HIV Treatment and the 8th Amendment

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Almost exactly two years ago, HEPP Report published an article discussing HIV+ inmates' constitutional rights to medical care in light of two divergent cases recently decided at the federal appellate court level.¹ This month's article re-examines those cases and looks at what has happened since then to guide correctional medical providers through this murky area of the law.

As HIV health care professionals know, everything changed in 1996 with the advent of Highly Active Antiretroviral Therapy (HAART), and more changes are on the horizon. As ever-changing standards for HIV treatment enter prisons and jails, correctional medical staff faces the unique issue of ensuring that patient care satisfies the 8th Amendment of the Constitution, the amendment prohibiting "cruel and unusual punishment." It is only natural that medical staff would want the courts to provide clear guidance as to what kind of treatment would and would not violate an inmate's rights. But the law rarely provides such clear and concise answers, and this is nowhere more evident than in 8th Amendment law.

Perhaps this is for the best. After all, courts are not in the business of diagnosis and typically preface 8th Amendment medical rulings with language to this effect. This means that courts will not second-guess a treatment decision unless there is compelling evidence that a particular action - or inaction - was clearly inappropriate. Therefore, it is unlikely that the courts will ever state, as a matter of law, that HIV-positive inmates are entitled to a certain type of care. Instead, courts will look to a medical provider's particular state of mind, in light of individual circumstances, to determine whether or not he or she has violated the 8th Amendment.

The 8th Amendment

The original intent of the 8th Amendment was to prevent tortures and other barbarous forms of punishment or actions that offend the "conscience of mankind." Estelle v. Gamble, 429 U.S. 97, 102 (1976). Later, 8th Amendment cases reflected a more idealistic vision, prohibiting actions incompatible with "the evolving standards of decency that mark the progress of a maturing society." Id. at 105. Under these principles the Supreme Court interpreted the

The courts would appear to come to opposite conclusions in HIV cases.

But further analysis shows that it may be just that: an appearance.

8th Amendment to include medical treatment, based on the fact that denying medical care would result in unnecessary suffering that could serve no penal purpose.

Later cases that apply Estelle have led to an interpretation of three basic rights for all prisoners: The right to access to care; the right to a medical opinion; and the right to have that opinion carried out. Estelle also affirmed the seminal test the Court will use to determine 8th Amendment violations: whether correctional staff has shown deliberate indifference to an inmate's serious medical needs.

The first time the Court seriously expounded on the test of "deliberate indifference" was in

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denying an inmate his HIV "cocktail" for just two or three days could amount to an 8th Amendment violation. In this case, the court said, it might. Id.

While these cases appear to contradict each other, they both apply the Farmer standard of deliberate indifference. The legal distinction between them is solely about the state of mind of the medical staff. The court in Perkins was aware of what established treatment protocols were, even citing medical text that affirms the necessity of protease inhibitors. 165 F.3d at FN9. However, without evidence that staff knowingly provided substandard care, there can be negligence or malpractice, but no constitutional violation.

By contrast, in Sullivan, there were myriad allegations that staff knew that denying HIV treatment for any length of time created serious risks. Indeed, there was testimony that it was "common medical knowledge that an AIDS patient taking protease inhibitors as part of an AIDS cocktail had to remain in strict compliance with that regimen at all times and without exception, lest the cocktail become ineffective." 216 F.3d at 1084.

Other courts have read the Farmer "deliberate indifference" standard perhaps more broadly. In Taylor v. Barnett, 105 F. Supp.2d 483 (E.D.Va. 2000), an HIV+ inmates' treatment regimen was changed, resulting in increased side effects and decreased efficacy. The inmate alleged that the change in treatment was motivated solely by cost considerations. 105 F. Supp.2d at 489. The court held that such an allegation, if true, was sufficient to show deliberate indifference and that treatment decisions made "solely upon cost considerations without medical rationale" are "unacceptable." Id.

