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AIDS ACTION NEWS!

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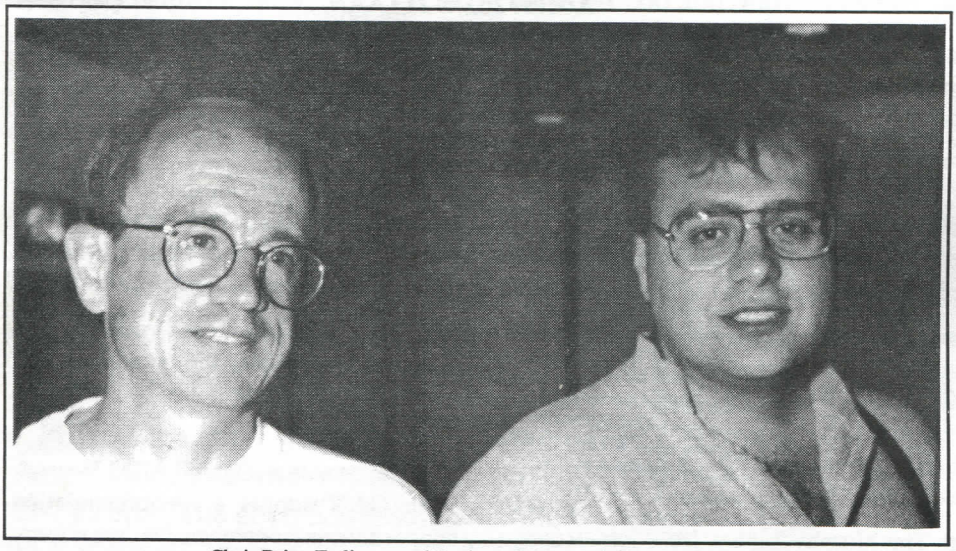
Issue 19 Fall 93

HIGHLIGHTS FROM THE 10 TH INTERNATIONAL AIDS CONFERENCE

BERLIN, JUNE 6-11, 1993.



Chair Brian Farlinger and Doriano Calvano of CRIT in Berlin

PATHOGENESIS

Our knowledge of how HIV progresses is slowly increasing. CD8 cells are important in controlling HIV replication in early disease. Following acute infection, HIV infects CD4 cells and macrophages in the lymph nodes. HIV strains evolve over time, becoming more virulent and replicating faster. The length of the asymptomatic period depends on how well CD8 cells control the non-cytopathic strain.

There are two types of T helper cells: TH1 and TH2. The TH1 response weakens after infection and TH2 response dominates, repressing the ability of CD8 cells to control HIV. It is theorized that IL-10 which is produced by TH2 may be the mechanism for this suppression. CD8 activity can be increased by TH1 production of IL-2 and IL-12. In vitro, adding IL-2 can switch back the response to dominant TH1 cells. Another approach might be to suppress the cytokines produced by TH1, ie, IL4 and IL-10. Drug companies are keen to develop an anti-IL-10 agent for a "home run " in the fight against AIDS.

Manipulating cytokines is not simple and is very risky. Given that AIDS is a multi-factorial, multi-phasic and overlapping process this is not likely to be a single agent success.

Cytokine imbalance is also thought to be key to the development of Kaposi's Sarcoma (KS). Basic fibroblast growth factor is the most important inflammatory cytokine which is believed to set off KS. Cytokines may also be helpful in therapy. For example IL-2 is reported anecdotally to enhance immune competence. Cytokines should be monitored more closely in patients. It is quite possible that they may serve as surrogate markers in future trials.

Gallo indicated that the feasibility of immunosuppression in early or intermediate disease should be determined since the harmful activation of the immune system occurs in the latent phase. He noted that a few HIV positive transplant patients who were given cyclosporine A did better than transplant patients who did not receive it. This concept of blocking the activation of the immune system should be studied further. At the same time, therapy should be

(Continued on page 12)

IN THIS ISSUE

AIDS ACTIONS!

AIDS ACTION NOW! ACTIVITIES IN RECENT MONTHS

Summary of advocacy and radical actions taken by AAN! over the last couple of months.

May 31 • AAN! attends a HOOD (HIV Ontario Observational Database) committee meeting. Funds are released so that work can begin on this project.

June 16 • AAN! attends a meeting with Glaxo to review the status of their Phase II/III trials of 3TC. Despite our request, the compassionate arms of these trials will not be opened until OCTOBER.

June 17 • AAN! attends a meeting of the Toronto Clinical Trials Group. Dr. Brian Conway outlines his work on viral load and resistance studies and Dr. Bill Cameron outlines some proposed clinical trials being considered by the Ontario division of the Canadian Trials Network.

