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HEPP NEWS

June 2000 Vol. 3, Issue 6

HIV
EDUCATION
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PROJECT

Sponsored by the Brown University School of Medicine Office of Continuing Medical Education and the Brown University AIDS Program.

ABOUT HEPP

HEPP News, a forum for correctional problem solving, targets correctional administrators and HIV/AIDS care providers including physicians, nurses, outreach workers, and case managers. Published monthly and distributed by fax, HEPP News provides up-to-the-moment information on HIV treatment, efficient approaches to administering HIV treatment in the correctional environment, national and international news related to HIV in prisons and jails, and changes in correctional care that impact HIV treatment. Continuing Medical Education credits are provided by the Brown University Office of Continuing Medical Education to physicians who accurately respond to the questions on the last page of the newsletter.

EDITORS

Anne S. De Groot, M.D.
Director, TB/HIV Research Lab,
Brown University School of Medicine

Frederick L. Altice, M.D.
Director, HIV in Prisons Program,
Yale University AIDS Program

Joseph Bick, M.D.
Chief Medical Officer,
HIV Treatment Services
California Department of Corrections
California Medical Facility, Vacaville

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In accordance with the Accreditation Council for Continuing Medical Education Standards for Commercial Support, the faculty for this activity have been asked to complete Conflict of Interest Disclosure forms. Disclosures are listed at the end of articles. All of the individual medications discussed in this newsletter are approved for treatment of HIV unless otherwise indicated. For the treatment of HIV infection, many physicians opt to use combination antiretroviral therapy which is not addressed by the FDA.

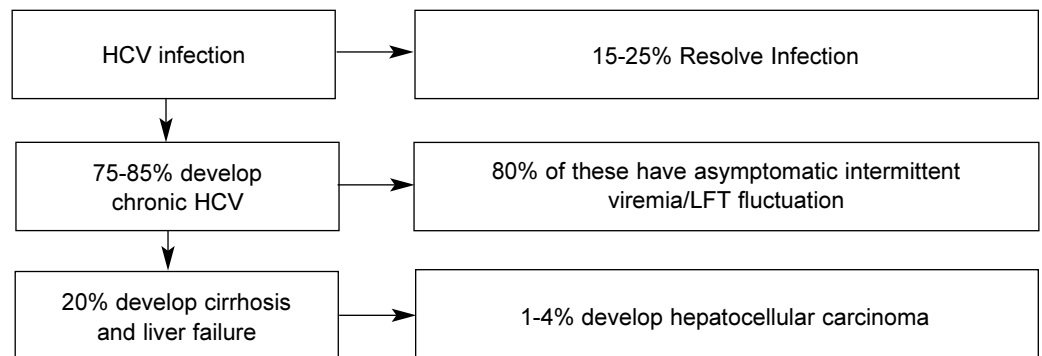
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THE CORRECTIONAL DOCTOR'S DILEMMA: HEPATITIS C TREATMENT

Anne S. De Groot, M.D.*, Joseph Bick, M.D.** Editors HEPP News

The hepatitis C virus (HCV) is responsible for 60-70% of chronic hepatitis and 30% of cirrhosis, end stage liver disease, and liver cancer in the United States. Approximately 1.8% or close to 4.5 million Americans are infected with HCV, and HCV causes an estimated 8,000-10,000 deaths each year in this country. 75-85% of those infected with HCV develop chronic liver disease (1). Chronic infection varies in severity and clinical course. Many of those infected will have normal liver enzymes and no clinical symptoms. Approximately 50% of these individuals are unaware of their HCV infection (2). Of those who develop chronic liver disease, perhaps 20% will eventually progress to cirrhosis and several percent will develop liver carcinoma (1).

FIGURE 1. Patterns of Disease in Hepatitis C Infection



Among individuals who have persistent HCV infection, 80% are asymptomatic, despite intermittent viremia and abnormal fluctuations of their liver function tests. These individuals have the capacity to infect others. HCV is responsible for approximately 40% of the 25,000 annual deaths in the U.S. from chronic liver disease (1). HCV is grouped into six genotypes and more than 90 subtypes; genotypes 1a and 1b are more common in the United States and less responsive to antiviral therapy.

HCV EPIDEMIOLOGY IN CORRECTIONS

During the 1980's an average of 230,000 new HCV infections occurred each year in the US (3). The number of new infections declined after the introduction of improved methods for the detection of HCV in the blood supply.

Currently, most HCV transmission is associated with injection drug use (IDU). 79% of current IDUs have HCV infection (3). Young IDUs acquire HCV infection at rates four times higher than they acquire HIV; after five years of injection drug use, 90% of users are HCV infected. Non-Hispanic blacks and African Americans have higher rates of HCV infection and chronic disease than whites; most cases of HCV infection are found among persons who are male, members of minority populations, and 30 to 49 years of age (3).

Given the linkages between HCV infection and drug use, gender, age, and minority populations, it is not surprising that almost one third (1.4 million) of the 4 million individuals in the United States who are believed to be infected with HCV pass through correctional facilities each year (2). The prevalence of HCV infection among U.S. prisoners is at least 10-fold higher than the estimated prevalence of 2% in

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the general population (4, 2). Where surveys have been carefully performed, HCV infection rates among inmates have ranged between 30 and 40% (5). Estimates of HCV infection in state correctional facilities range from 28% (Texas) to 54% among women in California (see Figure 2). HIV-infected incarcerated women exhibit a slightly higher HCV co-infection rate than HIV-infected incarcerated men (see Figure 2).

