c. Audit-C
 - d. Drug use questionnaire
 - e. Urine drug screen

As depicted in the **screening algorithm**, the initial evaluation of patients with hepatitis C should include a psychiatric and substance use history. Family members and other significant persons may be very helpful at providing additional information later, as long as the patient consents. It is important to let patients know why we are asking them about psychiatric and substance use disorders. Most patients will cooperate if they



understand that these problems are common among patients with hepatitis C, and can complicate treatment if they are not recognized and treated.

Patients with preexisting psychiatric disorders should be asked about any current symptoms. Current substance use should be documented, including amount and frequency of consumption of alcohol, tobacco and other drugs such as heroin, cocaine, amphetamines, or non-medical use of prescription medication. Since depression and substance use disorders are so common prior to and during hepatitis C treatment, we recommend use of standardized procedures such as urine drug screens and questionnaires for evaluating depressive symptoms and substance use in order to make this process easier and more consistent. As shown in **Appendix F**, this can consist of a single form that can be given to patients to fill out at the beginning of their initial visit for hepatitis C evaluation.

C. Current serious suicidal ideation or suicide plan OR history of psychosis or bipolar disorder

Objective

Identify patient who needs to be stabilized before continuing in the algorithm.

Annotation

Risk factors for suicide:

- Prior suicide attempt and lethality of prior acts
- Level of intent and formulation of plan
- Greater preoccupation (e.g., frequency, intensity, and duration of thoughts)
- Availability of lethal means for suicide (e.g., firearms or pills)
- Family history of completed suicide
- Presence of active mental illness (e.g., severe depression or psychosis)
- Presence if substance abuse
- Current negative life events (e.g., loss in personal relationship
- Feelings of hopelessness or helplessness





It is important to consider the patient's history of violent acts as an increased risk for violence toward self or others. Patients who report suicidal ideation should be referred to a mental health practitioner (if they are not currently being seen by a mental health provider) or consult with their current MH provider, if possible. , If a patient represents a risk to self or others, providers should follow local, states, and federal guidelines which should be already well established. (We may want to include an additional more thorough section on suicide risk factors and evaluation)If mental health services are not readily accessible and the patient is not felt to be stable, consider treatment with antidepressant after ruling out bipolar disorder. It is important to assure depression is properly managed prior to proceeding with antiviral treatment.

Patients with a history of bipolar disorder are at risk of developing mania when taking antidepressants. Patients who have ever been treated for bipolar disorder or taken mood-stabilizing medications such as lithium, divalproex (valproate) or carbamazepine (tegretol) should be referred for psychiatric evaluation.

Psychotic disorders include schizophrenia, schizoaffective disorder as well as others and are characterized by symptoms such as hallucinations, delusions and disorganized thoughts. Patients who have been treated for a psychotic disorder or taken an antipsychotic medication such as haldol, thorazine, risperidone, olanzapine etc should be referred for evaluation by a mental health practitioner.



D. Current depressive disorder (as demonstrated by)

- BDI > 18
- Meets DSM-IV criteria for Major Depression
- Currently receiving treatment for depression
- Positive Screen for posttraumatic stress disorders (PTSD)

Objective

Identify patients with depression or PTSD.

Annotation

Prior histories of depression and active depressive symptoms are common in patients with hepatitis C. Posttraumatic stress disorder also occurs more frequently in these patients and is often undiagnosed. Systematic use of standardized inventories or questionnaires to test for current depressive symptoms can improve accurate detection and diagnosis (5, 10, 15).

Screening for and management of depression

Key Points:

- Use the Beck Depression Inventory (BDI) for depressive symptom
- Screen patients at baseline, and every 2-4 weeks thereafter during interferon based therapies.
- Patients with significant depressive symptoms should be evaluated for a history of bipolar disorder, PTSD, and medical causes of depression should be considered.
- Determine whether an anti-depressant and/or referral to a mental health specialist are indicated based on BDI scores, coupled with the patients' diagnostic information.

The Beck Depression Inventory (BDI) is easy to use and fast, and correlates well with other types of questionnaires when used to evaluate hepatitis C patients (16) and is recommended for all patients. Other possible scales that can be used include the CES-D (17), the PRIME-MD (18) or the Zung Depression Self Rating Scale (19). Symptom rating scales for depression should not be used as a substitute for clinical interviews. Elevated



depression symptom scores should trigger a more thorough evaluation of depressive symptoms, utilizing DSM-IV criteria (Appendix G).

For more information on management of major depressive disorders, or to view the screening instruments mentioned above, go to the following web site: http://www.oqp.med.va.gov/cpg/MDD/MDD_cpg/content/MDDapp_fr.htm
Even in those patients who may not be candidates for antiviral treatment, identifying and treating current psychiatric or substance use disorders will improve patient function and quality of life.

The Beck Depression Inventory (BDI)

The BDI is a 21-item self-report questionnaire focusing on depression symptoms during the previous week **(Appendix E)**. Each question on the BDI is scored from 0-3 and a total is reached by summing the score for each question. For example, question 1 of the BDI has the following four options:

Table 1.

I do not feel sad.	Score=0
I feel sad.	Score=1
I am sad all the time and I can't snap out of it.	Score=2
I am so sad or unhappy that I can't stand it.	Score=3

Scoring the BDI

All questions are scored in the same way. A filled circle by the first option offered is scored as a 0, the second option as 1, the third as 2, and the last as a 3. The form is scored by adding up the points indicated for each question, with the cumulative scores ranging from 0-63. Scores in the range of 0-9 indicate low levels of depressive symptoms or distress. BDI scores from 10-18 indicate the presence of mild to moderate depression. BDI scores in the 19-29 range indicate moderate to severe depression. Item number 9 on the BDI asks about suicidal ideation and at a minimum this question should be reviewed and discussed with the patient if suicide ideation is acknowledged.

