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HEPP REPORT

April 2003 Vol. 6, Issue 4

HIV & HEPATITIS
EDUCATION
PRISON
PROJECT

INFECTIOUS DISEASES IN CORRECTIONS

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ABOUT HEPP

HEPP Report, a forum for correctional problem solving, targets correctional physicians, nurses, administrators, outreach workers, and case managers. Published monthly and distributed by email and fax, HEPP Report provides up-to-the moment information HIV/AIDS, hepatitis, and other infectious diseases, as well as efficient ways to administer treatment in the correctional environment. Continuing Medical Education credits are provided by the Brown University Office of Continuing Medical Education. HEPP Report is distributed to all members of the Society of Correctional Physicians (SCP) within the SCP publication, CorrDocs (www.corrdocs.org).

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DEVELOPING A SYSTEMATIC APPROACH TO HEPATITIS C FOR CORRECTIONAL SYSTEMS: CONTROVERSIES AND EMERGING CONSENSUS

By Scott Allen, M.D., Medical Director, Rhode Island Department of Corrections*

As guidelines for the diagnosis, evaluation and treatment of chronic hepatitis C virus (HCV) emerge in the community at large, correctional medical communities are wrestling with the challenge of establishing an appropriate and consistent response to an epidemic that disproportionately affects incarcerated populations. Controversies regarding the management of HCV are brought to a head in jails and prisons, where there is a high prevalence of disease (12-35% according to Centers for Disease Control (CDC) estimates¹) and a legal obligation to provide access to medical care.

Two recent publications, the MMWR Recommendation and Report on the Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings¹ and the 2002 NIH Consensus Statement on the Management of Hepatitis C² begin to frame the key issues facing correctional health services. Soon after these reports were published, several hundred correctional administrators, correctional physicians, hepatologists, infectious disease specialists, public health professionals and other interested parties met in San Antonio for a conference on the management of HCV infection in corrections. In the aftermath of the conference, data shared at the meeting and various approaches taken by different systems have been discussed and debated. It should be noted that most of what was discussed at this conference did not address the unique challenges of HCV management in jail correctional settings.

While controversies abound concerning the management of HCV in corrections, the discussion was notable for several areas of emerging consensus. Perhaps the most noteworthy was the agreement that all systems need to develop and establish a systematic approach to the management of HCV infection.³

In this article, I review existing HCV management controversies from the correctional perspective, document an emerging consensus among correctional practitioners, and provide suggestions for future directions in HCV care.

IMPACT OF DISEASE

Controversy: While the high prevalence of disease in corrections is widely accepted, debate has centered on the clinical significance of infection to correctional health care systems. Given that HCV appears to lead to morbidity and mortality in only a minority of infected individuals, and for that minority, progression to fibrosis, cirrhosis and death is expected to take decades, some argue that the immediate impact to the clinical health of currently incarcerated inmates should be minimal.

Emerging Consensus: Despite the very recent recognition of the epidemic, available information suggests that the HCV epidemic among the incarcerated is decades old. Data from liver biopsies in several correctional systems (including Virginia⁴ and Louisiana⁵) show that many patients already have advanced fibrosis and cirrhosis, consistent with longstanding infection. In other facilities, HCV infection has emerged as a leading cause of in-custody death.^{6,7} End-stage liver disease is now recognized as the leading cause of death in HIV-positive populations, especially in those patients who are responsive to HAART.⁸ Given the prevalence of HCV in corrections and considering projections from the CDC regarding anticipated cases of cirrhosis, end-stage liver disease and hepatocellular carcinoma, correctional communities should anticipate rising morbidity and mortality from HCV-related disease in the near term.

Recommendation: In order to better understand the HCV problem in the correctional setting, more data need to be collected and shared. Wide variations in rates from state to state and even from facility to facility are likely. Collecting national and facility-specific data is essential in order to adapt national guidelines and recommendations to local HCV management.

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DEVELOPING A SYSTEMATIC... (continued from page 1)

Correctional health care systems, perhaps in conjunction with NIH, CDC, and local or regional departments of health should consider developing a central database similar to existing cancer and HIV/AIDS registries. Correctional health care workers should be encouraged to report and circulate experience and outcome data, cost-effectiveness data and novel strategies for the diagnosis and management of HCV infection through peer-reviewed journals, correctional newsletters, and conferences.

SCREENING

Controversy: Given the high prevalence of HCV infection in correctional settings, some have argued in favor of universal screening, while others believe targeted screening of inmates is the right approach.

Emerging Consensus: Both universal and targeted screening methods have been used in correctional systems. In Indiana, the legislature recently implemented mandatory screening of all inmates for HCV and HIV. Testing is performed by the Indiana Department of Health and requires several blood samples from each inmate; as a result, correctional health officials had to adjust intake procedures after the legislation was passed.⁹

Other states use targeted approaches. In Wisconsin, an innovative risk-based assessment was performed to target individuals for hepatitis screening.¹⁰ Using the screening criteria of testing all inmates with a history of injection drug use (IDU), hepatitis B virus infection, or elevated ALT, 90.8% of individuals with HCV were identified, while only a quarter of the population (26.8%) required testing. Comparison of expected costs based on 8,000 inmates/year at a reception center with a HCV prevalence of 13.2% (probably a low figure compared to other states, DOC officials admit) predicted an estimated \$100,000 in savings on blood tests per year.

