STATE OF WASHINGTON

Department of Corrections

REPORT ON THE MANAGEMENT OF HEPATITIS C IN THE CORRECTIONAL ENVIRONMENT

Report to the Legislature
December, 1999

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EXECUTIVE SUMMARY

Introduction

Section 222, chapter 309 Laws of 1999, requires the Department of Corrections to prepare a report outlining its plan for managing hepatitis C in the correctional environment. In response, the Department broadened the efforts begun in March 1999 and developed not only a guideline for identifying offenders eligible for pharmacological therapy, but a disease state management protocol for hepatitis C, as described below. In addition to clinical management, this approach addresses public health concerns about preventing transmission of the virus. As required, the Department worked with recognized experts and used information available from the National Institute of Health and other states' correctional departments as resources to develop the guideline for pharmacological treatment that is part of this protocol.

Background

Hepatitis C is a blood-borne infectious disease annually infecting approximately 30,000 people in the United States. Over the 20 years following infection, the disease can become chronic and lead to a serious liver condition called cirrhosis. Increasingly smaller subsets of infected people develop life-threatening complications, including liver cancer. Cancer and other life-threatening outcomes appear in about 3 percent of the original infected population. Hepatitis C is currently the leading reason for liver transplants in the country.

Approximately 1.8 percent of Washingtonians may be infected with this virus. In a recent study, 25 percent of offenders entering the Department of Corrections tested positive for the hepatitis C virus. Fifty percent of these offenders had laboratory results indicating a potential for having chronic hepatitis C.

In 1995, the Department began researching a uniform approach to managing hepatitis C. Interferon, the only therapy then recognized in the medical literature, had a success rate of about 12-15 percent. It also had serious side effects and was very expensive. A group of Department physicians developed clinical criteria to help identify offenders who might best respond to the therapy. In 1996, the Department adopted a policy including these clinical criteria and requiring authorization prior to rendering interferon therapy. This policy is still in effect.

Since that time, the Federal Food and Drug Administration approved a new, more effective pharmacological treatment for hepatitis C with a 40 percent success rate. Also, the National Institute of Health and the Centers for Disease Control and Prevention published recommendations for diagnosing and treating hepatitis C. In March 1999, given these new developments, the Department began a literature review for the purpose of evaluating its current policy and guideline.

Disease State Management Protocol for Hepatitis C

The Department has developed a plan of action, referred to above as the disease state management protocol for hepatitis C, for managing offenders who are infected with this virus and are in a state correctional facility. This proposed plan is consistent with Legislative request.

The disease state management protocol for hepatitis C includes:

- A guideline for determining eligibility for pharmacological therapy;
- Medical case management by the Department's primary care providers and infection control nurses;
- Offender education to prevent the transmission of the virus;
- Chemical dependency treatment to prevent the transmission and reinfection of the virus;
- Mental health assessment and intervention as appropriate to address adverse mental health responses to the medication;
- Oversight and technical assistance by the Department's medical director and the Central Utilization Review Committee to assure appropriate management and timely interventions; and
- Clinical data collection to track offenders participating in the protocol.

Options

The Department evaluated three options for how to manage offenders in the correctional setting. The first option proposes the Department continue its current practice, which is to provide pharmacological intervention to only the few offenders who met very specific clinical criteria. This can be done within existing resources. However, this option is not consistent with current national guidelines, it is not consistent with the mandate of the Legislature, it will have limited impact on effectively managing the condition, and it does not address preventing transmission of the virus. However, this approach is less costly.

The second option proposes the Department institute mandatory testing of all current and incoming offenders and implement the disease state management protocol for hepatitis C described above. This approach assures all offenders infected with the virus are identified and appropriately managed, but mandatory testing is not consistent with what is done in the community or in other correctional systems. The cost of this option is estimated to be $9,715,816 to manage the current population and an additional $3,568,626 for the incoming population each year.

The third option includes the disease state management protocol for hepatitis C, as described above, with a voluntary testing component. This option provides the Department the opportunity to test, manage, and treat, if eligible, all offenders who request testing and are positive for the virus. It is hoped offenders will self refer as a result of the Department's prevention education program because they recognize they participated in high-risk behavior. It is assumed those who want to be tested are truly concerned about their health and will be compliant with the protocol. Voluntary testing is consistent with other correctional and community models. It will also promote appropriate use of state resources and a prudent return on the invested cost of the program. The estimated cost for this program is $4,180,465 for the current population and $1,606,512 for the incoming population each year.

Recommendation

Assuming funding is provided, the Department of Corrections recommends implementation of option 3, voluntary testing with management according to the disease state management protocol of those offenders who test positive for the virus. This comprehensive plan for managing hepatitis C best addresses the total health needs of infected offenders in a cost-effective manner, while acknowledging the Department's role in contributing to the public's health.

Introduction and Background

Section 222, chapter 309 Laws of 1999, directs the Secretary of the Department of Corrections to report on how the Department plans to manage hepatitis C in the offender population. As specified, the Department developed a treatment guideline for pharmacological intervention in conjunction with experts in the field and in a manner that is similar to or consistent with those produced by the National Institute of Health and other state correctional systems. The other components of the recommended plan include offender prevention education about the disease, a process for how and when offenders will be tested, and a description of how the disease will be managed whether or not the offender is eligible for pharmacological treatment. The Department evaluated three different options. The analysis of these options is included in this report. This report also includes an estimate of the number of offenders that have hepatitis C in the Washington prison system. As required, an estimate of funding needed to implement the Department's recommendation is provided.

Overview of Hepatitis C

Hepatitis C, formerly referred to as non-A, non-B hepatitis, is the most common blood borne infection in the United States. Through the 1980s, blood product transfusions and intravenous drug use were the primary sources of infection. After 1992, when a new test for hepatitis became available to screen blood donor products, transmission through blood products became rare. For unknown reasons, infection transmitted through intravenous drug use also began to decline in the late 1980s. As a result, the rate for new infections has dropped 80 percent from the peak in the mid-1980s. Intravenous drug use accounts for about 60 percent of the new infections that have occurred since the mid-1990s. Other risk factors for transmission of hepatitis C are tattooing without sterilized needles, and using intranasal cocaine.[1]

Whether sexual contact is a risk factor for the spread of hepatitis C is unclear. Most people in a long-term monogamous relationship appear to be at low risk of spreading or contracting the disease. The Centers for Disease Control statistics show that 1 in 65 people who have a hepatitis C partner will contract the disease in this manner. However, having sex with multiple partners seems to increase the risk of transmitting hepatitis C. Women seem to become infected this way from male partners more frequently than the reverse.[2]

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1 Centers for Disease Control and Prevention. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. MMWR 1998; 47 (No. RR-19)::1-37.
Alter, MJ. Epidemiology of Hepatitis C. Hepatology 1997, 62S-65S.

2 Colin, Molly. Being in Charge A Guide to Living with Chronic Hepatitis B and C. Schering Corporation;1998, 28.

Of the approximately 30,000 members of the non-incarcerated population who become infected annually, 80 percent, or 24,000, develop a chronic infection.[3] Studies show that of those who develop chronic infection, approximately 4,800 (20 percent) will develop cirrhosis of the liver in an average of 20 years from the time they were infected.[4] Regular consumption of alcohol expedites the development of this condition. Subsequently, 960 (20 percent) of these people, or 3.2 percent of the originally infected population, will develop serious symptomatic and life threatening liver complications related to the cirrhosis. Of those who develop serious complications of cirrhosis, 192, less than 1 percent of the original population, will develop cancer of the liver in an average of 30 years from the time they were infected[5] (See Attachment A). Hepatitis C is the leading indication for liver transplantation in the United States.[6]

Many people with hepatitis C do not realize they are ill because they have no symptoms. Some experts estimate that 10 to 70 percent of patients with hepatitis C have mild, non-specific symptoms, described as flu-like, muscle and/or joint aches, headaches, nausea and loss of appetite, and sometimes stress and depression. An estimated 20 to 30 percent develop jaundice. Fatigue seems to be the most prevalent symptom for those infected.[7]

Pharmacological Treatment of Chronic Hepatitis C

Treatment for chronic hepatitis C has long been controversial.[8] Varieties of interferon have been the primary drug of choice for treatment since the 1980s. However, the sustained response rate with the different types of interferons alone lingered around 15 percent for all patients treated and there are serious side effects to the medication including depression and suicidal behavior or ideation.[9] Since it could not be predicted which patients with the virus would be among those 15 percent who would respond to the drug and who would progress to serious health problems, treating everyone with interferon has not been popular in the medical community. Physicians consider whether or not the risk for side effects outweighs the risk to the patient, who may or may not develop a serious complication and may or may not respond. In light of the low efficacy rate and the lack of long term studies, some community physicians have chosen not to treat and to wait and see what new information becomes available or what new drug is

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3 Alter, Mj, et. al. The prevalence of hepatitis C virus infections in the United States, 1988 through 1994. New England Journal of Medicine 1993:341:556-62.

4 Alter, MJ, et. al. The natural history of community–acquired hepatitis C in the United States. New England Journal of Medicine ed 1992; 327:1899-905.

5 Seeff, LB, et. al. Long term mortality after transfusion-associated non-A, non-B hepatitis. New England Journal of Medicine ed 1992; 327:1906-11.

6 Primary liver disease of liver transplant recipients 1991 and 1992 (from the UNOS Scientific Registry). UNOS Update. 1993;9:27.