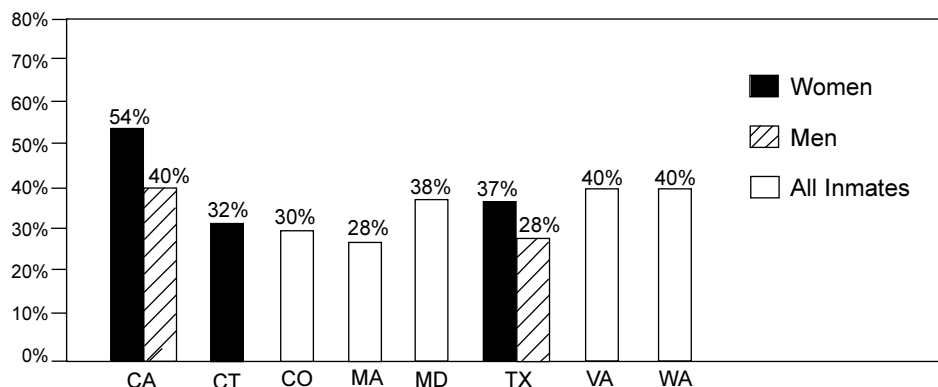
WHO SHOULD GET TESTED FOR HCV?

The CDC specifically recommends testing persons in settings with potentially high proportions of injection drug users (see Table 1). For instance, the CDC lists correctional institutions, HIV counseling and testing sites, or drug and STD treatment programs as potential settings (3). It should be noted that sexual transmission and maternal-infant transmission is uncommon. Testing should be accompanied by appropriate counseling and medical follow-up. Even if treatment is not to be initiated, persons who test positive for HCV should be given information about risk and prevention of disease and risk of transmission to others. Co-infection with HIV has been said to reduce HCV antibody test accuracy, however a recent study by Thio et al. suggested that third-generation antibody based assays are sufficiently accurate for diagnosis (13).

TREATMENT OPTIONS

There are two basic approaches to the treatment of HCV: monotherapy with interferon alpha, or combination therapy with interferon alpha and ribavirin. Combination therapy is more expensive and has a higher incidence of side effects, but is significantly more effective. When interferon is used alone, approximately 30-35% of patients will become HCV RNA negative after treatment, but only 15-20% will have a sustained response once therapy is stopped (3). With combination therapy, the initial response rate increases to

FIGURE 2. Percentage of HCV Infection Among Inmates: Available Data



This figure shows the prevalence of HCV in certain state correctional populations. Percentages are shown by gender where data were available. These prevalence studies are not necessarily comparable across states because different methods were used to compile the data. HCV prevalence in reporting states is the following; California: 40% of men and 54% of women (6); Connecticut: 32% of women (7); Colorado: 30% (8); Maryland: 38% (9); Massachusetts: 27.5% (Hamden County) (10); Texas: 28% of the men and 37% of women (4); Virginia: 30-40% (11); Washington: 30-40% (12).

50-55% and the sustained response after treatment is completed is 35-45% (3). In general, combination therapy should be used unless there are contraindications to the use of ribavirin. (See HIV 101 on page 8.)

Interferon alpha 2-a and alpha 2-b are given subcutaneously three times a week in a dose of 3 million units. Consensus interferon is administered in a dose of 9 µm thrice weekly. A new formulation, pegylated interferon, will be dosed once a week and leads to sustained levels of interferon, which may increase efficacy. Ribavirin is administered orally in a dose of 1000 mg daily for those who weigh less than 75 kg and 1200 mg daily for those > 75 kg. Treatment with ribavirin may reduce fibrosis of the liver, which slows advancement of liver disease (14). (See HEPPigram on page 6 for an HCV treatment algorithm.)

TREATMENT-ASSOCIATED SIDE EFFECTS

IFN side effects commonly include fatigue, myalgias, headache, nausea, vomiting, fever, irritability, and depression. Hematological abnormalities, such as anemia, are common. Severe adverse effects

include major depression, seizures, and generalized bacterial infections (3). Dosing IFN in the evening and pre-medicating with ibuprofen is often used to reduce myalgias. Decreasing the dosage of IFN may be helpful; severe side effects result in the discontinuation of treatment in 5 to 10% of patients. Paradoxical worsening of hepatitis may also occur, and is thought to be due to an autoimmune response. Treatment should be discontinued in patients who have rising serum ALT levels to greater than twice the baseline.

Ribavirin can produce hemolytic anemia, which can be life threatening in patients who have heart disease and cerebral vascular disease. Close monitoring of the patient and blood counts are imperative. Ribavirin can also cause fatigue, pruritus, rash, and nasal stuffiness. Furthermore, ribavirin is teratogenic, and therefore contraindicated in women patients who are considering becoming pregnant and their male partners. Sexually active women and men should use birth control during treatment and for at least six months after completion of a ribavirin regime. A male prisoner leaving prison fewer than six months after cessation of treatment needs to be warned to avoid having unprotected sex, leading to pregnancy with a female partner, until risk of teratogenicity has passed.

The incidence and severity of side effects can be very high. Since it can be difficult for incarcerated patients to quickly access their clinician, it is important to:

- spend time preparing the patient for the potential side effects;
- consider following these patients in a dedicated liver clinic; and
- consider the use of a nurse or other staff person to regularly check in with patients who are receiving HCV treatment so that side effects can be rapidly addressed.