The new guidelines published by the CDC suggest that all inmates be questioned regarding risk factors (see box) for HCV infection during their entry medical evaluations, and all inmates reporting risk factors for HCV should be tested. As the specificity of any test is a function of prevalence, the CDC further recommends that the sensitivity of risk-factor based screening be periodically determined, and that expanded testing be considered (i.e. to patients denying risk factors) when risk factor prevalence, including IDU, is > 75% and prevalence of infection among those who deny risk factors is also high (>20%).¹

Recommendation: The period of incarceration provides an important window of opportunity to diagnose and educate those at risk for

Those at risk for HCV include persons who:

- ◆ injected drugs intravenously and shared unclean injecting equipment;
- ◆ received a clotting factor concentrate produced before 1987;
- ◆ were on long-term hemodialysis;
- ◆ have evidence of chronic liver disease including persistently abnormal ALT levels; or
- ◆ received a transfusion of blood or blood components or an organ transplant before July 1992.

To read the complete report, go to <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5201a1.htm>.

hepatitis C. In addition to providing an opportunity for the evaluation and treatment of those with HCV, the identification of infected individuals has the potential to reduce subsequent transmission in the community. At a minimum, correctional facilities should have a systematic plan for screening based on risk factors and disease prevalence in the facility.

EVALUATION

Controversy: While there is widespread agreement that liver biopsy can be a useful tool to evaluate chronic HCV, the cost-effectiveness of offering biopsies, or even requiring biopsies is widely debated.

Emerging Consensus: There is general agreement that patients with early stage disease, particularly those with stage 0-1 disease, can be counseled to defer treatment. Therefore, liver biopsy may permit clinicians to defer treatment in some cases, avoiding unnecessary treatment and reducing the overall cost of care. In Virginia, implementing a management strategy for evaluating and treating HCV that included liver biopsy was found to be cost-effective. All inmates in the Virginia Department of Corrections are offered HCV testing, and those that test positive for HCV RNA are offered liver biopsy. The Virginia strategy of triaging patients to care or no care depending on liver biopsy results limits treatment to inmates with "clinically significant" disease and, according to official estimates, saves almost \$125,000 per 100 patients.⁴

Recommendation: I believe that liver biopsy is an essential tool in evaluating a patient for treatment. Although remote facilities may find liver biopsy difficult to access, biopsy is helpful in counseling the patient on the status of disease and the relative indication or contraindication for treatment. Given the data on its cost-effectiveness and clinical utility, biopsy of potential candidates for treatment is recommended. In patients with infection caused by genotypes 2 and 3, where 24-week courses of treatment are associated with high response rates, biopsy may be less important.

TREATMENT

Controversy: Correctional health care providers and administrators worry that liberal inclusion criteria to treatment will result in an overwhelming demand for therapy.

Emerging Consensus: Legal and ethical considerations make it inadvisable to provide barriers to treatment simply to minimize the cost impact to institutions. However, clinically based strategies aimed at stratifying candidates for therapy is defensible and advisable.

Systematic approaches that take into consideration a variety of factors, including the likelihood of progression to cirrhosis based on clinical data and risk factors, allow for targeting high-risk patients for treatment. Most practitioners are now selectively advising medical treatment for those HCV-infected inmates who are clinically appropriate and who are anticipated to remain incarcerated for the full course of treatment.

"Clinically appropriate" patients include those with stage 2, 3, and compensated stage 4 liver disease. Stage 1 rapid fibrosers (as determined by serial liver biopsies) may also be considered for treatment. Treatment can safely be deferred in patients with stage 0-1 fibrosis, although the decision should be individualized and based on an informed consultation with the patient.

Institutions with clinically defensible systematic approaches - even those with liberal inclusion criteria - end up treating only a percentage of those patients potentially eligible for treatment. The vast majority of treatment candidates will appropriately be deferred to treatment after release due to short length of incarceration. Of the remainder, a great proportion will elect to defer treatment after balanced informed consent based on early-stage disease or documented slow progression.

Recommendation: All correctional health care programs should develop systematic, evidence-based guidelines for HCV management. Such guidelines, however, should never supplant the clinical judgement of the clinician, and decisions should always be made in consultation with the patient. Given the superior response rates of pegylated interferon plus ribavirin vs. standard interferon therapy plus ribavirin for treatment of genotype 1, treatment with pegylated interferon is recommended.¹¹

PATIENTS WITH PSYCHIATRIC ILLNESS AND/OR HISTORY OF SUBSTANCE ABUSE

Controversy: The correctional population has a high prevalence of individuals with a history of substance abuse and mental illness

Continued on page 4

LETTER FROM THE EDITOR

Dear Correctional Colleagues:

As I contemplate the April HEPP Report articles, I have come to the conclusion that we could not have chosen two more controversial and current issues in health care today - the treatment of HCV infection in prisoners and the administration of smallpox vaccine to health care professionals.