June 23 • AAN! attends an OACHA (Ontario Advisory Committee on HIV and AIDS) meeting. The definition of AIDS and insurance issues are discussed.

June 27 • Tens of thousands of people staged a die-in on the streets of downtown Toronto as part of the annual Lesbian and Gay Pride Day march. The die-in, organized by AAN! symbolized the people who have died, not simply due to a terrible disease, but because of government neglect and inaction.(see pictures on page 8,9)

July 7 • AAN! meets with Tim Murphy, Liberal MPP for St. George/St. David to discuss the Ontario drug reform proposal and viatical companies.

July 8 • AAN! writes to Ruth Grier urging her to introduce viral burden and drug resistance tests crucial to monitoring and planning individuals' treatment regimens.

July 12 • AAN! writes to Floyd Laughren outlining some of the problems people with HIV have in their dealings with the insurance industry. These include screening out gay male applicants for life insurance, problems obtaining living benefits, discriminatory exclusions and caps on HIV-related costs, and discrimination in the administration of insurance plans (see Peter Amenta's article on page 5)

July 13 • AAN! hosts an information session on the Berlin conference (see report on page 1)

July 19 • The AIDS Programme Committee, co-chaired by AAN!'s Tim McCaskell, meets to develop draft criteria for funding requests. This committee has $1.2 million per year to disburse on AIDS projects.

July 29 • AAN! represents people with HIV and AIDS at Minister Ruth Grier's press conference announcing the opening of the Wellesley ambulatory services facility.

August 4 • AAN! writes to Prime Minister Kim Campbell urging her to intervene in the Simon Thwaites case to have the government's appeal dropped. Simon Thwaites was dismissed from the Armed forces in 1989 because of his HIV status. He took immediate legal action and finally received judgment in his favour in June of 1993.

August 7 • AAN! spokesperson Glen Brown speaks at a demonstration for Prisoners' Justice Day, sponsored by PASAN, Prisoners with AIDS Support Action Network.

AUGUST 20 AND 21 • AAN!, with CATIE and Vancouver PWA Society, sponsors a workshop on AIDS research priorities in Toronto.

August 25 • The insurance working group established in response to our letter of July 12 holds its first meeting.

Sept. 9 • AAN! attends a consultation meeting to discuss a proposal to improve services to HIV positive women through Women's College and Sick Children's Hospitals.

Sept. 9 • AAN!'s Tim McCaskell attends a meeting with the AIDS Program Committee, the committee that distributes money given to the province by Burroughs Wellcome from AZT sales.

Sept. 10 - 12 • AAN! attends an Ontario AIDS Network meeting. The OAN adopts a recommendation supporting our position on comprehensive drug reform.

Sept. 15 • AAN! attends Partner's meeting of From All Walk Of Life, and insisted that fund raising decisions such as coroprate sponsorship, be more democratic and accountable in the future .

Sept. 22 • AAN!'s Tim McCaskell AAN! attends an OACHA (Ontario Advisory Committee on HIV and AIDS) meeting.

Sept. 30 • A reponse to the Province's Drug Program proposal is written and circulated.

Oct. 6 • Glen Brown presents and Brian Farlinger accepts on behalf of James Thatcher, the Builder of The Year Award from the Advocacy Resource Centre for the Handicapped.

Oct. 7 • AAN! meets with Liberal Health critic Barbara Sullivan.

Oct. 10 • AAN! mounts a demonstration in front of the Primrose Club where Jean Chrétien is speaker.

Oct 12 • AAN! organizes a public forum for Simon Thwaites on HIV discrimination in the military.

Oct 14 • AAN! mounts a noon demonstration in front of the David McDonald's campaign office where Kim Campbell was speaker.

AIDS TREATMENT IN TORONTO ARE WE UP TO SCRATCH?

Toronto is thought to provide some of the best AIDS care in North America but a recent study by AIDS ACTION NOW! and the Community Research Initiative Toronto (CRIT) indicates that many people living with AIDS and HIV may not be receiving basic standards of treatment.

In 1989 CRIT established an observational data base which now collects treatment information on more than 700 HIV+ patients through their primary care physicians office. When activist researchers reviewed a sample of these cases there were some alarming results.

PCP

PCP (pneumonia) is a major danger for people with less than 200 T cells. The good news is that PCP is almost completely preventable with the use of prophylaxis. The bad news is that according to the data bases, 30% of those with T cell counts between 100 and 200 appear not to be doing any PCP prophylaxis. Of those with less than 100 T cells, 9% are not taking precautions to prevent this serious illness.

