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Infectious Diseases in Corrections

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IDCR

INFECTIOUS DISEASES IN CORRECTIONS REPORT

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ABOUT IDCR

IDCR, a forum for correctional problem solving targets correctional physicians, nurses, administrators, outreach workers, and case managers. Published monthly and distributed by fax and email, IDCR is ACCME accredited and free of charge. Since its founding in 1998, IDCR has served as an important resource for correctional health care providers by offering the newest and most relevant information on the management and treatment of infectious diseases within the correctional setting. Continuing medical education credits are provided by Medical Education Collaborative (MEC). This publication is jointly sponsored by IDCR and MEC. This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of MEC and IDCR. MEC is accredited by the ACCME to provide continuing medical education for physicians.

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INCORPORATION OF THE AST PLATELET RATIO INDEX (APRI) INTO THE HCV EVALUATION AND TREATMENT PATHWAY IN THE TEXAS DEPARTMENT OF CRIMINAL JUSTICE (TDCJ)

- **Spotlight:**
  Perspective: Potential Legal Pitfalls of HCV Management in Corrections and How to Avoid Them
- **HCV 101:**
  Metavir Scoring System

OBJECTIVES

- The learner will be able to explain how and why the Texas Department of Corrections incorporated a serum marker of hepatic fibrosis into its HCV evaluation and treatment guidelines.
- The learner will be able to summarize elements of HCV treatment policies that could aid in the reduction of litigation from HCV-infected inmates.
- The learner will be able to describe the Metavir Scoring System and it's implication for the treatment of HCV.

Purpose Statement

The purpose of this newsletter is to increase the knowledge of physicians in correctional systems on determining what tests to use to assist them in treating HCV patients and what to include in a rationale HCV policy to prevent legal problems.

DISCLOSURES AND CREDENTIALS:

FACULTY DISCLOSURE

The employees of Medical Education Collaborative have no financial relationships to disclose. 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.

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Incorporation of the AST Platelet Ratio Index (APRI) into the HCV Evaluation and Treatment Pathway in the Texas Department of Criminal Justice (TDCJ)

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Introduction

Prisons and jails in the U.S. bear a disproportionate share of the total United States population with hepatitis C virus (HCV) infection. The primary source of HCV infections in the U.S. is illegal injection drug use.[1] Since drug offenders make up 21% of state and 55% of federal prison populations and even greater percentages of offenders report past drug use 2, it is not surprising that the prevalence of HCV infection in correctional facilities (15% - 40%) is significantly higher than in the general population (1.8%).[1,3] Additionally, it has been estimated that at least a third of all HCV-infected persons in the U.S. pass through a correctional facility in any given year.[4] These circumstances provide a unique opportunity for correctional systems to identify, treat, educate, and ultimately interrupt the transmission of HCV by prisoners who are released back into the community since HCV is acquired primarily from risk behaviors occurring outside of the correctional setting.[5] Scarce health care funding for HCV treatment within corrections is one reason why this opportunity has not been exploited. With an estimated 400,000 HCV-infected offenders behind bars at any one time, the potential cost of comprehensive screening, testing, treatment, and prevention programs would be enormous.[3]

Nonetheless correctional systems are assuming responsibility for treating many of these inmates who have chronic HCV infection since courts have found that it is an Eighth Amendment violation to deny HCV treatment to an offender who has significant liver disease that is amenable to antiviral treatment.[6] Consequently, correctional systems are facing challenges in developing evaluation and treatment guidelines that address logistical and financial limitations to treating HCV infections among offenders. For example, since continued HCV care for inmates after release is generally not available, duration of incarceration has been adopted as an exclusionary criterion for treatment by many correctional jurisdictions. Likewise, among offenders with chronic HCV infection and no medical or psychiatric contraindications to treatment, ALT levels may be used to decide who should be considered for antiviral therapy because of the geographical and security challenges of transporting patients to a facility where liver biopsy can be done.[7] Logistically, using ALTs may make sense; yet one large collaborative study demonstrated that ALT levels lack adequate sensitivity and specificity on which to base treatment decisions in the correctional setting or elsewhere.[8]

Liver biopsy remains the gold standard in making treatment decisions regarding HCV infection; and it should be emphasized that deferral of treatment is appropriate and cost effective for those with little or no evidence of fibrosis provided that appropriate follow up conducted periodically to assess disease progression.[9] But there is a general consensus that even the gold standard is not perfect. First, liver biopsy is expensive and associated with low, but predictable rates of morbidity and mortality.[10] Further, the histopathological samples obtained by percutaneous liver biopsy are often not representative of the overall condition of the liver or may not be large enough to make an accurate diagnosis.[11] Finally, the interpretation of fibrosis is dependent upon the skill and experience of the pathologist reading the biopsy specimen.[12] For all of these reasons, there has been a great deal of basic and clinical research aimed at identifying noninvasive markers of hepatic fibrosis that can be used to accurately predict significant fibrosis for patients with HCV infection as well as other conditions associated with hepatic fibrosis. Although many serum markers of hepatic fibrosis have been identified, none has been identified that can entirely replace the need for liver biopsy.

This article describes why and how The Texas Department of Criminal Justice (TDCJ) incorporated one of these serum markers of hepatic fibrosis, the AST Platelet Ratio Index (APRI), into its HCV evaluation and treatment guideline.