In the past, much of the controversy regarding HCV treatment was due to poor sustained response rates to therapy that is not only expensive, but also fraught with significant side effects. Although potential side effects are still worrisome, combination therapy with pegylated interferon and weight-based ribavirin now provides improved sustained response rates, making therapy more attractive to both the patient and the provider. Approximately one third of those infected with HCV in the U.S. cycle through the correctional system. We have a remarkable opportunity to improve the health of the nation by screening, testing, counseling, and when possible, providing treatment to the incarcerated.

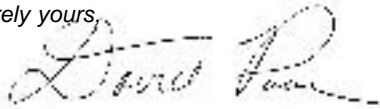
In corrections, and elsewhere in health care, the very real issue is, how can we pay for this effective, but expensive treatment? The answer is local, state, and federal funding, which there is less of in recent months due to downward trends in the economy and the war in Iraq. We must continue to educate our administrators and legislators to ensure that when funds become available, they can be requested and allocated for effective HCV treatment.

In this month's lead article, Dr. Scott Allen convincingly advocates for a systematic approach to managing hepatitis C in corrections. Such an approach will vary among the varying correctional jurisdictions and will be based on current and future resources. Despite the current inability to treat every prisoner who has HCV infection, we should screen and test those who may be affected and provide appropriate counseling regarding transmission to others, the importance of avoiding alcohol, and the potential for future treatment options.

In this month's spotlight, Dr. Joe Bick outlines the threat faced by correctional facilities that employ individuals who have received the smallpox vaccination, and reviews CDC guidelines for preventing transmission while the inoculation site heals.

After reading this month's issue, you should be familiar with the issues surrounding the approach correctional institutions are taking with HCV-infected inmates, as well as CDC guidelines for smallpox vaccination and the precautions that should be taken to minimize transmission of the vaccinia virus while the inoculation site heals.

Sincerely yours,



David Paar

FACULTY DISCLOSURE

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

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DEVELOPING A SYSTEMATIC... (continued from page 2)

- two groups who have historically been excluded from treatment or who have been associated with poor treatment outcome.¹²

Emerging Consensus: Owing to the controlled environment of the correctional setting, the traditionally challenging patient groups - those with histories of substance abuse and/or mental illness - may find themselves in one of the safer environments for therapy with interferon and ribavirin.

The contraindication to therapy for HCV infection in those with substance abuse was lifted in the 2002 NIH consensus statement, following a review of the published data regarding efficacy of treatment of HCV in patients with IDU and alcoholism.¹³ However, experts agree that HCV treatment should be coupled with substance abuse counseling and referral for treatment. Sobriety is largely enforced in the correctional setting, making it a more stable environment in which to contemplate medical therapy for HCV infection. Stable psychiatric illness is no longer considered an absolute contraindication to treatment with interferon based therapies.

Psychiatric illness, and in particular depression, has historically been seen as a relative contraindication to therapy given the potential of treatment to cause depression.¹⁴ On the order of a third of all patients treated with interferon can be expected to develop symptoms of major depression. In Rhode Island, in a review of 90 patients treated with standard IFN and ribavirin, 60% of the patients had a history of mental illness, 44% had a history of depression, 8% were diagnosed with psychosis and 4% had a documented history of a prior suicide attempt. Patients were stabilized and cleared by the psychiatry team prior to the initiation of therapy and followed closely

by the psychiatric team during therapy. No patient had to discontinue therapy due to psychiatric side effects.¹⁵

Recommendation: A history of substance abuse is no longer a contraindication for treatment of chronic HCV infection. Linking medical therapy with referral to substance abuse treatment, however, is a good idea. Still, the absence of available substance abuse treatment programs in a correctional setting should not be used to justify withholding treatment. Counseling should include discussion of harm reduction (clean needle access through provider prescriptions, needle exchange programs and pharmacy purchases, where available) in the event of relapse of drug use post-treatment.

In facilities where mental health care is available, an effort should be made to coordinate the evaluation and treatment of candidates with both chronic HCV infection and mental health problems. The close clinical follow up available in correctional settings may provide a safe environment for the treatment of HCV-infected patients who also have a psychiatric illness. While treatment of patients with unstable psychiatric illness remains contraindicated, patients who have clinically stable mental illness may be safely treated. The decision should be made on a case-by-case basis with input from the patient, the medical provider and the treating psychiatrist.

COST

Controversy: High prevalence of HCV combined with historically high utilization of medical services among inmate patients have caused legitimate concern among correctional health care administrators that the cost of treatment could overwhelm already constrained correctional health care budgets.

