

## PITT MEN'S STUDY

### NEWS AND NOTES

Fall 1989

(412) 624-2008

#### AZT HELPFUL TO PEOPLE WITH ARC

Zidovudine (AZT) significantly slows progression of HIV infection when given to persons with early AIDS-related complex (ARC) and asymptomatic HIV infected people according to results from a placebo-controlled, multicenter clinical trial supported by the National Institute of Allergy and Infectious Diseases in collaboration with Burroughs Wellcome Company.

"For the first time, the benefits of anti-retroviral treatment for patients with early symptomatic HIV infection have been clearly shown," Dr. Fauci, NIAID Director said. "In this study, significantly fewer persons receiving zidovudine progressed to advanced ARC or AIDS. This finding could extend treatment to an estimated one to two hundred thousand persons with early symptoms of HIV infection. It also emphasizes how critical it is that persons at risk for HIV infection be tested and seek prompt medical care."

The randomized, double-blind trial was coordinated by Margaret Fischl, M.D., University of Miami. It included 713 HIV-infected persons having T4 cell levels

between 200 and 800/mm<sup>3</sup> and one or two HIV-associated symptoms, such as oral thrush, chronic rash, or intermittent diarrhea. Participants received either placebo or 200 milligrams of zidovudine every 4 hours (1200 milligrams per day) over a period of 3 to 20 months. Fewer than 5 percent of the participants experienced serious side effects.

As of July 1989, 50 of the 713 participants had progressed to advanced ARC or AIDS. Of these, 36 participants were in the placebo arm of the study, whereas only 14 were in the zidovudine arm. The benefit of zidovudine was demonstrated only in those participants who had T4 cell counts between 200 and 500 when they entered the study.

"This study clearly shows that early intervention is important in HIV infection and that zidovudine is well tolerated in persons with early ARC," Dr. Fischl said.

Food and Drug Administration Commissioner Frank E. Young, M.D., Ph.D., said, "The FDA will work closely with the NIAID and Burroughs Wellcome Company to translate these important results into wider availability of zidovudine to this category of symptomatic HIV-infected persons."

## United States Senate

WASHINGTON, DC 20510

July 14, 1989

Dear MAC Study Volunteer:

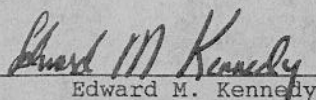
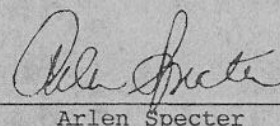
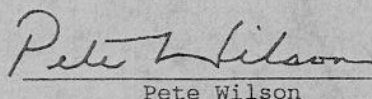
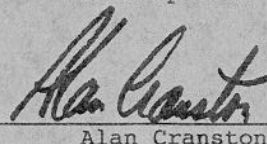
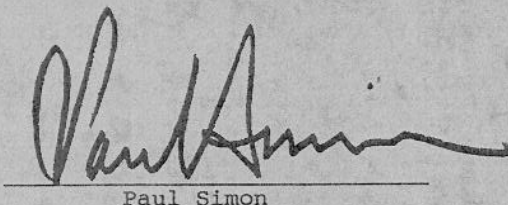
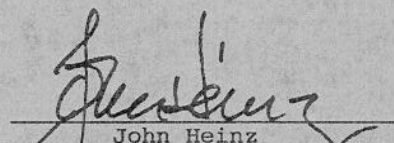
We are writing to express our gratitude and support to you for your continuing efforts as a volunteer in the Multicenter AIDS Cohort (MAC) Study. With its sites in Baltimore, Chicago, Los Angeles, and Pittsburgh, the MAC Study has been a leader in the national effort to understand the natural history of HIV infection among gay and bisexual men.

The battlegrounds in the war against AIDS are located not only in the hardpressed communities across this land but in laboratories throughout the country. Although we are saddened by the toll this disease is taking on friends and fellow citizens, we must continue to marshal our best efforts to the continuing challenges that AIDS presents.

Your commitment to the MAC study is helping to provide extremely valuable information. Because of your willingness to give of yourself, we are all moving closer to a world without AIDS. And in this long battle, the real un-sung heroes are people like you --- with the dedication and generosity to continue to do all that is humanly possible to put an end to this epidemic.

Thank you for volunteering for the study and for your continued active participation. You are part of a noble army of caring people who will, in the end, restore health to our nation.

Sincerely,

  
Edward M. Kennedy  
Arlen Specter  
Pete Wilson  
Alan Cranston  
Paul Simon  
John Heinz  
Barbara A. Mikulski



### THE MYTH OF AN END TO HIV INFECTION AMONG GAY MEN

Studies which describe HIV risk reduction behavioral changes among gay men have been misinterpreted to support arguments that gay men are no longer being infected with HIV.