7 Centers for Disease Control and Prevention. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. MMWR 1998; 47 (No. RR-19): 1-37.

8 Koretz, RL. Interferon and chronic non-A, non-B hepatitis: whom are we treating? Hepatology1990;12:613-5.

9 McHutchison JG et.al. Interferon Alpha-2b alone or in combination with ribarvirin as initial treatment for chronic hepatitis C. New England Journal medicine 1998;339;1485-92.
Bennett WG, et. al. Estimates of the cost effectiveness of single course of interferon-alpha-2b in patients with histologically mild chronic hepatitis C. Ann Intern Med 1997; 127:855-65.

approved. This is a safe approach given that chronic hepatitis C is a slow progressing condition and most complications do not develop for about 20 years after the onset of the disease.

However, current research, including large studies published in the leading medical journals last year and this year, demonstrate that by combining interferon with the anti-viral drug, ribavirin, better outcomes are achieved than using interferon alone. The combining of these two drugs, referred to as combination therapy, now increases the response rate to 40 percent. In other words, 40 percent of the patients who receive this therapy will not show the presence of the virus in their body 6 months after completing the therapy.

Although this is a marked improvement, much controversy still exists. The long-term benefits of the treatment are still unknown. Most research equates successful treatment to eradicating the virus from the blood, normalizing blood tests that measure liver function, and improving the microscopic appearance of the liver. Since chronic hepatitis C progresses very slowly and this treatment has just become available, researchers have had difficulty in assessing the effects of the treatment on the development of cirrhosis and its complications, liver cancer, and death. Definitive data to answer the questions, "Does it prevent these conditions from developing or do infected persons continue to progress to this state?" will not be available for many years.

Consequently, some physicians are still hesitant to treat, because of insufficient outcome data to justify the high cost and potential adverse side effects. However, in university centers and larger cities the therapy is being used. Many providers treating patients are collecting data regarding treatment interventions and outcomes to help them evaluate and adjust their own practice.

Other researchers have evaluated the cost-effectiveness of the treatment of chronic hepatitis C with interferon therapy. Three of these studies published in prominent medical journals estimate that treating individuals between the ages of 18 and 60 years old with chronic hepatitis C is equal to or more cost-effective than treating hypertension or high cholesterol with medication, or treating severe coronary artery disease with surgery.[10] Preliminary cost-effectiveness studies comparing monotherapy, using interferon alone, to combination therapy, found the latter more cost-effective, although definitive studies remain to be done.

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10 Wong JS et. al. Pretreatment evaluation of chronic hepatitis C: risks, benefits, and costs. JAMA 1998;280:2088-93.
Bennett WG, et. al. Estimates of the cost effectiveness of single course interferon-α2b in patients with histologically mild hepatitis C. Ann Intern Med 1997;127:855-65
Kim WR et. al. Cost effectiveness of 6 months and 12 months of interferon -α-therapy for chronic hepatitis C. Ann Intern Med 1997;127:866-74.

Chronic Hepatitis C in Correctional Settings

There is limited information available about the prevalence of chronic hepatitis C or its impact in the prison population. It is not known whether the estimates for the complication rates in the general population are applicable to the offender population. Recent statistics from the Federal Bureau of Prisons demonstrate the number of deaths from liver disease surpassed those from Human Immuno-Deficiency Virus and is now the third leading cause of death among their offender.[11] Heart disease and cancer remain their leading causes of death. A 1998 analysis of offender deaths found the same pattern exists in this state.

The only formal study published about the prevalence of hepatitis C in the correctional setting is from the California Department of Corrections. This study found that 39 percent of male and 55 percent of female offenders entering the California correctional system in 1996, were hepatitis C positive. [12]

At the time this report was prepared, the only other published study about hepatitis C in United States correctional settings was written by staff from the Rhode Island Department of Corrections. That study surveyed state correctional departments about the screening and treatment of chronic hepatitis C. Thirty-six states and the District of Columbia responded. The report was published in 1999, making the information over two years old at the time of publication. [13]

In 1996, according to the Rhode Island study, only Colorado reported routinely screening for hepatitis C. The rest of the states, including Washington, responded "No", although some did clarify that high risk or symptomatic offenders were screened.

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[11] Kendig N, Information presented at the Society of Correctional Physicians' National Meeting, November 1999

[12] Ruiz, JD, et.al. Prevalence and correlates of hepatitis c virus infection among inmates entering the California correctional system. West J Med 1999;170:156-160

[13] Spaulding, Anne. Hepatitis c in state correctional facilities. Prevention Medicine. 1999;28;92-100.

The rest of the key indicators from the Rhode Island survey are summarized below:

Survey of States' Corrections Departments Summarized Responses

	Type and Frequency of Response		
Do you treat hepatitis C?	Sometimes-27	Never-8	Other-2
Do you have an interferon protocol?	Yes-4	No-27*	Developing-6
Number of doses used in 1995?	Able to report-10	N/A or 0- 27	

This report indicates each state is addressing the condition differently (See Attachment B for this report and more detailed survey results).

Over the last three years, the treatment of chronic hepatitis C in the correctional setting has been in a state of transition. While working on our guideline, Department of Corrections staff were in telephone contact and/or email correspondence with numerous states that were somewhere in the process of developing a treatment guideline. Guidelines available from other states were collected and used as references for the Department's latest guideline. Many states are struggling with how to manage hepatitis C, but some states are continuing to not address it.

Prevalence of Hepatitis C in the Washington State Department of Corrections' Offender Population

For the purpose of this report, the Department collected preliminary data about the number of offenders entering the system who were positive for hepatitis C in the month of October 1999. Every offender who participated in intake that month at the Washington Corrections Center and the Washington Corrections Center for Women was tested for the hepatitis C virus. If the hepatitis C test was positive, a liver enzyme test (ALT) was done to give a "rough measure" of the amount of liver damage present. The Department consulted with the Department of Health on the study design and they found the study results to be statistically valid.

The data collected was used to project the percent of the population that is hepatitis C positive being admitted to the Department. Twenty-five percent of the offenders admitted to the system in the month of October were hepatitis C positive. In comparison, the information reviewed from a nation-wide study estimates 1.8 percent of the general population in this state is hepatitis C positive. Of those offenders who tested positive in October, 48 percent had elevated liver enzymes which may mean they are candidates for developing or have chronic hepatitis C. (Remember, in the general population 80 percent

* This number erroneously includes Washington State. In July 1996, the Department implemented a policy about using interferon to treat hepatitis C.

of the acutely infected becomes chronically infected). A more detailed distribution of these results is provided below:

	Number of offenders tested	Number Hepatitis C positive	Percent of Hepatitis C positive	Elevated ALTs	Percent with elevated ALTs
WCC	374	89	24%	48	54%
WCCW	61	20	33%	4	20%
TOTAL	435	109	25%	52	48%

Extrapolating this information to the Department's total incarcerated population of 14,000 offenders, 25 percent, or 3,500, could be hepatitis C positive. Then, if the risk for chronic infection is 80 percent, 2,800, of these infected offenders may develop or have chronic infection. Continuing to apply the rate of progressive disease states found in the general population and reported on page 2, 20 percent, or 560, of those chronically infected may go on to develop cirrhosis in about 20 years from the time of their infection. Another 20 percent of those offenders, or 112, may develop a serious complication related to their cirrhosis; and 22 more offenders, or 20 percent, of those may develop liver cancer in about 30 years from the time they are infected.

In the current offender population, using the data in the Offender Based Tracking System for Health Services, 680 offenders are recorded as having hepatitis C. One hundred and two of these offenders have co-existing liver disease, including cirrhosis, that is most likely related to their hepatitis C.

Washington State Department of Corrections and the Cost-Effective Management of Hepatitis C

Current Approach to Treating this Disease

In July 1996, the Department of Corrections implemented a policy to treat chronic hepatitis C using interferon-alpha (See Attachment C). Various physicians who practiced in our institutions use a consensus process to develop the policy and treatment guideline over a period of several months. The physicians included internists, general practitioners, and an infectious disease specialist. This policy requires authorization by a panel of three physicians prior to initiating pharmacological therapy.

As referenced earlier, in 1996, there was limited published data available about the long-term outcomes and benefits of using interferon to treat chronic hepatitis C. Some of the physicians wanted to aggressively treat the disease, but the majority wanted to wait and see what progress was made in available treatments and the possible impact on sustained results. In addition, community gastroenterologists who were treating offenders were not recommending treatment with interferon. Even though the literature could not provide sufficient evidence of a sustained response for everyone with the virus, there was

acknowledgment there may be some specific clinical indications as to when a person with hepatitis C may respond to therapy. The guideline developed attempts to identify those patients who exhibit these specific clinical indications.

To address the issue of treatment for these specific offenders, Department physicians agreed to a peer review process whereby three medical directors from facilities where the offender was not housed would review a request by the attending provider to treat the offender with Interferon. Providers disagreeing with the panel's decision could request reconsideration of the decision through the Health Services Unit at headquarters. Offenders could use the Department's formal grievance process to request reconsideration of the panel's decision. Approximately, eight cases were referred by providers for prior authorization to treat chronic hepatitis C with interferon. In all cases, the physician peer review committee members agreed the referral did not meet the clinical indications established in the Department's guideline. All these offenders continued to receive ongoing monitoring of their condition and treatment for any symptoms they developed.