When to administer the BDI

All patients should be given the BDI at their first contact with the HCV clinic. Patients about to receive interferon-based therapy should be monitored with a BDI just prior



to initiation of interferon and at 2-4 week intervals. Patients, who do not become psychiatrically symptomatic during interferon therapy, should be monitored for at least the first 3 to 6 months, and periodically after that, as indicated. Those who are started on an antidepressant should be monitored throughout the treatment course at 2-4 week intervals, or as clinically indicated.

Management of depressive symptoms

Note: Very few clinical studies exist in this population. The following recommendations are based on recent uncontrolled studies conducted in VA hepatitis clinics as well as clinical experience treating several hundred patients (10, 20). Although this protocol has worked well in that setting, providers should keep in mind that recommendations may change in the future as more data become available. Furthermore, clinicians must apply individual clinical judgment to the management of each specific clinical situation.

Current evidence indicates that patients who score between 6 and 10 on the BDI may be at increased risk for developing worsening depressive symptoms during interferon therapy. These patients should be screened at each clinic visit or at least every 2 weeks to access for worsening depression. Generally patients with BDI scores under 10 are considered asymptomatic and would not be pretreated or prophylactically treated with antidepressant medications. Although selective serotonin re-uptake inhibitors (SSRI's) have a high safety profile, some of the side effects of SSRI's are shared with IFN including headache, nausea, insomnia and anxiety or restlessness. Also no prophylactic antidepressant studies have been conducted in patients with HCV that access the risks and benefits of such a strategy. Although not predictive, other risk factors that may increase the risk of developing depression during interferon therapy include a history of 2 or more psychiatric diagnosis and a family history of affective disorders including depression and bipolar disorder (manic-depression). In certain instances prophylactic SSRI treatment may be considered based on patient preference, on clinician judgment and on consideration of prior history and risk factors for major depression, only after side effects and the potential risks of SSRI pretreatment have been discussed and other psychiatric disorders have been ruled out particularly bipolar disorder. If depressive symptoms emerge during IFN therapy, bipolar disorder as well as the relative contribution of medical conditions (e.g. anemia, hypothyroidism) to these symptoms should be considered before antidepressant treatment is begun.

Studies suggest that patients who have BDI scores of 10-18 prior to IFN therapy are at risk for developing major depression during IFN therapy (10). These patients should be evaluated for a major depressive disorder (MDD) using DSM-IV criteria and, if they meet



criteria for diagnosis, started on antidepressants. If patients do not meet criteria for MDD, a clinical judgment should be made regarding the use of antidepressants and psychiatric referral should be considered. As PTSD often presents with depressive symptoms it should be ruled out or if suspected, the patient should be referred to a mental health care provider. Referral to a psychiatrist should be considered within 2 weeks for patients who score above 18 on the BDI. Psychiatric referral should occur for any patient with a score of 2 or more on BDI item #9, suicidal ideation. Serious suicidal ideation (such as having a plan, making a will, saying goodbye to friends) is a psychiatric emergency requiring immediate and mandatory referral to a psychiatrist.

http://www.oqp.med.va.gov/cpg/MDD/MDD cpg/MDD toc fr.htm

Patients who score greater than 18 on the BDI should be referred to a mental health practitioner prior to initiating interferon treatment. Although current data indicates that antidepressants are effective for the treatment of depression in HCV patients both on and off of interferon, other treatment options should be considered. This includes education, cognitive behavioral therapy, and other supportive measures. The potential risks and side effects of each option should be explained to patients.

Selective serotonin reuptake inhibitor antidepressants such as citalogram should be considered as an initial antidepressant agent (Appendix A). SSRI's are safe, effective and easy to use. Patients who are prescribed an antidepressant should be followed at 2-4 week intervals with the BDI and be told to call the clinician at any time with worsening symptoms. Patients with BDI scores indicative of mild to moderate depression who respond well to an antidepressant medication may not need referral for psychiatric care. Referral for psychiatric consultation should be initiated in patients with BDI scores indicative of more severe levels of depression (>18), those with other current active psychiatric disorders such as PTSD or bipolar disorder, those that respond poorly to an initial course of antidepressant medication or refuse treatment with SSRI, or in those who report current serious suicidal ideation. Patients and clinicians should be able to recognize possible side effects of SSRI's, which include headache, insomnia, nausea, etc.



Table 2. BDI scoring and Treatment Recommendations for Patients Receiving Interferon Based Therapies (See Screening Algorithm, page 5)

Score	Interpretation	Recommendation
0-5	Normal, not depressed	Monitor depressive symptoms during interferon therapy at 2-4 week intervals.
6-9	High normal scores may predispose for depression during interferon-based treatment.	Consider prophylactic antidepressant treatment prior to initiating interferon therapy. Patient preference, clinician judgment and possible MDD risk factors should be considered. Discuss risk/benefits of antidepressant treatment with patient. Monitor depressive symptoms during interferon therapy at 2-4 week intervals.
10-18	Mild to moderate depression	If meets DSM-IV criteria for MDD start antidepressant, after evaluating for medical contributions and history of bipolar disorder. Refer to mental health if depressive symptoms do not improve. If patient does not meet criteria for MDD, continue to monitor every 2-4 weeks and consider referral to mental health provider
19-29	Moderate to severe depression	If no current mental health provider: refer to mental health immediately and follow up to ensure successful referral. If the patient has a mental health provider, contact the provider to discuss co-management. If suicide risk is moderate or high, refer urgently to mental health. Follow legal mandates concerning involuntary treatment if applicable.
30-63	Severe depression	Urgent referral to mental health. Assess for suicide risk and proceed accordingly. Follow legal mandates concerning involuntary treatment if applicable.