Some courts have inferred that medical staff was deliberately indifferent simply because the risk of harm from the alleged action or inaction was exceedingly obvious (Davis v. Prison Health Services, 2002 WL 237871, 2 (D.Del.)), or that non-medical rationales for treatment decisions would almost always constitute deliberate indifference (Cloud v. Goldberg, 2000 WL 157159, 3 (E.D.Pa.)). For example, a pattern of missed dosages due to lockdowns or transfers could amount to a constitutional violation.

Ensuring an Inmate's Rights Under the Eighth Amendment

Because deliberate indifference is analyzed only in light of the individual circumstances of each case, how can medical staff in correctional settings know where the line is between constitutional and unconstitutional treatment? Amidst the ambiguities and semantic struggles within the body of 8th Amendment law, there is one constant upon which medical staff can rely: "whether one puts it in terms of duty or deliberate indifference, prison officials who act reasonably cannot be found..."
Dear Correctional Colleagues:

At first glance, you may be surprised that this month’s lead article has a legal, rather than a medical, theme; however, I think you will agree that it is useful for correctional health care professionals to understand the legal basis for inmates’ constitutional right to health care. What is a bit more difficult to grasp is exactly whether the standard of health care for prisoners is the same as for patients on the outside. Indeed, the cases discussed indicate that the courts feel that these standards may differ. Speaking from my experience within my own state, where I help coordinate the care of approximately 2500 HIV-infected individuals, I believe that the standard of care is the same for all HIV-infected individuals regardless of incarceration status.

What is clear from the article is that the courts have helped to establish better health care systems for incarcerated patients. But that is only part of the story. An increased awareness of social issues that started in the 1960s and 1970s, health care professionals choosing to work in corrections (rather than it being a last resort for unqualified workers), and voluntary compliance with standards set by the Joint Commission for the Accreditation of Health Care Organization and other regulatory boards have all helped to elevate the standard of correctional health care to its present status. We at HEPP Report also like to believe that we have contributed to this new spirit of professionalism that characterizes the practicing correctional HIV provider. We have done this by providing state-of-the art HIV and infectious diseases management information to our readership over the last five years. Going forward, we can all strive to make maximal suppression of HIV viral replication the standard of care in our own institutions. By doing so, we can prevent progressive immunosuppression and reconstitute our patients’ depleted immune systems. This in turn will serve to avert opportunistic infections and malignancies, and lead to longer, healthier lives for those we serve.

Our commitment to treating HIV/AIDS patients is especially critical in light of the CDC’s study of incarceration history among people with HIV/AIDS. The finding: 48% of the 2,639 HIV/AIDS patients questioned reported having been incarcerated at least once (see this issue’s Spotlight for more details). The study emphasizes how important it is for correctional health care providers to encourage at-risk inmates to undergo HIV testing and provide education for all prisoners about risk-reduction methods.

After reading this issue, readers should be familiar with legal issues in correctional health care, specifically as they relate to the standard of care provided to HIV+ inmates; how the courts have ruled on previous cases; and the 8th Amendment standards by which correctional health care providers are judged.

Sincerely yours,

David Paar, M.D.
liable" under the 8th Amendment. (Farmer, 511 U.S. 842, a standard that incorporates due regard for prison officials’ "unenviable task of keeping dangerous men in safe custody under humane conditions.")

In practical terms, this means that medical staff who stay reasonably abreast of HIV treatment developments and practice in good faith can never be deliberately indifferent, providing they afford their inmates the benefit of their medical skill.

**Conclusion**

While courts look at patients' suffering from a variety of disease entities, HIV is of particular interest to the judiciary because of its high prevalence within the correctional environment. As with poor treatment of HIV, poorly-treated tuberculosis or other infectious entities would be held to similar standards. The controversy and litigation concerning HIV can be attributed to initial resistance in some correctional settings to treat the disease adequately.