Emerging Consensus: As previously stated, systematic, clinical-based approaches (such

as those used by the Federal Bureau of Prisons) can direct medical treatment to those most likely to progress to cirrhosis and are clinically and ethically justifiable. Within the context of such approaches, only a minority of patients ultimately receives treatment.¹⁶ In Rhode Island, where one of the more inclusive treatment protocols has been established and the prevalence of HCV infection stands at 27%, less than 5% of HCV positive patients are receiving treatment at any given time, and the cost of HCV-related treatment is limited to 5% of the total healthcare budget.³

Recommendation: Systematic approaches to screening, evaluation and treatment will mitigate the high cost of HCV care in correctional settings. However, the high prevalence of HCV infection - a treatable disease - in the context of an obligation to provide access to care can still be expected to have a significant impact on correctional budgets in the near term. Continuing efforts to educate the legislatures, executive branches, public health agencies and the broader community should be encouraged.

CONCLUSION

While screening, evaluation and treatment inclusion and exclusion criteria for HCV in corrections will continue to be hotly debated, there is emerging consensus regarding some aspects of HCV disease management. Chief among them is the growing recognition that all correctional systems will need to develop and implement an evidence-based systematic approach to the large numbers of patients housed within correctional institutions in the United States. As correctional systems move forward in responding to this challenge, it is essential that data regarding disease prevalence, morbidity and mortality and treatment outcomes and cost-effectiveness be collected and disseminated.

*DISCLOSURES: Nothing to disclose.

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SMALLPOX ALERT IN JAILS AND PRISONS

By Joe Bick, M.D.*, Director, HIV Treatment Services, California Medical Facility, Vacaville, California Department of Corrections

While our nation's jails and prisons might appear to be a safe place to be to avoid the potential health risks associated with smallpox, this may not be the case. Many correctional employees serve as reservists in the military, while others are being trained to diagnose or treat individuals who are suspected of having smallpox. Both groups are among those who may be vaccinated against smallpox, which should be of concern to those providing health care to immunocompromised inmates. Transmission of the virus used for smallpox vaccination is a well-recognized phenomenon that can lead to devastating consequences in those with underlying medical disorders. This article is intended to provide a brief summary of what those responsible for correctional health care need to know about smallpox vaccination. Information that follows is based on recently published Centers for Disease Control and Prevention (CDC) guidelines.^{1,2,3}

Overview

Smallpox vaccine is made from live vaccinia virus and does not contain variola virus, the causative agent of smallpox. Because vaccinia viral replication and shedding occurs at the vaccination site, unintended transmission can occur from as early as two days after vaccination until the scab separates from the skin two to three weeks later.

Replication of vaccinia virus can be enhanced among immunosuppressed patients. Except in the setting of an outbreak, smallpox vaccination is contraindicated for individuals with atopic dermatitis (eczema) or other skin conditions that disrupt the epidermis; women who are pregnant or who may become pregnant in the 28 days after vaccination; and those immunosuppressed due to HIV infection, autoimmune conditions, malignancy, radiation treatment, medications, or other immunodeficiencies.

Persons with HIV infection might have an increased risk for severe adverse reactions resulting from exposure to live-virus vaccines. Because the HIV epidemic began after routine smallpox vaccination ended in the 1970s, data are limited regarding the risks from vaccination among HIV-infected persons.

On March 25, 2003, the CDC reported that among 25,645 civilians who have been vaccinated, there have been three cases of myocardial infarction, one of which resulted in death; two cases of angina, and two cases of myopericarditis. Based upon this information, the CDC added the recommendation that persons with known cardiac disease such as cardiomyopathy, previous heart attack, angina, or other evidence of coronary artery disease be temporarily deferred from smallpox vaccination.

Transmission of Vaccinia Virus

Vaccinia can be transmitted to others from an unhealed vaccination site. Although nosocomial transmission of vaccinia from either patients or health care workers to patients has been described, transmission usually requires close interaction as would occur in a household or dormitory setting.

Cases arising from transmission through contact with a recently vaccinated person have resulted in either eczema vaccinatum (EV) or inadvertent inoculation (when vaccinia virus is transferred from a vaccination site to a second location on the body or to a close contact), occurring 5-19 days after exposure to the source case. The incidence of contact vaccinia in the 1960s was 2-6/100,000 first-time

vaccinations. Since there are many more people living today with severe immunocompromising conditions, this may underestimate the current risk.

Preventing contact transmission

The CDC's Advisory Committee on Immunization Practices (ACIP) believes that optimal infection-control practices and appropriate site care should prevent transmission of vaccinia virus. Those providing direct patient care or who are in contact with inmates should keep their vaccination site covered with gauze dressing to absorb exudates; this dressing should be covered with a semipermeable membrane to minimize the risk of transmission. The dressing should also be covered by a layer of clothing until the scab separates, which may take 14-21 days. Dressings used to cover the site should be changed frequently to prevent maceration and accumulation of exudates.

Since transmission occurs through contact with the vaccination site, the most critical measure in preventing contact transmission is consistent hand hygiene with antimicrobial soap and water or an approved alcohol-based hand-rub (one that contains >60% alcohol) after any contact with the vaccination site or contact with materials that have come into contact with the site.

The CDC recommends that hospitals provide a program in which designated staff (available 24 hours a day) assess the dressings of all vaccinated health care workers daily before shifts begin, determine if dressings need changing, and change the dressing as needed. In correctional settings, designated personnel may be responsible for assessing vaccination sites of correctional officers. These designated staff should assess the vaccination site for local reactions and for vaccine take, reinforce education regarding the need for meticulous hand hygiene, and record and report serious adverse events after vaccination. When feasible, staff responsible for dressing changes for teams should be vaccinated, but having nonvaccinated staff change dressings is acceptable. All persons handling bandages should observe contact precautions.