A second concern is what prophylaxis people are using. Septra is clearly the most effective prevention for PCP and US studies show that 90% of people can either tolerate it, or if they have a reaction, can be made to tolerate it, through desensitization. Yet in Toronto only approximately half of those with T cells below 200 are using septra. The data base shows no evidence of doctors desensitizing patients who have problems with this drug.

Anti-virals

Many people are not taking anti-virals, (26% of those with less than 100 T cells, 11% of those between 100 and 200, and 24% of those between 200 and 500). Given concerns about weak benefits and serious side effects from existing anti-virals these figures may reflect informed choice.

Of those under 500 who take anti-virals, AZT is still most popular (58%). Only 17% use combination therapies, in spite of increasing evidence that combinations of available anti-virals (AZT plus DDI, or DDC) are more effective than any one agent alone.

Of those who still have more than 500 T cells only 22% take anti-virals. While American studies have shown benefit for such early treatment, the recent European Concorde study disputes these findings. In Canada anti-virals continue to be labelled for use by those with under 500 T cells, which clearly discourages such early use. A 1992 AAN! survey found that half of Toronto HIV physicians would not prescribe anti-virals to those with more than 500 T cells, a situation that seriously restricts the options for many people with HIV.

A final concern flagged by the study is an apparent failure of physicians to order important tests. While there is still debate on the usefulness of newer tests such as P24 antigen and antibody, beta 2 microglobulin and neoptrin, significant numbers of HIV+ patients in some groups appeared not to have been given even standard tests for syphilis,(55%), hepatitis B, (36%), TB, (25%), or toxoplasmosis, (21%), all enormously dangerous infections for people with depressed immune systems.

A data base is only as good as the information that is stored there. Do the results of this study indicate a failure to provide basic treatment and testing, or simply a failure to properly report treatments and tests provided? The only people to know for sure are people living with AIDS and HIV. If you have doubts about the level of care you are receiving you should consult AAN!'s AIDS and HIV Management Goals which describes appropriate tests, treatment options and prophylaxis for different T cell levels. If your doctor is not providing these then it's time you sat down and found out why.

For the full 18 page report Living with AIDS: An Analysis of Treatment Standards and Practices in Toronto or a copy of AIDS and HIV Management Goals contact CRIT at 324-9505. CRIT can also advise you in how to enrol in its observational data base and make your data work for the whole community.

AIDS, WHAT'S IN A NAME

by Tim McCaskel

Last January the Centres for Disease Control in the US established a new definition of AIDS.

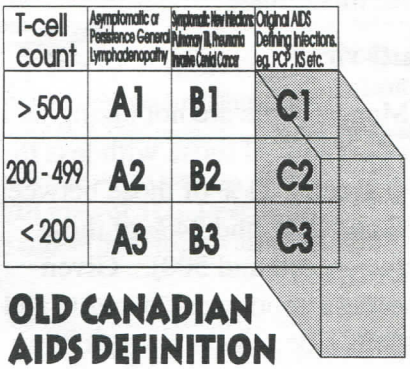
The old definition of AIDS was a list of opportunistic infections like KS, PCP etc in the presence of HIV. That meant that people who were HIV+ and quite sick, but with the wrong diseases, did not officially have AIDS and could therefore be denied a range of benefits.

The new CDC definition moved to correct this. It not only added a number of new diseases to the list, such as pulmonary TB, pneumonia and cervical cancer, but also included anyone with less than 200 T cells. The new definition increased the number of recognized cases in the US by 75,000, and included many women and IV drug users for the first time.

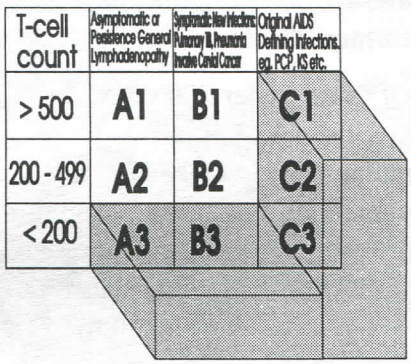
So what about Canada? Typically the government is still discussing what to do and therefore we still operate on the old CDC definition. Somebody quipped, "There's a new cure for AIDS for many American PLWAs. They can just cross the border and presto! they don't have it any more."