Serum Markers of Hepatic Fibrosis

Serum markers of hepatic fibrosis reflect the state of fibrosis and fibrogenesis within the liver. These markers can be divided into two groups: Indirect and direct markers. Indirect markers include common clinical tests such as platelet counts, serum transaminases, glutamyl transpeptidase (GGT), and total bilirubin - all of which measure hepatic function. In contrast, the direct serum markers more accurately reflect the complex process of fibrogenesis. Fibrogenesis is a dynamic process characterized by deposition and degradation of the extracellular matrix (ECM) of the liver by stellate and other fibrogenic cells within the liver. Many serum markers of ECM remodeling are under investigation. A few examples are hyaluronic acid, metalloproteinases (MMPs), specific tissue inhibitors of metalloproteinases (TIMPs), macroglobulin, apolipoprotein A1, and haptoglobin.[13,14] Many clinical studies have documented the correlation between serum markers of hepatic fibrosis with stage of fibrosis on liver biopsy to determine which markers, or more accurately, combinations of markers can accurately predict insignificant fibrosis (F0,

Continued on page 3

Letter from the Editor

Dear Correctional Colleagues,

The management of hepatitis C virus (HCV) was one those topics that was guaranteed to get a room full of correctional health care professionals into uproarious debate. Saddled with an astoundingly high prevalence of HCV among inmates, prisons and jails have had to deal with the cruel double edge of HCV treatment; therapy can be curative but is expensive, difficult to tolerate and has disappointingly low rates of success. The limitations of HCV therapy have prompted many correctional systems to withhold or restrict this treatment. Meanwhile, as HCV therapy has become more commonplace in the free world and clinical studies make clear the benefits of treatment, there has been increasing pressure for HCV therapy to be made widely available to prisoners.

In response more correctional systems have come to embrace HCV therapy and have crafted procedures and policies regarding the diagnosis and treatment of this infection. Recently, *IDCR* reported on the approach taken by prisons in Hawaii and in this issue we provide a report by Dr. David Paar from Texas who describes an innovative strategy that system has developed to identify patients who are most appropriate for HCV therapy while avoiding liver biopsy. In addition, Dr. Lester Wright shines a spotlight on a unique program in New York State to maintain HCV therapy continuity following prison release.

As most of us are well aware, the threat of litigation has motivated the adoption of HCV therapy in correctional systems in no small way. Dr. Joseph Paris, former Medical Director for the Georgia Department of Corrections, in this issue provides his perspective on the legal pitfalls of HCV management in a correctional setting.

Over the past few years more of our inmates have obtained the opportunity to receive treatment for their HCV and different systems, prisons (and even some jails) have devised their own approaches to this infection. Alas, the old HCV in corrections debate has died down only to be replaced by other controversies - many of which you can be assured will be covered in forthcoming issues of *IDCR*.

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Incorporation of the AST Platelet... *(continued from page 2)*

F1), which does not require treatment, from significant fibrosis (F2, F3, F4), which does require treatment.[15-21] See HCV 101 for an explanation of the fibrosis staging score.[22]

Not all of these tests are directly comparable because existing studies differ in their definition of fibrosis staging as well as in the population in which they have been validated. Given these limitations, it can generally be stated that using many of these tests, approximately 50% of patients can be classified as having either insignificant fibrosis or significant fibrosis obviating the need for further evaluation by liver biopsy. The other 50% of patients will require liver biopsy to determine extent of fibrosis. Of course, even the best serum marker tests are not 100% accurate. Thus the decision not to biopsy based on a serum marker assay alone is incorrect. Other factors that might be taken into account when assessing the accuracy of a serum marker of fibrosis include historical data such as alcohol intake, physical examination findings such as enlarged spleen, or laboratory data such as prolonged coagulation times that suggest that the serum marker assay is inaccurate.[9] Table 1 lists and characterizes the serum markers of hepatic fibrosis generally available to clinicians practicing in the U.S.

APRI in the TDCJ

Until January 2007, the University of Texas Medical Branch - Correctional Managed Care (UTMB-CMC), which provides health care to approximately 80% of offenders incarcerated in the TDCJ, followed an HCV treatment guideline that relied on hepatic transaminase elevations rather than liver biopsy to determine suitability for HCV treatment. This guideline was recently modified after studies conducted within prisons suggested that it was more cost effective to base HCV treatment decisions on liver biopsies rather than on transaminase elevations.[23] In addition, it was decided to incorporate a non-invasive marker of fibrosis into the guideline in order to reduce the number of biopsies needed for treatment decisions.

The APRI score was selected because it is a simple formula (AST divided by platelet count) based on commonly ordered and inexpensive laboratory tests and has been prospectively validated, in part, with prisoner liver biopsy specimens and laboratory values at UTMB.[20,24] In previous studies, using lower and upper cut-off values of 0.42 and 1.2, respectively, the APRI accurately classifies 60% of people with HCV as having either insignificant fibrosis (F0, F1) or significant fibrosis (F2, F3, F4).[20] In the other 40% of patients, percutaneous liver biopsy must be used to assign stage of fibrosis in order to make a treatment decision. By using the APRI, it was anticipated that the number of biopsies performed on HCV positive offenders would be reduced by approximately 50% in comparison to a guideline that did not incorporate the APRI or other serum marker of hepatic fibrosis.

The IDCR-O-Gram shows how the APRI has been incorporated into the UTMB - CMC HCV management guideline. Because HCV genotype II and III infections respond well to a six month course of pegylated interferon plus ribavirin, all genotype II and III patients are considered potential candidates for therapy regardless of APRI score. This makes sense from a public health view point as well; eliminating these infections leads to a decrease in the overall reservoir of infection. All HIV/HCV co-infected patients are candidates for treatment and receive a liver biopsy to aid in treatment decisions.