The Offender Health Plan Sets the Standard

In December 1996, the Department implemented the statutorily required Offender Health Plan and supporting policy. This plan established a uniform set of standard health care services for offenders and was based on the State of Washington Basic Health Plan. A committee including representatives from the Departments of Health, Corrections, Social and Health Services, the Health Care Authority, and the Office of the Attorney General wrote the plan. The Offender Health Plan stipulates that the Department of Corrections will only provide and reimburse for services that are medically necessary.

Excluded services include those which are:

- not supported by sufficient evidence to indicate that the service will directly improve the length or quality of the offender's life;
- not supported by sufficient evidence to draw conclusions. Indications of sufficient evidence is demonstrated by:
  - concurrence through peer review (as defined by the National Association of Insurance Commissioners);
  - well controlled studies;
  - study outcomes which are directly or indirectly related to the length or quality of life; and
  - reproducibility, both within and outside research settings.
- not expected to have a beneficial effect on the length or quality of life, or not outweigh the expected harmful effects; and
- not the most cost effective method available to address the disease, illness, or injury. (Cost-effective meaning there is no other equally effective intervention available or suitable for the patient which is more conservative or substantially less costly.)

Until recently, the decision to not uniformly provide interferon therapy to treat chronic hepatitis C was consistent with this provision of the Offender Health Plan. However, development of a new treatment regimen producing better long-term outcomes and sustainable results and the production of hepatitis C management guidelines by The National Institute of Health and the Centers for Disease Control and Prevention warrant the development of a new treatment guideline by the Department. In addition, correctional departments in other states and the Federal Bureau of Prisons are actively addressing the issue of chronic hepatitis C in the incarcerated population.

Reviewing the Current Treatment Guideline

The advances cited above provides the Department with a credible "best practices" approach to treating the disease. Since March 1999, representatives from the Department's Office of Correctional Operations Health Services Unit and two physicians who practice in Department facilities have completed a literature review, collected and reviewed treatment guidelines from other health care providers, payers, and other state's Department of Corrections; and drafted a new chronic hepatitis C treatment guideline. The new medical director has assumed a leadership role in establishing the clinical direction in which the Department should move.

In September 1999, there was an educational meeting for Department providers about the treatment and management of hepatitis C. The guest speaker at the meeting was Robert Carithers, M.D., hepatologist from the University of Washington. Dr. Carithers' presentation provided our physicians and mid-level providers with more current information about the management of hepatitis C and allowed them to discuss current trends in treatment with a recognized national expert in the field. The draft guideline was presented at this meeting. Comments, concerns, and suggestions for modification were requested and encouraged.

In addition to the review and input by our own providers, the Department requested comments and input from:

- Robert Carithers, M.D., and
- many of the gastroenterologists and heptologists who practice in various Washington communities and regularly provide care to the offender population, including Michael Lyons, M.D. and John Carrougher M.D., from Tacoma Digestive Disease Center; James Harri, M.D., from Walla Walla; and George Cox, M.D., of Everett.

While developing the draft guideline, it became apparent that what would be needed was not just a product to assure Department clinicians consistently identify optimal candidates for pharmacological treatment, but rather a comprehensive plan that would establish appropriate and uniform management of any offender with hepatitis C. Consequently, the draft guideline was expanded to establish expectations for periodic, but regular,

monitoring of all offenders who are known to be hepatitis C positive. This approach would allow the Department to address hepatitis C from the perspective of disease state management, which includes strategies like prevention education and chemical dependency treatment to prevent transmission, rather than dealing with just the issue of rendering pharmacological treatment (See Attachment D for this comprehensive protocol).

In an effort to promote optimal outcomes from the therapy, the proposed protocol includes specific criteria that should be met in order to receive pharmacological therapy. The decisions about inclusion and exclusion criteria were based on medical and non-medical indications. The medical indications are consistent with the Federal Food and Drug Administration's recommendations and warnings and other available guidelines or protocols, both from correctional and non-correctional settings. The non-medical indications are consistent with the guidelines or protocols available from other correctional settings, including the Federal Bureau of Prisons (See Attachment E, a simplified version of the draft treatment guideline detailing this inclusion and exclusion criteria).

An example of a medical indication for why an offender could be excluded from pharmacological treatment is the presence or history of an existing condition which could be made worse, possibly resulting in death, if given the medication. An example of a non-medical exclusion is when the offender's remaining period of incarceration is too short to allow the offender to complete the 24 to 48 weeks of treatment prior to release. Pharmacological treatment would not begin during the incarceration period because:

- the Department cannot be assured it will be completed post release; If the full course of treatment is not completed, the condition will continue to be present. This would not be an efficient and prudent use of state resources; and
- it will result in a disruption of the continuity of care; and
- this would make the management of hepatitis C consistent with how other diseases are managed under the Offender Health Plan.

Offenders not receiving pharmacological treatment would be regularly monitored until the period of incarceration is complete, benefiting from regular evaluations and education about their disease state. Prior to release, offenders would be provided assistance and consultation on how to enroll for medical benefits through other programs that they may be eligible for, including but not limited to Medical Assistance, the Veteran Administration, and/or the Basic Health Plan. The Department cannot assure the offender will receive treatment under any of these plans.

The proposed protocol provides for the treatment of chronic hepatitis C using combination therapy. This regimen requires the administration of interferon three times a week and ribavirin daily. As previously stated, this therapy now has the best-documented outcomes. However, in those cases where this may not be the best treatment for an

offender's specific situation, the Department's medical director would address exceptions.

The Department's Proposed Plan to Implement a Disease State Management Protocol for Hepatitis C

Review of the proposed "Disease State Management for Hepatitis C" protocol indicates that management of this disease can be rather complex and detailed (See Attachment D). In order to assure optimal management, the Department's proposed protocol, or plan, includes:

1) Medical Case Management by the Infection Control Nurses

All offenders infected with the hepatitis C virus would be managed by this specially trained nurse responsible for:

- educating the offenders about their disease and prevention of transmission and reinfection;
- assuring that all diagnostics, random drug screens, evaluations, and consults are scheduled and completed;
- assisting offenders with managing adverse effects to the therapy;
- assuring the data is entered into the data system described below; and
- reporting information to and consulting with the clinicians, as indicated.

2) Tools to Case Manage

To assist the infection control nurses the following tools have been drafted:

- a "Worksheet for Screening of Hepatitis C Positive Patients for Possible Pharmacological Therapy" to support appropriate and consistent screening (See Attachment F);

- a "Hepatitis C Management Activity Sheet" to support the timeliness of consultations and diagnostic tests required in the screening and treatment phases and, when possible, through the post-treatment periods to assess for a sustained response (See Attachment G); and

- a "Hepatitis C Treatment Protocol-Patient Contract". This document would serve as a comprehensive informed consent form. It details for offenders what they can expect throughout the course of therapy and stipulates that their total and complete cooperation and compliance is required. Without the offender's thorough commitment to the therapy period, the treatment would not be of any benefit and therefore, not cost-effective (See Attachment H).

3) Comprehensive Data Collection System

The Department would collect all pertinent information about hepatitis C positive offenders, and track them as they participate in the disease state management protocol. The Department would be able to identify offenders who:

- do not progress to the chronic phase;
- become chronic but not eligible for treatment and why
- start treatment;
- discontinue treatment and why;
- complete treatment; and
- achieve a sustained response, when available.

4) Management by Onsite Providers

Mid-level providers and physicians who practice at the facilities would regularly monitor the health care status of these offenders. These providers would regularly assess the offender's response to therapy, review lab work, adjust medication, reinforce education, confer with the infection control nurse, and consult the Department's medical director, as indicated. [14]

5) Vaccinations for Hepatitis A and B

Vaccinations against hepatitis A and B would be offered to all identified offenders with chronic hepatitis C to prevent the possibility of contracting a dual infection, which can result in death.

6) Consultation with the Department's Medical Director

The Department's medical director would provide consultation and technical assistance for the infection control nurses and the medical providers to support appropriate application of this protocol and assist with the special needs of any offender's specific situation.

7) Pre-authorization through Central Utilization Review

The Department's Central Utilization Review Committee would authorize all pharmacological therapy. This provides an opportunity to assure appropriate and consistent management of all cases. It also allows the Department to apply

[14] At any point in the protocol, including the endpoints where the progress towards pharmacological treatment is stalled, the provider at the facility could consult with the Department's medical director to discuss the status of the case to date. This discussion should assure appropriate interventions have been taken and to determine measures needed to move the case in the best direction for the offender, as indicated.

"Continuous Quality Improvement" techniques as it reviews each case and assures quality-outcome orientated medical management.

8) Chemical Dependency Treatment

Since the primary mode of transmission of this virus is through intravenous drug use and the sharing of needles, the proposed protocol includes the completion of a chemical dependency course, if indicated. Chemically dependent offenders who have not been treated for their dependency will probably not benefit from treatment. In addition, any offender who responded to the treatment and then returns to these risky behaviors can become re-infected, eliminating all benefits to the offender and to the public's health. Successful chemical dependency treatment should help assure the offender is not re-infected after completing therapy or passes the virus to another person.

Offenders with chronic hepatitis C would have to agree to submit to random drug toxicology screens during the initial assessment and through the treatment phase of the protocol. An offender who fails to pass a screen will be referred to the chemical dependency treatment program. If the offender had already started the hepatitis C treatment, this therapy will be discontinued until the offender completes the chemical dependency treatment.

