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HIV Education Prison Project HEPP NEWS

Aug. / Sept. 1999 • Volume 2, Issue 8

Brown University School of Medicine Providence, RI 02912
tel: 401.863.2180 • fax: 401.863.2660 • www.hivcorrections.org

About Hepp

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

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

The goal of HEPP News is to provide our readers with reports of effective and cost-conscious HIV care that can truly be implemented with the correctional environment. We hope our newsletter achieves that goal.

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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 beneath the authors' names.

All of the individual medications discussed in this newsletter are approved for treatment of HIV unless otherwise indicated. For the treatment of HIV infection, many physicians opt to use combination antiretroviral therapy which is not addressed by the FDA.

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Clinical Trial Research in Correctional Settings

David Alain Wohl, MD

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Speaker's Bureau: Roche, Bristol-Myers Squibb, Glaxo
and Roxane*

Prisoners, because of their relatively stable environments and availability, have historically been attractive, if not preferred, research subjects. Phase I drug toxicity studies, malaria treatment trials and radiation exposure experiments have notoriously been conducted utilizing prison inmates (1-3). However, with the evolution of research ethics and subsequent regulations, investigations involving prisoners have undergone fundamental changes over the past three decades.

Many advancements in establishing ethical standards for research conduct have stemmed from landmark events such as the Nuremberg "doctors' trials" of 1946; the 1964 statement by the World Medical Association (WMA), commonly known as the Declaration of Helsinki, and the convening by the U.S. Department of Health, Education and Welfare of the Belmont Commission in 1976 (4-6). While these events have set forth fundamental protection of human research subjects in general, each has also significantly impacted the use of prisoners in research.

Autonomy in Prison: An Oxymoron?

At the heart of all attempts to codify ethical research practices is the concept of informed and voluntary consent. The major codes and commission reports require that research subjects must agree to participate in studies free from "coercion," "constraint," "duress" or "elements of force." However, many argue that the prison setting is inherently coercive and severely limits the autonomy of prisoners to make a free choice. An opposing perspective argues that prisoners should not be denied the opportunity to make informed decisions to volunteer for properly designed research protocols.

The Belmont Commission Report recognizes the difficult balance between avoiding overt and subtle coercion of inmates as study sub-

jects and allowing inmates the choice to participate. According to the authors of the Belmont Report, "On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced."

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HEPP is holding the following conferences:

Clinical Trials in Corrections

Providence, Rhode Island
October 13-15, 1999

Conference will review the practice and legal and ethical aspects of clinical trials in correctional settings. A consensus meeting on the 15th will seek to identify a consensus on practical guidelines for holding clinical trials. Contact Betsy Stubblefield via fax (401.863.1243) or e-mail (hepp-news@brown.edu), or visit www.hivcorrections.org

HIV/AIDS Behind Bars

Call for Abstracts

HEPP at BRUNAP is sponsoring a pre-conference colloquium on November 6 at the NCCHC conference that will discuss public health and corrections collaborations. Accepting abstracts of 500 words addressing this topic until September 22. Please fax (401.863.1243) or e-mail (hepp-news@brown.edu) questions to Betsy Stubblefield. Visit www.hivcorrections.org for more information.

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Clinical Trial Research in Correctional Settings

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A personal story:

Can ethical research be performed in correctional settings?

The mention of research in prison for most conjures up images of forced experimentation on captive human guinea pigs by callous scientists.

However, research practice in prisons has dramatically changed over the past 30 years, fueled in part by the dark legacies of Nuremberg, Willowbrook and Tuskegee and intense media scrutiny of suspect human subject research.

The result has been an ongoing examination of how clinical trials are conducted, particularly in so-called 'vulnerable' populations such as prisoners. Can clinical research be conducted ethically in correctional settings?

As a clinical trialist working with subjects who are incarcerated, I believe the short answer is a resounding yes. The longer answer, however, adds caution: only if you are able to continuously and vigilantly act to safeguard that the fundamentals of ethical research are strictly adhered to. Our HIV clinical research program in prisons emerged from the observation that HIV was concentrated in our state correctional facilities.

Despite this, little was known about issues of integral importance to HIV health care providers such as inmates' attitudes and behaviors regarding their HIV infection, treatment and care.

In addition, it was evident to us, as it has been to others, that response to HIV therapy appeared to differ from that of the free world, with many inmates experiencing profound and durable responses to almost minimalistic antiretroviral therapies.

To address these issues, we have embarked on a series of clinical research efforts in our state prisons. To eliminate overt coercion of potential research subjects, our research group has gone to great lengths to disabuse patients of the notion that study participation results in any special rewards. It is made clear that volunteering will not result in special privileges, diet or access to medical personnel and will not have any impact on length of sentence or on parole. These points are discussed verbally and are detailed in the informed consent which is read to potential subjects. (See Heppigram).