Systematic monitoring of patients with a questionnaire such as the BDI is important as early identification and treatment of depression will not only improve symptoms, but may reduce treatment dropouts and interferon dose reductions due to psychiatric symptoms.



Web Page references

The BDI and several other depression screening tools are available for VA employees at the "Major Depressive Disorder in Adults – VA/DOD Clinical Practice Guidelines" web page: www.oqp.med.va.gov/cpg/MDD/MDD_cpg/content/appendices/mdd_app1_fr.htm

This page is located on the Office of Quality Performance Website at: www.oqp.med.va.gov

These scales are also available from the Psychology Departments at VA Medical Centers.

Screening for post traumatic stress disorder (PTSD) in patients with hepatitis C

Key points:

- Use the primary care PTSD screening tool as a quick and efficient means to inquire about traumatic events.
- If the PTSD screen and interview indicate likelihood that the patient has PTSD, the patient should be referred to the appropriate provider.

Many patients seen at the VA who have hepatitis C also have a diagnosis of PTSD. This may or may not have been diagnosed in the past. In veterans, all patients should be screened for PTSD using a brief questionnaire (**Appendix B**) (21).

The VA primary care PTSD screening tool

The VA primary care PTSD screening tool efficiently screens for symptoms of PTSD. When asking about traumatic events, make no assumptions about the meaning or impact of traumatic events for an individual; instead acknowledge any reported distress, and show interest and concern. Unless you have appropriate mental-health training and will be the person to evaluate or treat the patient, it is not advisable to elicit a detailed account of the trauma or to challenge the patient's report in any way.

Clarify any positive responses indicated on the PTSD screening tool. Identify whether the patient has had a traumatic experience; determine if any endorsed screen items are really trauma-related symptoms and not just a negative event in that person's life (such as a recent



divorce or death in the family); and finally determine whether endorsed screen items are disruptive to the patient's life.

Scoring the PTSD screen

Positive responses to these questions in addition to endorsement of a traumatic event indicate an increased likelihood that the patient has PTSD and needs further evaluation. Such patients should be referred to the appropriate mental health department (21).

If ongoing traumatic events appear to be a part of the patient's life, the practitioner should consider immediate referral for mental-health services.

E. Possible Substance Use Disorders (SUD's)

Objectives

Identify individuals who have or are at risk for developing alcohol or other drug related medical or social problems.

Identify patients who need further assessment to diagnose their substance use disorders and develop plans to treat them.

Annotation

Many patients with hepatitis C also have current or undiagnosed substance use disorders. Whether alcohol or other drugs are used, the hepatitis C patient is at greater risk for hepatic damage than their non-hepatitis C counterparts. The initial screening for substance use is intended to rule out those patients for whom the provider identifies "no indications for further screening regarding substance use". Further it allows for identification of patients who need further assessment in order to diagnose and develop an appropriate management plan.

SUD screening should be done routinely in all patients, or clinically significant substance use will be missed. Routine screening also decreases the potential subjectivity of assessments, an important goal in this stigmatized population.



Screening for and management of substance use disorders (SUD) in patients with hepatitis C

Key points:

- Screen all patients for current and past non-medical substance use.
- Use the AUDIT-C to screen patients for both heavy nondependent drinking and alcohol dependence.
- Use the Drug Use Questionnaire to specifically quantify other drug use.
- Urine toxicology screening should be done routinely after patients give informed consent.
- Patients should receive feedback about screening results and the risks of use.
- Screening results help the care provider determine whether a brief intervention is appropriate or if the patient should be referred for further assessment and treatment.

Note that is important to check with your laboratory to determine what drugs are included in a routine UDS. It is advised to include opioids (both natural, like morphine, and synthetic, such as oxycodone & methadone), amphetamines, cocaine, and benzodiazepines.

Questions about SUD's should be asked sequentially. In addition to screening for the presence of alcohol abuse or dependence, it is essential to determine quantity and frequency of use. Persons drinking at a medically hazardous rate may not meet criteria for alcohol abuse or dependence, even in the presence of hepatitis C.

Screening for and management of Alcohol Use Disorders

Alcohol use in patients with Hepatitis C

It is important for clinicians to know patients' drinking levels in order to gauge their potential risk for developing problems. Present data indicates that patients with chronic hepatitis C may be harmed if they ingest > 30 grams of alcohol per day (about 3 drinks)(22). This may worsen fibrosis progression and increase the risk of cirrhosis and liver cancer. Lower levels of daily alcohol use may be harmful in women with hepatitis C. There are no data at the present time that indicate whether lower levels of alcohol use can be considered



"safe" in patients with hepatitis C. Alcohol use during interferon-based antiviral therapy may impair response, hence abstinence from alcohol is recommended during this type of antiviral therapy. At the same time, it is not clear that patients who continue to drink occasionally should be excluded from therapy. Alcohol use can be discussed with patients in the context of general health problems, where they can be provided a non-stigmatizing opportunity to obtain valuable risk reduction information. For more information regarding assessment of quantity and frequency of alcohol use, see the VA/DOD Clinical Practice Guideline for the Management of Substance Use Disorders at:

http://www.oqp.med.va.gov/cpg/SUD/SUD CPG/ModuleA/frameset.htm

Using the Audit-C

The Alcohol Use Disorders Identification Test (AUDIT-C) is superior to other screening tests like the CAGE because it screens for hazardous use as well as abuse and dependence (**Appendix E**). Answers to quantity and frequency questions indicate whether the patient is drinking at a rate that is medically hazardous, regardless of whether they meet criteria for abuse or dependence. These distinctions are important in determining the clinician's response (23). In the general population, a score on the AUDIT-C test > 6 indicates a high likelihood of hazardous use or dependence and requires obtaining additional substance use history or a referral. In this hepatitis C infected population we suggest using a score on the AUDIT-C test >4 as an indicator to further investigate the patients substance use.