9) Mental Health Assessment and Treatment

Depression and suicidal ideation are serious side effects of the pharmacological treatment for hepatitis C. Consequently, the proposed protocol includes an assessment of the offender's mental health history and current status during the initial screening phase and again immediately prior to the treatment phase. An offender may be excluded from treatment if his or her mental health can be compromised by this medication. When indicated, a psychiatric evaluation would be conducted to assure an accurate clinical assessment. This process may identify offenders who were not previously known to be mentally ill, but would now need intervention prior to initiating the therapy for hepatitis C.

It would also be necessary for the Department to provide mental health intervention to any offender receiving the hepatitis C therapy who suddenly develops psychiatric symptoms as a side effect. The literature reports 33 percent of the research subjects in the clinical trials of this treatment developed mental health side effects. The Department would add a two-hour training session to the annual mandatory block training sessions regarding the signs and symptoms of depression and suicidal behavior. This training would be conducted to support timely recognition and appropriate safe intervention by non-medical staff until a referral to a mental health professionals could be completed. The mental health professional would conduct a psychiatric evaluation and implement a treatment plan, as appropriate to manage the

offender. These offenders may require a more aggressive treatment plan than just decreasing or discontinuing the therapy for the hepatitis C.

10) Offender Education and Screening

The proposed disease state management protocol incorporates sound public health strategies. All offenders would be educated about hepatitis C at intake as part of an educational program including information on Human Immune-Deficiency Virus, tuberculosis, and other issues of special concern to correctional populations. Offenders would be informed about the disease, the risk factors for contracting and transmitting the virus, and the possible implications. In addition, educational materials would be available in the living units and the outpatient clinics. A team of the Department's infection control nurses would develop the prevention education materials with the consultation of the Department's medical director. A variety of resources would be used to produce this information, including those available from the public health system and the pharmaceutical companies.

It is hoped education about the risk factors for hepatitis C will encourage offenders to avoid risky behavior and to seek testing. To support this effort, the statutorily required medical co-payment fee for offender initiated visits would not be assessed on any offender who seeks testing/screening for this condition.

In addition to educating all offenders about the disease and the indications for screening, offenders who are known to be positive for hepatitis C would receive additional education and counseling from their medical case managers. The team of infection control nurses and the Department's medical director would also develop this information. The focus of this education would be to reduce risky behaviors and improve self-care, thereby preventing transmission to others and preventing re-infection of those who are successfully treated.

Reassessment of Previously Identified Cases

As mentioned above, there are approximately eight cases which were previously referred to the physician peer review group for authorization to treat pharmacologically. Since these did not meet the Department's current guideline, authorization was not granted. In addition to these cases, there have been several offenders who have come forward requesting treatment. The clinicians felt that the clinical indications from the guideline currently in effect were not met, so a request for authorization was not submitted.

Assuming funding is received, the Department will adopt the new protocol. These offenders and the other offenders known to have co-existing liver disease will be evaluated for appropriateness for receiving the combination therapy. An assessment of their current status will be conducted using the new disease state management protocol. A specific plan of care will be developed and implemented for each individual depending on what points of the protocol need to be addressed. Offenders excluded from

pharmacological treatment because they do not meet the eligibility criteria will receive the other interventions called for in the proposed protocol, including chemical dependency treatment, if indicated, education, and monitoring. In addition, offenders excluded because their release date is pending, will receive assistance in filing for medical coverage through a health care payer for which they may be appropriate, just as provided for in the protocol.

Evaluation of Options

The Department evaluated three options, or scenarios, as to how to best manage this condition in the correctional setting. The analysis of each one is provided below:

Option 1: Continue the Current Approach:

Option one continues managing offenders with chronic hepatitis C according to the current policy and guideline. Only a minimal numbers of offenders would ever receive pharmacological intervention because very few would ever meet this guideline. This guideline is not consistent with the guidelines now being recommended by the National Institute of Health, the Centers for Disease Control and Prevention, or that of other state's correctional systems. It places the Department at risk for failing to follow what is becoming deemed a "best practice" in treating hepatitis C. If the Department chose this option, it would not be compliant with the Legislative mandate in Section 222, chapter 309 Laws of 1999. In addition, this approach fails to recognize the public health concerns about transmitting the disease to others either during or after the incarceration period. However, this approach would require limited funding to support.

Option 2: Mandatory Testing and Implementation of the Proposed Disease State Management Protocol:

In this option, mandatory testing for hepatitis C will be conducted on all offenders. Offenders in the current population who are not known to be positive will be tested. All incoming offenders will be tested at intake. Any offender found to be infected with the hepatitis C virus will be managed under the Department's "Disease State Management Protocol for Hepatitis C" described in this report. Consistent with the protocol, any offender identified as positive for hepatitis C will be further evaluated to establish the presence of chronic hepatitis C and to determine eligibility for treatment. If offenders are not eligible for treatment, they will continue to be monitored, counseled, and managed as called for in the protocol, including receiving prevention education and chemical dependency treatment, if it is indicated.

This option would assist the Department in assuring identification and appropriate management of all offenders who are infected with the virus. Treatment, for those who are eligible, education, and chemical dependency treatment, as indicated, for all infected offenders should help prevent the transmission of the virus to others and the reinfection of the successfully treated offender. However, this approach is more aggressive than that

used for identifying infected patients in the general population or other correctional settings. Universal screening or testing is not being done elsewhere and it would mean a higher standard of care is being offered to the offender population.

Estimated costs to manage the current population of approximately 14,000 offenders are $9,715,816. In addition, an estimated $3,568,626 is needed to manage the incoming population estimated at 6,000 per year. (See Attachment I, "Option #2: Mandatory Testing" for a detailed accounting of the costs).

Option 3: Voluntary Testing and Implementation of the Proposed Disease State Management Protocol:

The third option differs slightly from option two, in that in this option, testing is voluntary. At reception, all offenders will receive educational information about this disease and its infectious nature. Educational material will also be available to offenders in their living units and in the health care clinic. Then any offender concerned about having the virus may request testing for the virus. In addition, any offender reporting high-risk behavior, or a blood transfusion prior to 1992, will be counseled and strongly encouraged to request testing. Consistent with Option 2, any offender identified as being positive for the virus will be managed under the "Disease State Management Protocol for Hepatitis C", as described in this report. Any offender identified as positive for hepatitis C will be further evaluated to establish the presence of chronic hepatitis C and to determine eligibility for treatment. Offenders not eligible for pharmacological treatment will continue to be monitored, counseled, and managed as called for in the protocol, including receiving chemical dependency treatment, if it is indicated.

This option assures treatment for those who are probably most motivated to request testing and treatment and therefore, most likely to complete the difficult treatment regimen. Treating those most motivated to improve their health should prevent the transmission of the virus to others and may prevent the development of the more complicated liver diseases caused by hepatitis C. A voluntary approach to testing is consistent with the approach the Department uses to manage Human Immuno-Deficiency Virus and other conditions. All testing is consensual, except for mandatory tuberculin tests and any court ordered testing. This option is also consistent with the model being used in the general community and other correctional protocols reviewed. Testing for hepatitis C is being provided to those who request it or who consent after being encouraged by their provider because of high-risk behavior.

In addition, this option will be less costly to implement than Option 2. Estimated costs for implementing Option 3, voluntary testing and disease state management protocol, for the current population of 14,000 offenders is $4,180,465. In addition, an estimated $1,606,512 is needed to manage the incoming population estimated at 6,000 per year. (See Attachment I, "Option #3 Voluntary Testing" for a detailed accounting of the costs).

Recommendation

The Department of Corrections recommends implementing Option 3, as described above, because this option assures a public health-oriented and reasonable, yet cost-effective way to manage hepatitis C in the offender population. It allows offenders, who are concerned about their health, to request testing and evaluation for eligibility of pharmacological treatment in a manner that is consistent with that being used in other correctional settings and the general population. It also includes criteria for determining eligibility for treatment that is consistent with "best practices", while providing a very comprehensive management plan that includes offender prevention education, chemical dependency treatment and mental health therapy for those for which it is indicated to assure maximum benefit.