Since this guideline was adopted, Snyder, et al. [24] have published an algorithm in which the APRI and the FIBROSpect II (see Table 1) are used to sequentially screen a prospective cohort of patients undergoing liver biopsy for evaluation of HCV infection. The APRI was used as an initial screening tool for the prediction of fibrosis. The FIBROSpect II was used to assess the group of patients whose APRI score was indeterminate. Using this strategy the percentage of 93 prospectively assessed patients whose fibrosis could be accurately predicted, using liver biopsy as the standard, was 74.2 %. This suggests that it may be possible to combine these tests to further reduce the number of biopsies necessary to make accurate diagnosis of stage of fibrosis.

Summary

Correctional institutions are treating increasing numbers of offenders with HCV infections. Treatment guidelines can promote cost effective means of evaluating and treating HCV infections through judicious application of non-invasive means of assessing fibrosis. UTMB-CMC has incorporated the APRI into its evaluation and treatment regimen and will assess its effectiveness in ongoing quality assurance programs.

Table 1. Serum Markers of Hepatic Fibrosis.

Serum Marker	Comment	Ref.
Forn's Score	A model with a complicated, nonproprietary formula using age, GGT, platelet count, and cholesterol to select patients at very low risk of significant fibrosis (F0, F1). A score below 4.2 had a negative predictive value of 96% in excluding patients with insignificant fibrosis (F0F1). Approximately 50% of patients could be classified without biopsy using this model. The model did not perform as well in selecting patients with significant fibrosis (F2, F3, F4).	14
HCV - FibroSURETM	This is a proprietary test that combines α_2 macroglobulin, haptoglobin, total bilirubin, apolipoprotein A1, GGT, and ALT with a patient's age and gender in a patented algorithm to predict fibrosis and necroinflammatory activity. A score of < 0.2 was able to exclude patients with insignificant fibrosis (F0, F1) with a negative predictive value of 90% and a score of > 0.8 had a 90% positive predictive value of significant fibrosis (F2, F3, F4).	15
FIBROSpect II®	This proprietary test uses hyaluronic acid, TIMP-1, and α_2 macroglobulin in a patented algorithm to calculate a score that predicts fibrosis. Using a cut off value of 42, the test is 71.8 % and 55.1% sensitive at detecting F2, F3, F4 fibrosis and F0, F1 fibrosis respectively.	16
HepaScore®	This proprietary test uses α_2 macroglobulin, hyaluronic acid, GGT, and total bilirubin along with age and sex in a patented formula. In an internal validation by Quest Diagnostics a score > 55 is 88% sensitive and 69% specific for the presence of hepatic fibrosis (F2, F3, F4).	17
APRI	In the original paper, an APRI score of < 0.5 had an 86% negative predictive value of excluding significant fibrosis. In a refinement and prospective validation of the APRI at another center it was shown that in 60% of patients studied, an APRI value < 0.42had a 93% negative predictive value in excluding F2, F3, F4 fibrosis and an APRI of > 1.2 had a 93% positive predictive value of including this diagnosis. Patients who fall in the indeterminate zone between 0.42 and 1.2 cannot be accurately classified and require a live biopsy to stage fibrosis.	18, 19
Fib-4	A relatively simple, nonproprietary calculation: (age [year] x AST [U/L])/(platelets [109/L] x ALT [U/L]) that has been proposed as an accurate marker of fibrosis in HIV HCV co-infected patients.	20

Continued on page 4

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SPOTLIGHT: PERSPECTIVE: POTENTIAL LEGAL PITFALLS OF HCV MANAGEMENT IN CORRECTIONS AND HOW TO AVOID THEM

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Introduction

Hepatitis C virus (HCV) infection is common among the incarcerated and it is generally agreed that inmates with risk factors for this infection should be offered testing for HCV.[1-4] Such testing has been found to identify high numbers of HCV-infected inmates, but the role of correctional systems in the management of the HCV-infected inmate has been subject to considerable debate within prisons and jails, the professional and lay press and the courts. What follows is a description of the major legal aspects of HCV management in prisons and jails and a suggested set of rational approaches to avoid litigation.

A rational HCV policy: Screening

Given the high prevalence of HCV in correctional settings, correctional health care systems large and small need to offer HCV testing to all inmates reporting or evidencing positive risk factors for infection and should also have policies that permit inmates to request HCV screening. Mandatory HCV testing of inmates, like mandatory HIV testing, may have unintended negative consequences, such as discouraging testing and risking stigmatization, and should be avoided.

Inmates who are confirmed to be HCV - infected should be counseled with respect to transmission potential and to the risks and benefits of HCV treatment. All HCV-infected persons should be offered vaccination for hepatitis A virus, hepatitis B virus and be screened for HIV infection.

A rational HCV policy: Staging

Once active HCV infection is diagnosed, assessment of HCV disease severity follows. The goals of disease staging are two-fold: to accurately assess the extent of liver damage for the benefit of the patient and physician and to aid in HCV treatment decision-making. Severity of liver disease can influence discussion of whether to initiate HCV therapy and also be a factor when deciding whether to continue or halt therapy when treatment related toxicities develop.

A liver biopsy is often used to assess the status of HCV patients although alternative, non-invasive markers of liver disease are being developed and put into practice (see Main article). Depending on the liver architecture, a Grade and a Stage of liver pathology can be assigned by a pathologist. Grade is defined as a histologic assessment of necro-inflammatory activity (not fibrosis). The degree of fibrosis found is assigned a Stage. Different systems exist to assign these Grades and Stages numbers from 0 to 4 or from 0 to 6 (se HCV 101). The numbers have prognostic significance.[5]

While there are challenges to obtaining liver biopsies for inmates of some correctional systems including the need to transport to patients to outside medical facilities, the utility of this procedure is largely now accepted. Further, testing inmates for HCV and/or performing liver biopsies is not very expensive when compared to the potential costs of treating large numbers of HCV positive inmates with IFN-based therapies and other drugs.[6]

A rational HCV policy: Treatment

In devising a rational HCV policy for either large or small correctional systems, physicians and managers need to have a clear idea of the medical goals sought.