This misinterpretation rests on two false assumptions. The first is that changes among gay men who are members of studies reflect behavior changes among all gay men. This is false because people who join studies like the Pitt Men's Study are different from people who do not. They are usually more health conscious, more "out," more highly motivated, better informed about AIDS, and better educated. In addition, these men have access to educational programs that other men do not have.

The second assumption is that the reduction in infection among the men in these studies is somehow acceptable. To say that a 1%-2% new infection rate per year is a dramatic decrease may be accurate but it means that in 10 years there may be an additional 10%-20% of men in studies who are infected. Such an increase is unacceptable from a public health point of view. Approximately 2% of the Pitt Men's Study population is becoming infected each year. When added to the men in our study who were infected when they joined, we can expect about 50% of our men to be infected in the next fifteen years if the present rate of infection continues.

The myth that continued HIV infection is ending among gay men is dangerous to our health. First, it leads to a feeling of complacency. The fact remains, engaging in anal intercourse and other unsafe behaviors now is more likely to result in HIV infection than ever before. This is because more men are infected now and the chances of choosing an infected partner are, therefore, increased. Second, the myth serves as a rationale to those officials and politicians who do not want to support the funding of HIV prevention education targeted to gay men.

We do not know what behavior changes have occurred outside of study groups. Since HIV continues to be transmitted at unacceptable rates within study groups, it would appear that gay men outside of such studies are transmitting HIV at least at the same or higher rates than before. The need for prevention education among gay men is more important now than ever before.

### AEROSOLIZED PENTAMIDINE APPROVED TO PREVENT ONSET OF PNEUMOCYSTIS CARINII PNEUMONIA

Using unpublished data from the Pitt Men's Study and other Multi-Center AIDS Cohort Study (MACS) sites, the FDA in a highly unusual move recently approved the use of aerosolized pentamidine for people with HIV infection who have a T-helper cell count at or below 200 or who have a history of *Pneumocystis carinii* pneumonia (PCP). In an interview with *PI Perspective*, a publication of Project Inform, Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases (NIAID), said that the current analysis of national MACS data confirms the belief that people face the most serious risk of PCP when their T4 cell count falls below 200, whether or not they have had PCP before, and whether or not they have other HIV-related symptoms. Since PCP is the leading cause of death among people with AIDS, effective prevention will have very beneficial effects on the health of people infected with HIV and people with AIDS.

The FDA's announcement is expected to lead to increased use of aerosolized pentamidine as a preventative measure even among asymptomatic HIV infected people.

The ability to prevent pneumonia from developing among such people gives great weight to the Pitt Men's Study Community Advisory Board's recommendation that people at risk should be tested for HIV and those testing positive should be regularly monitored by a health care professional.

- f. "I haven't had sex in four years. Being unsafe just one time won't hurt."

## AIDS IS STILL GAY IN PENNSYLVANIA

Gay and bisexual men still constitute the great majority of people diagnosed with AIDS in Pennsylvania. About four out of five newly diagnosed cases of AIDS are among gay and bisexual men. The much publicized shift to IV drug users and heterosexuals is, in fact, a very small shift except perhaps in New York and northern New Jersey. The following table describes Pennsylvania AIDS cases by the risk group of the person with AIDS:

PENNSYLVANIA AIDS CASES (June, 1989)			
	Alleg.	Phil.	PA
<u>By Risk</u>			
Gay	75%	72%	66%
Gay/IVDA	4%	9%	7%
IVDA	6%	11%	14%
Blood	8%	1%	5%
Heterosexual	2%	3%	4%
Other	5%	4%	4%
TOTALS	100%	100%	100%

## PITT TREATMENT EVALUATION UNIT

The Pitt Treatment Evaluation Unit (PTEU) is one of 45 nationally-funded AIDS Clinical Trial Groups (ACTG). The goal of the ACTG program is to find and evaluate

drugs for the treatment of AIDS and other conditions caused by the human immunodeficiency virus (HIV).

The following PTEU studies are open for enrollment. For more information about eligibility criteria, please call (412) 647-8125 or 8123. All calls are confidential.