TABLE 1. HCV Testing is Recommended for the Following Persons

Persons who should be tested routinely for hepatitis C virus (HCV) infection include:

- Persons who have injected illegal drugs, including those who injected once or a few times many years ago and do not consider themselves drug users.
- Persons who were ever on chronic hemodialysis.
- Persons with persistently abnormal alanine aminotransferase levels.
- Persons diagnosed with HIV infection.
- Sexual partners of persons diagnosed with HIV infection.
- Persons residing in correctional facilities.
- Persons who received a transfusion of blood or blood components before July 1992, and persons who received an organ transplant before July 1992.
- Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood.

Source Consulted: Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. MMWR October 16, 1998; 47(RR19);1-39

LETTER FROM THE EDITOR

Dear Colleagues,

To treat, or not to treat? That is the question currently faced by correctional clinicians who provide care to incarcerated hepatitis C (HCV) infected patients.

This month's main article is an update on last year's issue by Dr. Anne Spaulding on HCV/HIV co-infection. (July/August 1999) The good news is that response rates to dual therapy for hepatitis C are greater than anticipated, particularly among patients who were formerly considered to have "untreatable" (stage 4) HCV. Furthermore, patients who respond to therapy after the first six months of treatment tend to continue to do well, whether concurrently HIV infected or not.

However, potentially severe treatment side effects such as depression and bone marrow suppression (both of which can be particularly dangerous in the correctional setting) have dampened some clinicians' enthusiasm for treatment. Furthermore, incarcerated patients who are considered likely to continue to drink alcohol, use drugs, and who may be re-exposed to recurrent HCV infection after release from prison are usually considered poor candidates for treatment, particularly where treatment resources are limited.

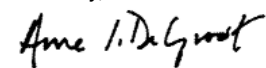
Therefore, when considering HCV treatment the correctional physician must ponder (1) correctional health system policy; (2) clinical guidelines for selecting patients for treatment; (3) risks versus benefits of treatment and (4) the individual patient's profile. As a result, most correctional clinicians currently treating HCV-infected individuals consider the initiation of HCV treatment on a case-by-case basis.

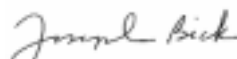
After reviewing this issue, readers should be able to provide a synopsis of current views on the pathogenesis of HCV infection, and identify current guidelines for initiating therapy and managing HCV treatment in incarcerated patients with or without concurrent HIV infection. Additional information on existing treatment regimens for hepatitis C is provided in HIV 101, and a flow diagram describing one approach to initiating treatment is provided in our Heppigram.

Next month newsletter editorial assistant, Betsy Stubblefield will carry the July issue of HEPP News with her to the International Conference on AIDS in Durban, South Africa. She'll give you a front line report after her return in the August issue.

Send us your comments and requests for information. If you wish, we'll print your requests for information in the HEPP News July 2000 International issue. Be sure to provide an email address or mailing address, and get set to receive feedback from all over the world!

Sincerely,


Anne S. De Groot, M.D.


Joseph Bick, M.D.

The editorial board and contributors to HEPP News include national and regional correctional professionals, selected on the basis of their experience with HIV care in the correctional setting and their familiarity with current HIV treatment. We encourage submissions, feed-back, and correspondence from our readership.

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Managers

Dennis Thomas
HIV Education Prison Project

Michelle Gaseau
The Corrections Connection

Layout

Kimberly Backlund-Lewis
The Corrections Connection

Promotion and Distribution

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Editorial Associate
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HIV Education Prison Project

Associate Editors

Betty Rider, M.A., M.S.
North Carolina Division of Prisons

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Stephen Tabet, M.D., M.P.H.
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THE CORRECTIONAL DOCTOR'S DILEMMA...

(continued from page 2)

Without a good support system, a high percentage of patients will fail to complete therapy. Because of the high cost of treatment, time spent preparing patients and supporting them while on treatment is likely to be cost effective.*

Other interventions that are thought to be helpful for the management of HCV include hepatitis A (HAV) vaccination (8). Superinfection with HAV may be associated with fulminant liver failure in HCV patients. For similar reasons, HBV vaccination is also recommended if the patient is not previously immune. (see HEPPigram, page 6).

HIV AND HCV CO-INFECTION

Analyses of the effect of HCV and HIV co-infection on progression of either disease are often confounded by concurrent risk factors for progression. However, available data seems to indicate that HIV infection may worsen HCV liver disease. Persons who are co-infected (HIV and HCV) appear to have a 12 to 300 fold higher risk of developing hepatocellular carcinoma than non-carriers (15). Furthermore, antiretroviral agents can contribute to liver inflammation, and this may be more frequent in those who have underlying chronic hepatitis due to HCV or HBV (1).

The impact of HCV infection on HIV infection is less clear. In some studies, HCV infection does not appear to have an effect on the progression of HIV (16). Other studies have reported an association between more rapid progression to AIDS or death in HIV-infected patients; particularly among those who were co-infected with HCV genotypes 1a and 1b (17, 18).