Eighth Amendment rulings have contemplated changes in medical wisdom. As the court noted in Sullivan, the more inappropriate a treatment decision is in light of a patient's serious need, the more likely it is that staff members were deliberately indifferent. 216 F.3d at 1084. Thus, as certain treatments become established protocols, and knowledge about drug resistance and HIV become commonplace in the medical profession, correctional medical staff will likely be increasingly held to those standards of knowledge by virtue of their obviousness. It is highly unlikely, however, that courts will ever cease to recognize the particular realities of working within the correctional environment.

**DISCLOSURES:**

*Nothing to disclose*

**REFERENCES:**

2. Unpublished decisions cannot be used as binding legal precedent.

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**HEPPGRAM: Proposed Decision Tree for Initiating or Restarting Antiretroviral Therapy**

Correctional doctors face important decisions regarding starting or restarting therapy for HIV+ patients while evaluating inmates at intake. HIV+ inmates may have experienced an interruption in therapy for any number of reasons (see the lead story for more discussion on the legal implications of this). This decision tree was developed by HEPP editors to describe a framework for decisions on restarting treatment for an HIV-infected inmate who enters a facility off medications. As always, actual decisions regarding ART are complex and involve talking with patients to thoroughly discuss treatment options.

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Intake: inmate/patient meets criteria for ART.

Patient currently on ART with minimal (<7 days) disruption.
  Continue ART
  Check viral load.

Patient not currently on ART.
  Previously on ART
  ART naive

Wants ART
  Measure baseline viral load and CD4 T-cell counts.

Doesn't want ART
  Educate

Stopped ART due to significant side effects.
  Select a new regimen, adding at least two new drugs to which expect minimal resistance.

Stopped ART because although adherent, had virologic or clinical failure.
  Has been off ART for <2 weeks.
  Restarts therapy less urgent.
  Review medical records.
  Review adherence (poor adherence side effects).
  Prior regimen suboptimal.
  Select new regimen, modify at least two drugs.

Stopped ART for other reasons.
  Has been off ART for >2 weeks.
  Restarting more urgent.
  Restart same regimen ASAP.
  Carefully monitor viral load and CD4 count, looking for possible failure. If poor response, consider genotyping and select a new regimen.

Educate, offer therapy if appropriate
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HEPPigram: Proposed Decision Tree for Initiating or Restarting Antiretroviral Therapy... (continued from page 2)
ACCESS TO CARE
Access to care was a key theme at this year’s International AIDS Conference in Barcelona, Spain held in July 2002. Access to antiretroviral drugs, lab work such as CD4 counts and viral load (VL) monitoring, and HIV-knowledgeable clinicians are key elements of the struggle against HIV disease. Although the discussion focused on the developing world, much of what was presented in the session on the incarcerated echoed what has been known in the U.S. prison community for years: prisoners have a higher prevalence of HIV, other STDs, HCV, and drug use than the general population. Inmates often live on the edges of society and have less access to testing and treatment. Ultimately, presenters agreed, incarceration can be a pivotal time and place to test and treat a community at high risk for HIV infection.

U.S. UPDATE
According to Ted Hammett of Abt Associates group, 25% of HIV-infected people in the U.S. cycle through prisons and jails in any given year. This translates to 2.2% (40,000) of inmates being HIV-infected compared with 0.3% of the total U.S. population. The burden of HIV among prisoners is generally higher in developed (rather than developing) countries, especially in those countries with high incarceration rates such as the U.S. (666/100,000).1

Another important theme of the conference that applies to corrections is that prevention and treatment efforts work best when offered together. In a study from the Project START team2, researchers interviewed 18-29 year-old releasees about their perceptions on infection, personal experiences, and strategies for protection in regard to substance abuse and sexual activity in prison. The sentiments from these recent releasees were that access to drugs and alcohol were as common within corrections as they were on the street. Releasees alleged that they were able to access these commodities from other inmates, outside visitors, and corrections staff, and paid for them with cash or sexual favors. They claimed that needles for injection drug use came from diabetics, were commonly shared, and rarely cleaned. The interviewees estimated that more than 50% of prison inmates were using drugs, alcohol, or both while incarcerated.