Administrative Leave for Vaccinated Health Care Workers

The ACIP recommends that administrative leave is not routinely required for newly vaccinated health care personnel unless they are physically unable to work because of systemic signs and symptoms of illness; have extensive skin lesions that cannot be covered adequately; or are unable to adhere to the recommended infection-control precautions. However, the CDC expects that as many as 30% of the nation's hospitals may opt out of the voluntary immunization program because of concerns about health risks to those being vaccinated and the potential transfer of vaccinia to vulnerable populations. Each correctional system should take these issues into account when making a decision concerning administrative leave or reassignment.

Adverse Events of Vaccination

Adverse reactions are usually self-limited and include fever, headache, fatigue, myalgia, chills, local skin reactions, nonspecific rashes, erythema multiforme, lymphadenopathy, and pain at the vaccination site. Adverse reactions that might require further evaluation or treatment include inadvertent inoculation, generalized vaccinia (GV), eczema vaccinatum (EV), progressive vaccinia (PV), postvaccinal central nervous system disease, and fetal vaccinia.

Continued on page 6

SMALLPOX ALERT... (continued from page 5)

Persons with PV, EV, and severe GV or inadvertent inoculation might benefit from therapy with vaccinia immune globulin (VIG) or cidofovir, available from the CDC under Investigational New Drug protocols.

Inadvertent inoculation is usually self-limited and no additional care is needed. However, inoculations of the eye and eyelid require evaluation by an ophthalmologist and might require therapy with topical antiviral or antibacterial medications, VIG, or topical steroids.

GV is characterized by a disseminated maculopapular or vesicular rash, frequently on an erythematous base, which usually occurs six to nine days after first-time vaccination. This condition is usually self-limited and benign, although treatment with VIG might be required when the patient is systemically ill or found to have an underlying immunocompromising condition.

EV occurs among persons with a history of atopic dermatitis (eczema), and is a localized or generalized papular, vesicular, or pustular rash, which can occur anywhere on the body, with a predilection for areas of previous atopic dermatitis lesions. Patients with EV are often systemically ill and usually require VIG.

PV is a rare, severe, and often fatal complication among persons with immunodeficiencies, characterized by painless progressive necrosis at the vaccination site with or without metastases to distant sites (e.g., skin, bones, and other viscera). This disease carries a high mortality rate, and management of PV should include aggressive therapy with VIG, intensive monitoring, and tertiary-level supportive care.

Central nervous system disease, which includes postvaccinial encephalopathy (PVE) and postvaccinial encephalomyelitis (or encephalitis) (PVEM), can occur after smallpox vaccination. PVE is most common among infants aged <12 months. Although no specific therapy exists for PVE or PVEM, supportive care, anticonvulsants, and intensive care might be required.

Fetal vaccinia, resulting from vaccinia transmission from mother to fetus, is a rare, but serious, complication of smallpox vaccination during pregnancy or shortly before conception. It is manifested by skin lesions and organ involvement, and often results in fetal or neonatal death. It is recommended that pregnancy be avoided until 28 days after vaccination. Pregnant individuals who are considering vaccination (and pregnant spouses of vaccinated personnel) should be made aware of this risk.

Making the Diagnosis

Conditions easily confused with vaccinia infection (i.e. varicella, herpes zoster, herpes simplex, and enteroviruses), should be considered first, in particular for someone who has not been vaccinated or had contact with an individual who was vaccinated.

Serologic testing for vaccinia is uninformative because it cannot be used to distinguish vaccinia immunity from vaccinia infection unless baseline antibody titers are available.

Diagnostic tests for vaccinia are available only for research purposes, but are undergoing multicenter validation studies that might enable FDA to approve the test reagents for diagnostic use.

Prophylaxis for Those at High Risk

Prophylactic treatment with VIG is not recommended for persons or close contacts with contraindications to smallpox vaccination who are inadvertently inoculated or exposed.

Reporting adverse events

Suspected cases of these illnesses or other severe adverse events after smallpox vaccination should be reported immediately to state health departments and to the Vaccine Adverse Event Reporting System. Reports can be made online at <https://secure.vaers.org/VaersDataEntryIntro.htm>. To request clinical consultation and IND therapies for vaccinia-related adverse reactions for civilians, contact your state health department or the CDC's Clinician Information Line (877-554-4625). Those with suspected adverse events should be removed from work until evaluated and cleared to return.

Timing of Tuberculosis Screening and Smallpox Vaccination

Suppression of tuberculin skin test (TST) reactivity has been demonstrated after administration of smallpox vaccine. Health care workers scheduled to receive an annual TST should not receive the skin test for one month after smallpox vaccination to prevent possible false-negative reactions.