We strive to only conduct studies that pose no more than a minimal risk to subjects. The issue of exposure to risk became a major issue and learning experience when we conducted a treatment trial in which one arm of the study received abacavir. It became evident that some of the incarcerated subjects were unable to immediately contact the study staff if they suspected they were developing an abacavir hypersensitivity reaction, say, late one Saturday at a site with no medical staff on duty until Monday. To us, this placed these subjects at greater risk than those not incarcerated. As a result, we decided to scale the scope of our study down to facilities with 24 hour-per-day, 7 day-per-week nursing and developed an appreciation of how research in prison poses unique challenges that are difficult to anticipate without an understanding of the complexities of a correctional system.

Research should, in general, aim to benefit the population being studied. Certainly, given the concentration of HIV in correctional settings, HIV-related research in prisons is appropriate and, I argue, necessary. Recently our group has initiated studies of patterns of antiretroviral adherence and the utility of directly observed therapy in prisons. Other researchers have elegantly studied the effect of continuity of medical care on recidivism, while others have reported on inmate attitudes toward condom and bleach availability. Each of these investigations relates directly to experiences encountered by inmates and the study results will be applicable to the inmate populations studied.

*In the dynamic world of HIV care, time waits for no one. For those doing time we should offer nothing less than what we offer those who are free, including ethically constructed clinical research. We are challenged, however, to answer the questions and develop the innovative therapies that will benefit prisoners and possibly others in way that is moral and reflects that we have learned a lesson from our past. **David Alain Wohl, MD***

enced to engage in research activities, for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected." Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma, the report states (6).

The presence of unethical influence over inmates to enter clinical trials may be overt; for example, the awarding of special privileges or a sentence reduction. However, coercion can also be subtle. Increased access to medical care and opportunities to interact with others during study-related activities might constitute undue inducement.

The institutional review board's (IRB) role is to be vigilant in determining if coercion is present. The IRB Guidebook, published in 1993 by the National Institutes of Health (NIH), charges IRBs with determining whether advantages received by prisoner subjects are sufficient to impair the inmate's ability to freely choose to enroll (7).

Which Studies Apply?

Federal policy mandates that only certain kinds of research are appropriate for prisoner participation. These studies present no more than a minimal risk to the subject. Minimal risk is defined as "risk of physical or psychological harm that is no greater than that encountered in the routine lives of healthy persons." (8) Research considered appropriate for prisoner participation includes studies of criminal behavior, prison life, conditions affecting prisoners as a class and therapies likely to benefit the prisoner subject. Therefore, phase I and II treatment trials are not appropriate in correctional settings.

In general, prisoners should not be selected for research when other, less vulnerable and burdened populations can address the scientific question being posed. This issue of distribution of the burden of research is addressed in the Belmont Report:

"Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens, and on the appropriateness of placing further burdens on already burdened persons.

Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children), and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions." (6)

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LETTER FROM THE EDITOR

Dear Colleagues,

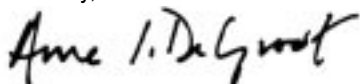
With the end of summer comes the usual flurry of Fall activities. You have already received notice of HEPP's Clinical Trials in Correctional Settings conference, scheduled for Oct 13-15 here in Providence (see Save the Dates for more information). We look forward, with excitement, to that meeting, where a who's who of correctional medical providers will discuss ethical, legal, and operational aspects of trials with leaders in the fields of medical ethics, HIV research and law. This issue of HEPP News features a lead article by David Wohl describing the history of clinical trials, and a "personal" note by David on his own experience in the North Carolina Department of Corrections.

Since one of the criteria for ethical research is "good clinical practice," it is entirely appropriate that this month's issue also include a description of case management - again in the NC DOC. The program, described by Faye Duffin, fits our idea of optimal case management, although we believe 48 clients per case manager is a little high, especially if they have to travel to more than one institution (see reference 6 in her piece). This statement would probably hold true for many states where HIV case management is operational. Those states that aren't fortunate enough to have case management may wish to contact Faye Duffin, or her supervisor Medical Director Barbara Pohlman, at the NC DOC, for more information.

This month's issue includes two tools that will be useful to HIV providers in correctional settings. In keeping with our case management features, we have provided you a full page, standardized HIV care flow sheet for the management of the HIV infected inmate. We've also included a list of criteria for informed consent that is relevant to the Clinical Trials article. After reading this issue, readers should be able to list which types of research are appropriate for prisoner participation, identify requirements for prisoner research as described by federal codes and commission reports, and outline the essential components of HIV nurse case management in correctional settings.

Next month, for our First Anniversary Issue, we'll feature an update on HIV treatment by one of our editors, and insights on how a large state system manages to adapt to rapidly changing clinical guidelines for HIV. We're proud to let you know that this issue marks our first anniversary, and we'd like to thank you for your continued interest in our publication.