Moreover, 15.6% of the interviewees admitted to having sex while incarcerated. Although inmates expressed a desire to do what they could to protect themselves against HIV and other STDs, they were pessimistic about their ability to do so due to prison guidelines that usually prohibit distribution of condoms.

IMPORTANCE OF HIV TESTING IN CORRECTIONS
While much of the work on HIV in corrections focuses on the percentage of inmates with HIV infection, the CDC3 investigated the issue from the opposite perspective and asked: How many people with HIV/AIDS have ever been incarcerated? Of the 2,639 patients questioned, 48% answered that they had been incarcerated at least once. Twelve percent of that group were initially diagnosed in a correctional facility. The proportion of HIV-infected persons having ever been incarcerated are shown by sex and age in Figures 1 and 2.

This study emphasizes that because a large proportion of HIV-infected people have been incarcerated at least once, it is important that correctional physicians encourage HIV testing for at-risk individuals and educate prisoners about risk-reduction methods.

A study from the Harvard School of Public Health examined the barriers to HIV testing perceived by incarcerated men in the U.S.4 The main barriers reported for testing prior to incarceration included a lack of time, low priority, insufficient resources, low perceived risk for HIV infection, and fear of knowing the results. According to study participants, many of these barriers are alleviated in prison. In most correctional facilities, testing is free, easily accessible, and convenient; in some settings, testing is mandatory. Unfortunately, while the men reported an increased use of testing services inside correctional institutions, many alleged that they did not receive their test results and reported insufficient pre- and post-test counseling. The study concluded that while access to testing in corrections is vital, the corresponding support services must also be available.

LESSONS LEARNED FROM THE XIV INTERNATIONAL AIDS CONFERENCE
Many of the themes evident during the conference were applicable to the challenges of HIV in prisons and jails. HEPP Advisor Helene Gayle, MD, of the Bill & Melinda Gates Foundation, reminded us “effective prevention is more than just education.”5 This is especially true in corrections, where traditional education may not be effective due to high illiteracy rates. Correctional health care providers should employ a combination of approaches in order to reach the largest number of at-risk individuals and must understand the resources available to the patient population.

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Routine Screening of Inmates at Intake

A significant number of persons infected with HIV, tuberculosis (TB), hepatitis, syphilis, gonorrhea, and/or chlamydia are unaware of being infected at the time of their entry to prison or jail. Screening and prevention programs differ widely among correctional institutions, ranging from mandatory testing to testing only at the inmates’ request.

The recently released National Commission on Correctional Health (NCCHC) report to Congress on the status of soon-to-be-released inmates found that:

- A “significant proportion” of prisons and jails do not adhere to CDC standards with regard to screening for and treating latent and active TB. About 10 percent of state and federal prisons and about 50 percent of jails do not have mandatory TB screening for inmates at intake and annually thereafter.
- Approximately 500,000 individuals latently infected with TB are released each year from jails and prisons.
- Less than one-quarter of jail inmates undergo routine laboratory testing for syphilis during incarceration.
- Approximately 500,000 individuals with sexually transmitted diseases (STDs) are released each year from jails and prisons.

The NCCHC report finds that due to the high prevalence of infectious diseases among the incarcerated, routine screening can be cost saving and cost-effective in most situations. For those systems unable to implement universal screening for STDs, targeted age-based and symptom screening for some STDs can be even more cost-effective.

