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Maine AIDS Care

AIDS Consultation Service Maine Medical Center

Fall 1994

HIV in Women

Brief Overview

The most recent AIDS statistics have put the epidemic into chilling perspective. HIV infection is now the second leading cause of death in young men in the United States. HIV is the 3rd leading cause of mortality in young minority women, more deadly than suicide and homicide.

In the second decade of the AIDS epidemic the new cases of AIDS reported in 1992 among women have increased 9.8%, compared to 2.5% for men. For the first time, more women were infected through sexual contact than I.V. drug use.

The greatest growth in new cases has been among minority women, who make up 19,544 of the 36,690 cases of AIDS reported through June 1993. Only cancer and heart disease outrank HIV infection in mortality of young black women, whereas AIDS is the ninth leading cause of death in white women.

Newest CDC data confirms that the epidemic is spreading most rapidly among teens, especially girls. In 1993, 15% of U.S. cases of AIDS were women. Maine statistics for June 1994 show that 8% of recently reported AIDS cases were women.

Diagnosis of HIV in Women

The natural history of HIV disease is similar in men and women. A primary HIV syndrome ("flu-like", "mono-like") may occur within 1-2 months of infection, to be followed by an asymptomatic phase that usually persists for years. As in men, early symptoms of immune decline may include dermatologic disease (worsening seborrheic dermatitis, psoriasis, warts, shingles, etc.) and, later on, thrush. In addition, women with HIV may develop chronic or recurrent monilial vaginitis. Herpes genitalis and pelvic inflammatory disease may become protracted and

difficult to treat. Unlike men, Kaposi's sarcoma, however, has rarely been reported in women.

To diagnose HIV in women, physicians should include a sexual history as part of their medical evaluation, be alert to HIV-related symptoms, and be able to facilitate HIV testing when appropriate.

Management of HIV Disease in Women

Although most studies of HIV disease and its treatment were based on men, recent work suggests a similar disease course and treatment response in men and women. One very important observation in women with HIV is the increased incidence of cervical dysplasia and carcinoma. Up to 50% of women with HIV disease may have cervical dysplasia, with the highest rates occurring in women with lower CD4 counts. PAP tests are recommended on an every 6 month basis in women with later stages of HIV. Although the sensitivity of PAP tests for dysplasia in women with HIV has been questioned, a report at the recent Yokohama International Conference showed similar sensitivity of colposcopy and PAP screening. However, when PAP tests are abnormal, colposcopy should be done to further evaluate the condition, and may be necessary for subsequent follow-up. Despite the high evidence of dysplasia, invasive cervical carcinoma is rare.

Prevention

Routine examination offers an important opportunity for discussion of sexually transmitted diseases and their prevention. The value of barrier contraceptives and topical spermicides in the prevention of herpes, chlamydia, and HIV should be reinforced in women who are at risk.

Mother to Child Transmission of HIV Decreased by AZT Treatment

Transmission of HIV infection from an HIV infected woman to her child may occur in utero, during delivery, or during postpartum breast feeding. Previous studies have revealed a range of transmission risk (10% to 40%), with the highest risk occurring in women with late stage HIV disease, or in developing countries.

The results of a new study (ACTG 076) of the effect of AZT on vertical transmission of HIV were recently released. This study demonstrated a 2/3 reduction in mother to child transmission of HIV in the AZT treated cohort. This study included women 14 - 34 weeks pregnant who had not previously been treated with AZT. The protocol involved AZT treatment of the mother (500mg/d) until labor, then initiation of IV AZT (2mg/kg) until childbirth. Following this, infants were treated with AZT for 6 weeks. No adverse effects of this regimen were noted in pregnant women or in their babies, with the exception of a transient anemia.

As a result of this study, the FDA approved the use of AZT in HIV positive pregnant women. Additionally, the U.S. Public Health Service issued guidelines (see insert) that incorporate the uncertainties regarding the effectiveness of these treatments when women have later disease, prior history of AZT use, or later stage pregnancy.