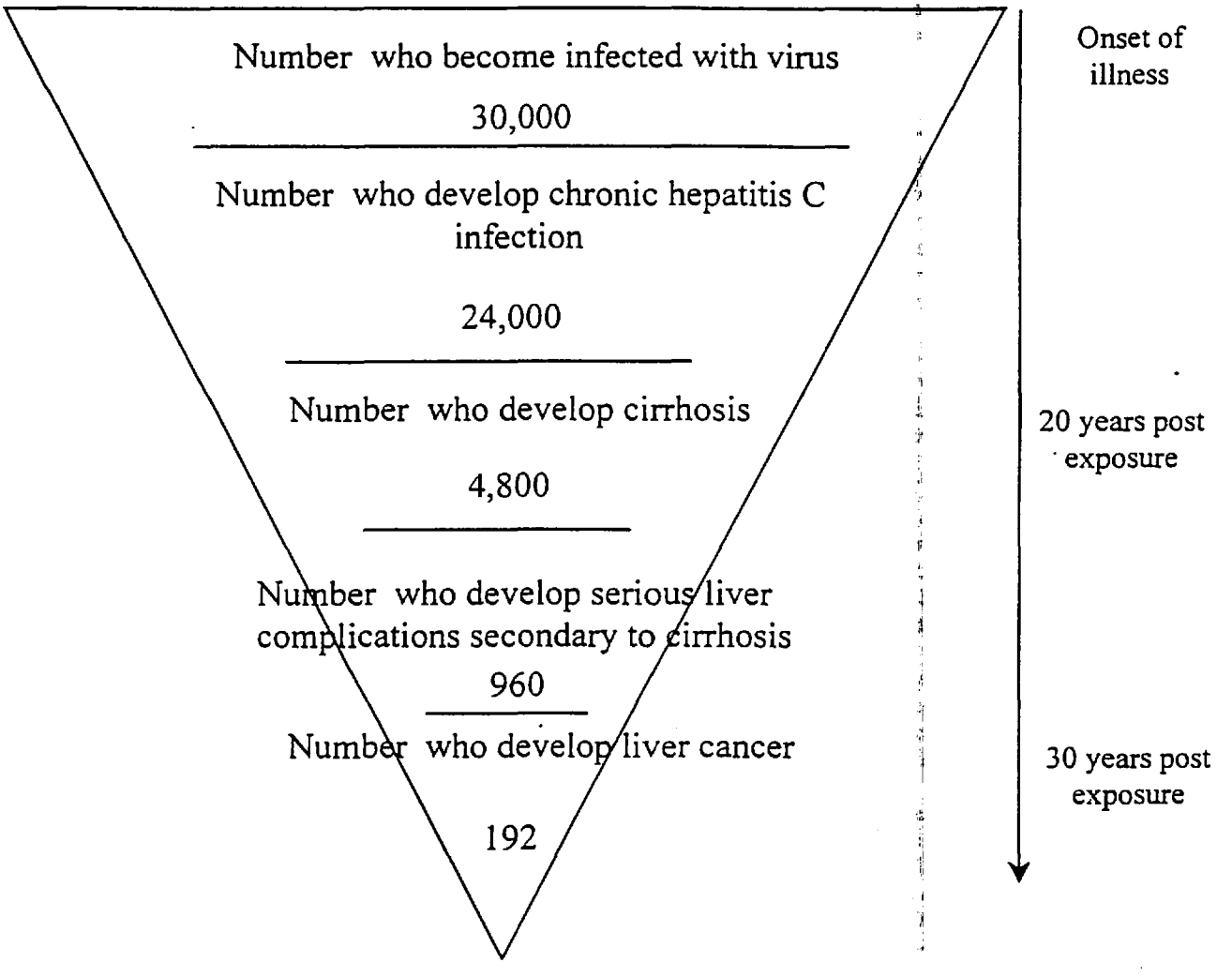
Conclusion

The Department's vision is to provide a comprehensive program, as described in this report as a "Disease State Management Protocol for Hepatitis C". This approach, developed by Department health services staff, should assure an optimal outcome in the management of this disease through identification by testing, ongoing monitoring by the provider and a medical case manager, prevention education of the entire incarcerated population, chemical dependency treatment, as indicated, mental health assessment and intervention, when appropriate, and pharmacological treatment, when eligible. However, the funding needed to support implementation of Option 3 is not available in the Department's base budget since an extensive treatment program like the one described has not been previously provided by the Department.

ATTACHMENTS

ATTACHMENT A	Diagram: Impact of Virus on the General Population
ATTACHMENT B	Publication : Hepatitis C in State Correctional Facilities
ATTACHMENT C	DOC Policy 670.040: Interferon Therapy for Hepatitis C
ATTACHMENT D	Diagram: Disease State Management Protocol for Hepatitis C
ATTACHMENT E	Pharmacological Therapy for Chronic Hepatitis C: Inclusion/ Exclusion Criteria
ATTACHMENT F	Worksheet for Screening of Hepatitis C Positive Patients for Possible Pharmacological Therapy
ATTACHMENT G	Hepatitis C Management Activity Worksheet
ATTACHMENT H	Hepatitis C Treatment Protocol: Patient Contract
ATTACHMENT I	Cost Model for Option #2: Mandatory Testing and the Disease State Management Protocol
ATTACHMENT J	Option #2: Model for Determining Eligibility of Offenders in Current Population
ATTACHMENT K	Option #2: Model for Determining Eligibility of Offenders in Incoming Population
ATTACHMENT L	Cost Model for Option #3: Voluntary Testing and the Disease State Management Protocol
ATTACHMENT M	Option #3: Model for Determining Eligibility of Offenders in Current Population
ATTACHMENT N	Option #3: Model for Determining Eligibility of Offenders in Incoming Population
ATTACHMENT O	Model for Determining Response of Recipients to Pharmacological Combination Therapy

Impact of Virus on the General Population



ATTACHMENT B

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Hepatitis C in State Correctional Facilities[1]

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Background: No previous studies have examined the extent to which correctional facilities in the United States screen for and treat hepatitis C (HCV) infection.

Methods: Medical directors of state correctional facilities responded to a survey assessing the degree to which prisons screen for and treat hepatitis C. To estimate numbers of inmates eligible for interferon treatment and to examine costs associated with HCV management, we constructed a feasibility model that incorporated screening criteria used in California and Rhode Island.

Results: Thirty-six states and Washington, DC, responded, resulting in a survey response rate of 73%, representing 77% of all inmates in state facilities nationwide. Colorado alone reported routine screening. Only California reported conducting a systematic seroprevalence study, which found that 39.4% of male inmates were hepatitis C antibody positive in 1994. Seventy-three percent of the respondents sometimes consider treating with interferon. Four states follow a standard protocol. The feasibility model suggests that treating suitably screened inmates is a reasonable expenditure for correctional systems.

Conclusion: Prison may be an appropriate setting for treatment of hepatitis C. If accompanying substance abuse issues are addressed, instituting HCV treatment for certain eligible incarcerated individuals may be a worthy target for public health dollars.

Key Words: hepatitis C; prisons; review; cost analysis.

INTRODUCTION

Hepatitis C virus (HCV) was recognized in the mid-1970s as a distinct, "non-A, non-B," viral cause of transfusion-associated hepatitis; it was successfully cloned in the following decade [1]. The development of an enzyme-linked immunosorbent assay (ELISA or EIA) made it possible to screen donors for antibodies to HCV. Subsequently, the risk of acquiring HCV through transfusion dropped to less than 1 in 10,000 per unit transfused [2]. Approximately 4 million Americans are currently infected with HCV [3]. Due to the public health implications, the National Institutes of Health (NIH) recently held a conference to develop a consensus statement on the management of hepatitis C [2].

The route of HCV transmission can be identified in more than 90% of HCV infections [2]. While the virus shares transmission routes with HIV and hepatitis B, HCV is transmitted most efficiently parenterally. Thus, a major risk factor for acquiring HCV in the United States today is injection drug use, which accounts for 50% of new infections and over one-half of chronic infections [3]. Recently, intranasal cocaine use has also been linked with HCV transmission, perhaps secondary to epistaxis and sharing of straws [4]. Given the association between HCV transmission and illegal drug use, it is likely that a large proportion of those involved with the criminal justice system are HCV positive. For example, in 1994, California found an HCV seroprevalence of 39.4% in incarcerated males [5] compared with the HCV seroprevalence of 0.5% by EIA reported in the general blood donor population [4,6]. Given the relatively high rate of false positives by EIA in populations with low HCV prevalence, this value probably overestimates the actual seroprevalence in donors. Approximately 83% of the nation's 2 million iv drug users are incarcerated at some time [7]. Thus, a significant portion of the 4 million Americans with hepatitis C have involvement with the correctional system.

In Rhode Island, 19.4% of prisoners are serving sentences for drug-related offenses, including manufacture, delivery, and possession of drugs. Random urine

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drug tests on inmates return positive in about 2%, indicating some in-prison drug use. Surveys estimate that up to 80% of inmates have a history of substance abuse.

Approximately 85% of individuals infected with HCV will develop chronic HCV infection [4,8]. The natural history of the infection typically follows an indolent course [9], although studies following patients over 2 decades estimate that about 20% of those with chronic HCV infection progress to cirrhosis within 20 years [10]. One to five percent may develop hepatocellular carcinoma (HCC) within this period. Once cirrhosis is established, HCC develops at a rate of about 4% per year [11]. Hepatitis C is now the leading indication for liver transplantation in this country [2].

Interferon (IFN) has been used to treat chronic hepatitis C since the mid-1980s [12]. Use of IFN-α2b results in a sustained response in approximately 20% of recipients [13–16]. Sustained response is defined as no detectable virus by PCR and normalization of transaminases at 6 to 12 months after a completed treatment course. Patients who respond to IFN show remission of inflammation on liver histology [16–18]. Theoretically, this should decrease the risk of lethal sequelae of chronic HCV infection. The NIH consensus statement endorses a standard initial therapy of thrice-weekly injections of interferon for a period of 12 months [2]. The statement also details guidelines for initiating therapy. Some chronic medical conditions, such as autoimmune diseases, are contraindications to treatment. Furthermore, substance abuse should be treated prior to initiating therapy. Alcohol use is associated with exacerbation of HCV-related disease [9,19–21]. Injection drug use places people at risk for reinfection, and animal studies demonstrate that prior HCV infection does not confer protective immunity [22,23].

Applying guidelines for managing HCV is particularly important within high-risk populations. In Rhode Island, prison physicians discovered the need for clear management criteria when they found a high HCV prevalence in their population. Until recently, all inmate kitchen workers were prospectively screened for hepatitis B, hepatitis C, and HIV. Officials felt screening was necessary to appease prisoners who worried they could acquire these diseases from infected food handlers. Of those screened, approximately one-third of 450 tested positive for antibodies to HCV. The policy was changed because screening food handlers for these viral illnesses had no practical implications. However, a large number of HCV-positive inmates were already identified and were asking for treatment.