HCV treatment in those who also have HIV infection can be as successful as in non-HIV infected individuals (19). In contrast, treatment of HIV infection may be more difficult to manage in patients who have HCV co-infection, as hepatotoxicity to anti-HIV therapy appears to be more common among these individuals. Therefore, patients who are co-infected with HCV and HIV might benefit from sequential treatment of their infections (20). In many cases, it is better to control HIV infection and restore the immune system first. Following successful HCV treatment, co-infected patients are not more likely to relapse

TABLE 2. Factors Associated with Sustained Response to aIFN Therapy

- early normalization of ALT levels
- low serum HCV-RNA levels
- HCV genotype other than genotype 1
- mild chronic hepatitis on liver
- biopsy age <45 years

TABLE 3. Suggested Inclusion Criteria for Hepatitis Treatment in Prisons[^]

- Persistently elevated ALT levels
- Detectable HCV RNA
- A liver biopsy indicating either portal or bridging fibrosis or at least moderate degrees of inflammation and necrosis (For more discussion of the necessity of the liver biopsy, see Wong J. Cost effectiveness of ribavirin/interferon alpha-2b after interferon relapse in chronic hepatitis C. *Am J Med.* 2000 Apr 1; 108(95): 366-73.)
- No infractions for illicit alcohol or drug use
- Commitment to discontinue alcohol or drug use
- Control of major medical illnesses, including HIV infection (CD4+ count usually >400)
- Good control of any psychiatric illness, especially depression
- Age >18 and <60
- Pregnancy test negative
- Depending on genotype, length of stay in prison > 6-12 months from initiation of treatment (if after care cannot be ensured, some systems may require a longer stay)
- No signs of decompensated liver disease
- Transaminases greater than upper limits of normal
- Platelet count >75,000/mL
- Hematocrit >30%, albumin >3.5mg/dL, creatinine <1.5 mg/dL, INR* <1.2
- Thyroid function tests normal, no elevated autoantibody titers (ANA, AMA)*
- Absence of advanced cirrhosis on liver biopsy
- Before treatment with ribavirin:
 - No evidence of coronary heart disease
 - Birth control, if conception possible (men and women)
 - Women should have monthly pregnancy tests if conception is possible

Patients for Whom Treatment is Not Recommended:

Including those who do not meet the criteria described above as well as:

- Patients who have infractions for alcohol or injection drug use (Treatment should be delayed until these behaviors have been discontinued for >6 months.)
- Patients with major depressive illness, cytopenias, hyperthyroidism, renal transplantation, evidence of autoimmune disease, or who are pregnant.

[^]Some correctional facilities, such as the Adult Correctional Institute of Rhode Island, have developed their own criteria.

*INR= international normalized ratio; ANA= antinuclear antibody; AMA=antimicrobial antibody

Source consulted: *MMWR* 1998, October 16. 47 (RR19).

after HCV treatment than patients who do not have concurrent HIV infection (19, 21).

Currently, treatment of hepatitis C, where exclusionary criteria are not present, is recommended for patients when CD4 and viral load values reflect good response to antiretroviral treatment. Although some controversy remains in regard to the definition of a good response to HAART, a stable CD4 T cell count greater than 400 with an undetectable viral load is generally accepted.

COST BENEFIT ANALYSES

With the high prevalence of HCV infection among incarcerated individuals, there is a concern that treatment of HCV could overwhelm some system's healthcare budgets. Some cost benefit analyses, however, have provided data in favor of treatment of those with HCV. A recent decision analysis performed by Wong demonstrated that six months of therapy with interferon alpha resulted in a net savings in the range of \$400 to \$3,500 over the lifetime of each patient (22).

Dr. Wong's analysis ranked interferon treatment in the same range of cost effectiveness as stool guaiac testing, pneumococcal vaccination, coronary bypass surgery, and mammography.

The analysis did not include cost data for combination therapy with interferon and ribavirin, a more effective intervention for HCV, which might yield even more favorable savings estimates. More recently, Wong suggested using the three month outcome of treatment as a test for response. This approach may be less expensive and easier to implement in correctional settings, and he found (in a non-correctional model), to do so would reduce the cost of managing patients with chronic HCV, without any detrimental impact on patient outcomes (23).

CONCLUSION

As with many other chronic medical conditions, much of the morbidity and mortality attributable to HCV does not manifest itself

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*The 1997 consensus statement, which includes extensive discussions of the natural history of HCV, diagnosis, and treatment, can be found at the following internet website: http://odp.od.nih.gov/consensus/cons/105/105_intro.html.

CORRECTIONAL DOCTOR'S DILEMMA...

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until well after many infected inmates have paroled. Correctional systems are faced with the dilemma of how to prioritize treatment for HCV compared to treatments for other expensive medical conditions for which there are more effective treatments and oftentimes more imminent sequelae. These concerns and the limited efficacy of currently available treatments for HCV have influenced some correctional systems to adopt highly restrictive inclusion and exclusion criteria for HCV treatment (8, 10). While criteria based on medical outcomes are clearly required, correctional physicians need to weigh other exclusion criteria more carefully, keeping in mind that a year 2000 dollar spent on treatment may reduce the eventual cost (to society) of caring for patients who may require liver transplants in 20 to 30 years (10).

Treatment of HCV infection in HIV infected patients also bears careful consideration. It is currently standard HIV care practice to screen all HIV infected patients for viral hepatitis antibodies. Screening does not need to take place during incarceration if prior records are obtained or if the stay is brief.

In summary, the high prevalence of HCV infection and the availability of expensive treatments with limited efficacy force difficult decision making in correctional health facilities. In community settings, most clinicians now treat HCV infected patients who meet treatment criteria with combination IFN/ribavirin therapy. Guidelines for the selection of patients who are candidates for therapy in correctional settings have been developed but not widely adapted. Correctional facilities are urged to adopt guidelines for prioritizing whom will receive HCV therapy. Cost-sharing between correctional facilities and public health is a subject that needs to be explored, particularly if 30% of all people with HCV in the community cycle through correctional facilities. Treatment of these individuals to reduce HCV morbidity and mortality will have broad implications for general public health.