Sincerely,



Anne S. De Groot, MD
Editor, HEPP News
Co-chair, HIV Education/Prison Project



David Thomas, MD
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SAVE THE DATES

Update on Optimal Sequencing of Antiretroviral Therapy, Series Two: Initiation of Therapy: Potency vs. Class

CME-accredited telephone conference calls on September 16, and 22, 1999

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Antiretroviral Update for the Next Millennium

October 12, 1999
Satellite video conference

Contact: Carol Kiner,
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4th National Conference on Chronic Disease Prevention and Control: Multi Disciplinary Care of the HIV-Infected Adult

October 27-29, 1999
Atlanta, GA

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United States Conference on AIDS

November 5-8, 1999, Denver, CO
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Contact: for more information, call 202.483.6622 x343
or visit www.nmac.org

Clinical Trial Research in Correctional Settings

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The use of placebos must also be applied in an ethical manner when research involves vulnerable populations. In the wake of the Tuskegee syphilis study, where poor African American men were not informed that they were part of an infected natural history cohort, it is imperative that all procedures and treatments be known and understood by the subject. Placebos can be used as part of a control group only in special circumstances and almost never when administered alone without a concomitant active agent. Use of placebos or inclusion of an untreated control group requires approval of the Department of Health and Human Services if the research is federally supported (7).

Guidelines for Regulating Prison Research

1976 Belmont Report

<http://www.grants.nih.gov/grants/oprr/humansubjects/guidance/belmont.htm>

1989 Revised Version of the Helsinki Declaration

<http://helix.nih.gov:8001/ohsr/helsinki.php3>

Office for Protection from Research Risks (OPRR)

http://grants.nih.gov/grants/oprr/oprr_t.htm

FDA Requirements

http://www.nih.gov/grants/oprr/irb/irb_guidebook.htm

Confidentiality

Protecting the privacy of prisoners is difficult even when they are not part of a clinical trial. Simply being moved from a cell to

a clinic can make an inmate conspicuous to others.

In addition, there are breaches of confidentiality when non-medical staff have access to medical records. Study activity that increases the frequency of clinic visits or risks confidentiality in other ways must be minimized. Maintaining confidentiality for inmates may involve elaborate safeguards and protections such as storing study related documents separately from the medical record, integrating study visits with routine clinic visits and carefully labeling any medication dispensed.

IRBs

The primary responsibility for review and oversight of clinical research is the IRB. All research involving prisoners should be evaluated by an IRB. The board should meet the requirements specified in the Code of Federal Regulations [45 CFR 46.304].

Research and Race

A disproportionate number of persons incarcerated in the United States are members of racial minorities. As such, research in correctional settings may place a particularly unfair burden on minority prisoners despite the efforts of the investigators to fairly select subjects. Historically, the opposite has generally been true; white prisoners have usually been over-represented in research. This may have been due to biased selection, allowing white inmates to benefit from the privileges that were historically associated with participation in research trials (9).

However, as more members of racial and

ethnic minority groups are incarcerated and the coercive inducements for study enrollment are eliminated, there is a potential for minorities to be disproportionately represented in clinical research in prisons.

While individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects. This may be accomplished by attempting to have the racial make-up of the study population reflect that of the population affected by the disease being studied. For research investigating conditions specific to prisoners, the disproportionate inclusion of racial minorities may be justified as representative of the composition of the prison population.

Summary

Prisoners need to be protected from research that is exploitative and which can pose undue risks. Inmates must not be included in research solely because they are part of a convenient and readily accessible population. When undue coercion and influence are minimized to the greatest degree possible, prisoners may be able to make an informed decision regarding participation.

It is incumbent upon investigators and IRBs to be familiar with the regulations guiding research in correctional settings and to determine if the proposed research is suitable for prisoner participation. When designed and implemented correctly, research involving prisoners is likely to benefit inmates as a class, and become an asset to research in general.

REFERENCES:

1. Procedures Used at Stateville Penitentiary for the Testing of Potential Antimalarial Agents. *JClin Invest.* 27, no. 3 (part 2) (1948): 2-5.
2. Jessica Mitford, "Experiments Behind Bars: Doctors, Drug Companies, and Prisoners," *Atlantic Monthly.* 23, January 1973, 64-73.
3. U.S. Department of Energy: Advisory Committee on Human Radiation Experiments, http://tisnt.eh.doe.gov/ohre/roadmap/achre/chap9_2.html.
4. Shuster E. Fifty years later: the significance of the Nuremberg Code. *New England Journal of Medicine.* 337(20):1436-40, 1997 Nov 13.
5. Medical Ethics Committee. Proposed revision of the World Medical Association Declaration of Helsinki. Ferney-Voltaire, France: World Medical Association, 1999. <http://www.grants.nih.gov/grants/oprr/humansubjects/guidance/belmont.htm>
6. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Belmont Report: Ethical principles and guidelines for the protection of human subjects of research. Washington, D.C.: Government Printing Office, 1983 <http://www.med.umich.edu/irbmed/ethics/belmont/BELMONTR.HTM>.
7. The IRB Guidebook - 1993. Office for Protection from Research Risks - NIH, http://www.nih.gov/grants/oprr/irb/irb_chapter6.htm#gt.
8. Code of Federal Regulations, title 45, part 46: 45 CFR 46.305 and 45 CFR 46.306, 1991.
9. Jon M. Harkness, "Vivisection and Vivishooters: Medical Experiments on American Prisoners before 1950," paper presented at "Regulating Human Experimentation in the United States: The Lessons of History," Columbia College of Physicians and Surgeons, New York, 23 February 1995.