Authorities agree that the goal of HCV treatment is to achieve a Sustained Viral Response (SVR). SVR may not represent a true "cure". Rather, it may mark a cessation of viral activity and suppression of viral replication for prolonged periods. Cessation of viral replication has been associated with improvements in liver histology and enzymes. Although early studies of patients with SVR suggest possible lengthening of survival, a final word on survival is not in.

Further complicating matters is the unclear natural history of HCV infection. This is one of the most controversial and hotly debated topics in hepatology today. There seems to be two extreme positions. For some, HCV infection is an indolent disease which may take 20-30 years to claim the lives of approximately 20% of those infected - especially if the patient drinks alcohol. Since inmates generally cannot obtain alcohol regularly, their liver disease would be more likely to progress slowly. Others feel that the HCV virus is aggressive, causes rapid liver disease progression (especially in patients co-infected with HIV) and may be fatal in 5 years or less. According to this way of thinking, in order to avoid severe morbidity and mortality patients must be treated as soon as possible.

In a study of 123 HCV-infected patients who did not receive HCV therapy, serial liver biopsies showed that fibrosis scores progressed very slowly over the course of years.[5] The authors extrapolated these findings to suggest that up to 50 years may elapse from initial HCV infection to advanced, potentially fatal cirrhosis of the liver. They concluded that the best predic-

Continued on page 5

PERSPECTIVE: POTENTIAL LEGAL PITFALLS...
(continued from page 4)

tors of fibrosis were the extent of serum ALT elevations and the degree of hepatocellular necrosis and inflammation on liver biopsy. Their conclusion: "Patients with normal ALT and mild histology can safely defer treatment" has been often cited by correctional medical authorities formulating rather restrictive inmate treatment eligibility policies.

The impact of length of sentence prior to treatment approval

A difficult question regarding inmate eligibility for IFN-based therapy is whether there is enough time to complete such treatment. The Federal Bureau of Prisons has led the way with policies and guidelines that required sufficient sentence time to complete the treatment. The rationale was predicated on the fact that it is generally difficult to ensure continuation of IFN treatment upon inmate release. An interruption of a few weeks would cause the loss of benefit of previously given treatments, with the need to restart the treatment course from the beginning and a risk that the treatment would still be effective.

For Genotype 1 HCV (the most common in U.S. prisoners) 48 weeks was and is the recommended duration of IFN-based therapy. Since two, three, or more months may be needed to complete initial evaluations, only inmates with well over a year left in their sentences would qualify for IFN-based therapies. In jails, the vast majority of inmates are held for shorter periods. Therefore, they would not generally be eligible for HCV therapy. The exception would be the few inmates sentenced to jail terms of over a year. Unfortunately, some jail physicians would assume that most inmates are not be eligible and therefore do not initiate testing, counseling, vaccination, and other very necessary ministrations for any inmates.

In prisons, the situation was somewhat clearer, because prisons house a number of inmates serving very long sentences who easily meet the length of sentence requirement. However, prisons also house substantial numbers of inmates with sentences of five years or less. Because of overcrowding, early release of these prisoners may occur at any time. In addition, many inmates regularly appear before Parole Boards and may unexpectedly be granted parole. It follows that, in some systems, state prisoners' length of stay may be hard (if not impossible) to calculate. In order to make rational decisions on IFN therapy, prison providers must understand the system of inmate release in use.

Should HCV treatment be given by specialized consultants?

As knowledge on HCV became more sophisticated, a number of Infectious Diseases (ID) and Gastroenterologists (GI) became HCV consultants. A major issue evolved for correctional physicians (Internists, Family Physicians) regarding whether to treat their own HCV inmate/patients or to refer them to specialists. Very few correctional Internists or Family Physicians have the training and expertise to perform their own liver biopsies. While in principle therapies for HCV are not that complex, they frequently require concomitant treatment with antidepressants, erythropoietin, granulocyte stimulating factor, and other stimulants of the blood forming organs. In many correctional systems, a division of labor evolved where HCV consultants would see the inmate/patients at time of performance of liver biopsy, IFN therapy initiation, and the management of any serious side effects of therapy. Primary care prison/jail physicians would follow the patients closely and would refer them to the consultants as clinically indicated. In a number of correctional systems, telemedicine became a very useful tool for HCV consult follow up. However, in this writer's experience, very few consultants would schedule an inmate/patient for liver biopsy or IFN treatment initiation unless they had seen the patient in person at least once.

The concept of HCV Pre-Therapy Checklist

At the beginning of this decade, a number of large correctional system physician/managers observed that physicians unfamiliar with HCV management may initiate IFN-based therapy for inmate/patients who were poor candidates by virtue of coexisting physical or mental health issues and adherence to therapy issues, among other reasons. These incorrect startups by inexperienced practitioners endangered patient health and greatly increased costs. For these reasons, and following the leadership of the Federal Bureau of Prisons Health Services, several large systems developed the concept of a Pre-Therapy Checklist. This list enumerated the various evaluations required for consideration of HCV treatment and also listed all the medical/mental health contraindications to IFN in a single sheet. The Georgia Department of Corrections (GDC) adopted this system in 2003. At the time, there were substantial benefits from this policy. Since pharmacists would not issue IFN to an inmate unless the Pre-Therapy Checklist was complete, the document became a road map guiding the workup. Items were completed in a sequence leading to liver biopsy. A consequence of the use of this system was that Inmates refusing one or more items listed in the Pre-Therapy Checklist were considered to be refusing therapy, as treatment required completion of the checklist evaluations.