*ACS Treatment
Information Hotline
(800)871-2701*

Summary of National Trials Specific To Women

Natural History Trials

A large scale study of the natural history of HIV disease in women, funded by the federal Centers for Disease Control and Prevention in Atlanta, and called the HIV Epidemiology Research Study (HERS), is being conducted at 4 sites across the country. Now in its first year of accepting patients, the 5 year study is enrolling a diverse group of 200 HIV-positive women and 100 high-risk women at each site. Most of the HIV-positive women will be asymptomatic and have CD4 counts above 200.

A companion study, called the Women's Interagency HIV Study (WIHS), is being sponsored by the National Institute of Allergy and Infectious Diseases in Bethesda, MD. Like HERS, WIHS will focus on identifying clinical signs of HIV in women.

Both studies will try to identify factors that affect the progression of the disease in women. They will focus on gynecological issues, but also measure survival, psycho-social issues, access to health care, and quality of life.

Other Significant Studies:

Begun in 1990 the Heterosexual AIDS Transmission Study (HATS), has investigated risk factors tied to heterosexual transmission of HIV in women, particularly the unexplained higher risk among female cocaine users.

Preliminary analysis has shown that female cocaine users have similar knowledge and behaviors toward HIV as non-cocaine users. The difference is that cocaine users have more sexual partners and more cases of other co-existing STDs.

An NIAID-supported study is comparing women's diagnosis and survival compared to men's. Findings indicate that women whose infections are detected early survive as long as men and respond to treatment similar to men.

Two studies within the AIDS Clinical Trials Group are looking at incidence of cervical dysplasia in women. The focus of one of the studies is comparing vaginal 5 Fluorouracil (5-FU) therapy to standard therapy for preventing recurrence of cervical dysplasia.

The Women and Infants Transmission Study (WITS), begun in

1989, continues to look at the natural history of HIV in pregnant women. A second study on women and infants is underway at the University of Medicine and Dentistry in New Jersey, and includes the effects of illegal drugs on pregnancies in HIV- positive women.

Two early clinical trials sponsored by NIAID are enrolling women of childbearing age for two experimental vaccines. A third candidate vaccine trial is planned for pregnant women this fall.

News Briefs from Yokohama

In addition to the new information on the benefits of AZT use in seropositive pregnant women, the following observations from the 10th International Conference on AIDS may be of particular interest to clinicians:

1. Acyclovir appears to have a role as adjunctive therapy in HIV disease.

Replication of Herpes viruses (HSV, CMV, EBV, etc.) may activate co-existing HIV infection. Therefore, acyclovir, which inhibits replication of some herpes viruses, might be expected to have an indirect impact on HIV disease in these patients. Previous studies have suggested that the adjunctive use of high dose acyclovir (3-4 g/day) with AZT improves CD4 cell counts and/or survival in HIV infected persons. The results of the Multicenter AIDS Cohort Trial were presented in Japan. This large observational study demonstrated a survival benefit in patients receiving daily acyclovir (600-800 mg/day) in addition of AZT. The benefit was not limited to patients with a history of active herpes infections, though the vast majority of patients in this study were likely to be infected with HSV or CMV. The benefit of acyclovir was most apparent in patients with lower CD4 counts or AIDS defining illness. Although these studies are not conclusive, many clinicians are now adding acyclovir (600-800 mg/d) to other treatment regimens in HIV infected patients with later stages of disease.

2. New Measures of Viral Load (PCR for HIV RNA, branched DNA tests) Have Predictive Value in Determining the Course of HIV.

Evidence continues to mount that measures of viral load may predict the clinical course of HIV. New sensitive techniques that measure viral DNA or RNA in serum or peripheral blood cells may prove useful in determining responses to anti-retroviral agents, allowing clinicians to monitor course and adjust therapy. Although these techniques are not in routine use, preliminary studies suggest that they may play a major role in the near future.