Level of Use

The nature and intensity of alcohol-related problems vary according to consumption: In men, drinking more than about three drinks a day on average increases risk for adverse effects. The higher the level of consumption, the greater the risk of negative health effects, including cirrhosis, cancer, heart disease, stroke, traumatic injury, and depression. Heavy drinking substantially increases the development of fibrosis, cirrhosis, and hepatocellular carcinoma in the presence of hepatitis C infection. For healthy persons who currently drink, the following guidelines currently apply:

- Men No more that two drinks per day on average, and no more than five drinks per occasion
- Women No more than one drink per day, and no more than four drinks per occasion (24)
- Men and women over age 65 No more than one drink per day (25)



Table 3. Hazardous Alcohol Use (24)

Definition	Male	Female	Comments
Typical drinks per week	≥14	≥7	Standard drinks (each drink is approximately 13 grams of alcohol): • 12 ounces of beer • 5 ounces of wine • 1.5 ounces of 80-proof spirits
Maximum drinks per occasion	≥5	≥4	May vary depending on age, ethnicity, medical and psychiatric co-morbidity, pregnancy, and other risk factors



Screening for and management of Non-Alcohol related SUD's

Screening for SUD's other than heavy drinking

- Use the Drug Use Questionnaire to assess non-medical drug use other than heavy drinking (**Appendix D**).
- Screen all patients at baseline with a urine toxicology screen, after obtaining appropriate consent from the patient
- When recording screening results, indicate that a positive screen is not a diagnosis. Diagnosis requires a complete clinical interview.
- Present results of a positive screen and conduct all discussions about substance use in a matter-of-fact, nonjudgmental manner. It is helpful to frame the discussion in terms of the effects of substance use on the liver in the presence of hepatitis, and on treatment for hepatitis C.

The Drug Use Questionnaire

The purpose of the drug use questionnaire is to determine when further exploration of drug use is indicated. A positive screen should be seen as an alert to the practitioner of the possible presence of drug use disorders, and an indication to obtain further substance use history through direct interview. The routine administration of a urine toxicology screen can help identify substance-using patients who deny current drug use (including non-prescription use of pharmaceuticals). The patient should be informed that a urine toxicology screen is being ordered as a part of the routine patient evaluation, and that these results will be part of the medical record. This test can be omitted if a patient refuses, but the patient should be informed that the issue of substance use might need to be discussed further at future appointments. Refusal of a urine toxicology screen will indicate that referral for further substance use evaluation should be considered. For more information, see the VA/DOD Clinical Practice Guideline for the Management of Substance Use Disorders, at: http://www.oqp.med.va.gov/cpg/cpg.htm.

Family members and other significant persons such as close friends may provide valuable information, especially if the patient is minimizing their use or associated problems. If the patient consents, interviewing them (usually alone) can help verify or refute patient self-report.

Urine drug screening for heroin, morphine, codeine, methadone, benzodiazepines, cocaine, amphetamines, marijuana/hashish, and PCP is recommended. However, variation in screening exists from site to site and clinicians may need to request that additional substances be screened for. In addition, because non-prescription use of pharmaceuticals is



common in medical populations, hepatitis clinic staff should include a request to the lab to screen for synthetic opioids (oxycodone, hydrocodone). Note that a positive urine drug screen may be falsely positive. If a patient denies drug use in the face of a positive drug screen, order a confirmatory test from the laboratory (usually GC/MS). Confirmatory tests have a high degree of accuracy.

Brief Intervention

All patients who undergo screening for alcohol and drug use should be told the results. Those who screen negative because they are abstinent should be commended for their health-conscious lifestyle. For patients with positive findings from the screening a follow-up recommendation or treatment plan is needed. Abstinence from alcohol and other drugs is strongly recommended for patients with hepatitis C. This can be discussed with the patient in the context of the discussion about screening results. It is important to offer these patients the option of being referred to a specialist in treatment of alcohol and/or drug use disorders. Whether the patient chooses to see a substance use specialist in treatment of alcohol and/or drug use disorders. Whether the patient chooses to see a substance use specialist or not, the impact of substance use on hepatitis C should be discussed with all patients. These brief interventions can be quite effective, especially when conducted in a non-judgmental, educational manner, and when the connection between alcohol or drug use and hepatitis is made clear (26).

The purpose of a brief intervention is to:

- 1) provide feedback about screening results and risks of use in relation to hepatitis C
- 2) advise the patient about the need to abstain
- 3) assess the patient's readiness to change
- 4) identify potential barriers to change
- 5) discuss specific goals and strategies for change
- 6) support the patient's efforts to change

After conducting a brief intervention, schedule a follow-up visit within 1-2 months to determine how successful the intervention was. Address barriers to change and provide motivational support. Continue to see the patient until either abstinence is established or it becomes clear that the patient requires more specialized treatment.

A brief intervention is an appropriate response for those patients with mild to moderate substance use problems that may not require treatment in a more formal setting (26). Even dependence may respond to a properly conducted brief intervention. Furthermore, brief intervention in a primary care setting does not wield the stigma associated with longer-term specialized treatment. The physical condition or health concern that



brings the patient to a clinician's office offers a "teachable moment" in which the risk factors associated with alcohol and other drug consumption can be pointed out and behavior potentially changed (27).

Patients should be referred to an addiction specialist when:

- 1) there is a recent history of alcohol use or dependence or an AUDIT-C score > 4
- 2) the patient drinks at a hazardous rate and does not respond to a brief intervention
- 3) there is a recent history of intravenous drug use
- 4) there is a history of serious abuse of prescription drugs such as sedatives or pain killers (opioids)
- 5) a patient in remission from a substance use disorder relapses or is concerned that relapse may be imminent
- 6) the patient requests it

F. High risk for developing mental health or substance use disorders during antiviral treatment?

Objective

Identify patients that are at high risk for developing substance mental health and/or substance use disorders.