However, the Pre-Therapy Checklist approval-denial mechanism became a major litigation target. Although, intended as a checklist (a method to ensure that all necessary medical history and blood testing was documented and fell within certain parameters), inmates and plaintiff's attorneys have represented the checklist as a remote clinical consultation and that the approving physician was conducting a consultation without the benefit of a physical examination. Such a misconception has rendered the tool difficult to explain and implement. At this time, the author does not recommend its use.

Discharge planning for inmates undergoing IFN therapy

As discussed above, unexpected releases of inmates on IFN therapy may occur at any time. If the inmate knows his or her future county of residence, correctional health care staff should be ready to coordinate with the appropriate department of public health or other center for continued care. In this writer's experience, however, very few health deaprtments are set up to treat indigent HCV patients. Major IFN manufacturers have created HCV Patient Assistance Programs precisely for such patients to provide these medications to qualified patients. Consequently, upon learning that a given inmate on IFN may leave the institution, staff should provide the inmate with health record summaries and educate the inmate on medication storage and administration and the availability of patient care programs. The first few weeks after release are a hectic time. The ex-inmate may need time for stabilizing his/her situation before being able to seek medical services. Issuing the exiting inmate 30 days of IFN-based medications plus an appropriate supply of syringes and needles is one way to ensure continued treatment while community care is being established.[7]

Strategies for preventing legal troubles

This author has experienced a number of legal cases related to HCV care of prisoners. In a typical case, an inmate sued because after the finding of Stage 2 fibrosis on a liver biopsy and persistently normal ALT levels his IFN treatment was deferred, with continuing monitoring. Another inmate sued because he did not receive treatment. His liver biopsy had showed cirrhosis. He had florid ascites and had repetitive GI bleeding episodes. Another inmate sued because his IFN-based regimen had been delayed one year. Although he was eventually treated, he did not achieve SVR. His claim was that perhaps the earlier treatment would have increased his likelihood of achieving SVR.

All of these inmates sued in Federal Court. None has prevailed. Still, these cases are time consuming, expensive to defend, and disturbing to all practitioners involved. It seems that HCV-related issues are like a legal lightning rod. In the author's opinion, as of 2007, the following so called "exclusions from IFN therapy", still in use in many jurisdictions, may be challenged in Court:

- Exclusions due to ALT levels
- Exclusions due to prior drug history
- Exclusions due to psychiatric history
- Exclusions due to time to serve
- Exclusions due to co-infection with HIV
- Exclusions due to liver cirrhosis
- Exclusions due to previous treatment

With respect to persistently normal ALT levels, there has been a stream of recent papers showing that patients with persistently normal ALT levels may have ongoing histological deterioration, and that their response to IFN-based therapies is almost comparable to these patients with abnormal ALT levels.[8]

Continued on page 6

PERSPECTIVE: POTENTIAL LEGAL PITFALLS...
(continued from page 5)

Exclusions due to prior drug history have been used by certain systems.[9] The author estimates that these exclusions would fare poorly in court today because such history may be remote and not relevant to the inmate's state of mind at time of treatment. It appears that a positive random drug testing, however, would be a much better indication of the likelihood of drug addiction relapse after release.

In a similar manner, exclusions solely due to a positive, remote history of psychiatric problems (including history of past suicide attempts) would not be acceptable in court. Instead, one would have to document that a given inmate would not be a good candidate for IFN-based therapies due to a contemporary psychiatric condition (or suicidality) that is not responding to appropriate treatment. These patients would be better candidates for therapy after psychiatric stabilization. Exclusions due to insufficient time to serve had been generally acceptable to the courts until a few years ago. The author has observed that a number of similar cases where he was involved as an expert witness for the defense had to be settled. It seems that defense attorneys, judges and juries are migrating towards the idea that IFN-based therapies should be started regardless of uncertainty of release date. The rationale is that correctional practitioners would not delay therapy for diabetes, cancer, anemia, and the like, solely based on duration of sentence. Treatment should be offered, the thinking goes, together with appropriate arrangements for continuity of care should the sentence be too short.

Exclusions due to co-infection with HIV are no longer acceptable. The available literature clearly shows that these co-infected patients do achieve SVR (albeit less often).[10] Likewise, compensated liver cirrhosis is no longer a valid reason for exclusion from treatment.[11]

With respect to the difficult issue of re-treatment, it seems that the non-correctional HCV specialists are routinely offering re-treatment to suitable candidates that failed a less powerful regimen in the past. The author believes that the standard of care in corrections should reflect that of the community.

Conclusion

HCV management has proved to be one of the more litigious areas of correctional health care. While litigation related to the management of the HCV-infected inmate cannot be completely eliminated it is evident that in order to avoid legal action or to prevail in litigation regarding HCV diagnosis and therapy of inmates one needs to construct a system of policies rooted in the available evidence. Such rational approaches to the management of this prevalent viral illness make for good sense and good medicine.

The author was the Medical Director of the Georgia Department of Corrections (GDC) from 1996 to 2005. In collaboration with specialists, he wrote the GDC HCV Policies, versions of 1999, 2003, and 2004. These are available in electronic form directly from the author. Requests should be addressed to joeparis@pol.net.