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<th>AN APPROACH TO INFECTIOUS DISEASE INTAKE SCREENING</th>
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<tbody>
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<td>HIV</td>
</tr>
<tr>
<td>• Encourage all those with risk factors to be tested</td>
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<tr>
<td>• Provide education to all concerning decreasing the risk for transmission</td>
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<tr>
<td>• Refer HIV-infected patients for evaluation for treatment</td>
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<tr>
<td>HCV</td>
</tr>
<tr>
<td>• Encourage all those with risk factors to be tested</td>
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<tr>
<td>• Provide education to all concerning decreasing the risk for transmission</td>
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<tr>
<td>• Provide education to all those infected concerning avoiding further liver injury i.e. alcohol avoidance</td>
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<tr>
<td>• Refer HCV-infected patients for evaluation for treatment</td>
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<td>• Vaccinate those who are non-immune for HAV</td>
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<td>HBV</td>
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<td>• Vaccinate all those who are non-immune</td>
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<td>Syphilis</td>
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<td>• Encourage all those with risk factors to be tested</td>
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<td>• Refer those who are infected for treatment</td>
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<td>Gonorrhea and Chlamydia</td>
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<td>• Encourage all those with risk factors to be tested</td>
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<td>• Provide education to all concerning decreasing the risk for transmission</td>
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<td>• Refer those who are infected for treatment</td>
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Logistical barriers (e.g., short periods of incarceration, frequent inmate movement), lack of resources, and lack of leadership can present formidable obstacles to providing screening (and treatment) at intake. However, model programs such as those in Massachusetts’ Hampden County Correctional Center and Virginia’s Fairfax County Jail have demonstrated that through collaboration with public health departments and community-based organizations these barriers can be overcome.

XIV International AIDS Conference Update...
(continued from page 6)

Paul Farmer, AIDS researcher from Harvard Medical School, commented on the problem of HIV infection in prisons: “The largest cities in the world will have to deal with [the problem of HIV concentration in their] prisons and jails or these sites will continue to seed the epidemic. First, [they must] deal with harm reduction and then [they must deal with] access to treatment and care.”

We will “pay now or pay later,” said Gayle; the longer we wait, the more we will pay, both financially and “in human life and suffering.” While “the best time to plant a tree is 20 years ago, the next best time is now.”

REFERENCES:
7. African Proverb, as quoted by Helene Gayle (see reference 12).
HCV
FDA Approves Pegasyis Monotherapy
The FDA has approved Pegasyis (pegylated interferon, Roche brand) as monotherapy for the treatment of hepatitis C. Adults with chronic hepatitis C who have compensated liver disease and who have not previously been treated with interferon alpha are approved for the drug, which must be injected once a week. The FDA is reviewing Roche’s application for combination therapy of Pegasyis and ribavirin; approval is expected in December. http://www.natap.org, 10/16/02

New Jersey to Pay for Testing and Treatment of Inmates with HCV
New Jersey announced it will immediately begin covering the costs of hepatitis C testing and treatment for prisoners who are infected with the virus. Under a new agreement with Correctional Medical Services, the state will cover the cost of testing, medications and any additional staff needed to administer the program. Other states with similar programs have reported spending $15,000 to $25,000 per inmate for testing, monitoring, and treatment. New Jersey has identified 1,170 HCV-positive inmates. http://www.kaisernet.org, 11/01/02

HIV
Study: HAART Alters Mortality Patterns
As HAART was introduced and became more widely used, AIDS-related deaths in San Francisco declined, while mortality associated with non-AIDS-related malignancies, chronic diseases and injection drug use has not changed, according to a recent study by Dr. Janice K. Louie from the University of California, San Francisco. The study analyzed deaths among AIDS patients in San Francisco from 1994 to 1998. Reuters Health, 10/24/02

Mental Health Issues Common, But Often Neglected in HIV Patients
While approximately four out of five patients with HIV suffer psychiatric symptoms, only about a third of patients reported having ever been asked by their physicians about these symptoms. A supplement to the Journal of the International Association of Physicians in AIDS Care (IAPAC) stated that the most common self-reported psychiatric symptoms were depression, anxiety, insomnia, lethargy, irritability, impaired concentration, and mood swings. Most physicians in the survey (80%) attributed the psychiatric symptoms to antiretroviral drugs, but the study’s author pointed out that symptoms (especially from Efavirenz) tend to resolve after the first month. Psychostimulants, antidepressants, and tricyclics can also be used effectively in some patients. http://www.hivandhepatitis.com, 10/28/02