Annotation

Throughout antiviral treatment clinicians need to monitor both patients mental health and substance use status. Certain patients may be at higher risk for developing mental health and substance use disorders during treatment. The following are considered indicators of high risk for the development of these disorders during antiviral treatment.

- BDI score of 6 18
- Currently drinking >2 drinks/day
- History of PTSD
- History of 2 or more past psychiatric diagnoses

G. **Ongoing patient monitoring**



Objective

Identify patients experiencing neuropsychiatric symptoms or substance use issues during antiviral treatment.

Annotation

Throughout antiviral treatment providers should maintain ongoing evaluation of the mental health and substance use status of the patient. Neuropsychiatric symptoms can be monitored every 2-4 weeks for at least 12 weeks using the standardized scales discussed in annotation B. Substance use also needs to be assessed routinely, especially amongst patients found to be at high risk for developing substance use disorders.



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Appendix A

Anti-depressants for initial treatment of depression in hepatitis C patients

Name (trade name*)	Tablet size	Half-life	Initial dose	Titrate dose to
SSRI's				
Citalopram (Celexa TM)	20, 40 mg	33-37 hr	20 mg/day	40-60 mg/day
Escitalopram (Lexapro TM)	10, 20mg	27-32 hr	10 mg/day	10-20 mg/day
Sertraline (Zoloft TM)	50, 100 mg	26 hr (62-104)	50 mg/day	50-200 mg/day
Fluoxetine (Prozac TM)	10,20 mg	48-72 hr (96-384)	20 mg/day	20-40 mg/day
Paroxetine (Paxil TM)	10,20,30 and 40 mg	21 hr	20 mg/day	20-60 mg/day
Others with unique actions				
Venlafaxine XR (Effexor TM)	37.5,75,15 0 mg	5-11 hr (9-13)	37.5-75mg/day	225 mg/day, max
Bupropion SR (Wellbutrin TM)	100 and 150 mg	14 hr (8-24)	100mg bid	150 mg bid

^{*}Brand names included in this material are provided as examples only and their inclusion does not mean that the Department of Veterans Affairs or any other Government agency endorses these products. Also if a particular brand name is not mentioned, this does not mean or imply that the product is unsatisfactory.

All SSRI's are equally effective. Citalopram and sertraline may be considered first line agents as they have few drug-drug interactions, are well tolerated, and have a reasonable cost. As fluoxetine is the only generic SSRI available its cost is significantly less than other agents. As other SSRI's become available in generic form clinicians should check with their pharmacists as costs will likely change.

See the following page {Appendix B) for an overview of the side effects typically associated with the medications above.



Appendix B

Common side effects of these antidepressants

Antidepressant medications can cause side effects. These are generally mild, occur early in treatment, and often resolve over time. However, some can be serious, and patients should be advised to contact their doctor if they experience unusual and/or annoying effects that may be medication related. The side effects of SSRI's and interferon may overlap and adding an SSRI during interferon treatment may worsen some symptoms. SSRI related side effects should be monitored and addressed during therapy.

The following is a list of common side effects associated with antidepressants. For a comprehensive list of side effects please reference MicroMedex on the VA CPRS system, or other side-effect reference texts.

SSRI's (Citalopram, Escitalopram, Sertraline, Fluoxetine, Paroxetine)	CNS: headache, somnolence, insomnia, agitation or anxiety GI: nausea, diarrhea, vomiting, GU: sexual dysfunction.
Venlafaxine	Has typical SSRI side effects listed above But may also cause sweating and high blood pressure, which should be monitored throughout treatment.
Bupropion	Insomnia, agitation, irritability. It is not associated with sexual dysfunction but should not be used in patients with a history of seizure.



Appendix C

Primary Care PTSD Screen

In your life, have you ever had any experience that was so frightening, horrible, or upsetting that, in the past month, you...

Have had nightmares about it or thought about it when you did not want to?

YES NO

Tried hard not to think about it or went out of your way to avoid situations that reminded you of it?

> YES NO

Were constantly on guard, watchful, or easily startled?

YES NO

Felt numb or detached from others, activities, or your surroundings?

NO YES

Current research suggests that the results of the PC-PTSD should be considered "positive" if a patient answers, "yes" to any two items or the single hyper-arousal item (item #3).



Appendix D

ALCOHOL USE DISORDERS IDENTIFICATION TEST (AUDIT-C)

Please circle the answer that is correct for you.

- 1. How often do you have a drink containing alcohol?
 - (0) Never (1) Monthly (2) Two to four (3) Two to three (4) Four or more or less times a month times a week times a week
- 2. How many drinks containing alcohol do you have on a typical day when you are drinking?
 - (0) 1 or 2 (1) 3 or 4 (2) 5 or 6 (3) 7 to 9 (4) 10 or more
- 3. How often do you have six or more drinks on one occasion?
 - (2) Monthly (4) Daily or (0) Never (1) Less than (3) Weekly monthly almost daily

SCORING AUDIT:

Add scores from all three items

Score >4 - In hepatitis C infected patients, we recommend that a score > 4 be used as an indicator for further assessment of substance use. Note that in the general population, a score > 6 indicates a high likelihood of hazardous use or dependence and requires obtaining additional substance use history or referral.



Appendix E

Drug Use Questionnaire

1. Please indicate how often you have used each of the following drugs in your lifetime:

Drug	Never Used	Used 1-5 times	Used more than 5 times	Year last used
Marijuana/hashish				
Cocaine				
Methamphetamine/Speed				
Heroin				
LSD/PCP				
Ecstasy/MDMA				

2. Have you ever injected any drugs, even once? Yes	No
---	----

3.	Have you e	ver used p	prescription	drugs such	as painkillers	or sedatives	for non-med	dical purposes?

Yes

No

4. Hav	ve you ever had treatment for alcoh	Yes	No	
	If yes, how many times?	Last time treated?		

SCORING THE DRUG USE QUESTIONNAIRE

Question 1: Positive if any drug used > 5 times in life or any drugs used in past year

Questions 2-4: Any yes is positive.