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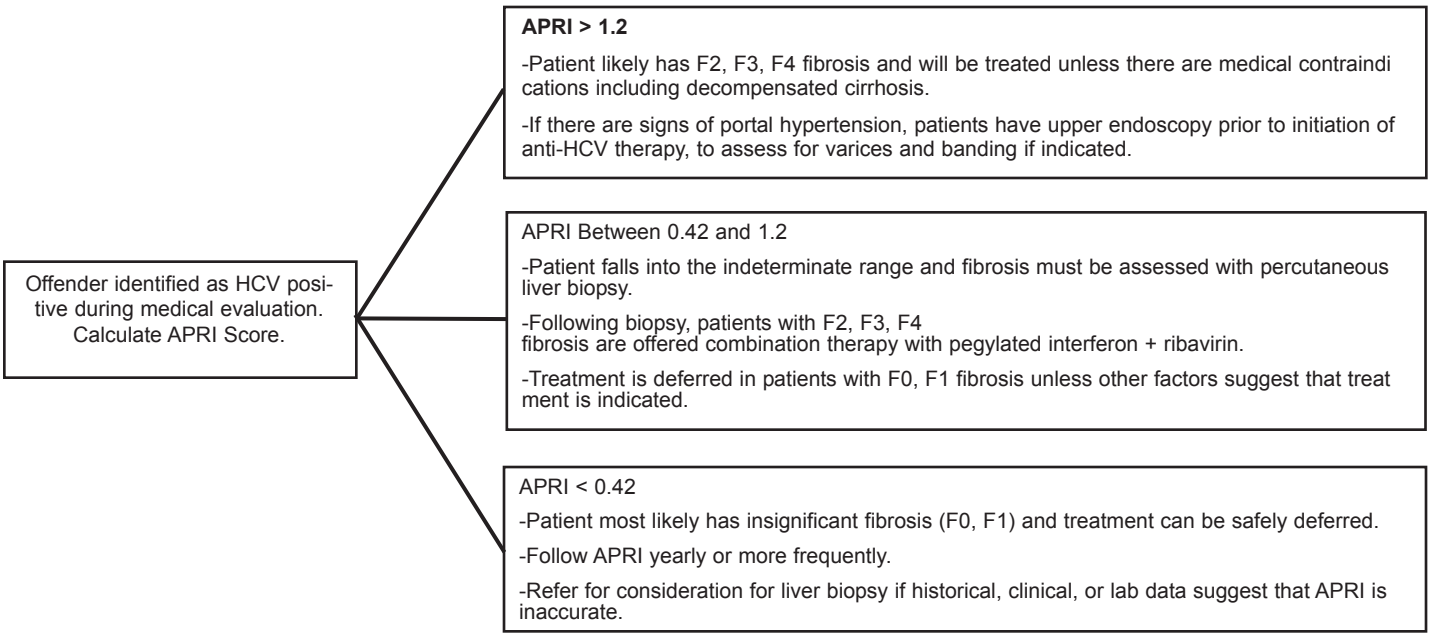
IDCR-O-GRAM: TEXAS DEPARTMENT OF CRIMINAL JUSTICE HCV ASSESSMENT ALGORITHM



HCV 101

Metavir Scoring System	
Stage	Amount of Scarring
0	No Scarring
1	Minimal Scarring
2	Scarring has occurred and extends beyond the areas of the liver that contain blood vessels
3	Bridging Fibrosis is spreading and connecting to other areas that contain fibrosis
4	Cirrhosis or advanced scarring of the liver

Disease Burden for Hepatitis-C in the United States

		2005	2004	2003	2002	2001
Number of Acute Clinical Cases Reported		No Data	No Data	No Data	No Data	No Data
Estimated Number of Acute Clinical Cases		3,200	4,200	4,500	4,800	3,900
Estimated Number of New Infections	**Current**	20,000	26,000	28,000	29,000	24,000
	Historical			Mean	Min	Max
				67,000	36,000	179,000
				232,000	180,000	291,000
Number of Persons with Chronic Infections				3.2 Million Persons		
Estimated Annual Number of Chronic Liver Diseases Deaths				8,000-10,000		
Perecent Ever Infected				1.60%		

HCV incidence peaked in the late 1980s but has declined since with the screening of blood and blood products for the virus.

Source: CDC.2006

Resources

Federal Bureau of Prisons Viral Hepatitis 2005 Clinical Practice Guidelines
http://www.bop.gov/news/medresources.jsp

Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings. CDC. MMWR. January 24, 2003 / 52(RR01);1-33.
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5201a1.htm

CDC's Hepatitis C Coordinator Website Portal
http://cdc.gov/ncidod/diseases/hepatitis/resource/coordinators_portal.htm

National HCV Prison Coalition
http://www.hcvinprison.org/

HCV Advocate
http://www.hcvadvocate.org/

Department of Health and Human Services
2006 Adult and Adolescent Antiretroviral Treatment Guidelines
http://www.aidsinfo.nih.gov/guidelines/

International AIDS Society-USA Panel
2006 Recommendations of the Treatment for Adult HIV Infection
http://jama.ama-assn.org/cgi/content/full/296/7/827

CDC's Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm

American Academy of HIV Medicine
http://www.aahivm.org/

Hepatitis C Virus - Source: CDC

Self-Assessment Test for Continuing Medical Education Credit

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for continuing Medical Education through the joint sponsorship of Medical Education Collaborative, Inc. (MEC) and *IDCR*. MEC is accredited by the ACCME to provide continuing medical education for physicians.

Medical Education Collaborative designates this educational activity for a maximum of 1 AMA PRA Category 1 Credit™. The target audience for this educational program is physcians. Physicians should only claim credit commensurate with the extent of their participation in the activity. Statements of credit will be mailed within 6 to 8 weeks following the program.

Objectives:

- The learner will be able to explain how and why the Texas Department of Corrections incorporated a serum marker of hepatic fibrosis into its HCV evaluation and treatment guidelines.
- The learner will be able to summarize elements of HCV treatment policies that could aid in the reduction of litigation from HCV-infected inmates.
- The learner will be able to describe the Metavir Scoring System and its implication for the treatment of HCV.