3. Combinations of Antiretroviral Therapy Show Promise.

Although the results of several large trials of combination anti-retroviral therapy are not yet available, combination regimens continue to show promise in pilot studies.

The addition of protease inhibitors, which prevent viral assembly in HIV-infected cells, may be beneficial, particularly when used in combination with reverse transcriptase inhibitors. Several protease inhibitors are now entering phase III trials.

4. Oral Gancyclovir Effective for Prevention of and Suppression of CMV Retinitis and Gastrointestinal mucosal Disease.

Although not yet released by the FDA, oral gancyclovir may prevent 50% of cases of CMV retinitis, and can be effective in long term treatment of CMV retinitis.

In Memory....

Karen Kalustian M.D.

10/02/53 - 09/29/94

Dr. Kalustian, 40, died of a cerebral aneurysm on Sept. 29, 1994. A graduate of Hampshire College, and University of Mass. Medical School, she completed her residency in the Dartmouth-Maine Family Practice Program where she served as chief resident.

She established a practice as a family physician in Augusta and Gardiner, Maine. During her 8 years in practice, Dr. Kalustian became well known throughout Maine for her skill and commitment to the care of persons with HIV infection. In addition to her superb abilities in comprehensive patient care, she distinguished herself as an educator of health care providers and of the community. She was very active in shaping informed public policy with regard to the care of persons with HIV. A memorial fund has been established in her name to benefit community projects. Contributions may be made to Karen S. Kalustian Memorial Fund, 44 Blaisdell St., Augusta, Me 04330.

Active Treatment Arm of ACTG 076

Prepartum (mother)	Zidovudine 100 mg po 5x day
Labor/Delivery (mother)	Zidovudine IV loading dose 2 mg/kg; continuous infusion 1 mg/kg/hour
Postpartum (infant)	Zidovudine syrup 2 mg/kg po 4x day for 6 weeks.

Management of GYN Infections in HIV+ Women

Reference Used: The Sanford Guide to HIV/AIDS Therapy July 1993-1994

Problem	Treatment
<p><u>Vulvovaginal Candidiasis / Yeast Infection:</u> May be the 1st symptom of HIV infection in women, 1/3 of women with HIV develop chronic genital yeast infections. Causes severe itching & burning, odor, and "cheesy" discharge.</p>	<p><u>Topical (Vaginal):</u> a. Miconazole nitrate 200 mg vag. tabs (1qd hs x 3 days) or 2% cream (5gm) qd hs x7 days b. Clotrimazole 100 mg vag. tabs(2 qd hs x 3 days) or 1% cream (5 gm) qd hs x 7 days</p> <p><u>Oral</u> a. Fluconazole 150 mg p.o. qd. x3 days (<i>Not an FDA-approved indication</i>) b. Itraconazole 200 mg p.o. qd. x3 days (<i>Not an FDA-approved indication</i>)</p> <p><u>Suppressive Therapy</u> Fluconazole 50 mg po 3x/week or 200 mg po 1x/week is under study.</p>
<p><u>Human Papillomavirus (HPV)</u> Associated with the development of anogenital warts which may cause obstruction, abnormal pap smears, warts on the cervix, and possibly cancer-causing tissue growth; strongly associated with genital dysplasia. Cervical warts should not be treated until results of pap smear are known; avoid treating pregnant women.</p>	<p>Podofilox or 25% podophyllin in tincture of benzoin applied topically (apply weekly x4) Alternatives: cryotherapy with liquid nitrogen, electrocautery. Pap smears (q 6 months) Colposcopy with cervical biopsy if pap is abnormal.</p>
<p><u>Pelvic Inflammatory Disease (PID)</u> Possibly caused by sexually transmitted organisms and though to be associated with chlamydia, with pelvic inflammation of the upper genital tract; also common are collections of pus in the fallopian tube or ovary. More common and more serious in women with HIV.</p>	<p><u>Outpatient</u> (temp <38, WBC <11,000, minimal evidence of peritonitis, active bowel sounds, qd p.o. intake): a. <u>Ceftriaxone</u> 250 mg IM single dose plus doxycycline 100 mg bid po x14 days b. <u>Cefoxitin</u> 2.0 gm IM single dose plus probenecid 1.0 gm. concurrently plus doxycycline c. <u>Ofloxacin</u> 400 mg po bid plus metronidazole (500 mg bid) or clindamycin (450 mg q6h) for 14 days.</p> <p><u>Hospitalized</u> a. <u>Cefoxitin</u> 2.0 gm q 6h IV plus doxycycline 0.1 gm IV q 12 hr. x min. 4 days and afebrile x48 hrs. b. <u>Clindamycin</u> 900 mg q. 8 hr. IV plus gentamicin (same time frame). Follow with oral agent doxycycline) to complete 14 days.</p>
<p><u>Herpes Simplex Virus (HSV)</u> Chronic lesions on vulvar or vaginal walls</p>	<p><u>Mucocutaneous:</u> Acyclovir 200 mg po 5x/day x10 days</p> <p><u>Suppression:</u> Acyclovir 400 mg p.o. bid indefinitely.</p>