1. Ampligen (038) - This 36-week study aims to determine the most effective and tolerable dose of Ampligen in persons who are HIV positive but asymptomatic or who have early-stage ARC. The study will also determine the effect of different doses of Ampligen on virological and immunological parameters. Volunteers must come in twice a week for intravenous infusions.
2. Interleukin 2 and AZT (067) - This 26-week study is evaluating the safety and tolerance of these two drugs, as well as their interaction, in persons who are symptomatic with HIV. A five-day hospitalization is required.
3. Pharmacokinetic Studies (033, 037) - Studies are underway to evaluate the interaction between high and low doses of the antibiotic Bactrim and AZT. These studies are open to HIV infected persons who are asymptomatic, persons with ARC and persons with AIDS. The studies will determine whether the tolerance or effectiveness of these drugs is altered when they are administered in combination. Participation requires several overnight hospitalizations.
4. Treatment for prevention of PCP (021, 081) - These studies are designed to evaluate the effectiveness of treatments to prevent Pneumocystis carinii pneumonia (PCP) in patients who are receiving AZT. These studies are open to persons with AIDS who have already had PCP or persons with advanced HIV infection who have not had PCP.
5. Comparison of ddI and AZT (116, 117) - These studies compare the effectiveness and tolerance of ddI and AZT in individuals who have symptomatic HIV



infection. Protocol 116 is for individuals who have been receiving AZT for less than twelve months, and protocol 117 is for individuals who have been on AZT therapy for twelve months or longer.

6. Evaluation of ddI in AZT intolerant individuals (118) - This study compares the effectiveness and tolerance of two doses of ddI in individuals who are symptomatic with HIV and are intolerant to AZT.
7. Combination study of CD8+ cells and interleukin-2 with AZT (080) - This is a study to determine the effects of increasing the number of CD8+ cells in persons who are symptomatic with HIV. Interleukin-2 and AZT will also be administered in this study which requires a five day hospital stay and several outpatient visits for intravenous therapy.

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### PERSAD CENTER ESTABLISHES NEW FAMILY PROGRAM

Responding to the many requests for services from families, Persad Center has developed, over the past several months, new therapy and support programs. These services include individual counseling and separate therapy groups for the loved-ones of persons with AIDS, for parents and friends of lesbian and gay persons, and for wives of gay and bisexual men.

All groups meet on a weekly basis and are facilitated by Mary Beth Rauch, M.Ed. Ms. Rauch has worked with families for the past fifteen years and is a member of the American Association for Marriage and Family Therapists, the American Association for Counseling and Development, the American School Counselors Association, and the Association for Specialists in Group Work.

Persad Center is a mental health agency licensed by the Commonwealth of Pennsylvania that specializes in services for sexual minorities (primarily lesbian and gay persons). Since 1982, the agency has provided support services for all persons affected by AIDS. Persad also provides lectures and trainings on sexual minority and AIDS-related topics for professional and non-professional groups.

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### NEWS AND NOTES



*Our clinic seems to be a farm team for the Tuesday Night Bowling League. Ric Witt, our head clinician and Paula Somerville were members of the 1st place team, "Club Members" and the second place team*

*"Kumba" respectively.*

*Tony Silvestre, our Director of Community Programs, met with Governor Casey and his staff members to discuss needed AIDS programs in Pennsylvania. Kerry Stoner, Executive Director of the Pittsburgh AIDS Task Force and member of our Community Advisory Board and five leaders from community-based groups in Philadelphia were also invited.*

*Cindy Sutton is the new System's Analyst for the Neuropsychiatric Study. In addition to maintaining the standards of excellence established by Dean, she brings her own special skills in information processing to the position.*

*Kathleen Aleva began work as a Research Associate in the NP Study at the beginning of August, coming to us from a similar position in the Department of Neurology. She has a varied background, having had a number of jobs around the country and the world as she*

Vince, Tony, Mario and Jolie (Joey for short). She loves to read, recently finishing the latest mystery by Lillian Jackson Braun about a feline sleuth. And after spending a week sailing down the Potomac, she is fast becoming a "sailing addict."

She finds work with the study very satisfying. "I can't think of a more important issue to be working with. The staff and the volunteers are joys to work with."



#### **Joseph Carra, Project Coordinator of the Neuropsychological Study**

Being raised on the grounds of a children's home in upstate New York where his dad was executive director, Joe developed a life-long interest in the helping professions. This interest continued through his undergraduate education at Brown University and at SUNY at Buffalo where he graduated magna cum laude in psychology. Joe received his M.S. degree in clinical psychology from the University of Pittsburgh in 1985. While at Pitt he received two NIMH training grants and has published in a number of journals.

Joe was drawn to research when he unexpectedly developed an interest in computers, statistics and the scientific method while pursuing his studies. His interest in the helping professions and his affinity to research served him well in his work on a research project which examined neuropsychologic recovery among people receiving liver transplants. Looking for more opportunity to interact with people, Joe joined the Pitt Men's Study staff in January 1989. At the study, he performs psychological evaluations, attends to administrative responsibilities and works closely with Dr. Becker and NP staff around issues of data management and analysis.