1. A liver biopsy is not always the best indicator of whether or not a patient should receive HCV treatment EXCEPT for the following reasons:

   A. The histopathological sample from a liver biopsy is not always large enough to make an accurate diagnosis.
   B. A liver biopsy is expensive.
   C. The interpretation of fibrosis is dependent upon the skill of the pathologist analyzing the specimen.
   D. A liver biopsy is associated with high and predictable rates of morbidity and mortality.

2. With the use of many serum marker tests, approximately 20% of patients can be classified as having either insignificant fibrosis or significant fibrosis obviating the need for further evaluation via liver biopsy.

   TRUE or FALSE?

3. Which of the following serum markers of hepatic fibrosis is a proprietary test:

   A. HCV-FibroSURETM
   B. APRI
   C. Fib-4
   D. Forn's Score

4. According the author of the spotlight article, which of the following "exclusions from IFN therapy" may be challenged by the legal system:

   A. Exclusions due to liver cirrhosis
   B. Exclusions due to limited time to serve
   C. Exclusions due to current drug use
   D. Exclusions due to co-infection with HIV
   E. A, B, and D

5. Issuing the exiting inmate 30 days of IFN-based medications in addition to an appropriate supply of syringes and needles is a way to ensure continued treatment while the inmate initiates community care.

   TRUE or FALSE?

In order to receive credit, participants must score at least a 70% on the post test and submit it along with the credit application and evaluation form to the address/fax number indicated. Statements of credit will be mailed within 6-8 weeks following the program.

Instructions:

- Applications for credit will be accepted until September 30, 2008.
- Late applications will not be accepted.
- Please anticipate 6-8 weeks to recieve your certificate.

MEDICAL EDUCATION COLLABORATIVE®
The Authority in Continuing Education

Please print clearly as illegible applications will result in a delay.

Name: _____ Profession: _____

License #: _____ State of License: _____

Address: _____

City: _____ State: _____ Zip: _____ Telephone: _____

Please check which credit you are requesting ___ ACCME or ___ Non Physicians

---

I certify that I participated in IDCR monograph -September 2007 Issue

Please fill in the number of actual hours that you attended this activity.

Date of participation: _____

Number of Hours (max. 1): _____

Signature: _____

Please Submit Completed Application to:

Medical Education Collaborative
651 Corporate Circle, Suite 104, Golden CO 80401
Phone: 303-420-3252 FAX: 303-420-3259
For questions regarding the accreditation of this activity, please call 303-420-3252

COURSE EVALUATION

I. Please evaluate this educational activity by checking the appropriate box:

Activity Evaluation					
	Excellent	***Very Good***	***Good***	***Fair***	***Poor***
Faculty					
Content					
How well did this activity avoid commercial bias and present content that was fair and balanced?					
What is the likelihood you will change the way you practice based on what you learned in this activity?					
Overall, how would you rate this activity?					

II. Course Objectives

Were the following overall course objectives met? At the conclusion of this presentation, are you able to:

- The learner will be able to explain how and why the Texas Department of Corrections incorporated a serum marker of hepatic fibrosis into its HCV evaluation and treatment guidelines. **YES** **NO** **SOMEWHAT**
- The learner will be able to summarize elements of HCV treatment policies that could aid in the reduction of litigation from HCV-infected inmates. **YES** **NO** **SOMEWHAT**
- The learner will be able to describe the Metavir Scoring System and its implication for the treatment of HCV. **YES** **NO** **SOMEWHAT**

III. Additional Questions

a. Suggested topics and/or speakers you would like for future activities.

_____

b. Additional Comments

_____

Save the Dates

HIV Therapy, Management & Emerging Treatment Options
Live Satellite Video conference & Webcast
October 3, 2007
12:30-2:30 p.m. EST
Visit: www.amc.edu/hivconference
518.262.4674 or
ybarraj@mail.amc.edu

Tuberculosis Program Manager's Workshop
Newark, NJ
October 3, 2007
Visit: www.umdnj.edu/globaltb/courses/tbworkshop.htm

45th Annual Meeting of the Infectious Diseases Society of America
San Diego, CA
October 4, 2007
Visit: www.idsociety.org/Meetingshome.aspx?id=238

National Conference on Correctional Health Care
Nashville, TN
October 13-17
Visit: http://www.ncchc.org/education/national2007.html

2007 Annual Conference: Medicine in the Face of Addiction
Society of Correctional Physicians (SCP)
October 14, 2007
Nashville, TN
Visit: http://www.corrdocs.org/framework.php?pagetype=educonference&bgn=1

15th Annual HIV/AIDS Update and Border Health Summit
South Padre Island, TX
24 to 26 October, 2007
Visit: http://www.valleyaids.org

The Liver Meeting 2007
58th Annual Meeting of the American Association for the Study of Liver Diseases
Boston, MA
November 2-6, 2007
Visit: https://www.aasld.org/eweb/DynamicPage.aspx?webcode=07am

2007 United States Conference on AIDS (USCA)
Palm Springs, CA
November 7-10, 2007
Visit: http://www.cdcnpin.org/scripts/display/confdisplay.asp?confnbr=6149

AIDS in Culture IV: Explorations in the Cultural History of AIDS
Mexico City
December 9-13, 2007
Visit: www.aidsinculture.org

News and Literature Reviews

Tattooing in prisons - Not such a pretty picture

Tattoos have recently grown in popularity; recent estimates assert that 10% to 16% of all U.S. adolescents between the ages of 12 and 18 have at least one tattoo. As the prevalence of tattoos increases, so does the risk of transmitting blood borne viruses (BBVs). Recent case studies in prisons have linked unsafe tattooing practices with HIV and hepatitis C virus (HCV) infection in persons with no prior history of intravenous drug use (IDU). Although tattooing is prohibited in most prisons, it is still a relatively common practice in most correctional facilities today and is often conducted without the use of clean needles and unused ink.