SPECIAL REPORT - HIV Case Management In Corrections:

The HIV/AIDS Outreach Program of the North Carolina Division of Prisons

Introduction:

As the director of Nursing and Ancillary Services at the New York State Department of Correctional Services, it is my pleasure to introduce this piece on the subject of case management of HIV in the correctional setting. Overseeing the nursing practice and continuing education needs of over 500 nurses in the New York State Department of Correctional Services (NYSDOCS), Division of Health Services, is certainly challenging but rewarding as well. Case management of HIV-infected inmates is inherent in correctional nursing practices in light of the high HIV profile of prison populations. Provision of care to HIV-infected inmates takes a focused, coordinated and concerted effort by our health care professionals- the largest unique of which is the professional nursing staff. This affords the nurses the unique opportunity of fostering and participating in intra-disciplinary collaboration with their nurse peers.

The following article by Faye Duffin describes North Carolina Department of Prisons' (NCDOP) HIV Care Model of case management. Outreach Nurses, as case managers are known in the NCDOP, facilitate early identification, education and prevention of HIV with individualized case management interventions for the known HIV-infected inmates, emphasizing trust building client-caregiver relationships. The Outreach Nurses also promote inter-disciplinary collaborations by providing education to all members of correctional staff.

Indeed, the tasks the NCDOP outreach nurses perform seem to be numerous and critical to the provision of good HIV care, bringing me to my final point: The most difficult task we engage in as partners in correctional health care is the budgeting of our time. The standard case-load for an HIV case manager outside corrections is in the range of 30 to 40 patients, due to the complex nature of HIV care. Inside corrections, case loads tend to be much higher. Faye Duffin's article accurately reflects the challenges as well as the rewards of HIV case management in the correctional setting.

*Christine C. Mulligan, R.N., M.S.
Director of Nursing & Ancillary Services,
N.Y. State Department of Correctional Services*

Faye A. Duffin, R.N.,C., B.S.
NCDOP Infection Control Coordinator

The North Carolina General Assembly established the basic structure of today's HIV care model in the North Carolina Division of Prisons (NCDOP) in 1994 (1). The model includes three critical components: care directed by a team of HIV-experienced physicians, a team of outreach nurses focused on HIV care and education, and comprehensive case management (during incarceration and discharge planning). Wisely, NCDOP has stayed the course set by the legislature, providing HIV care that is consistent with current treatment guidelines and community standards (2). This article will address the role of the case manager, or "outreach" nurse, as we are called in the NCDOP.

As nurses, we are well aware that almost all of our incarcerated patients eventually return to the community. Their health status will affect the community as a whole, especially if the inmates are affected by infectious diseases such as HIV, TB and sexually transmitted diseases that they could transmit to members of their family or community. Often, their conditions have not been treated because they have had limited access to health care prior to incarceration. Therefore, prison and jail settings are critical points of access to address the preventive and primary health care needs of this hard to reach population, and to plan for interventions that will return them to the community in good health (3). Our role in the task of preventing and treating medical conditions in this population will save public and correctional resources and protect communities to which they return.

Considering the broad scope and importance of integration of services required to care for inmates with HIV/AIDS, skilled nursing case managers are an essential part of the health care team (4). Thus at the initiation of the outreach program in the NCDOP, eleven nurses were hired and trained by NCDOP to provide patient education, case management and discharge planning to the HIV-infected inmates in the prison population.

Over the years, the program has evolved to include many of the activities provided by community outreach programs. Therefore, in keeping with the nurses' desire to improve patient confidentiality and trust, the nurses chose to be identified as "Outreach Nurses." The outreach program nurses' role includes early identification, education and prevention; case management of the known HIV positive inmate; technical and professional support to staff; and discharge planning.

Early identification, education and prevention

All new admissions are required to participate in HIV education and prevention sessions at the time of intake. One outreach nurse is assigned to each intake center. The main purpose of the intake session is to increase awareness of HIV risk factors and behaviors, and to encourage the newly admitted inmates to get tested. We also use this opportunity to provide information on prevention techniques through lectures, interactive group discussions, and videos. We try to cover a broad range of topics in our one intake session, such as basic HIV pathophysiology, transmission risks, and signs and symptoms of HIV infection and associated opportunistic infections. We also offer HIV education and testing programs to incarcerated women, in collaboration with the local health department. Through early intervention with incarcerated women, we hope to provide information on HIV prevention, identify women who are infected and in need of treatment, and identify and treat HIV-infected pregnant women, thereby preventing transmission of HIV to their children.