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SPOTLIGHT

Rob Lyerla

HEPP News interviewed Rob Lyerla, PhD, about the hepatitis C epidemic in our communities and correctional facilities. Dr. Lyerla is an epidemiologist in the Hepatitis Branch of the National Center for Infectious Disease, Centers for Disease Control.

HEPP News: Reports have found that 33% of all hepatitis C infected people pass through correctional institutions each year. As you know, one of the biggest dilemmas for correctional healthcare providers is whether or not to treat HCV infected inmates or to let them wait and seek treatment once they have returned to the community. What would be the burden to correctional institutions if they decided to treat eligible HCV patients?

Rob Lyerla: There are a number of considerations to account for in answering that question. Number one- it's presumptive to think that everyone who is antibody positive is eligible for treatment. We have to give responsibility to the primary care provider to decide if a person is eligible. To date, questions of eligibility have not been answered on a national scale.

The first question is, since HCV screening is voluntary, how many inmates want to be screened? Some studies say that as many as 40% will reject STD screening. If such testing is not mandatory, we may expect to see the same results with HCV testing. Next, of those who agree to be screened, how many are actually positive? Of those who test positive, how many are infected? Then, of those infected, how many are eligible for treatment?

Treatment eligibility is not only a clinical decision. History of injection drug use is an important consideration. Although not necessarily a contraindication, clinicians may advise against treatment if the patient has not been through a treatment program.

Another condition to consider is history of mental illness. Federal Bureau of Prisons Medical Director Newton Kendig says that 85% of his inmates have a history of mental illness. In any given state you're likely to find that a prison has more mental health beds than the state mental health institutes.

Finally, it is important to ask if the inmate wants to be treated. Side effects can be pretty severe. Will the patient be able to comply with the treatment regimen? [For more inclusion criteria, also see main article].

After you have been through these eligibility criteria, you get down to a small number of people who are eligible for treatment. This fact indicates to prison systems that HCV treatment may not be as big a financial burden as they think.

The important message to get across is that HCV patients should know how to protect themselves from damaging their liver and progressing to cirrhosis. They should also know how to avoid spreading it to their partners and peers.

HN: Do you think public health departments recognize hepatitis C in prisons as a threat to the public health?

RL: That depends on the state and the relationships that DOCs (departments of correction) have with departments of public health (DPH). My own perception is that there should be a stronger relationship between the two because clearly there is not a big jump between public health and public safety. The department of corrections is for safety, and the department of public health is for health and safety. Partnerships between the two departments may greatly reduce the burden of disease on the public health. For instance, some of our research indicate that among those with acute hepatitis B infection (HBV), 30% have a history of incarceration. Since 1981, we've recommended that inmates have HBV vaccination, and some correctional systems have found ways to get funding from the state for vaccine programs. In some states, the DPH is working closely with juvenile detention centers to vaccinate young offenders. Clearly, vaccinations in prisons would reduce morbidity outside the prison. So I think it would be beneficial to everyone involved to have corrections and public health work closely to reduce the burden of disease in both the community and correctional setting.

HN: What do you think correctional care providers and inmates need to know about hepatitis in order to reduce the burden of disease behind bars?

RL: I think there is a lot of misinformation out there. There is an onus of responsibility on the DOCs to be up to date on treatment and management of HCV infection. It is not only inmates but staff people who are ill-informed. HAV, HBV, and HCV are all diseases with which we must contend. We have to move people beyond thinking that they're at risk for only one disease. This population is at risk for a lot of illnesses; syphilis, TB, HCV, HIV. Prisons and jails are a focal point of people with histories of high risk behavior and infections. It falls on prison doctors and administrators to stay informed. Doing so might possibly reduce the prevalence and spread of these infectious diseases in the general public.

CORRECTIONAL DOCTOR'S DILEMMA...

(continued from page 5)