Hellard et al. conducted a cross-sectional survey of tattoo and drug use history, along with HCV status, across the five largest correctional facilities in Victoria, Australia. The study surveyed 642 inmates in total, 133 of whom were female. A total of 449 prisoners (70%) reported having at least one tattoo. Of this group, 156 of inmates (35%) claimed to have been tattooed while in prison, while another 26 individuals (6%) reported to have been tattooed while in a juvenile detention facility. A significant portion of inmates who had received tattoos outside of prison said they had done so through the use of a nonprofessional tattoo artist. The study also demonstrated that prisoners who have a history of IDU were more likely to have at least one tattoo and were also more likely to have acquired a tattoo in prison.

Prisoners who were tattooed in prison had a significantly higher risk of HCV-infection, even after adjusting for IDU history, tattooing outside of prison, body piercing, and length of time in prison. These findings raise questions as to whether or not correctional facilities should provide safer tattooing alternatives for incarcerated persons such as the use of professional tattoo artists and providing sterile tattooing equipment and training to inmates.

Tattooing in prisons-Not such a pretty picture. Hellard, M et al. American Journal of Infection Control. 2006;35:477-80.

Project ECHO: Linking University Specialists with Rural and Prison-Based Clinicians to Improve Care for People with Chronic Hepatitis C in New Mexico

Specialists at the University of New Mexico School of Medicine have begun collaborating with rural clinicians, the Indian Health Service, and prisons in an effort to improve the quality and accessibility of healthcare for New Mexicans living with HCV. The effort, named the Project Extension for Community Healthcare Outcomes Project (Project ECHO), seeks to use telemedicine and distance-learning methods to discuss HCV case studies in patients at rural clinics. Project ECHO is designed to share the knowledge of HCV specialists with primary-care physicians, an endeavor of great importance given that nearly all of the counties in New Mexico are listed as medically underserved and almost half are considered to have health professional shortages. Although an estimated 32,000 New Mexicans are currently living with HCV, infectious disease specialists, gastroenterologists, and hepatologists with experience in HCV treatment are few and far between. As such, Project ECHO has used teleconferencing and videoconferencing; internet-based assessment tools; online presentations; and telephone, fax, and e-mail communications to connect specialists with health care providers across New Mexico. Project ECHO partner organizations, which are recruited through statewide health care conferences, conduct a one day training workshop for clinicians, after which clinicians shadow ECHO team members in the University of New Mexico HCV Clinic.

Since Project ECHO's inception in June 2003, 173 clinics have been conducted and a total of 1,843 disease-management case studies have been presented. Moreover, health care providers in New Mexico have earned 2,997 hours of continuing education credits and 390 hours of on-site training through this project. In this way, Project ECHO has been an extreme success and is now being considered as a model of how to train primary-care physicians in providing quality care for other chronic medical conditions. Satellite ECHO projects are now underway in other parts of New Mexico and cover such areas as substance abuse disorders, rheumatology, and mental health disorders. The project's founders are hopeful that ECHO team's approach to strengthening the abilities of health care providers could be implemented in developing countries with a high prevalence of disease and limited health care resources.

Project ECHO: Linking University Specialists with Rural and Prison-Based Clinicians to Improve Care for People with Chronic Hepatitis C in New Mexico. Arora, S. et al. Public Health Reports. 2007;122:74-77.

Promoting HCV Treatment Completion for Prison Inmates: New York State's Hepatitis C Continuity Program

This study sought to overcome some of the major barriers in providing HCV treatment to incarcerated persons in New York. In particular, Klein et al. focused their attention on how to best maintain continuity of HCV antiviral treatment for inmates, regardless of their length of stay in correctional facilities. Many correctional systems, including the New York State Department of Corrections Services (DOCS), have policies that do not allow for the initiation of HCV antiviral treatment for patients with limited time left in their sentence as continuation of therapy post-release was not assured. The Hepatitis C Continuity Program was established in an effort to allow inmates to be treated for HCV infection while in prison, regardless of their length of stay in the correctional setting, and to continue treatment through a community-based health care partner after their release.

The Program used the combined efforts of the DOCS, the New York State Department of Health (DOH), the New York City public hospital system, and the Health and Hospitals Corporation (HHC) to establish connections between the correctional setting and community health care providers and social workers, as well as establish protocols for incorporating releasees into community health care settings. The DOCS manages most prerelease activities, including scheduling an initial post-release appointment and ensuring that antiviral drugs are given to each inmate upon their release. Hospital staff members work with parole officers in making further all medical appointments with the releasee.

Twenty-one health care facilities in New York City now accept inmates and releasees for HCV monoinfection or HCV/HIV coinfection treatment. The urban and suburban locations of these facilities are such that they will be geographically accessible to an estimated 87.1% of releases being treated for HCV. The Hepatitis C Continuity Program demonstrates that it is possible to initiate HCV treatment for prisoners, regardless of their length of stay in prison. While it is perhaps too soon to evaluate the effectiveness of the Program, it is clear that both the individual releasees and society as a whole stand to benefit from this program's success.

Promoting HCV Treatment Completion for Prison Inmates: New York State's Hepatitis C Continuity Program. Klein, S. et al. Public Health Reports. 2007;122:83-88.

Compiled by: Christine Devore - IDCR Intern