Smallpox Resources

- ◆ **Smallpox vaccination overview for clinicians:**
<http://www.bt.cdc.gov/agent/smallpox/vaccination/clinicians.asp>
- ◆ **Clinical evaluation tools:**
<http://www.bt.cdc.gov/agent/smallpox/vaccination/clineval>
- ◆ **Clinical specimen collection guidance:**
<http://www.bt.cdc.gov/agent/smallpox/vaccination/vaccinia-specimen-collection.asp>
- ◆ **CDC Clinician Information Line: 877-554-4625**
- ◆ **Center for the Study of Bioterrorism:**
<http://www.bioterrorism.slu.edu/>
- ◆ **Johns Hopkins Center for Civilian Biodefense Strategies:** <http://www.hopkins-biodefense.org/>

DISCLOSURES: *Nothing to disclose.*

FOOTNOTES:

1. CDC. *Vaccinia (Smallpox) Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2001. MMWR 2001 Jun 22; 50(No. RR-10):1-25.*
2. *Recommendations for Using Smallpox Vaccine in a Pre-Event Vaccination Program. Supplemental Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR 2003 Feb 26; 52(Dispatch):1-16.*
3. CDC. *Smallpox Vaccination and Adverse Reactions: Guidance for Clinicians. MMWR 2003 Feb 21; 52(No. RR-4):1-28.*

ASK THE EXPERT: Case Study – 36-year-old male with hepatitis C and HIV infection

Case presented and discussed by Stephen Tabet, MD, MPH, Assistant Professor of Medicine, University of Washington, and Director, Northwest Correctional Medicine Education Program.

A collaboration with the Northwest AIDS Education and Training Center, with Stephen Tabet, MD, and Kate Willner.

Case: A 36-year-old bisexual male with B3 HIV disease is expected to be incarcerated for nine months. On intake, the CD4 lymphocyte cell count is 542 cells^{mm} (31%), up from a nadir of 240 (17%), with an HIV bDNA < 50 copies/ml. He is currently on d4T 40 mg bid, 3TC 150 mg bid, and nelfinavir 1250 mg bid and has never had any opportunistic infections. He denies any injection drug use (IDU), but does report a remote history of brief intranasal cocaine use. He is found on screening laboratory testing to have mildly elevated liver enzymes (AST 76 and ALT 91) with normal LDH, bilirubin, albumin, prothrombin time, hematocrit, and platelet count. He reports symptoms of depression (difficulty sleeping, decreased appetite, and anhedonia) and appears depressed. The examination is otherwise normal; in particular there is no evidence of spider angioma or palmar erythema. The provider screens the patient for hepatitis; an enzyme immunoassay (EIA) shows that the patient tests positive for hepatitis C virus (HCV) antibody and hepatitis B (HBV) core and surface antibody, but negative for hepatitis A (HAV) antibody.

What would you do for this patient? Should HAART be stopped?

Discussion: It is difficult to determine the cause of liver toxicity in HIV/HCV co-infected patients on HAART. Ritonavir may be the most common cause of antiretroviral-related hepatotoxicity, but all antiretrovirals can damage the liver. Regardless of the etiology, HAART should be continued in this patient given the mild transaminitis and no evidence of synthetic dysfunction. Given the high rate of HBV and HCV co-infection in HIV-infected patients, and particularly among incarcerated persons, it is incumbent upon the provider to rule out an infectious etiology as was done with this patient. It is controversial whether RIBA confirmation is necessary with positive EIAs in high-risk patients, given that new-generation EIAs have high positive predictive value in high-risk patients such as this one.

What if this patient had screened EIA negative?

A recent study published in JAIDS¹ reported that between 6% and 19% (depending on the HCV RNA method used) of HIV-infected HCV antibody-negative patients had HCV viremia. HCV viremia in persons without HCV antibodies was associated with HIV acquisition through sexual contact as opposed to parenteral risk factors and lower CD4 lymphocyte count. Most experts recommend follow-up HCV RNA in all HIV-infected patients who screen HCV antibody negative, but are still suspected of harboring HCV infection.

Another reason to do a follow-up HCV RNA is that up to 10% of patients infected with HCV actually clear the virus (HCV antibody positive and RNA negative) although the rate appears lower in HIV/HCV co-infected patients.

I would suggest checking the liver enzymes in one month and, if stable, checking every two to three months thereafter. Also continue to monitor his T cell subsets, HIV RNA, kidney function, glucose and electrolytes every three months if they all remain stable. I would advise periodically monitoring a fasting lipid panel.

An important early step is to obtain HAV and HBV serologies, as was done in this case. HCV-infected persons are at higher risk of going on to fulminant hepatic failure if they contract HAV or HBV than are people who do not have HCV infection. Therefore, those who have not had prior infection should be vaccinated.

Why not just vaccinate against both hepatitis A and B and save the cost of the serologies?

That strategy would be fine for HAV, but not for HBV. HAV has no chronic carrier state, but providers must rule out chronic active hepatitis B (hepatitis B surface antigen positive). Given that this patient was negative for HAV antibodies, he was then vaccinated against HAV.

Should hepatitis C treatments be discussed next?