* Consultant: Agouron Pharmaceuticals, Bristol-Myers Squibb

Speaker's Bureau: Agouron Pharmaceuticals, Bristol-Myers Squibb, Glaxo Wellcome

**Consultant: Agouron Pharmaceuticals, Bristol-Myers Squibb

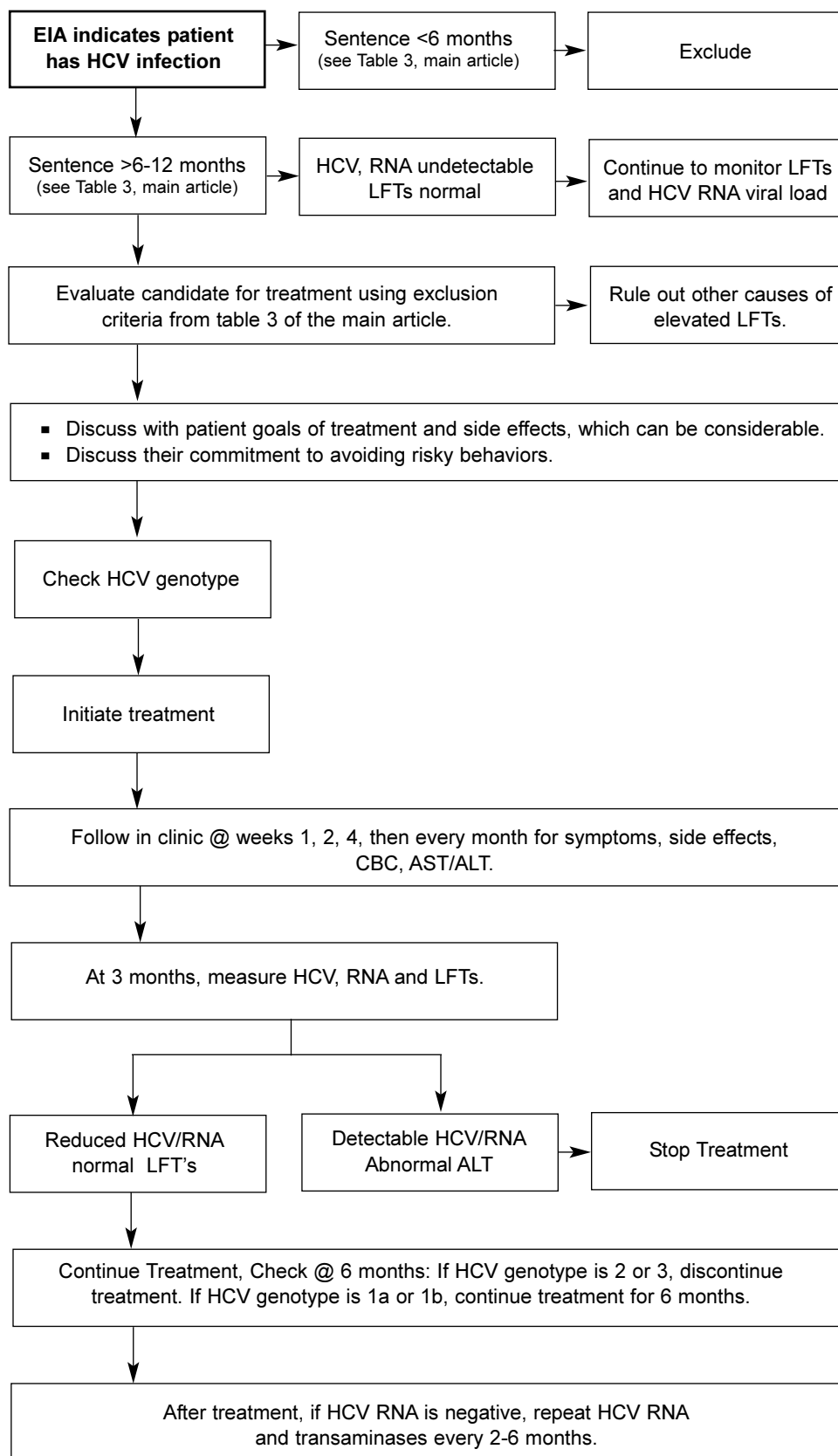
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HEPPIGRAM

Management of HCV Treatment



SAVE THE DATES

5th New England Correctional Health Care Conference: Integrating Correctional and Public Health

June 28, 2000
Sturbridge, MA
Sturbridge Host Hotel & Conference Center
CME credit available.
Call: 781.890.3434
Fax: 781.890.2766
Email: chcc@icg-ps.com.

2000 American Correctional Association (ACA) Summer Congress

August 14-16, 2000
San Antonio, TX
Call: 800.222.5646, ext. 1922
Fax: 1-301-918-1900
Visit: www.corrections.com/aca

24th National Conference on Correctional Health Care

September 9-13, 2000
St. Louis, MO
Cervantes Convention Center
CME credit available.
Call: 773.880.1460
Fax: (773) 880-2424
Email: ncchc@ncchc.org
Visit: www.ncchc.org

HIV/AIDS Behind Bars

Call for Abstracts.

HEPP News is sponsoring a pre-conference colloquium at the NCCHC conference listed above that will discuss the outcomes of HIV education and prevention interventions in correctional settings.

Accepting 500-word abstracts until August 7. Please fax or e-mail questions to Matt Stark: fax: 401-863-1243; matthew_stark@brown.edu.

United States Conference on AIDS (USCA)

Sponsored by the National Minority AIDS Council (NMAC)
October 1-4, 2000
Hyatt Regency
Atlanta, GA
Early Bird Registration Ends June 30th
Scholarship Applications Due June 30th
Contact: Oscar Medrano
at omedrano@nmac.org
202.483.6622 ext. 343
<http://www.nmac.org/usca2000/default.htm>

HEPP News and NMAC will be hosting a morning seminar at USCA addressing how to enact improvement plans for HIV care in corrections.

Management of HIV/AIDS in the Correctional Setting: A Live Satellite Videoconference Series, Antiretroviral Update 2000

October 3, 2000
12:30- 3:30 E.S.T.
2.5 CME credits available
Call: (518) 262-6864
Email: santosm@mail.amc.edu

NEWS FLASHES

HCV Management in Corrections: Medical Director of FBOP Weighs In

In the May issue of *Preventive Medicine in Managed Care*, Medical Director of the Federal Bureau of Prisons, Newton Kendig, published his recommendations for HCV management in correctional settings. The article details risk factors for HCV infection, counseling and screening strategies, indications for drug therapy, evaluating inmates for treatment, monitoring inmates during treatment, and release planning. (Kendig N. Hepatitis C Management in Correctional Facilities. *Prev Med in Managed Care*. 2000, May. 1(1): S33-S41.)