Correctional facilities in the United States participated in a nationwide survey to determine which methods are being used to evaluate and treat this potentially curable form of chronic hepatitis.

METHODS

A one-page survey was mailed to the Commissioner of the Department of Corrections for each of the 50 states plus the District of Columbia in December of 1996. A cover letter directed the commissioners to forward the survey to their medical program director for completion. Survey questions asked respondents for the number and gender of inmates in their jurisdiction and total number for the state, whether their system was privatized, what was the HIV-seropositivity rate, whether hepatitis C was tested for routinely, and the number of hepatitis C tests performed and the percentage that returned positive. Detailed information about specific HCV screening methods was not elicited. If the jurisdiction treated hepatitis, the survey went on to ask whether liver biopsies were performed, how many patients received interferon, how many doses of interferon were administered, and whether a written treatment protocol existed. Respondents were invited to send sample protocols. Finally, the survey queried whether a systematic seroprevalence study had been conducted.

Responses were returned by mail or fax between December 1996 and March 1997. Medical program directors of nonresponding state correctional facilities were telephoned in March and April 1997 and asked to complete surveys at this time. A second copy of the original survey was faxed to contacted nonresponders. Subsequent replies, returned by mail or fax, were collected between April and July of 1997.

A hepatitis C screening and treatment model was developed based on practice guidelines and data generated from the Rhode Island prison population to determine how many inmates would be eligible for treatment. Specific inclusion and exclusion criteria were applied to the total number of inmates to arrive at the number of prisoners who would most benefit from treatment. Total cost of HCV management in these patients was then estimated to determine if treatment would be economically feasible within the prison system. Absolute cost of interferon per patient was obtained from the manufacturer, and the cost of pretreatment workup was ascertained from accounting records in the prison laboratory.

RESULTS

Survey

Thirty-six states and the District of Columbia replied, resulting in a response rate of 73% (Table 1). No more than one response was returned by each state. Some surveys were answered by medical directors responsible for only part of a given state's correctional system. The responding states collectively represent 77% of all inmates in state correctional facilities nationwide, or

TABLE 1

Demographics of Responding State Correctional Facilities

State	Privatized	No. of inmates	% Male	HIV%[a] per survey
Alaska	No	3,800	80	Unknown
Arizona	No	23,000	94	1.2
Arkansas	No	8,583	93.4	1.0
California	No	144,939	93.1	2.5
Colorado	No	10,000	92	1.5
District of Columbia	No	9,000	95	*10.0*
Florida	n/a	64,024	n/a	3.4
Georgia	n/a	33,200	94	3.0
Idaho	Yes	3,832	100	0.3
Indiana	No	17,726	n/a	*1.0*
Kansas	Yes	7,300	90	*0.5*
Kentucky	No	12,179	94	1.0
Maine	Partial	1,550	99.9	0.3
Maryland	Yes	21,500	n/a	5.0
Massachusetts	Yes	10,500	93.3	3.5
Michigan	Partial	36,226	96	1.0
Minnesota	No	5,090	95.5	*0.1*
Missouri	Yes	20,185	94	0.3
Nebraska	No	3,180	90	0.7
Nevada	No	8,300	n/a	1.6
New Hampshire	No	2,055	n/a	0.7
New York	No	66,934	95	14.0
North Dakota	Yes	760	93	0.5
Oklahoma	No	14,700	90	0.7
Oregon	No	8,700	93	1.1
Pennsylvania	Yes	34,000	95	n/a
Rhode Island	No	3,294	93.2	*3.0*
South Carolina	Partial	21,094	94.3	3.6
South Dakota	Yes	2,157	93	*1.0*
Tennessee	n/a	13,827	97	1.2
Texas	No	132,346	92.5	2.4
Utah	No	4,584	95	0.4
Virginia	No	25,200	94.6	1.7[b]
Washington	No	12,579	92	1.0
West Virginia	n/a	2,600	95	*<1.0*
Wisconsin	No	14,137	95	0.9
Wyoming	No	1,300	n/a	0.3

Note. n/a, not available.

[a] Italicized numbers are estimates.

[b] Written comment included, "We test on demand or with symptoms."

about 800,000 people [24]. While 35 states (95%) reported seroprevalence data for HIV, only 1 state has completed a formal HCV seroprevalence study. Table 2 lists information regarding current screening and treatment practices for hepatitis C in responding facilities. Only Colorado reported "routine" hepatitis C testing. Thirty percent of its anti-HCV testing returned positive but only 1,224 tests were run in 1 year when the total number of inmates in the jurisdiction was 10,000. It was unclear how "routine" testing was defined. Nevada's nonroutine testing for HCV antibodies found a positive rate of only 10% by initial testing, and RIBA confirmed anti-HCV positivity of 1.2%. In Maryland, 67% of 120 tests performed were positive for HCV, and in Missouri, 59% of 840 tests performed were positive. In Utah, 83% of 87 tests were positive for HCV.

Twenty-seven (73%) respondents stated that some HCV antibody-positive inmates received treatment. Eight (22%) reported that their inmates never receive treatment and no facilities reported always treating. The extent to which a correctional system pursued treatment of HCV was not correlated with whether it was privatized. Four states (11%) follow a written protocol; an additional 6 (16%) are in the process of developing one. The number of doses of interferon dispensed, if known, are shown in Table 2. One patient receiving interferon three times weekly would receive 78 doses over 6 months and 156 doses over 1 year. Therefore, dividing the number of doses by 150 gives the approximate number of patients treated for an entire year.

Data regarding the number of inmates treated for hepatitis C, the numbers not treated, and the number of liver biopsies performed for the year was not forthcoming. Responses of states who provided information are shown in Table 3. Only nine states (24%) reported numbers of inmates treated for hepatitis C: five states reported that no inmates are currently treated, while Rhode Island reported treating 23 inmates. Six states (16%) provided data regarding number of liver biopsies performed per year: three reported none, the District of Columbia and Kansas reported 2, and Rhode Island reported performing 30 liver biopsies per year.

Only California conducted a formal study of HCV seroprevalence. This study was conducted in the fall of 1994 jointly by the California Department of Health Services, the Office of AIDS, and the California Department of Corrections [5]. The cross-sectional, blinded study showed the HCV seroprevalence rate by EIA-2 was 41% overall. The rate for men was 39.4%, with a higher rate among whites compared with minorities. Women had an overall rate of 54.5%, with the highest rate among Latinas, followed by whites. A lower than average rate was found among African-American women. Of identified intravenous drug users, 76.1% were HCV positive. In Rhode Island, over a 4-month period from September to December 1996, 37% of hepatitis C EIA tests returned positive. These data were generated mainly from prospective kitchen workers, a broad cross-section of the inmate population.

Model

In an attempt to assess costs associated with HCV management in the Rhode Island prison system, we created a model to estimate numbers of inmates eligible for screening and treatment (Fig. 1). We judge that of approximately 3,000 total inmates, only 40% will meet the length-of-stay requirement of at least 15 months (Table 4). After health education sessions, about 25% of the remaining 1,200 are expected to ask for screening.

TABLE 2

Screening/Treatment Protocols for Hepatitis C in State Correctional Facilities

State	Routine screening for HCV	% Screening HCV positive	Treatment of HCV	IFN protocol	No. of IFN doses used in 1995
Alaska	No	n/a	Sometimes	No	0
Arizona	No	n/a	Sometimes	Yes	n/a
Arkansas	No	n/a	Never	No	0
California	No	n/a	Sometimes	Yes	n/a
Colorado	Yes: 1,224 tests done	30%	Sometimes	Developing	1,158
District of Columbia	No	n/a	Never	No	0
Florida	No	n/a	Sometimes	No	n/a
Georgia	No	n/a	Sometimes	No	n/a
Idaho	No	n/a	Sometimes	No	200
Indiana	No	n/a	Sometimes	Developing	n/a
Kansas	No: 70 tests done	5–10% est	Sometimes	Developing	0
Kentucky	No	n/a	Never[a]	No	n/a
Maine	No	n/a	n/a	No	n/a
Maryland	No: 120 tests done	67%	Sometimes	No	n/a
Massachusetts	No	n/a	Sometimes	Yes	480
Michigan	No	n/a	Sometimes	Developing	n/a
Minnesota	No	n/a	Sometimes	No	236
Missouri	No: 840 tests done	59%	Sometimes	Developing	n/a
Nebraska	No	n/a	Sometimes	No	0
Nevada	No: 258 tests done	10% (RIBA 1,2%)	Sometimes	No	n/a
New Hampshire	n/a	n/a	Sometimes	No	1 case
New York	No: high risk only	n/a	Sometimes	No	1,325[b]
North Dakota	No: at least 1 done	n/a	Sometimes	No	10
Oklahoma	No	n/a	Sometimes	No	0
Oregon	No	n/a	Sometimes	No	60
Pennsylvania	No	n/a	Sometimes	Developing	n/a
Rhode Island	No: 507 Tests Done	37%	Sometimes	Yes	3,534
South Carolina	No	n/a	Sometimes	No	0
South Dakota	No	n/a	Never	No	n/a
Tennessee	No	n/a[c]	Not with IFN	No	0
Texas	No	n/a	Sometimes	No	265
Utah	No: 87 done, if Sx	33%	Sometimes[d]	No	n/a
Virginia	No	n/a	Sometimes	No	n/a
Washington	No	n/a	Never	No	n/a
West Virginia	No	n/a	Never	No	n/a
Wisconsin	No	n/a	Never	No	n/a
Wyoming	No: 5 tests done	20%	Never	No	0

Note: n/a, not available; est, estimate.