There are a number of good reasons to use the same definition of AIDS in the US and Canada:

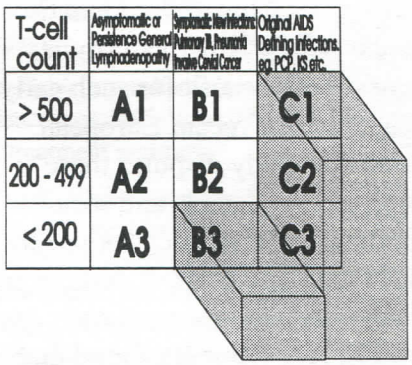
- The expanded definition will make it easier for many Canadian PLWAs to get disability benefits, access to subsidized housing, and other social benefits. With cutbacks in health care and social services, more and more services are likely to be tied to an AIDS diagnosis.
- Medically the 200 T cell level is an important marker. It is the recommended starting point for PCP prophylaxis for instance. An actual AIDS diagnosis will encourage doctors and patients to take serious precautions. Adding a less than 200 T cell count also makes it easier for doctors to diagnose AIDS, and helps avoid many intrusive procedures that are required to search for particular opportunistic infections.



OLD CANADIAN AIDS DEFINITION



NEW US AIDS DEFINITION



NEW CANADIAN AIDS DEFINITION

- In terms of statistics the new definition gives us a more accurate picture of who is seriously immune suppressed. The new definition tends to include more women, children and IV drug users who often don't have the same patterns of illness as gay men. It will also increase the number of recognized AIDS cases in the country, an important argument for more government funding.

With all these good reasons for change why the hold-up?

The decision has to be made by the Federal government in consultation with the provinces. The epidemiologists in the Federal labs say a new definition will mean they have to re-do all their calculations. There is a feeling that a sudden jump in recognized AIDS cases might scare the public. (Who horror of horrors might actually demand that the Feds provide more money for prevention and research.) The provinces are already scared--of having to provide more benefits and services to people affected. Both levels of government have reasons in wanting to minimize the epidemic.

The latest word is talk of a compromise--they'll accept the new diseases but not the under 200 T cell level part of the definition.

Reluctance to accept the new definition is part of a familiar story--governments doing everything they can to downplay the epidemic in order to shirk their responsibilities to PLWAs and the public. It is especially irrational given government policy about harmonizing AIDS research, drug release and treatment between Canada and the US. How are we to "harmonize" policies when we don't even agree on the definition of the disease?

Failure to change will mean that People Living With AIDS will once again get the short end of the stick, and the public will be encouraged to continue to overlook the seriousness of the epidemic. Call your Federal MP and tell her or him that AIDS shouldn't mean one thing in Canada and another south of the border. Better still, go to all candidates meetings during the election and ask the candidates where they stand. We must not allow the government to downplay AIDs by hiding behind a narrow definition of the disease. As usual in this long battle, lives are at stake.

Insurance Issues

AAN! has become aware of issues important to PHAs concerning the insurance industry. To this end, we met with Doug Elliot, a lawyer who deals with a number of cases concerning insurance companies and their policies, so that AAN! could develop a better sense of the wide range of issues involved.

The following outlines some major issues and possible solutions.

1. Living Benefits

The are relatively few insurance companies which provide living benefits, and those that do rarely provide adequate information regarding these benefits. Where the company does provide benefits, they are usually quite miserly with the typical maximum being $25,000.

A possible solution would be to develop regulations for all insurance companies which set out how to apply for living benefits, how life expectancy will be determined, the amounts to be paid out, etc.

2. Viatical Settlements

Because of the limited availability of living benefits, many PHAs resort to selling their policies to viatical companies based in the United States. However, the payouts on these settlements are usually small in comparison to the value of the policy. From what we know to date, viatical companies often engage in high pressure sales tactics, breach confidentiality and are highly intrusive into the lives of people with HIV and AIDS. At present, these companies are not licensed to operate in Ontario but the issue is under review by the government.

A possible position is that viatical companies should be considered for licensing in Ontario only if insurance companies continue to be unwilling to provide decent living benefits. If viatical companies are to be licensed, regulations must be put into place which ensure fair settlements and ethical business practices.

3. **Disability Coverage**

PLWAs have been unlawfully terminated from employment before applying for disability or even after taking disabilities. Often, changes in the company's insurance carrier result in changes to the coverage being provided to a person on disability. In some cases, the benefits are so poor that the person would be better off receiving benefits through the social assistance system but their disability coverage may make them ineligible for social assistance.

Specific rules are needed to govern such situations.

4. Redlining: Screening out Gay Male Applicants

Some insurance companies may be discriminating against gay men by attempting to screen out people based on personal characteristics deemed to be associated with risk of contracting HIV disease (eg. the use of sexual orientation as a factor in underwriting). In some cases, insurance is refused or offered at excessive rates to people in certain localities or occupations believed to attract a disproportionate number of gay men.