Summary of Clinical Situations and Recommendations for Use of Zidovudine (AZT) to Reduce Perinatal HIV Transmission

Per U.S. Department of Health & Human Services. Recommendations of the U.S. Public Health Service Task Force on the use of zidovudine to reduce perinatal transmission of human immunodeficiency virus. Morbidity and Mortality Weekly Report 43 (RR-1) August 5, 1994.

See Reverse Side for Protocol

Clinical Situation	Recommendation (See Reverse Side for ACTG Protocol 076)
Pregnant HIV-infected women with CD4+ T-lymphocyte counts \geq 200 who are at 14 - 34 weeks of gestation and who have no clinical indications for ZDV and no history of extensive (>6 months) prior antiretroviral therapy. (This represents the group studied in ACTG Protocol 076)	The health care provider should recommend the full ACTG Protocol 076 regimen to all HIV-infected pregnant women in this category. This recommendation should be presented to the pregnant woman in the context of a risk-benefit discussion: a reduced risk of transmission can be expected, but the long-term adverse consequences of the regimen are not known. The decision about this regimen should be made by the woman after discussion with her health care provider.
Pregnant HIV-infected women who are at >34 weeks of gestation, who have no history of extensive (>6 months) prior antiretroviral therapy, and who do not require ZDV for their own health.	The health care provider should recommend the full ACTG Protocol 076 regimen in the context of a risk-benefit discussion with the pregnant woman. The woman should be informed that ZDV therapy may be less effective than that observed in the ACTG Protocol 076, because the regimen is being initiated in the third trimester.
Pregnant HIV-infected women with CD4+ T-lymphocyte counts <200 who are at 14 - 34 weeks of gestation, who have clinical indications for ZDV, and who have no history of extensive (>6 months) prior antiretroviral therapy.	The health care provider should recommend initiation of antenatal ZDV therapy to the woman for her own health benefit. The intrapartum and neonatal components of the ACTG Protocol 076 regimen should be recommended until further information becomes available. This recommendation should be presented in the context of a risk benefit discussion with the pregnant woman.
Pregnant HIV-infected women who have a history of extensive (>6 months) ZDV therapy and/or other antiretroviral therapy before pregnancy.	Because data are insufficient to extrapolate the potential efficacy of the ACTG Protocol 076 regimen for this population of women, the health care provider should consider recommending the ACTG Protocol 076 regimen on a case-by-case basis after a discussion of the risks and benefits with the pregnant woman. Issues to be discussed include her clinical and immunologic stability on ZDV therapy, the likelihood she is infected with a ZDV-resistant HIV strain and, if relevant, the reasons for her current use of an alternative antiretroviral agent (e.g., lack of response to or intolerance of ZDV therapy). Consultation with experts in HIV infection may be warranted. The health care provider should make the ACTG Protocol 076 regimen available to the woman. Although its effectiveness may vary depending on her clinical status.
Pregnant HIV-infected women who have not received antepartum antiretroviral therapy and who are in labor.	For women with HIV infection who are in labor and who have not received the antepartum regimen component of the ACTG Protocol 076 regimen (either because of lack of prenatal care or because they did not wish to receive antepartum therapy), the health care provider should discuss the benefits and potential risks of the intrapartum and neonatal components of the ACTG Protocol 076 regimen and offer ZDV therapy when the clinical situation permits.
Infants who are born to HIV-infected women who have received no intrapartum ZDV therapy.	If the clinical situation permits and if ZDV therapy can be initiated within 24 hours of birth, the health care provider should offer the ACTG Protocol 076 postpartum component of 6 weeks of neonatal ZDV therapy for the infant in the context of a risk-benefit discussion with the mother. Data from animal prophylaxis studies indicate that, if ZDV is administered, therapy should be initiated as soon as possible (within hours) after delivery. If therapy cannot begin until the infant is >24 hours of age and the mother did not receive therapy during labor, no data supports offering therapy to the infant.