[a] "But about to change."

[b] "1995 No. IFN dose: 298 IFN-α2a; 1,032 IFN-2b."

[c] "We have experienced a very low prevalence of Hep C so far."

[d] "Only if symptoms."

Since 50–80% of IV drug users acquire HCV within 6 to 12 months of injecting [4], between 150 and 240 of the 300 are likely to have positive screens. However, we estimate that at most, 100 will meet clinical exclusion and inclusion criteria for treatment, and only 50 will demonstrate no drug or alcohol use for a period of at least 12 months. Of these, 10% will be excluded secondary to liver biopsy and/or laboratory results. Forty-five infected prisoners may begin IFN therapy. At 3 months, 25% will show no response by PCR and therapy will be discontinued. Of the remaining 34 treated, 10% will drop out of therapy due to intolerable side effects. Thirty-one HCV-positive prisoners may receive 12 months of IFN. Therefore, in the end, approximately 1% of the total prison population may receive the full course of IFN therapy.

We calculated the costs of screening and treating the number of patients presented in this model (Table 5). The total cost for our model is roughly $250,000. Drug treatment, available to varying degrees in most correctional systems, has obvious merits beyond allowing patients to qualify for hepatitis treatment. The Rhode Island Department of Corrections offers both support groups and residential treatment programs for in-

TABLE 3

Hepatitis C: No. of Inmates Treated in State Correctional Facilities in One Year[a]

State	No. treated	No. untreated	No. of liver biopsies
District of Columbia	0	0	0
Idaho	3	n/a	2
Kansas	0	0	0
Massachusetts	8	n/a	n/a
Nebraska	0	n/a	2
New Hampshire	1	n/a	n/a
Oregon	2	n/a	n/a
Rhode Island	23[b]	n/a	30
Wyoming	0	1	0

Note. n/a, not available.

[a] Only 9 respondents (24% of survey respondents) provided answers to these questions.

[b] At the time of the study.

mates. Methadone maintenance is provided only to pregnant females. Since these rehabilitative services would exist in the absence of hepatitis C, the cost of drug treatment programs was not included in the feasibility model.

DISCUSSION

We are in the midst of an HCV epidemic. Because of the correlation between parenteral and intranasal drug use and acquisition of HCV, a significant proportion of the population infected with HCV resides in prison. Treatment of an appropriate subgroup of this population may decrease their risk for cirrhosis and HCC and potentially prevent further transmission. We have initiated a discussion of this issue by assessing the current status of screening for and treating chronic HCV infection in state prison systems.

Our survey was purposefully short and directed; we received 37 of a potential 51 responses. States more active in the surveillance and treatment of hepatitis C may have been more likely to respond to the survey. This selection bias, if anything, would overestimate the extent of detection and management of the disease in a correctional setting. Incentives such as the promise of technical help in developing a hepatitis C protocol upon receipt of a completed survey may have resulted in a higher response rate.

Many of the surveys were returned with partial responses, estimates, and omissions of critical information. More complete responses may have been elicited had the respondents been telephoned in order to clarify the omissions. The questions that appeared to pose the most difficulties included the number of hepatitis C tests performed and the percentage of tests returning positive, the number of inmates treated and untreated, the number of liver biopsies, and the number of IFN doses. Unclear information and estimates may have introduced observer bias, making it difficult to interpret some of our results. For example, many states responded that they sometimes treat their HCV-positive inmates without providing discrete values for numbers treated. This may again overestimate the extent to which state facilities treat. Similarly, seven of eight states responding that they never treat HCV omitted the number of screening tests performed. It is not clear whether these states are not treating HCV-positive prisoners or simply not testing for the disease.

The survey did not request information on screening protocols. Only one state routinely tests for HCV. We assume that the other states are predominantly testing high-risk or symptomatic inmates or those who request testing. Based on California's seroprevalence studies, many potentially treatable inmates with hepatitis C may not be identified by these practices.

While most states are familiar with HIV seropositivity in their prison systems, only California reported knowing HCV seroprevalence, citing a rate of roughly 39%. This value is significantly higher than the rate for HIV, for which many prisons routinely screen. It is possible that similar rates would be found in other state prisons. Despite a lack of routine screening one state commented, "We have experienced a very low prevalence of Hep C so far." This lack of awareness of the potentially high prevalence of HCV may reflect the paucity of published data on HCV screening and treatment in the prisons.

Most prisons sometimes treat HCV, although only four have established IFN protocols. Many important questions remain to be asked. For example, what are the specific screening criteria used in most states? What inclusion criteria are used among the 73% of state facilities that sometimes treat HCV? How, specifically, is HCV treated in these facilities?

Issues of cost effectiveness potentially limit feasibility of treatment. Determined to provide standard of care in a financially restrictive environment, California and Rhode Island incorporated a set of inclusion and exclusion criteria into their IFN protocols (Table 4). In the year prior to instituting these guidelines, Rhode Island treated 23 inmates with IFN. This number was high compared with numbers reported in other states partly because, at that time, all prospective kitchen workers were screened for HCV. Some of the 23 inmates would not meet current inclusion criteria. Interferon protocols should allow us to identify the subset of patients who will benefit most from therapy.

We must assess the applicability of the current HCV treatment guidelines to the prison population. A recently developed framework proposes considering nine factors when deciding to implement health benefits for an inmate [25] (Table 6). In it, patient desire is an

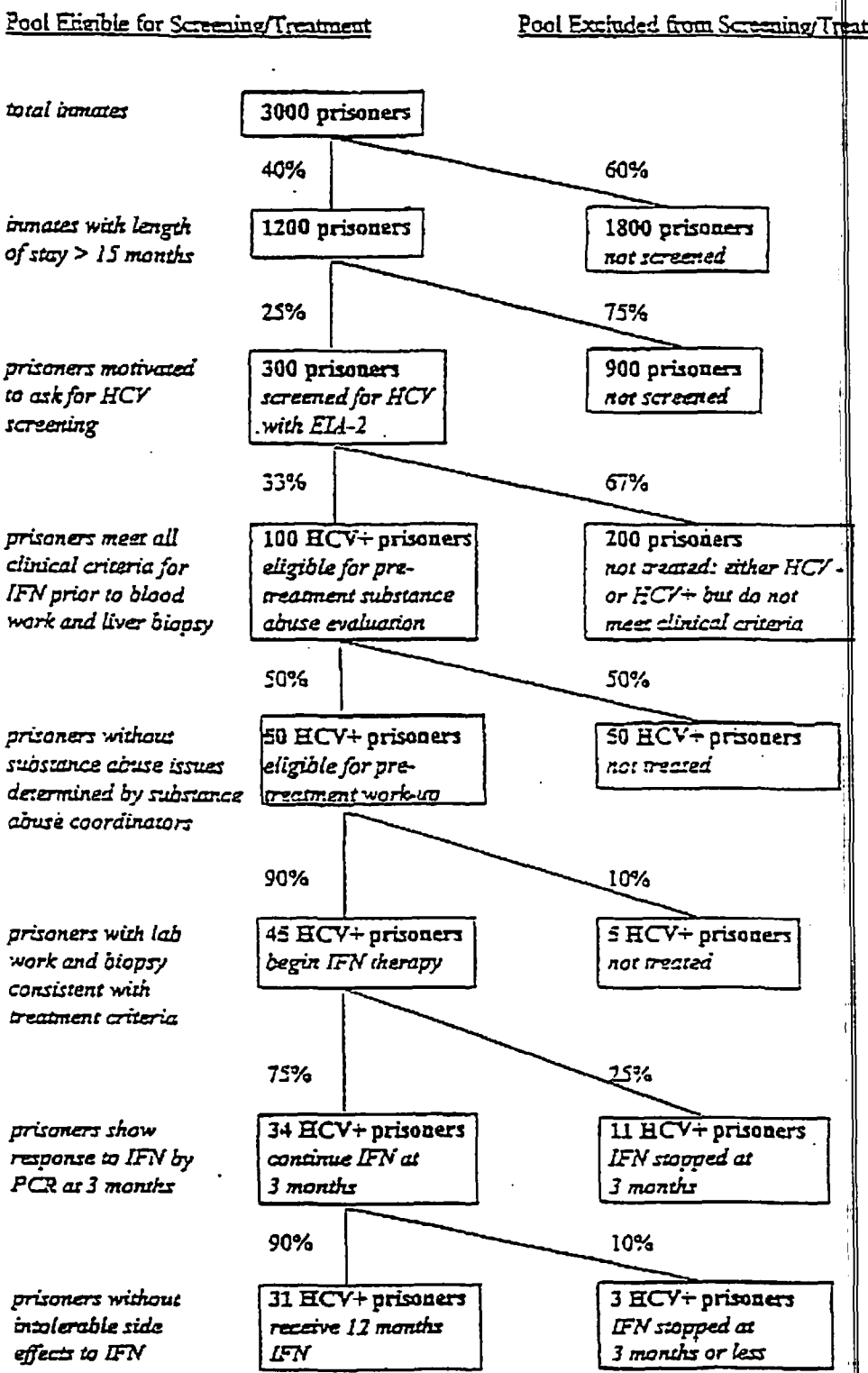

FIG. 1. Hepatitis C screening and treatment model in Rhode Island state correctional facility. Model based on estimates derived from experience within the Rhode Island state correctional system.