Case management for HIV infected inmates

Case management is an integral part of connecting inmates to available services concerning HIV and other health needs (4). By definition, the nurse case manager or outreach worker assesses, plans, implements, coordinates, monitors, and evaluates the options and services required to meet each of our patients' health needs, using communication and available resources to promote quality, cost-effective outcomes (5).

We are each responsible for case management at the prisons in our assigned region. Once identified, HIV infected inmates are assigned to an outreach nurse, who then provides that patient with additional education and counseling sessions. Similar to "outreach nurses" in local communities, we assist our patients as they navigate through the bureaucratic maze of HIV/AIDS care in a large and complex system. And, since we are assigned to more than one institution, our ability to follow patients after transfer to a new institution provides continuity of care. If, for example, records are not transferred with the patient, we can provide clinical information on the patient for the medical staff at the patient's new facility.

We are also responsible for reporting each of our HIV cases to the local health department and the Centers for Disease Control. For all newly diagnosed positive cases in North Carolina, we are required by law to ask the patient about the need for partner notification, and to arrange partner notification through the Department of Health and Human Services. Another important aspect of our job is to make referrals to mental health, chaplain, substance abuse, or other services as warranted.

Our role permits us to concentrate on educating the patient, allowing the physician specialist to concentrate on managing the disease. We emphasize the importance of adherence to treatment regimens and management of risky behaviors. We explain disease progression, interventions, and treatment, and we emphasize the importance of follow up with the specialists at the infectious disease clinic. We are responsible for monitoring adherence to medication, discussing side effects, controlling for medication interactions, and following up on laboratory test results. We also give the patient information on opportunistic infections.

The key: The client/caregiver relationship

We believe that our system works because the patients learn to trust the outreach workers. Our contact with the patient begins either at the time the HIV infected patient enters the system, or at the time HIV infection is first identified. Early and frequent contact lays the foundation for a trusting client/caregiver relationship (6)- which is often difficult to achieve with incarcerated patients. This trusting client/caregiver relationship allows the inmate to discuss problems that he or she might not be comfortable addressing with unit medical staff. We see each inmate regularly to discuss medication adherence and treatment compliance. We are also available to manage HIV-related problems when a unit nurse contacts us. After discussing the problem with the nurse, we decide whether we should visit the patient to discuss problems or concerns.

Most of our inmate patients are cooperative with us, and welcome our assistance, even requesting to see us personally when submitting their sick call forms. A few inmates are less receptive to having us participate in their care. Our role in those situations is to be sure to monitor the patient, to review the health care record, and to evaluate the type of symptoms the patient might be reporting to other health unit workers. We will periodically call on the

Continued on page 7

HEPPigram

A feature of HEPP News providing concise solutions to correctional HIV-related problems.

Components of Informed Consent

This information must be given to the subject in language understandable to the subject. No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Federal regulations require that the following information must be provided to each subject involved in research [Federal Policy §___116(a)].

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

The regulations further provide that the following additional information be provided to subjects, where appropriate [Federal Policy §___116(b)]:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. the approximate number of subjects involved in the study.

The complete regulations are available at: http://www.nih.gov/grants/oprr/irb/irb_chapter3.htm#e2. Special considerations for prisoners are available at: http://www.nih.gov/grants/oprr/irb/irb_chapter6ii.htm#g6

Resources / Opportunities

PROGRAMS:

StadtRelease: A Program for Post Release Adherence and Community Resources. The goal of the StadtRelease program is to directly provide, as well as to coordinate, access to resources for incarcerated and recently released HIV positive individuals to maintain health care and drug therapies during transition from prison to the free world.

Contact: Kimberly Betty, Stadtlanders Pharmacy/Corrections Division:
phone: 800.833.2510 x31458

Local Population/Area Epidemiologic Research on Drug Abuse-NIDA:

Sponsored by: DHHS, NIH, NIDA

Deadline: October 1, November 12, February 1, 2000, and March 12, 2000

This program announcement encourages research on the local population/area epidemiol-

ogy of drug abuse and its correlates and consequences.