Recent Study Supports Combination Interferon Alpha and Ribavirin

In the May issue of *AIDS*, researchers released promising results from a study involving 20 co-infected people treated with combination interferon alpha (IFN) and ribavirin. All subjects received 500 or 600 mg of ribavirin twice daily in combination with intravenous interferon alpha 2b at a dose of 3 million units three times per week. After six months of therapy, 10 subjects had undetectable HCV levels in their blood and the group's average liver enzyme levels had dropped significantly. Researchers conclude that combination therapy with IFN and ribavirin provides effective and safe therapy to some patients living with both HIV and hepatitis C. Further research is indicated to determine the sustainability of interferon-ribavirin combination therapy over the long-term. (*AIDS* 2000 14(7)839-844.)

Testing May Predict Hepatitis C Virus Outcome

Hepatitis C infection can lead to liver failure or liver cancer, and a small study now suggests it may be possible to predict which cases develop into chronic infections. Researchers studied 12 people with hepatitis C, focusing on the genetics of the virus after infection. According to a report in the journal *Science*, the researchers identified genetic changes that could help predict whether or not the infection would go away. The body is able to rid hepatitis C on its own in about 15 percent of cases, and the study found significant genetic changes in the virus during the early stages of infection for people whose disease would become chronic. (*Science* 2000;288:339-344).

Increasing Percentage of HIV-Related Deaths in the US Have Associated Liver Disease

10% of those with HIV who died in 1997 had liver disease as death co-factor, mostly due to hepatitis virus co-infection or HAART or both. Researchers from the Centers for Disease Control and Prevention (CDC) have reported that an increasing percentage of deaths in persons with HIV in the US have at least one form of liver disease as a co-factor. While not directly shown to be the cause, the vast majority appear to be associated with hepatitis virus co-infection or HAART. Virtually all of the viral infections would be due to either hepatitis B or hepatitis C. The researchers used death certificate information from all 50 states and the District of Columbia from 1987 to 1997. (10th International Symposium on Viral Hepatitis and Liver Disease April 9-13, 2000, Atlanta, Georgia).

Prisoners With AIDS, HIV Return at High Rate

An Arkansas DOC Medical Services official, Max Mobley, reported in May that 26 of the 35 HIV-infected inmates released in 1999 recently returned die to parole violations or new offenses. In a newspaper report, Mobley stated that he believes these HIV infected individuals have trouble paying for their medications on the outside, causing them to commit the offenses that send them back to prison. According to DOC spokeswoman Dina Tyler, the Arkansas DOC is considering the construction of a "Special needs" facility for geriatric, chronically ill, mentally ill and HIV/AIDS patients at a medium security prison planned for Malver, AR. (George, Emmett. *Arkansas Democrat-Gazette Online* (www.ardemgaz.com) 05/18/00).

Correction: Nelfinavir Mesylate (Viracept)

In the April issue of HEPP News we incorrectly printed the new formulation of Nelfinavir mesylate (Viracept, available from Agouron). The new tablet form of Nelfinavir mesylate (1250mg BID, 5 tablets) is film coated, not gel coated. The distinction is important for some patients who may not tolerate gel coatings.

COMING NEXT MONTH . . .

July HEPP News

Next month we'll put our finger on the pulse of HIV care in correctional settings outside the US, as we take you on our first annual "world tour" of HIV in corrections.

Therapy Commonly Used in HCV Treatment

Therapy	Form	Dose	Frequency
Monotherapy	alpha-2a, alpha-2b, consensus interferon*	3 million units (MU)/injection; consensus interferon 9µg/injection.	3x week subcutaneous
Combination Therapy	alpha-2a, alpha-2b, consensus interferon + ribavirin: oral antiviral agent	3 million units (MU)/injection; consensus interferon 9µg/injection.	3x week subcutaneous
		200mg capsules (1000mg/day for <75kg; 1,200mg/day for >75kg)	2x day

*Reserve for patients who have contraindications to ribavirin.

Monitoring

Hgb / Hct - weeks 1,2 and 4, then monthly
 WBC w/diff - weeks 1,2, and 4, then monthly
 Platelet count - weeks 1, 2, and 4, then monthly
 ALT- monthly
 Serum chemistries and renal function studies - monthly
 Thyroid-stimulating hormone - every 3 months
 Other signs to monitor include CBCs - anemia, thrombocytopenia, and leukopenia with dual therapy.

Duration of Treatment

Interferon monotherapy: 48-weeks, regardless of genotype.
 Combination therapy depends on viral genotype:

- HCV genotype 2 or 3: 24-week course of combination therapy yields results equivalent to those of a 48-week course.
- HCV genotype 1: 48-week course yields a significantly better sustained response rate.

Some experts advocate discontinuation of interferon monotherapy at 3 months if HCV RNA is still detectable or abnormal ALT. For Type I, continue dual therapy only if HCV RNA is negative at 24 weeks.

Adapted from Chronic Hepatitis C: Current Disease Management. NIH Publication No. 99-4230, May 1999. www.niddk.nih.gov.

RESOURCES

Patient's Guide to HIV Medicines and Guidelines for Their Use

November 1999 is a pamphlet produced by the National Minority AIDS Council (NMAC) that providers may wish to make available to their patients. The 23 page pamphlet is a comprehensive guide in both English and Spanish. Free copies are available through NMAC at 202-483-6622.