TABLE 4

Exclusion/Inclusion Criteria for Treatment of HCV[a]

	RI	CA
Absolute exclusion criteria		
Failure to enroll in substance abuse program for 12 months prior	+	+
History of documented use of iv drugs or alcohol in preceding 12 months	+	+
Poor control of a major medical illness or psychiatric illness	+	+
Length of stay in prison <15 months from initiation of treatment	+	+
Organ transplant recipient	−	+
Duration of infection >5 years	−	+
Clinical signs or symptoms of decompensated liver disease	+	+
Platelet count <75,000	+	+
HIV antibody positive	−	+
HCV viral load <3,500 or >350,000	−	+
Reasonable life expectancy <20 years	−	−
Liver biopsy: presence of cirrhosis, fatty infiltrate	−	−
Autoimmune disorder	+	−
Absolute Inclusion Criteria		
Serum HCV antibody positive	+	+
Age >18 or <65 years	+	+
Ect >30%, Alb <3.5 mg/dl, Cr <1.5 mg/dl, INR <1.2 thyroid function tests within normal limits	+	+
Consent signed for random drug and alcohol screens during treatment	+	+
Liver biopsy consistent with chronic viral hepatitis	+	+
LFT greater than upper limits of normal	+	−

[a] Rhode Island information from Dr. Anne Spaulding, Medical Program Director; California criteria created by committee steered by Dr. Nadim K. Khoury and Dr. John R. Covington, Assistant Deputy Directors, Health Care Services Division.

TABLE 5

Costs per Year for Screening and Treatment of Eligible Inmates in the RI Prison System Based on Model in Fig. 1

Procedure	Cost	No. of patients	Total cost
HCV EIA	$9.50	300	$2,850
Liver biopsy	$1,278	50	$63,900
Correctional officers' time[a]	$205	50	$10,250
Reagent costs			
Pretreatment workup[b]	$309	50	$15,460
Intratreatment follow-up[c]			
3-month course[d]	$251	14	$3,514
12-month course	$745	31	$23,095
IFN			
3-month course	$1,017.50	14	$14,246
12-month course	$4,070	31	$126,170
Total			$259,474

[a] Cost of 4 h of overtime for 2 state correctional officers.
[b] Includes CBC, LFTs, TSH, ANA, AMA, α-1 antitrypsin, ceruloplasmin, HCV qualitative PCR.
[c] Costs based on Schering's HCV flow sheet protocol.
[d] Based on previous studies, it is assumed 25% of those treated will not respond by 3 months and will receive no further treatment. Therefore, only 75% of those begun on IFN will receive the full 12-month course.

TABLE 6

Factors Influencing the Decision to Intervene[a]

1. Urgency of procedure.
2. Expected remaining duration of incarceration.
3. Necessity of procedure.
4. Probability of successful outcome of treatment, including the risk of adverse side effects.
5. Patient's desire (expressed or implicit) for the intervention.
6. Expected functional improvement as a result of the intervention.
7. Whether the intervention is for a preexisting condition.
8. Whether the intervention is a continuation of previous treatment for a chronic condition, or is the initiation of a new course of long-term treatment.
9. Cost.

[a] See Ref. 25.

important criterion for consideration of treatment; others are urgency and necessity of the procedure, likelihood of success and improved function with the intervention, whether the condition is preexisting, whether treatment was begun prior to incarceration, and what the cost and the remaining length of time within the system are. In Rhode Island, inmates receive health education about HCV. Only patients who subsequently request screening and treatment are considered for IFN therapy. As more prisoners are treated and have manageable side effects, the demand by fellow inmates for treatment increases. This population has tolerated interferon at rates similar to the general population. Furthermore, compliance rates are high because of close medical follow-up while in prison.

Inmates must demonstrate their desire for treatment by abstaining from injection drug or alcohol use for the 12 months prior to beginning treatment. Since sharing injection-drug-use equipment puts individuals at risk for HCV infection, we considered including inmates who may have injected but not shared equipment in the past 12 months. However, the patients' reliability with regard to this matter would be too difficult to assess. In addition, current drug users may be at higher risk of sharing equipment if clean paraphernalia is not available.

Correctional health care practitioners routinely consider duration of incarceration in their decision-making. For example, emergency care is not denied for an inmate with even the shortest sentence. On the other hand, elective surgery may be justified only if an offender will not have access to outside care for an extended period of time. In the case of HCV, one of the inclusion criteria for treatment in both Rhode Island and California is a length of prison stay of at least 15 months to allow for a 12-month treatment course with follow-up. While the cost of screening and treatment is potentially the limiting factor for many prison systems, cost–benefit analyses in nonincarcerated populations

[26–29] suggest that IFN is a cost-effective treatment for an appropriate subset of patients. In the correctional setting, the savings may not be realized during a single inmate's prison term, but rather in the long-term cost to society.

The costs of screening and treating the patients presented in our model totaled about a quarter million dollars. This represents roughly 3% of the total health care budget in the Rhode Island correctional system. A cost–benefit analysis of HCV treatment in the prisons is necessary to explore potential costs saved and quality of life gained with treatment.

It is important to evaluate all screening and treatment protocols that are implemented in a prison system. Of course, the most effective intervention program would be to decrease the acquisition of hepatitis C in the first place. Correctional health services could use strategies that have been successful in lowering the risk of acquiring HIV—peer education, substance abuse treatment—and apply them to hepatitis C prevention [30].

CONCLUSION

A significant portion of the HCV-positive population resides in prisons. The association holds true not just in the United States but also in other western countries. In fact, a study in the Sydney, Australia, prison system discovered an HCV seroprevalence of 37%, very similar to the value reported by California and Rhode Island [31]. Treating an appropriate subgroup of inmates may represent a public health expenditure that is cost effective. In this study, we found that only one state routinely screens all inmates for HCV infection. While the seroprevalence in most state prisons is unknown, the percentage of infected inmates is significantly higher than in the general population. Multiple cost–benefit analyses in nonincarcerated populations have shown that the benefits of treating hepatitis C outweigh the costs [26–29]. While a large proportion of state correctional facilities reported that treatment for HCV is sometimes considered, it appears that few inmates are actually treated. Furthermore, few states have set criteria to determine who should be screened and treated. We advocate the development of protocols that, while recognizing financial constraints within state correctional systems, ensure that appropriate inmates with hepatitis C are treated according to the current standard of care. Several new regimens for treating hepatitis C are under development, including combination treatment with ribavirin. As treatment becomes more effective and less costly, addressing HCV in prisons should become an even higher priority.

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ATTACHMENT C

DEPARTMENT OF CORRECTIONS

POLICY

POLICY NUMBER

670.040

TITLE

INTERFERON-ALPHA THERAPY FOR HEPATITIS C

EFFECTIVE DATE: July 17, 1996

AUTHORITY:

General authority of the Secretary of Corrections to manage and direct the Department, 72.09.050.

PURPOSE:

To provide guidance regarding the use of Interferon-Alpha to treat offenders with Hepatitis C.

APPLICABILITY:

Division of Prisons and Division of Community Corrections.

DEFINITIONS:

Guidelines Development Committee - A formally established committee of Department medical consultants and physicians representing all the major facilities, and the Health Services Utilization and Reimbursement Manager or designee. This committee is responsible for writing, developing, and implementing guidelines for determining appropriateness of medical treatment.

Review Panel - A subset group of the physicians participating on the Guideline Development Committee to discuss indications for treatment when the proposed treatment does not meet the established guidelines.

POLICY:

1. The Department will not authorize, prescribe, or reimburse for Interferon-Alpha therapy to treat the condition of Hepatitis C, except when approved through the prior authorization process described below.

2. Prior authorization for administering this treatment is required. The Review Panel will determine the appropriateness of the proposed treatment and make a recommendation to the Health Care Authority at the facility. The Review Panel will discuss the proposed treatment and clinical indications prepared by the consulting gastroenterologist with the physician representing the facility where the offender is housed. To assure objectivity, the Review Panel members will not have an affiliation with the facility where the offender is housed. The physicians participating on this panel will be rotated. The Review Panel's discussion will be coordinated through the Health Services Utilization and Reimbursement Manager or designee. This discussion may be conducted by a telephone conference call.

3. The grievance process should be utilized by any offender who wishes to appeal the recommendation of the Review Panel.

4. All situations requiring either clarification of the policy or a review of the panel's procedures will be directed to the Health Services Utilization and Reimbursement Manager or designee.

REVIEW:

The Policy Review Committee shall coordinate the review of Department Policies at least every two (2) years and update as needed.

REFERENCES:

None.

SUPERSESSION:

None.

7/17/96

Clinical situations in which further hepatic evaluation may be indicated and in which Interferon Alpha Therapy may be permitted in the Department of Corrections

1. Evidence of persistent or progressive hepatic synthetic function impairment manifest by:
   - *a.* **Coagulopathy** *(prothrombin time more than 2 seconds prolonged without other explanation)*
   - *b.* **Hypoalbuminemia** *(albumin less than 3.0 mg/dl without other explanation)*
   - *c.* **Hyperbilirubinemia** *(bilirubin greater than 2.0 mg/dl without other explanation)*
2. Evidence of extrahepatic manifestations of Hepatitis C that may respond to interferon alpha
   - a. **Essential mixed cryoglobulinemia**
   - b. **Membranaproliferative glomerulonephritis**
   - c. **Mooren corneal ulcer**