He finds his work with our volunteers most rewarding. "This may sound corny, but

I am continually astounded by the strength and courage of our volunteers. Some men show their strength by patiently dealing with the suffering that each new symptom or illness brings and others show it by refusing to let their diagnosis dominate their lives. I am always being asked about AIDS and our study when I am out socially and I never fail to comment on the courage of our volunteers."

Joe, who moved from Oakland to Murrysville two years ago, has adopted Pittsburgh as his home. "I like Pittsburgh's big small-town atmosphere and I couldn't be working with a better bunch of staff and volunteers."

When not at the computer or in the clinic, Joe spends his free time fishing, listening to classical music or racing his Honda CRX at autocrosses in the area.

#### **CONFERENCE ON LESBIAN AND GAY YOUTH**

A coalition of social service agencies and organizations is presenting a professional conference about lesbian and gay youth which will be held at the University of Pittsburgh on Saturday, October 28, 1989 from 9:00am to 4:00pm.

The conference will consist of keynote addresses by James Huggins, Ph.D., ACSW, Associate Director of Persad Center, Inc., and Stefan Wade, Director of SMYAL (Sexual Minority Youth Assistance League) of Washington, D.C., and ten workshops related to both professional settings and issues affecting lesbian and gay youth. The conference is oriented to professionals in educational, medical, mental health, church/synagogue, and residential settings.

Additional workshops will deal with drug and alcohol abuse, legal issues, youth at risk (including suicidal youths), parents and families of lesbian and gay youth, and HIV infection and other sexually-transmitted diseases. The fee for the conference is \$10.00.



Recent studies show lesbian and gay youth are at a higher risk than heterosexual youth in four areas: teen suicide, alcohol and drug addiction, family break-up and abuse, and HIV infection. The majority of lesbian and gay youth will first seek help with their issues within their local educational, medical, mental health, and religious settings. This conference is being planned to help these young people and professionals in these settings.

Co-sponsors for this event include Dignity/Pittsburgh, Persad Center, Pitt Men's Study, and the Gay and Lesbian Community Center of Pittsburgh.

For a brochure or for more information, write Dr. James Huggins, Persad Center, 5100 Penn Avenue, Pittsburgh, PA 15224 or call Dr. Huggins at 441-0857 or Sister Marguerite Kropinak at 441-2302.

were more likely to report physical symptoms of depression such as sleep problems and lower energy levels but not emotional or mood symptoms like feelings of discouragement or sadness.

In another study of mood, NP investigators examined the relationship between depression and symptoms of lymphadenopathy and oral thrush. Interestingly, they found that volunteers who believed that they had these symptoms tended to be depressed even though they may have not have actually been suffering from these problems. This finding emphasizes the value of careful monitoring of health by competent professionals familiar with HIV infection.

## NEUROPSYCHIATRIC SUBSTUDY UPDATE

A major finding to emerge from the national study is that seropositive men without AIDS symptoms do not perform more poorly on neuropsychological tests than do seronegative men. This contradicts previous studies which suggested that cognitive abnormalities tend to appear before the onset of AIDS. The large number of participants in the MACS and the rigor with which the research is pursued support the validity of our results. The results of this study will be published in an upcoming edition of the journal Neurology.

Also, analyses have been completed on questionnaire information about anxiety and depression obtained from volunteers in Pittsburgh and Baltimore. It was discovered that men with suppressed immune systems

## WORLD AIDS DAY

**December 1, 1989, is World AIDS Day. The Pitt Men's Study is planning to hold its annual memorial service on November 30, 1989, for men in our study and others who have died of AIDS. Watch your mail for more details.**

## GONORRHEA IN ALLEGHENY COUNTY

The good news is the number of gonorrhea cases in Allegheny County has dramatically decreased since 1984. The bad news is that the decrease seems to have leveled off. The following chart describes gonorrhea rates since 1984.

Area	Number of Cases by Year				
	1984	1985	1986	1987	1988
Allegheny County	3,947	3,931	3,372	2,636	2,684
Philadelphia	18,700	17,345	16,430	19,854	22,976
PA (excluding Philadelphia and Allegheny County)	8,072	8,703	7,676	7,698	6,617
<b>TOTAL</b>	<b>30,719</b>	<b>29,979</b>	<b>27,478</b>	<b>30,188</b>	<b>32,277</b>

These numbers suggest that Allegheny County residents and other Pennsylvanians outside Philadelphia have decreased behaviors that could lead to infection. It is clear, however, that substantial numbers of people are still engaging in activities that promote transmission.

Fewer than one hundred cases of syphilis are reported from Allegheny County each year. With so few cases it is difficult to draw conclusions concerning year to year fluctuations of syphilis.

NEWS AND NOTES is published by the Pitt Men's Study. All information and opinions are the sole responsibility of the Study and do not necessarily reflect the policies or views of the National Institutes of Health.