This patient has several other issues that need to be prioritized and dealt with prior to even discussing treatment for HCV. He should be educated regarding HCV infection transmission, just as one would with someone who initially tests positive for HIV infection.

Contaminated needles associated with IDU account for the majority of HCV infections in the developed world. Since 1992, at least two-thirds of new cases of HCV infection in the United States can be attributed to IDU. Although HCV was originally presumed to not be readily transmitted by sexual contact, there is mounting evidence that HCV is transmitted via sexual contact and HCV RNA has been detected in semen, vaginal secretions, and saliva, though whether the virus is replication-competent in these sites is not known. Sharing of razors and toothbrushes should be strongly discouraged given their potential for being contaminated with blood.

The next step would be to discuss the natural history of HCV with the patient, including that he is likely to have some liver damage, the extent of which is unknown. Although most people do not go on to end-stage liver disease with cirrhosis, this patient should be warned of the hazards of alcohol abuse and HCV.

The provider should explain that HIV accelerates the progression of HCV, and that cirrhosis and mortality rates are higher in co-infected patients than they are with HCV alone.

The provider can then discuss available treatments. Co-infected patients, especially with high CD4+ T cell counts, have been shown to have similar treatment response rates compared to people with HCV only. This individual's short incarceration period does not make him a good candidate to initiate the current optimal treatment - pegylated interferon and ribavirin for 6-12 months dependent upon HCV genotype. I would advise discussing the options available to him and would attempt to help him enter into the health care system in the community prior to his release.

This patient's co-morbid mental illness should be addressed. Incarcerated men and women have much higher rates of depression and other mental illnesses than the general population. Untreated depression is clearly correlated with poor adherence to antiretrovirals and is a relative contraindication to interferon therapy for HCV.

REFERENCE:

1. *Journal of Acquired Immune Deficiency Syndrome*. 2002 Oct 1;31(2):154-62.

SAVE THE DATES

9th Annual Jail Health Conference

May 12-13, 2003
Wisconsin Dells, Wisconsin
Call: 715-836-3636
Email: ce@uwec.edu
Visit: <http://www.uwec.edu/CE/>

American Correctional Association Summer Conference

August 9-13, 2003
Nashville, Tennessee
Call: 800-222-5646, ext. 1922
Visit: http://www.aca.org/conventions/conventions_2003_summer.htm

3rd Annual Intensive Review in Correctional Medicine

Sponsored by the Correctional Medicine Institute (CMI), the Society for Correctional Physicians (SCP), and Johns Hopkins University
September 4-6, 2003
Baltimore, Maryland
Baltimore Marriott Waterfront Hotel
Call: 314-607-1565
Email: admin@cm-institute.org
Visit: <http://www.cm-institute.org/>

43rd Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)

September 14-17, 2003
Chicago, Illinois
Call: 202-737-3600
Email: icaac@asmusa.org
Visit: www.icaac.org/ICAAC.asp

The United States Conference on AIDS

Sponsored by the National Minority AIDS Council
September 18-21, 2003
New Orleans, Louisiana
Call: 202-483-6622
Visit: www.nmac.org

National Conference on Correctional Health Care

October 4-8, 2003
Austin, Texas
Call: 773-880-1460
Visit: www.ncchc.org

41st Annual Meeting of Infectious Disease Society of America (IDSA)

October 9-12, 2003
San Diego, California
Call: 703-299-0200
Email: info@idsociety.org
Visit: www.idsociety.org

INSIDE NEWS

CDC Issues Health Alert for SARS

The Centers for Disease Control and Prevention (CDC) has issued a health alert for Severe Acute Respiratory Syndrome (SARS), a new respiratory illness apparently originating in Asia and now reported in several countries. The illness usually begins with a fever, chills, headache, myalgias and malaise, followed by a respiratory phase characterized by a dry, nonproductive cough and dyspnea. Persons with these symptoms who have traveled recently to Hong Kong, Guangdong Province in China; Hanoi, Vietnam, and Singapore; or their close contacts (if symptomatic); may be at risk and should be reported to the CDC. For more information, go to <http://www.cdc.gov/ncidod/sars/>.
CDC, 3/22/03

NY Lawmakers Push for Oversight of Inmates' Health

A package of bills that would extend New York State Department of Health Oversight to reviewing AIDS and hepatitis C care in prison facilities passed New York's Assembly Health Committee. Similar efforts in the past have failed, mainly for the lack of a majority sponsor in the Republican-dominated Senate. New York's Commission of Corrections, a watchdog group, is currently charged with establishing minimum health care standards for inmates, but critics charge that the prison system exists mostly without oversight, resulting in inconsistent care. Corrections officials maintain that what they are doing works and point to the decline of AIDS-related deaths and TB outbreaks in prisons in the last decade.
Associated Press, 3/23/03

HHS Announces Contracts to Develop "Safer" Smallpox Vaccines

Health and Human Services officials announced two contracts for the development of "safer" small-

pox vaccines that could be used to protect people with compromised immune systems, including people with HIV/AIDS. The administration agency discourages people with HIV/AIDS, eczema, atopic dermatitis and cancer, heart disease, as well as pregnant women and organ transplant recipients from receiving the current smallpox vaccine.
Kaiser Daily Reports, 2/27/03