A positive screen requires 1 item be positive

If any of the instruments are positive, obtain additional substance use history through interview or refer to a substance abuse practitioner (for more information, see the VA/DOD Clinical Practice Guideline for the Management of Substance Use Disorders, at http://www.oqp.med.va.gov/cpg/cpg.htm).



Appendix F

Hepatitis Clinic New Patient Self-Assessment

Today we would like to gather important information about your medical history and to confirm whether or not you actually have hepatitis (sometimes screening tests can be positive in people who do not have hepatitis). In addition we will be asking you to fill out some forms asking questions about depression, and other mental health issues, and about your use of tobacco, alcohol and other drugs. This is important because problems in those areas can affect patients with liver disease such as hepatitis. Also, it is important that we know about these problems because they can interfere with treatments that are given for hepatitis and other liver diseases.

Prior to your appointment today we would like you to fill out a few forms, which will be reviewed with a nurse. Completion of these forms is voluntary. Blood and urine tests will also be ordered, including a urine test for alcohol and other drugs. Along with the screening questions, the urine screening is part of the routine workup for patients with liver disease or hepatitis. The results of these tests will become part of your permanent medical record. Completion of these tests is also optional. This information is confidential and protected unless you consent to a release of your medical record or if release of the information is required by federal law. A federal law allows the U.S. Food and Drug Administration and other federal agencies to inspect medical records. Completion of any of the blood and urine tests is also voluntary. If you do not wish to have any of these done please discuss them with the nurse or physician.

If you have any questions before your appointment, please ask the nurse or physician.

We appreciate your time in completing this information.

The Hepatitis Clinical Care Team



DATE:

PART I. What are your possible risk factors for hepatitis C?
1) Have you ever had: (Please check all that apply including year of exposure to the risk factor)
Blood transfusions/organ transplants prior to 1992 Hemodialysis
Injecting "street" drugs with needles Tattoos/body piercing
Combat related blood exposure Acupuncture
Intranasal drug use
Unexplained liver disease or hepatitis
Multiple (more than 5) sexual partners or history of Sexually Transmitted Diseases
Exposure to other people's blood through skin/mucous membranes
2). Please list medical problems you have now:
3). Please list any mental health or substance abuse problems you have now or in the past.
4). Please list any surgeries you have had including the dates of those surgeries.
5). Please list all prescription medications you are now taking:
6). Please list any allergies that you have now:
o). Trease list any anergies that you have now.
7). Please list all over the counter medications, "herbals", vitamins and supplements you are now taking:





PART II. (If you have a current diagnosis of Post Traumatic Stress Disorder skip this section and proceed to part VI).

In your life, have you ever had any experience that was so frightening, horrible, or upsetting that, in the past month, you...

Have had nightmares about it or thought about it when you did not want to? 1.

YES

NO

2. Tried hard not to think about it or went out of your way to avoid situations that reminded you of it?

YES

NO

3. Were constantly on guard, watchful, or easily startled?

YES

NO

4. Felt numb or detached from others, activities, or your surroundings?

YES

NO

PART III.

Please circle the answer that is correct for you.

1. How often do you have a drink containing alcohol?

(0) Never

(1) Monthly or less

(2) Two to four times a month (3) Two to three times a week

(4) Four or more times a week

2. How many drinks containing alcohol do you have on a typical day when you are drinking?

(0) 1 or 2

(1) 3 or 4

(2) 5 or 6

(3) 7 to 9

(4) 10 or more

3. How often do you have six or more drinks on one occasion?

(0) Never (1) Less than monthly

(2) Monthly

(3) Weekly (4) Daily or almost daily



PART VI.

1. Please indicate how often you have used each of the following drugs $\underline{\text{in your lifetime}}$: Please circle the answer that is correct for you.

Marijuana/hashish	Never Used	Used 1-5 times	Used more than 5 times	Year last used:
Cocaine	Never Used	Used 1-5 times	Used more than 5 times	Year last used:
Methamphetamine/ Speed	Never Used	Used 1-5 times	Used more than 5 times	Year last used:
Heroin	Never Used	Used 1-5 times	Used more than 5 times	Year last used:
LSD/PCP	Never Used	Used 1-5 times	Used more than 5 times	Year last used:
Ecstasy/MDMA	Never Used	Used 1-5 times	Used more than 5 times	Year last used:
2. Have you ever inject	cted any drugs?	Yes	No	
3. Have you ever used		gs such as painkill es No	ers or sedatives t	for non-medical purposes?
4. Have you ever had	treatment for alco	shol or drug depen Yes	dence?	
If yes, how many time	es? I	Last time treated?		_



PART V. Please circle the answer that is correct for you.

 Do you currently smoke or chew tobacco 	Yes	Former smoker/user	No (if no go to part VI)
--	-----	--------------------	--------------------------

-•	Less than	pack/day to		pack/day	more than 1	•
2	How many cigarettes	ner dav? – <i>H</i>	Please circle the	answer that is	s correct for	· voi

less than 1 pack/day _ pack/day pack/day

3. What year did you start smoking?

4. Did you smoke or chew tobacco in the past? Yes No

If yes, for how many years_____ and how many packs/day _____? 5.



PART VI. Beck Depression Inventory (BDI, 21-items)

On this questionnaire are groups of statements. Please read each group of statements carefully. Then pick out the one statement in each group, which best describes the way you have been feeling the **past week, including today**. Circle the number to the right of the statement you picked. If several statements in the group seem to apply equally well, circle each one. Be sure to read all statements in each group before making your choice.