The legislation should make perfectly clear that it is an unfair business practice to ask an applicant questions concerning sexual orientation or to use sexual orientation as a basis for determining risk or premiums.

5. Discriminatory Exclusions and Caps on HIV-related Costs

Insurance companies ae obilgated to apply the same standards and procedures for ascertaining risk for all who apply for insurance and for determining which medical procedures are covered under a given policy. Unfortunately, this is not always the case for people with HIV. It is difficult for a person seeking to challenge a discriminatory cap or exclusion to prevail in an legal action based on traditional anti-discrimination statutes.

Specific statutory protection in Ontario may be required to ensure that employers and insurers treat HIV-related issues as they treat other illnesses.

6. Small Companies and AIDS Service Organizations

AIDS service organizations who employ people with HIV and AIDS as a matter of policy have difficulties in obtaining life, disability and health insurance at reasonable cost.

If the private sector is unwilling or unable to serve such groups, it may be necessary for government to fill the gap.

7. Discrimination in the Administration of Insurance Plans

Insurance companies have attempted unfairly to use the "pre-existing condition" and "material misrepresentation" clauses to avoid paying for legitimate medical expenses for the treatment of HIV-related illnesses. The only recourse is to pursue legal action. Unfortunately, people with AIDS often do not have the financial means, are too sick or lack the knowledge to pursue their rights.

Ontario should consider enacting specific regulations dealing with insurer abuse of pre-existing condition clauses, as some states in the United States have done.

AAN! has written a letter to the Minister of Finance (the Minister responsible for changing the Insurance Act) outlining some of our concerns and requesting a meeting to discuss possible solutions. In addition we have met with Tim Murphy, M.P.P., to discuss these issues.

An advisory committee has been struck by the AIDS Bureau of the Ministry of Health to look at such issues with a view to making recommendations to government on the changes required to the Act. AAN!'s contacts on the committee will ensure that our concerns are heard.

AAN! will continue to monitor the issues related to HIV/AIDS and insurance and take whatever action is required to ensure that these issues are addressed. As these issues further unfold, we will keep you informed.

By Peter Amenta

AIDS ACTION NOW

DRUG FUNDING UPDATE

On June 27th tens of thousands participated in a staged 'die in' on the streets of downtown Toronto as part of the annual Lesbian and Gay Pride Day parade. As the entire parade came to a halt, people symbolically died on the street, while others chalked in their outlines to record the loss to our communities due to the government's neglect and inaction. After the 'die-in' everyone jumped up chanting for more government action around AIDS. The 'die-in' was protesting the provincial government's failure to fund treatments needed by people living with HIV/AIDS.

AAN! and many others from communities affected by AIDS have long demanded that the provincial government develop a comprehensive funding program for all AIDS-related treatments. For example, in the spring of 1992 a working group was pulled together by the AIDS Bureau of the Ministry of Health to provide the foundations for such a program. The group, which was composed of a primary care physician, a clinic director, a community activist, and members of the Drug Programs Branch and the AIDS Bureau, produced a draft entitled *Comprehensive Drug Distribution and Payment Policy For Drugs Used in Treatment of HIV and HIV-Related Illnesses*. The policy's goal was to remove the financial barriers that currently prevent equitable access to vital HIV drugs. The basic principle of the proposed policy was that eligibility for drug coverage would be based on diagnosis and clinical need, not on an individual's financial resources. Furthermore, the group recommended that the cost of all drugs used in the treatment of HIV-related illnesses would be covered by the province.

Recently the Ministry of Health responded to activist demands in a discussion paper, *Drug Programs: Framework for Reform*. This document proposes coverage "for 'catastrophic' drug costs for those whose prescription drug costs are very high." This is a major step forward, but there are still many problems with the reform proposals. Firstly, public funding would only be available after individuals living with HIV/AIDS had paid the first $2 000 or 3% of net income, whichever is higher, of their drug costs. This directly contradicts the recommendations set out by the previous working group, which included representatives from the Ministry. Co-payments under any circumstances erect barriers to equitable access of health care, however they are particularly inappropriate for catastrophic illnesses such as AIDS. Catastrophic illnesses are by definition extremely disruptive to a person's previous living situation and, more concretely, create severe financial strains. The added burden of the cost of treatments becomes insurmountable for those in lower income brackets such as youth, single mothers, the unemployed, and those without private insurance. As a result of such a co-payment system those with low incomes would not be able to access vital treatments and would get sick or die from illnesses that could be prevented or delayed.