The Patient's Perspective



I tested positive for HIV in April of 1992. I received the news one afternoon, when I was home alone. What I heard was a death sentence. I was going to die. I am a nurse and had a basic knowledge about HIV. That knowledge went right out the window and I lived in a world of pure emotions; mostly fear and panic. I never dreamed that I would really test positive, after all I only was tested to humor someone else. I wasn't aware of any other women who had HIV. I basically viewed it as a "gay mans disease". I certainly couldn't tell anyone. I had seen and read the news stories about families who had been burned out of their houses and people who had lost their jobs, families and friends. What if that happened to me? What would people think? Does this mean that I am bad? Our society has placed an inordinate judgmental burden on people living with HIV. You have to have done something wrong to get this virus. If I had become infected because of a blood transfusion or as a consequence of being raped, then I am viewed as a poor innocent victim. However, if I acquired this virus as a result of unprotected sex or the use of IV drugs, then I am a "bad girl", and the implication is that I deserved it. I've heard numerous stories from other women who were misdiagnosed or undiagnosed because their physician thought that they couldn't possibly have HIV - they were "nice girls".

The burden and stress of living with such a huge secret finally outweighed my fears. I started to think about how I could disclose and to whom. I needed support. Could I get it and still protect myself, both physically and emotionally? I was lucky. I only lost my job and a few friends. I eventually decided to speak publicly. As a result I receive anonymous phone calls and letters telling me to move out of my neighborhood; they don't want "my kind" here.

It was very difficult for me to look to the various AIDS service organizations for help and support. I viewed them as being places that were set up for men and was very suspicious of their ability to be open to dealing with a woman. I eventually joined a support group for women and over time met about 10 other women from my area. My support group became very important to

me. It is a group of women who have experienced loss and yet still have hope. Many of them have been in this place before me and are able to tolerate my restlessness, my terror, my despair, my rage. It is a place where I can experience feelings that would be burdensome for others. Yet it is a double edged sword; for each person that I meet who can understand and support me is also someone whom I may watch get sick and die. And that's happened many times. There are many more women, (over 40), who live in my area that are HIV positive, who live in fear and are unable to go to a support group. Many do not feel safe enough to receive AIDS related mail or newsletters at their homes. They are afraid for their jobs, that their children may be ostracized, that their families will place blame, or for their physical safety. Having lived with my own secret for a limited period of time, I know how difficult that is.