HIV Serostatus Affects Rearrest Rates of Ex-prisoners

Researchers at the University of Washington presented results of a study contending that inmates with HIV infection are more likely to be rearrested upon release than HIV-negative inmates. Fifty-seven HIV-positive inmates were compared to 254 HIV-negative inmates at the King County Correctional Facility in Seattle, Washington. Using the log rank test in Kaplan-Meier survival analysis, statistical difference in the relative risk of rearrest occurred for the HIV-positive group, according to investigators. The full report, "Rearrest: Does HIV Serostatus Make a Difference?" was published in *AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV* (2002;14(6):839-849).
AIDS Weekly, 2/10/03

Prisoners Not Entitled to Hepatitis Treatment, Court Rules

The Montana Supreme Court denied prisoner Keith Brown's petition for hepatitis C (HCV) medication and returned the case to a lower court recently. The divided court said it needed an official determination of whether the diagnosis was correct. The court also asked for a determination on whether there is an effective treatment for HCV. In Montana, about 30 percent of the state's 2,750 inmates have hepatitis, according to the state's DOC chief medical officer.
Associated Press, 3/01/03

RESOURCES & WEBSITES

Society of Correctional Physicians

<http://www.corrdocs.org>

National Institute of Corrections

<http://www.nicic.org>

CDC 2002 STD Treatment Guidelines: Pocket Guides and Wall Charts

https://www2.cdc.gov/nchstp_od/piweb/stdorderform.asp

Pocket guide summaries and wall charts of CDC's 2002 STD Treatment Guidelines can be ordered online.

Pros & Cons: A Guide to Creating Successful Community-based HIV/AIDS Programs for Prisoners

<http://www.pasan.org>

By Rick Lines, Prisoners HIV/AIDS Support Action Network (PASAN), Toronto, Canada
This guide, available in English and French, provides background information on the prison sys-

tem, service/program ideas, and advocacy strategies to create community-based HIV/AIDS programs for prisoners with the goal of better defending the rights of prisoners and expanding the availability and accessibility of HIV/AIDS services. Includes chapters on the Prisons 101, HIV and Hepatitis C in Prison, Getting Started, HIV Prevention Education and Outreach, and Client Support and Advocacy. It also contains an extensive Resource section.

The guide can be downloaded, and single copies (sent by mail) are free. Orders for multiple copies or shipping outside of Canada must be pre-paid.

To obtain Pros & Cons, contact:

Canadian HIV/AIDS Clearinghouse
400-1565 Carling Avenue, Ottawa, ON, K1Z 8R1
Toll Free: 1-877-999-7740
Tel. (613) 725-3434
E-mail: aidssida@cpha.ca
<http://www.clearinghouse.cpha.ca>

SELF-ASSESSMENT TEST FOR CONTINUING MEDICAL EDUCATION CREDIT

Brown Medical School designates this educational activity for 1 hour in category 1 credit toward the AMA Physician's Recognition Award. To be eligible for CME credit, answer the questions below by circling the letter next to the correct answer to each of the questions. A minimum of 70% of the questions must be answered correctly. This activity is eligible for CME credit through October 31, 2003. The estimated time for completion of this activity is one hour and there is no fee for participation.

1. The smallpox vaccine is made from the variola virus, the causative agent of smallpox.
 - (a) True
 - (b) False

2. Unintended transmission of the smallpox virus can occur:
 - (a) Immediately after vaccination up to a period of a week
 - (b) Immediately after vaccination until the scab separates from the skin two to three weeks later.
 - (c) Two days after vaccination until the scab separates from the skin two to three weeks later.
 - (d) Two days after vaccination up to a period of one month.

3. Since smallpox transmission occurs through contact with the vaccination site, steps that should be taken to prevent contact transmission are:
 - (a) Consistent hand hygiene with antimicrobial soap and water or an approved alcohol-based hand-rub containing more than 60% alcohol.
 - (b) Covering the vaccination site with gauze dressing and a semipermeable membrane.
 - (c) Wearing clothing that completely covers the vaccination site.
 - (d) Changing the dressings daily.
 - (e) All of the above.

4. Pregnant women are at no increased risk from the smallpox vaccine.
 - (a) True
 - (b) False

5. An adverse reaction to the smallpox vaccine that might require further evaluation or treatment include:
 - (a) Fever
 - (b) Headache
 - (c) Local skin reactions
 - (d) Inadvertent inoculation of the eye or eyelid

6. The CDC's Advisory Committee on Immunization Practices recommends routine administrative leave for newly vaccinated health care personnel for the duration of:
 - (a) One week
 - (b) Three weeks
 - (c) Four weeks
 - (d) Only in cases where an individual is physically unable to work because of symptoms; has extensive skin lesions that cannot be adequately covered; or is unable to adhere to the recommended infection-control precautions.

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

1. Please evaluate the following sections with respect to:

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Main Article	5 4 3 2 1	5 4 3 2 1
Inside News	5 4 3 2 1	5 4 3 2 1
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