The proposal for reform also fails to include the costs of many drugs, vitamins, complementary therapies, and nutritional supplements, which are important for maintaining the health of an individual with a compromised immune system, but are not covered under the existing formulary. Again Ministry officials had supported such a reworking of the formulary in the working group in the spring and again they ignored this recommendation in preparing the recent reform proposals. Does the left hand know what the right hand is doing? In failing to address this issue, the Ministry has chosen to ignore the fact that PLWA/HIVs would be paying far more than $2 000 for treatment. How can AIDS-affected communities take the Ministry's claims to being committed to removing financial barriers seriously when such fundamental issues are ignored? The current drug formulary has to be completely revamped in order for a catastrophic drug program to work.

This would involve an immediate expansion of the formulary to include the full range of AIDS-related treatments.

- All licensed treatments must be covered as soon as they receive their notice of compliance.
- Similarly, all HIV/AIDS drugs showing promise of effectiveness and being used in primary care must be included. This means that experimental treatments have to be covered as soon as they are being used.
- The formulary must also include vitamins, nutritional supplements, and other complementary therapies that PLWA/HIVs are taking.
- A specific sub-committee with sufficient expertise to evaluate the effectiveness of new AIDS-related treatments with significant PLWA/HIV and HIV primary care physician representation would be useful in ensuring that the formulary functioned appropriately.
- HIV-affected communities need to call the government on its previous commitment to removing cost barriers.

Sustained pressure from various communities affected by AIDS has finally placed catastrophic funding on the agenda. But we need to keep up the pressure over the next few months so that we win the kind of policy PLWA/HIVs really need.

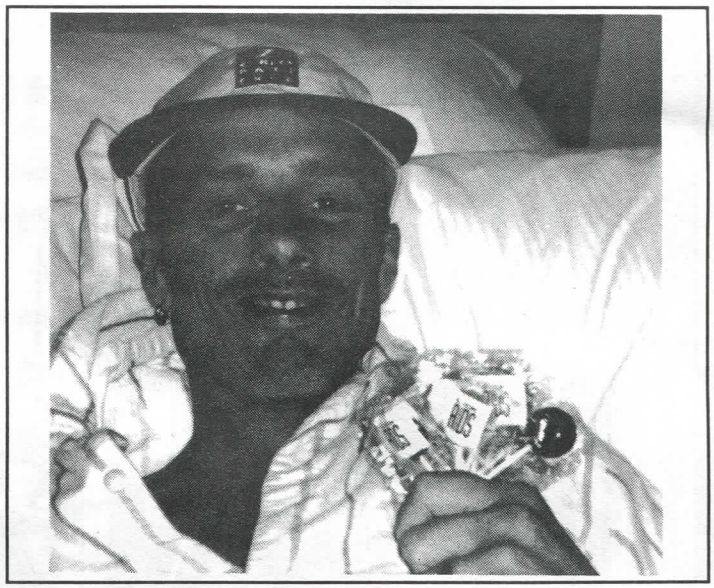
ANNUAL GENERAL MEETING

519 CHURCH STREET
COMMUNITY CENTRE
TUESDAY, NOV. 16 1993 8:00 P.M.

ALL WELCOME

AIDS ACTION NOW!

Paul Meagher



Paul Meagher died at his home on July 31, 1993 from AIDS. Paul had been active with AIDS Action NOW! since 1989 and became a member of Steering Committee in November 1992. As a member of AAN!'s Provincial Committee, Paul worked on the implementation process for the Advocacy legislation trying to ensure that the concerns of PLWA/HIVs were adequately represented.

Through the years, Paul was active with a number of community-based AIDS organizations. He volunteered with Casey House when it was first getting set up, he worked on Treatment Update at the Community AIDS Treatment Information Exchange (CATIE), and he served as co-chair of the Board at the Toronto People With AIDS Foundation.

Paul was one of the first staff members of the Provincial AIDS Hotline and as a Toronto Department of Public Health nurse, he worked at Hassle Free Clinic.

Paul spoke many times about the urgency for a cure for AIDS. He advocated for the rights of PLWA/HIVs and fought hard against discrimination and homophobia. His work made a difference for all of us and was a major contribution towards improving the quality of life for PLWA/HIVs.