Because I am an information oriented person and have access to a medical center library, I am constantly looking for information on Women and HIV. At first, I didn't find much. Most of the medical information was based on studies that were done on men. Women seemed to be either ignored or viewed as vessels or vectors of this virus. If it was acknowledged that women got HIV, why weren't there any studies about women? There was information about women transmitting it to their babies, but very little about women themselves. All of the drug studies were done on men. How does anyone know how my hormone levels may or may not react with these drugs. Does the different fat content of my body have any effect? Is my reproductive system affected by HIV? If so, how? It scares me and makes me very angry about how little is known. It wasn't until last year that the first large natural history study was started on women and the CDC changed it's definition of AIDS to include a women specific indicator. The uncertainty of living with this virus is like carrying a 20 lb bag of garbage on your shoulder and not knowing when it's going to break. I have enough to think about and to deal with, without wondering or worrying what's different about me because I'm a woman.

The decision to find regular medical care was huge. Everyone makes mistakes and no one knows everything; secretaries make typos, businesses make bad investments - but this is my life. Would I die an early death because I was not competent enough to discern and judge the incompetency of my doctor? It was over 6 months after my diagnosis before I went to a doctor, (after I finally found one who knew something about HIV and who would see me). My primary physician is my consultant. I respect his opinion and judgement and usually do take his advice to heart, but in the end it's my body; I have to "run the show". However I find myself in the position of having to educate other physicians. I resent the fact that I need to remind my GYN physician that I need to see her every 6 months for a pap smear or that she assumes because of my HIV status that I'm not sexually active and don't need birth control. It's not my job to stay informed enough so that I can inform her. I'm lucky because I have access to information that most women don't so that I can stay informed; and I have the skills to speak up, to question, and to talk back.

What do I need from a physician? I need your **educated professional** advice, not your personal judgments. What I need is personal medical care, not just medicine.

If you have any questions regarding Women & HIV or other HIV Management Issues, call the AIDS Consultation Service Information Hotline Monday - Friday 9:00am - 4:00pm at (800)871-2701.

World AIDS Cases	2,500,000*
US AIDS Cases	361,509
US AIDS Deaths	220,871
Total US cases and deaths reported through 12/31/93	

HIV & Women in the U.S.	
AIDS: 36,690	HIV : 80,000-140,000
Median Age for AIDS: 30-34	
Percentage of U.S. AIDS Cases: 15%	

Maine AIDS Cases	530
Maine AIDS Deaths	279
Total Maine cases and deaths reported through 06/30/94	

*Estimated

Educational Sessions

October 16, 1994	"Women's Health Care Issues Across the Life Span" Sponsored by USM at the Ramada Inn, Port.
October 19-21, 1994	"Care and Management of the HIV/AIDS Patient: A Course for Primary Care Providers" Sponsored by the New England AIDS education and Training Center, University of Mass. Medical Center
October 24, 1994	"HIV Disease - Nursing Implications" St. Josephs College
October 26, 1994	"Primary Care Management of HIV" Univ. of Me. Orono
October 27, 1994	"HIV Update" Wentworth Douglas Hospital, Dover, N.H.
November 1, 1994	"Yokohama Update" Mercy Hospital - ANAC Meeting
November 2, 1994	"Community, Advocacy, & Family Connections: Contemporary Practice with HIV/AIDS" Sponsored by USM & ACS at the Holiday Inn by the Bay, Portland.
November 14, 1994	"HIV Update" PenBay Medical Center, Rockport Me.
November 28, 1994	"Psychosocial Issues & HIV" at University of New England
November 30, 1994	"HIV Update" The AIDS Project, Portland, Maine
December 11, 1994	"Women and HIV" location TBA, Bangor Maine
January 19, 1995	"Outpatient Management of HIV" Grand Rounds, Mid Maine Medical Ctr, Waterville, Me.
February 15, 1995	"Outpatient Management of HIV" Grand Rounds, Franklin Mem. Hosp., Farmington, Me.

For more information regarding the above educational sessions, please call the ACS at 871-2099.

If you are providing an HIV/AIDS related Educational Session, please let us know at (800)871-2701.

Maine Medical Center
AIDS Consultation Service
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