Contact: Peter Hartsock
phone: 301.443.6720,
e-mail: ph45z@nih.gov or visit
www.nih.gov/grants/guide/pa-files/PA-95-059.html

WEB RESOURCES:

HEPP News Website:
www.hivcorrections.org

Adult AIDS Clinical Trials Group (AACTG):
<http://aactg.s-3.com/links.htm>

National Institute on Allergy and Infectious Disease (NIAID): <http://www.niaid.nih.gov/>

American Foundation for AIDS Research:
<http://www.amfar.org/>

Community Programs for Community Research on AIDS (CPCRA): <http://www.cpcra.org/>

HIV Network for Prevention Trials (HIVNET):
<http://www.niaid.nih.gov/daids/hivnet.htm>

AIDS Clinical Trial Information Service
<http://www.actis.org/>

HIVline: The Clinician's Educational Resource:
www.HIVline.com

NURSING RELATED WEBSITES:

Virginia Henderson International Nursing Library
<http://www.stti.iupui.edu/library/>

Association of Nurses in AIDS Care
<http://www.anacnet.org/>

News Flashes

Update on Prisoners in 1998

Over the past eight years, the prison population has grown 4.8%, according to the recently released Bureau of Justice Statistics Report, "Prisoners in 1998." The expansion rate for the women prisoner population was 40 percent higher than the rate for men (6.5% and 4.7%, respectively). The full report is available at <http://www.ojp.usdoj.gov/bjs/abstract/p98.htm>.

Access and Cost: Prison Health Care

HEPP editor Frederick L. Altice, MD was author of a recently published analysis of state and federal policies affecting correctional care (Pollack, H.A., Khoshnood, K, and Altice, FL. Health Care Delivery Strategies for Supervised Offenders. (Lead Article) *Journal of Health Care Finance*, 1999; 26(1), pp. 1-17. [in press]). According to the article, major problems of correctional care include a growing correctional population, increasingly complex clinical care due to HIV and other diseases, and the unexpected impact of certain Medicaid policy choices in recent years. The authors argue for collaboration between correctional health care providers, Medicaid managed care, and law enforcement in

efforts to address inherent health care delivery problems and develop comprehensive solutions.

New Correctional Health Care Newsletter

Despite the abundance of information available regarding HIV treatment, there are few resources that are specifically targeted toward providers who work in the correctional environment. One year ago, HEPP News was created to respond to the HIV specialists' critical need for information on HIV management in the correctional setting. Now we are pleased to introduce a second resource, *HIV Inside*, a new quarterly publication also accredited through Brown University. While HEPP News serves the needs of the correctional HIV specialist, *HIV Inside* was designed to provide a broader perspective on HIV management issues to all correctional professionals, including physicians, physician assistants, nurses, social workers, dentists, and administrative personnel. See sign up box at the end of this issue.

Update from our last issue on Hepatitis C

Two recent journal articles highlighted the prevalence of HCV in the US (Alter M,

Kruszon-Moran D, et al. *NEJM* 8/19/99; Vol. 341, No. 8, P. 556;) and recent treatment options (Koff R. *JAMA* 8/11/99; Vol. 282, No. 6, P. 511). Hepatitis C (HCV), hepatitis B (HBV), and co-infections with HBV and hepatitis D (HDV) account for approximately 90 percent of chronic viral hepatitis cases in the United States. Treatment of HBV with interferon alfa-2b was shown to be both effective and economical, while a new treatment option, lamivudine (3TC), was well-tolerated for chronic HBV infection when taken for a year. Meanwhile, the only effective treatment for HDV is high-dose interferon alfa, and sustained responses are not common. Treatment options for HCV were discussed in the last issue of HEPP News (see archives at www.hivcorrections.org).

Report from the HIV Cost and Services Utilization Study (HCSUS)

The June 30, 1999 issue of *JAMA* features an update from HCSUS, showing that access to HIV care has improved over the past three years, but has remained suboptimal for Blacks, Latinos, women, the uninsured and the Medicaid-insured. *JAMA*. 1999 June 23/30; 281:2305-2315.

HIV Case Management In Corrections:

Continued from page 5

patient to make sure they are aware of our services. This tactic seems to make the patient aware that we are concerned about their health needs, encouraging them to engage in care.

Discharge Planning

As inmates prepare for release, outreach nurses make arrangements for follow-up with resources in the community. Upon notification of discharge, we prepare a package of basic HIV material and a brief resource directory that directs inmates to resources needed for medical care within the community. We also initiate the paperwork for drug assistance approval through the North Carolina AIDS Drug Assistance Program, and we make contact with the clinics to which the patient will be discharged. It is NCDOP policy to provide patients with up to thirty days of medications upon release. We make every effort to find housing for the patients when needed. We have the support of the NCDOP and DHHS, as both organizations recognize that connecting the patient with community resources upon release are an important issue to the incarcerated population.

Upon discharge, we provide the patients with the following:

- A contract to sign that releases his/her medical data, including laboratory test results
- Phone numbers of resources in the community
- Information emphasizing prevention methods to reduce the likelihood of transmitting HIV infection within their community.

Even with our best efforts, some of our patients are lost to follow up after returning to the community - often because there are few resources available in the communities to which they are returning.