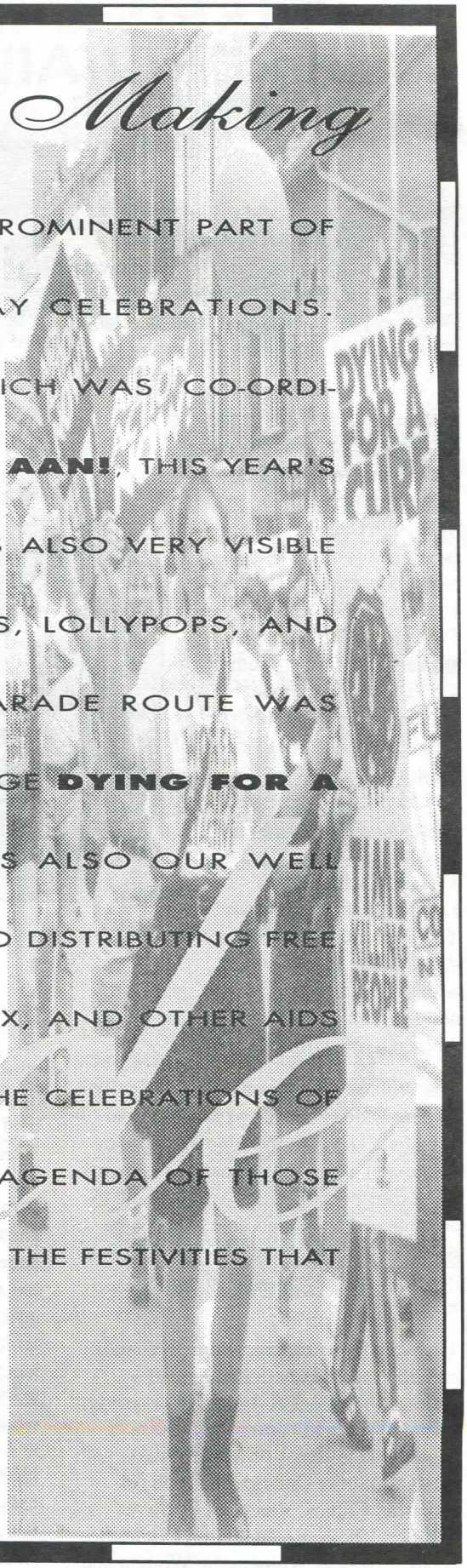
He is sadly missed by lover Alan Cornwall, his family, many friends and fellow AIDS Activists.

Paul requested that donations in his memory be sent to AAN! and/or CATIE, both at 517 College St, Ste 324, Toronto, Ontario M6G 1A8.

pride

HISTORY IN THE *Making*

AIDS ACTION NOW! WAS A VITAL AND PROMINENT PART OF THIS YEAR'S LESBIAN AND GAY PRIDE DAY CELEBRATIONS. APART FROM THE VERY EFFECTIVE DIE IN WHICH WAS CO-ORDINATED FOR THE SECOND YEAR IN A ROW BY **AAN!**, THIS YEAR'S THEME KILLING TIME = KILLING PEOPLE WAS ALSO VERY VISIBLE THROUGH THE USE OF PLACARDS, STICKERS, LOLLYPOPS, AND OTHER ASSORTED PARAPHERNALIA. THE PARADE ROUTE WAS LITTERED WITH PEOPLE CARRYING THE MESSAGE **DYING FOR A CURE.** AS IN OTHER YEARS, THERE WAS ALSO OUR WELL STAFFED **AAN!** BOOTH SELLING T-SHIRTS, AND DISTRIBUTING FREE INFORMATION AND BROCHURES ON SAFE SEX, AND OTHER AIDS AND HIV INFORMATION. **AAN'S!** ROLE IN THE CELEBRATIONS OF PRIDE DAY IS TO HIGHLIGHT THE POLITICAL AGENDA OF THOSE LIVING WITH HIV AS WELL AS PARTICIPATING IN THE FESTIVITIES THAT ONLY LESBIAN AND GAY PRIDE DAY CAN OFFER.



Report on AIDS Action Now!'s Women and HIV/AIDS Policy Discussion

Statistically Significant Enrollment of Women in Clinical Trials Urged

by Darien Taylor

On June 22, 1993, Linda Gardner and Darien Taylor led AIDS Action Now!'s monthly policy discussion. The topic was women with HIV/AIDS, and how AIDS Action Now! will position itself in relation to emerging AIDS issues of concern to women.

Darien and Linda reviewed AIDS Action Now!'s past work in this area. Through the Women's Caucus, we have always had a very strong presence at International Women's Day, producing brochures, stickers and T-shirts with strong messages about women living with HIV/AIDS, and our needs for more and better treatments, services and research. "This AIDS Brochure Is About Women", which Mary Louise Adams and Darien Taylor produced through AAN! some years ago was actually the first brochure to specifically and substantially address the needs of women living with HIV/AIDS.