Cacii	one. Be sure to read an statements in each group before making	your chore
1.	I do not feel sad	0
	I feel sad	1
	I am sad all the time and can't snap out of it	2
	I am so sad or unhappy that I can't stand it	3
2.	I am not particularly discouraged about the future	0
	I feel discouraged about the future	1
	I feel I have nothing to look forward to	2
	I feel that the future is hopeless and that things cannot improve	3
3.	I do not feel like a failure	0
	I feel I have failed more than the average person	1
	As I look back on my life, all I can see is a lot of failure	2
	I feel I am a complete failure as a person	3
4.	I get as much satisfaction out of things as I used to	0
	I don't enjoy things the way I used to	1
	I don't get real satisfaction out of anything anymore	2
	I am dissatisfied or bored with everything	3
5.	I don't feel particularly guilty	0
	I feel guilty a good part of the time	1
	I feel quite guilty most of the time	2
	I feel guilty all of the time	3
6.	I don't feel I am being punished	0
	I feel I might be punished	1
	I expect to be punished	2
	I feel I am being punished	3
1	I .	



I don't feel disappointed in myself	0
I am disappointed in myself	1
I am disgusted with myself	2
I hate myself	3
I don't feel I am any worse than anybody else	0
I am critical of myself for my weaknesses or mistakes	1
I blame myself all the time for my faults	2
I blame myself for everything bad that happens	3
I don't have any thoughts of killing myself	0
I have thoughts of killing myself, but I would not carry them out	1
I would like to kill myself	2
I would kill myself if I had the chance	3
I don't cry any more than usual	0
I cry more now than I used to	1
I cry all the time now	2
I used to be able to cry, but now I can't cry even though I want to	3
I am no more irritated now than I ever am	0
I get annoyed or irritated more easily than I used to	1
I feel irritated all the time now	2
I don't get irritated at all by the things that used to irritate me	3
I have not lost interest in other people	0
I am less interested in other people than I used to be	1
I have lost most of my interest in other people	2
I have lost all of my interest in other people	3
I make decisions about as well as I ever could	0
I put off making decisions more than I used to	1
I have greater difficulty in making decisions than before	2
I can't make decisions at all anymore	3
	I am disappointed in myself I am disgusted with myself I hate myself I don't feel I am any worse than anybody else I am critical of myself for my weaknesses or mistakes I blame myself all the time for my faults I blame myself for everything bad that happens I don't have any thoughts of killing myself I have thoughts of killing myself, but I would not carry them out I would like to kill myself I would kill myself if I had the chance I don't cry any more than usual I cry more now than I used to I cry all the time now I used to be able to cry, but now I can't cry even though I want to I am no more irritated now than I ever am I get annoyed or irritated more easily than I used to I feel irritated all the time now I don't get irritated at all by the things that used to irritate me I have not lost interest in other people I am less interested in other people I have lost most of my interest in other people I have lost all of my interest in other people I make decisions about as well as I ever could I put off making decisions more than I used to I have greater difficulty in making decisions than before



14.	I don't feel I look any worse than I used to	0
	I am worried that I am looking old or unattractive	1
	I feel that there are permanent changes in my appearance that make me look unattractive	2
	I believe that I look ugly	3
15.	I can work about as well as before	0
	It takes extra effort to get started at doing something	1
	I have to push myself very hard to do anything	2
	I can't do any work at all	3
16.	I can sleep as well as usual	0
	I don't sleep as well as I used to	1
	I wake up 1-2 hours earlier than usual and find it hard to get back to sleep	2
	I wake up several hours earlier than I used to and cannot get back to sleep	3
17.	I don't get more tired than usual	0
	I get tired more easily than I used to	1
	I get tired from doing almost anything	2
	I get too tired to do anything	3
18.	My appetite is no worse than usual	0
	My appetite is not as good as it used to be	1
	My appetite is much worse now	2
	I have no appetite at all anymore	3
19.	I haven't lost much weight, if any, lately	0
	I have lost more than 5 pounds	1
	I have lost more than 10 pounds	2
	I have lost more than 15 pounds	3
	I am purposely trying to lose weight by eating less Yes No	
	I	



20.	I am no more worried about my health than usual	0
	I am worried about physical problems such as aches and pain; or upset stomach; or constipation	1
	I am very worried about physical problems and it's hard to think of much else	2
	I am so worried about my physical problems that I cannot think about anything else	3
21.	I have not noticed any recent change in my interest in sex	0
	I am less interested in sex than I used to be	1
	I am much less interested in sex now	2
	I have lost interest in sex completely	3

Beck, Ward, & Mendelson, 1961



Appendix G

Shade circles like this:	First Initial Last 4 of SSN	Last Nam	e	Tod	ay's Date		
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						O Yes	O No
					0	0	0
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					0	0	0
					0	0	0
						O Yes	O No

\sim	Department of Veterans Affairs
V.	Veterans Affairs

PSQ page 2							
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					0	Yes	O No
					0	0	0
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	0	0	0		0		0
					M M	/ [Y Y Y
					0	Yes	O No
					0	0	0
					0	Yes	O No
					0	Yes	O No
							1499



Appendix H

DSM IV Criteria for Major Depression DSM-IV Diagnostic Criteria for MDD

The following criteria are from the DSM-IV Criteria for establishing the diagnosis of Major Depressive Disorder (MDD).

Diagnostic Criteria for Major Depressive Episode (from DSM-IV, page 327)

A major depressive episode is not always indicative of major depressive disorder. Other causes of a Major Depressive Episode besides MDD include, for example, Bipolar Disorders. (See criteria below.)