At the current time, the NCDOP does not follow up with inmates once they are released from the system. Since discharge planning and follow-up have been identified as a major concern for our patient population, a task force is being developed consisting of public health and correctional personnel. It is the goal of this committee to develop a collaborative process with community-based organizations which will address our patients' needs at the time of release, and improve the continuity of care.

Providing a resource for NCDOP staff

One of our newest roles at the NCDOP is to keep health care and correctional staff informed of new developments in the treatment and management of HIV and AIDS. We are able to stay updated through involvement in state, regional, and national HIV groups as well as county HIV task forces and AIDS Services Organizations. Our participation with these groups helps to provide valuable feedback to the community concerning the issues inmates face upon discharge.

Our administration recognizes the important role of the nursing staff on the health care team. As a result, we have become an integral part of the system-wide HIV education and training programs. We provide accurate, current and continuous information to the officers, and seek out opportunities for dialog. We are now involved in a new initiative to provide basic education on HIV to all correctional officers within the system. The communication links between correctional officers and staff enhance our ability to fulfill our many roles as problem solvers, facilitators, advocates, and educators.

Conclusion

Primary and preventive health care and education for the incarcerated population not only benefits the inmate; it benefits the community where they will eventually be released. We are in the forefront of innovative nursing because we bring the "third partner," the correctional officer, to the table. By including the trusting client/caregiver relationship established in our Outreach program, we create a team that brings the best HIV care possible to infected inmates.

REFERENCES:

- (1) General Assembly of North Carolina Extra Session 1994 House Bill 211.
- (2) Personal communication. Barbara Pohlman, MD, MPH: Director of the NCDOP Health Services/Medical Director.
- (3) Hammett, Theodore T. Public Health/Corrections Collaborations: Prevention and Treatment of HIV/AIDS, STDs, and TB. National Institute of Justice/Centers for Disease Control and Prevention. 1998.
- (4) Kirton CA, Ferri RS, Eleftherakis V. Primary care and case management of persons with HIV/AIDS [Review]. *Nurse Clinics of North America*. 1999 March; 34(1): 71-94.
- (5) Kongstvedt, P.R. "The Managed Health Care Handbook" Third Edition, p. 274.
- (6) Thompson AS, et al. Evaluation of an innovative program to address the health and social service needs of drug-using women with or at risk for HIV infection. *Journal of Community Health*. 1998 December; 23(6): 419-40.

HIV 101

Flow Sheet for the Management of the HIV Infected Patient

Name: _____ DOB: _____
 HIV Dx/Date: _____ HIV risk(s): _____ Allergies: _____

Clinical Data

Date							
Weight							
CD4 / (%)							
Viral Load							
WBC							
Hb/HCT							
PLT							
SGOT/AST							
SGPT/ALT							
AlkPhos							
Bili							
Amylase							
Lipase							
Triglycerides							
Cholesterol							

Antiretroviral Therapy

Date:							

Health Maintenance

PPD/date: _____ RPR/date: _____ PAP/date: _____
 _____ CXR/date: _____
 Toxo/date: _____
 Hep Screen date/results: A ___ / ___ B ___ / ___ C ___ / ___

Immunizations

Pneumovax: _____
 Hep A: _____
 Hep B: _____
 Influenza (yearly): _____
 Other: _____

Prophylaxis

PCP _____
 MAI _____
 Other _____

Consults

Ophthalmology: _____
 Other: _____

Problem List

Opportunistic Illnesses	Date	Other	Date

Hospitalizations

Date/dx	Date/dx

Critical Information

National Clinician's PEP Hotline: 888.448.4911
 National HIV Telephone Consultation Service: 800.933.3413
 HIV/AIDS Treatment Information Service website: www.hivatis.com
 HEPP News website: www.hivcorrections.org

Flow Sheet Developed By:

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 e-mail: heppnews@brown.edu
 fax: 401.863.1243

Spotlight on the North Carolina Department of Prisons

The territory of the NCDOP ranges from the sandy beaches of the Atlantic Ocean to the rocky Blue Ridge Mountains. The state's 81 prisons house 32,000 inmates (average daily census) and accommodate 20,000 new admissions each year. HIV-infected patients are neither isolated nor segregated, although patients who have more complicated management issues are housed in proximity to clinics staffed by HIV-experienced physicians.

HIV testing is voluntary, upon inmate request, when clinically indicated, or in the event of a bloodborne pathogen exposure with a consent form required prior to testing. Education about testing is provided at intake. As has been described for other states with voluntary testing (1, 2) the number of inmates known to be infected with HIV (identified using voluntary testing or self-report) is less than the total number of inmates who are believed to be infected.