Hepatitis C: Current Treatment Option and HIV Interactions

an online speech and slideshow given by Douglas T. Dieterich, MD Clinical Associate Professor of Medicine, New York University. This talk is available online at <http://HivInsite.ucsf.edu>. Software to hear the talk can also be downloaded at this site.

NEJM Review of USPHS/IDSA "Prophylaxis Against Opportunistic Infections in Patients With Human Immunodeficiency Virus Infection."

The USPHS/IDSA guidelines for prophylaxis against opportunistic infections in patients with HIV, released in the Morbidity and Mortality Weekly Report last August, are now available in the New England Journal of Medicine. Dr. Joseph Kovacs and Henry Masur review the guidelines and provide a perspective that incorporates recent developments and principals they believe should be used to guide clinicians through the care of OIs in HIV infected patients. Kovacs JA, Masur H. NEJM 2000, May 11; 342 (19) 1416-1429; (www.nejm.org).

HCV RELATED WEBSITES:

National Institute of Diabetes and Digestive and Kidney Disease
<http://www.niddk.nih.gov>

National Center for Infectious Disease, Hepatitis Branch
<http://www.cdc.gov/ncidod/diseases/hepatitis/>

The Hepatitis Information Network
www.hepnet.com

Expected Response: Combination Therapy versus Monotherapy

Sustained response: HCV RNA remains undetectable for 6 months or more after therapy stops.

Combination therapy consistently yields higher rates of sustained response than monotherapy. Combination treatment is more expensive and is associated with more side effects than monotherapy, but, in most situations, it is preferable. Factors that increase the likelihood of a response to therapy include non-type-1 genotype, a low baseline HCV RNA, age <45, gender (women show more success than men), and mild chronic inflammation on liver biopsy.

Monitoring Post-Therapy

Repeat ALT and HCV RNA 6 months after completion of full course of treatment.

Drug Interactions with Ritonavir

Hepatotoxicity can occur in association with antiretroviral therapy, depending on which medication is being used. Sulkowski, et al., found that patients on ritonavir had a five-fold higher risk for hepatotoxicity. (16) Their data indicate that antiretroviral-associated hepatotoxicity should be considered according to specific medication rather than drug classification or mechanism of action.

Abstracts and Summaries of the 10th International Symposium on Viral Hepatitis and Liver Disease (April 9-13, 2000, Atlanta, Georgia) available at:
www.hivandhepatitis.com (Conference website is www.hep2000.com)

Hepatitis: HealthlinksUSA
<http://www.healthlinkusa.com/Hepatitis.html>

Medline Plus Health Information on Hepatitis C
<http://www.nlm.nih.gov/medlineplus/hepatitisc.html>

SELF-ASSESSMENT TEST FOR CONTINUING MEDICAL EDUCATION CREDIT

Brown University School of Medicine designates this educational activity for 1 hour in category 1 credit toward the AMA Physician's Recognition Award. To be eligible for CME credit, answer the questions below by circling the letter next to the correct answer to each of the questions. A minimum of 70% of the questions must be answered correctly. This activity is eligible for CME credit through July 31, 2000. The estimated time for completion of this activity is one hour and there is no fee for participation.

There may be more than one correct answer for each question. Make sure you indicate all of the correct answers.

1. What percentage of patients infected with HCV are asymptomatic?
 - a) 9%
 - b) 20%
 - c) 55%
 - d) 72%
 - e) 80%

2. What percentage of annual deaths from liver disease are caused by HCV?
 - a) 1.8%
 - b) 4%
 - c) 15%
 - d) 20%
 - e) 40%

3. Non-responders to combination therapy can be identified by checking HCV RNA after ___ months of therapy.
 - a) 1
 - b) 2
 - c) 4
 - d) 6
 - e) 12

4. It is important to know the genotype of your patient's hepatitis C virus because genotype helps determine
 - a) successful response to therapy.
 - b) when to measure ALT and HCV RNA levels when monitoring the patient.
 - c) when to discontinue therapy in the context of non-response.
 - d) when to discontinue therapy in the context of response.

5. Which of the following statements is false?
 - a) Detectable response to HCV treatment may take four or five months to achieve, but those who fail to respond at 3-6 months are unlikely ever to respond.
 - b) A male prisoner leaving prison less than six months

after cessation of treatment needs to be warned that impregnating a woman before that time might lead to teratogenicity.

- c) If your patient has HCV I, positive response to treatment at 6 months should be followed by an additional months of treatment and monitoring.

6. Which of the following statements about HIV and HCV co-infection is false?
 - a) Available data indicates that HIV infection may worsen HCV liver disease.
 - b) Ritonavir has no significant effect on hepatotoxicity.
 - c) Response to HCV antiviral therapy in HCV patients with HIV appears no different than that of people not infected with HIV.

HEPP NEWS EVALUATION

5 Excellent 4 Very Good 3 Fair 2 Poor 1 Very Poor

1. Please evaluate the following sections with respect to:

	educational value					clarity				
Main Article	5	4	3	2	1	5	4	3	2	1
HEPPigram	5	4	3	2	1	5	4	3	2	1
HIV 101	5	4	3	2	1	5	4	3	2	1
Spotlight	5	4	3	2	1	5	4	3	2	1
Save the Dates	5	4	3	2	1	5	4	3	2	1

2. Do you feel that HEPP News helps you in your work? Why or why not?

3. What future topics should HEPP News address?

4. How can HEPP News be made more useful to you?

5. Do you have specific comments on this issue?

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