Fuzeon Given Priority Review Status
The FDA has given Enfuvirtide/T-20 (Fuzeon) priority review status. Roche and Trimeris Inc. announced that they expect a decision by March 16, 2003. http://www.natap.org, 10/15/02

BMS Extends Price Hold
Bristol-Myers Squibb (BMS) is extending its existing price hold on its three marketed anti-HIV medications to state AIDS Drug Assistance Programs (ADAPs) through March 2004. For information on BMS’s Patient Assistance Program, call 877-758-7877. http://www.natap.org, 10/11/02

Judge Hears Argument to End Oversight of Georgia Jail
U.S. District Court Judge Marvin Shoob heard arguments in a motion to end court oversight of the Fulton County, Georgia Jail. The court’s oversight began in 1999 after HIV-infected inmates filed suit over allegations they did not receive adequate medical care. Shoob said that the jail has made “substantial progress” in improving conditions for HIV-positive inmates, but did not issue an immediate decision on the motion. Atlanta Journal-Constitution, 10/18/02

South African Prisons ‘Breeding Ground’ for HIV/AIDS
Crowded South African prisons have become a “breeding ground” for HIV/AIDS, according to the AP/Seattle Post-Intelligencer. HIV/AIDS is believed to be largely responsible for the 500% increase in prison deaths between 1995 and 2001, reported a judge who oversees the country’s prison conditions. About 41% of the nation’s inmates are believed to be HIV-positive. AP/Seattle Post-Intelligencer, 10/21/02

Resources & Websites
HEPP Report
Includes archives of all issues http://www.hivcorrections.org

HIV and Its Treatment: What You Should Know, September 2002

National Institute on Drug Abuse
New Requests for Applications
http://www.nida.nih.gov/Funding/rfplist.html

Lipo2002 Abstracts
Abstracts from the 4th International Workshop on Adverse Drug Reactions and Lipodystrophy in HIV, (September 22-25 in San Diego) are now available for download. http://www.intmedpress.com

National Institute on Drug Abuse - New Requests for Applications
http://www.nida.nih.gov/Funding/rfplist.html

National HCV in Prison Coalition
http://www.hcvinprison.org/
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 May 31, 2003. The estimated time for completion of this activity is one hour and there is no fee for participation.

1. When applying the eighth amendment to the evaluation of care given to prisoners, courts look to:
   (a) Proof of deliberate indifference
   (b) Whether the action was medically appropriate
   (c) Whether the correct level of care was given
   (d) Whether the treatment met the latest medical standards

2. The Eighth Amendment specifically:
   (a) States that all inmates have the right to medical care
   (b) Prohibits cruel and unusual punishment
   (c) States that inmates have the right to litigate if they are not satisfied with their level of care
   (d) None of the above

3. Estelle v. Gamble (1976) has led to a widely-held interpretation that inmates have:
   (a) The right to access to care
   (b) The right to a medical opinion
   (c) The right to have a medical opinion carried out
   (d) All of the above

4. In Perkins v. Kansas Department of Corrections, the 10th Circuit Court ruled that denying an HIV+ inmate his protease inhibitor was unconstitutional.
   (a) True
   (b) False

5. The Courts are clear about the level and type of treatment that should be given to HIV+ prisoners, and generally rule accordingly in favor of inmates who have not received the medically accepted standard of care:
   (a) True
   (b) False

6. In Farmer v. Brennan, the Court clarified “deliberate indifference” as:
   (a) When prison staff knowingly acted or failed to act
   (b) Medical malpractice
   (c) Negligence
   (d) None of the above

HEPP Report Evaluation

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<th>4 Very Good</th>
<th>3 Fair</th>
<th>2 Poor</th>
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1. Please evaluate the following sections with respect to:
   educational value
   clarity

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   HIV 101      | 5 4 3 2 1 | 5 4 3 2 1 |
   Inside News  | 5 4 3 2 1 | 5 4 3 2 1 |
   Save the Dates | 5 4 3 2 1 | 5 4 3 2 1 |

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

3. What future topics should HEPP Report address?

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

5. Do you have specific comments on this issue?

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