On any given day in 1998, the NCDOP averaged 534 known HIV-infected inmates in the system.(3) The literature estimates that as

many as 40 to 50% of patients with HIV infection remain unidentified, on par with figures that have been described for other states (see Spotlight on the New York Department of Corrections, HEPP News, May 1999). Of those 530 or so inmates that have HIV infection, on average 36% (190) had CDC-defined AIDS, 64% (334) had HIV, 12% (64) were female, 86% (459) were between 24-44 years of age, and 84% (448) were African American. According to Barbara Pohlman, MD MPH, Health Services Director/Medical Director, the outreach nurse program (described in this issue) is a critical component of HIV management in the NCDOP. She reports that the HIV treatment program incorporates the most important precepts of correctional health care: good medical practice, good for the health of inmates, good for public health, and fiscally responsible.

HIV speciality care is provided under contract with four private HIV specialists and, for a few of the facilities, by contracting HIV specialists from the University of North Carolina at Chapel Hill. The HIV specialists work with the outreach

nurse to design treatment regimens and monitor the progression of HIV disease. All approved medications for HIV-therapy are currently on the formulary. HIV infected inmates have had access to HAART since 1998, consequently, AIDS deaths in the NCDOP have followed national trends (4). Inmates have also had access to clinical trials at selected facilities. The trial protocols are scrutinized by the UNC human studies committees and by NC DOP authorities for adherence to guidelines set out by the FDA and the Belmont Committee Report (see Dr. Wohl's article on page 1).

REFERENCES:

- 1) De Groot, AS, Hammet TM. Barriers to care of HIV-infected inmates: a public health concern. *AIDS Reader*, May/ June 1996; 78-87.
- 2) NYS DOC Spotlight, HEPP News, May 1999; 2(5).
- 3) Personal Communication. Barbara Pohlman, Medical Director at NCDOP, and Maruschack, L. HIV in Prisons and Jails, Bureau of Justice Statistics, 1999. <http://www.ojp.usdoj.gov/bjs/>
- 4) MMWR 1999 Jan 8; 47 (51&52): 1115-7.

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- Yes, I would like to sign up the following colleague to receive a complimentary subscription of HEPPNews fax newsletter.
- Yes, I would like to order the following back issues (please include volume/issue/date).
- Yes, I would like my HEPP News to be delivered as an attached PDF file in an e-mail (rather than have a fax).

NAME: _____

TITLE: _____ E-MAIL ADDRESS: _____

FACILITY: _____ (Optional) # of Inmates: _____

ADDRESS: _____

FAX: _____ PHONE: _____

SIGNATURE: _____ DATE: _____

Subscribe to *HIV Inside*

A new quarterly newsletter addressing HIV-management issues specific to correctional care.

If you are interested in receiving this free publication, please fill out the form below. In addition to receiving *HIV Inside*, this contact information will be entered into an HIV-management database, allowing additional education materials to be forwarded.

Name _____

Title _____

Agency/Facility _____

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City _____ State _____ Zip _____

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Fax back to Brendan Maney at World Health CME at 212.481.8534

Self-Assessment Test for Continuing Medical Education Credit

Brown University School of Medicine designates this educational activity for 1 hour in category 1 credit toward the AMA Physician's Recognition Award. To be eligible for CME credit, answer the questions below by circling the letter next to the correct answer to each of the questions. A minimum of 70% of the questions must be answered correctly. This activity is eligible for CME credit through October 15, 1999. The estimated time for completion of this activity is one hour and there is no fee for participation in this activity.

True or False:

1. ___ With the exception of the Belmont report, all codes and commission reports require that coercion, constraint, duress, or elements of force be absent when a subject agrees to participate in a study.
2. ___ Prisoners should not be selected for research when other, less vulnerable and burdened populations can address the scientific question being addressed.
3. ___ Ethicists agree that prisoners should be denied the opportunity to volunteer for human subject research.
4. Research considered appropriate for prisoner participation DOES NOT include:
 - a) studies of criminal behavior
 - b) prison life
 - c) conditions affecting prisoners as a class
 - d) phase I and II treatment trials
 - e) all of the above
5. Studies about nurse HIV case management have shown that
 - a) service integration is an essential part of the health care program
 - b) skilled nurse case managers ensure better HIV care in the correctional setting
 - c) nurse HIV case managers decrease the need for HIV medical specialists
 - d) trusting caregiver/client relationships are easier to achieve in the correctional setting
 - e) all of the above
 - f) a, b

6. The main components of a successful HIV nurse case management program DOES NOT include:
 - a) discharge planning
 - b) a trusting client/caregiver relationship
 - c) integrated service programs
 - d) equal numbers of HIV medical specialists and nurse case managers
 - e) any of the above

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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:

	educational value	clarity
main article	5 4 3 2 1	5 4 3 2 1
secondary article	5 4 3 2 1	5 4 3 2 1
HEPPigram	5 4 3 2 1	5 4 3 2 1
updates	5 4 3 2 1	5 4 3 2 1
save the date	5 4 3 2 1	5 4 3 2 1

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

3. What future topics should HEPP News address?

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

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