- A. At least five of the following symptoms have been present during the same 2-week period, nearly every day, and represent a change from previous functioning. At least one of the symptoms must be either (1) depressed mood or (2) loss of interest or pleasure:
 - 1. Depressed mood most of the day, nearly every day, as indicated by self or others
 - 2. Markedly diminished interest or pleasure in all, or almost all, activities
 - 3. Significant weight loss or weight gain (5 %/mo.) or loss/gain in appetite nearly every day.
 - 4. Insomnia or hypersomnia nearly every day
 - 5. Psychomotor agitation or retardation nearly every day (as noted by others).
 - 6. Fatigue or loss of energy nearly every day
 - 7 Feelings of worthlessness or excessive or inappropriate guilt nearly every day
 - 8. Diminished ability to think or concentrate or indecisiveness nearly every day
 - 9. Recurrent thoughts of death, recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide.
- B. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning
- C. Symptoms are not better accounted for by a Mixed Episode, Mood Disorder Due to a General Medical Condition, a Substance-Induced Mood Disorder, or Bereavement (normal reaction to the death of a loved one)
- D. Symptoms are not better accounted for by a Psychotic Disorder (e.g., Schizo-affective Disorder).



Diagnostic Screening Criteria for Major Depressive Disorder

Patients suffering from a Major Depressive Episode who also meet all of the following criteria should be diagnosed with MDD.

- 1. Presence of either a single (296.2) or recurrent (296.3) Major Depressive Episode(s), respectively. (See definition below.)
- 2. The major depressive episode(s) is/are not better accounted for by Schizo-affective Disorder and is/are not superimposed on Schizophrenia, Schizophreniform Disorder, Delusional Disorder, or Psychotic Disorder Not Otherwise Specified.
- 3. There has never been a Manic Episode (DSM-IV, page 327), a Mixed Episode (DSM-IV page 335), or a Hypomanic Episode (DSM-IV page 338). Note: This exclusion does not apply if all of the manic-like, mixed-like or hypomanic-like episodes are substance or treatment induced or are due to the direct physiological effects of a general medical condition.

American Psychiatric Association. 1994.



Today's Date: /			VISI	N:		
Gender O F O M	VA	where you wo	ork:			
Type of Practice: O Medical Doctor O Physician Assistant O Pharmaceutical Doctorate O Nurse Practioner O Clinical Nurse Specialist O Registered Nurse O Licensed Practical Nurse O Other (please specifiy) How many patients with he lid you see last month?	patitis C	profe Date (Mon Have	graduated from ssional school. you received the hth/Year) you attended a Feptorship in Minn If yes, when? (M How many staff treatment at you	Hepatitis Caeapolis? Sonth/Year do you cu	r) rently have	/
0 11-20						identified a Mental
2) 21-40 2) > 40 2) Not applicable 3) Don't know				N/A	`	in one)?
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> 40> Not applicable> Don't knowPlease rate your level of	esponse per	with the follo category.	OY ON O If no, was this o OY ON	O N/A done as a O N/A about this	result of rece	,
D > 40 Not applicable Don't know Please rate your level of Please choose only one related to the content makes sense medically It is well organized	Strongly disagree	with the follo category. Disagree	OY ON O If no, was this o OY ON wing statements: Neither agree or disagree	O N/A done as a O N/A about this	manual: Strongly agree	,
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Evaluation of the Minneapolis HCRC Mental Health and Substance Abuse Manual

Page 2 of 2

How useful did you find the information in each of the content areas?

Level of usefulness for your patients with hepatitis C	Not useful at all	Not very useful	Neither useful or not useful	Somewhat useful	Very useful
Setting up a collaboration with mental health practitioners?	0	2	•	•	0
Screening and management of depression?	0	2	•	· ·	•
Screening for Post Traumatic Stress Disorders?	0	(2)	•	·	0
Screening for substance abuse?	0	2	•	0	0
Screening and management of alcohol use disorders?	0	2	•	0	•
Screening and management of non-alcohol related substance use disorders?	0	2	•	0	•
Doing a brief intervention?	0	2	0	0	0

(IIII in one)? Never (Rarely	Occasionally	С) Regula	ırly			
After reading this manual, do you plan on changing your clinical procedures for: Please fill all that apply.								
Clinical Proce	dure			YES	NO	Does not apply	Don't know	
Screening for depression ①				②	3	•		
Diagnosing de	pression		0	-	0	•	0	
Managing depression (0		②	0	·	
Screening for	Post Traum	atic Stress Disorder	0		2	3	0	
Screening for alcohol (ETOH) use disorders ①			0		2	0	•	
Diagnosing ETOH use disorders ①				0	•	·		
Managing ET	OH use diso	rders	0		0	3	0	
Screening for non-ETOH substance use disorder				(2)	3	0		
Diagnosing no	n-ETOH su	bstance use disorders	0		0	0	0	
Managing nor	-ETOH sub	stance use disorders	<u>-</u>		(2)	0	\odot	

Thank you for completing this survey
Please fax or mail to:
Mary Wingert, HCRC coordinator
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The National Hepatitis C Program

The Department of Veterans Affairs (VA) leads the country in hepatitis C screening, testing, treatment, research and preparation. VA is the largest provider of medical care to people with hepatitis C infection in the United States.

The National Hepatitis C Program works to ensure that veterans with or at risk for hepatitis C receive the highest quality health care services from the VA system. Led by the VA's Public Health Strategic Healthcare Group (PHSHG) and carried out by comprehensive approach to hepatitis C prevention and treatment that includes screening, testing and counseling, patient and provider education, optimal clinical care, and management of data to continuously improve program quality.

The Hepatitis C Resource Centers (HCRC's), a part of the National Hepatitis C Program, develop best practices in clinical care delivery, patient education, provider education, prevention, and program evaluation that can be used by the entire VA health care system and other medical care systems. They function as field-based clinical laboratories for the development, testing, evaluation, and dissemination of new and innovation products and services for improving the quality of hepatitis C clinical care and education in every VA medical facility.

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