The Women's Caucus has had difficulty finding a focus outside of International Women's Day. At the June 22nd policy discussion, it was noted that it is the work of all members of AIDS Action Now! to be informed about and able to speak on issues relating to women with AIDS, and not just the responsibility of women members.

There are many organizations, activities and opportunities both locally and nationally that AIDS Action Now! could connect with and attempt to influence, regarding the issues of women living with HIV/AIDS: the Ontario Coalition for Abortion Clinics, Voices of Positive Women, The National Action Committee on the Status of Women, the Women and AIDS Network of Toronto, The Canadian Women and AIDS Study, the HIV Clinic proposal being brought forth by Women's College Hospital, etc.

Much of our discussion centred on the issue of women's involvement in AIDS clinical trials. Led by ACT-UP New York's Women's Caucus, AIDS activists have battled for many years for improved access to clinical trials for women. Here in Canada, the research and treatment climate is different than in the United States and AIDS Action Now! has always held that people should not be coerced into entering clinical trials in order to receive a treatment. They should enter a trial for altruistic reasons: to advance scientific knowledge. But with so little research done on HIV in women, on treatments that can manage our specific presentations of infections, and on how existing treatments affect women, we need to encourage women to participate in clinical trials while making sure that the research in which we participate is safe, accessible and relevant to us. Darien said that Voices of Positive Women has a new brochure called "HIV/AIDS Research and Women" which deals with a number of these issues.

Julia Barnett, Darien Taylor, & Linda Gardner

Are quotas the answer to enrolling women in clinical trials? Should clinical trials be held up until a certain number of women are enrolled? No matter how excellent the access to a clinical trial, the information derived will not be of use specifically to women unless two conditions are fulfilled: that a statistically significant number of women are involved in the trial (this number varies according to the total number of people enrolled in the trial and other factors) and that data and diagnostics for gathering data are focussed specifically on providing information about women. Also, women- specific trials need to be encouraged further.

Linda and Darien have been working recently with doctors at the Toronto Hospital's HIV Clinic to organize a forum for women living with HIV and their doctors. The focus of the forum would be on clinical/ treatment and advocacy/ support issues. This forum will take place on October 29th and members of AIDS Action Now! are encouraged to get involved with the working group producing this forum. Ongoing work for AAN! on women's issues will hopefully emerge from this event.

A NOTE ON INFORMATION/ POLICY DISCUSSIONS: AAN! holds informational policy discussions every fourth Tuesday of the month (except during the summer and at Christmas) at 8:00 pm. at the 519 Church Street Community Centre. These discussions are wide-ranging and open to anyone who is interested in sharing their ideas or informing themselves.

AIDS Politics of Health: Election '93

In this election campaign, Canadians are demanding that candidates address the issues which affect our lives.

AIDS-related illnesses are already a leading cause of death in young men, and the number of new cases each year continues to rise. The number of women infected with HIV is growing rapidly.

Here are some questions to ask your local candidates about their commitment to confronting AIDS.

1) COORDINATING A CANADIAN RESEARCH EFFORT

If we are to seriously tackle the AIDS epidemic, a well-funded, coordinated research effort is urgently needed. It is imperative that a research plan be developed, built on Canadian advantages, such as publicly-funded health care.

- If elected, would you support the allocation of more money for basic HIV/AIDS research, and for independently funded clinical research into HIV/AIDS?

2) SUPPORT FOR COMMUNITY GROUPS

The resources of community groups across Canada are being stretched to the breaking point as a result of the AIDS crisis.

The AIDS Community Action Programme (ACAP) provides funds to community-based organizations to strengthen their participation in care, support, prevention education and community development. Its budget of $7 million is insufficient to meet the needs of those who rely on its resources.

- Do you support an increase in funding to the AIDS Community Action Programme to at least $9 million this year? Do you support an annual increase to keep up with inflation?

Photo by Jake Peters

AAN!'s Chair Brian Farlinger face to face with Jean Chrétien outside the Primrose Club, demanding funding for AIDS research.

3) ADDRESSING POVERTY

Poverty, and the emotional trauma it causes, accelerate the progress of HIV. Furthermore, poverty is often at the root of conditions which spread HIV. Unfortunately, for those who must stop working, whether due to discrimination or for health reasons, the lack of an adequate financial safety net takes a serious toll. Less than half of the Canadian paid labour force is covered by employer-based insurance plans. For those able to overcome discrimination in obtaining private disability insurance (a significant hurdle unto itself), and able to convince insurers of their disability, payments are often below subsistence level. Social assistance provides for a standard of living considrably below the poverty line in all Canadian jurisdictions.

- Do you support increasing payments for all federal programmes, including Unemployment Insurance, the Canada/Quebec Pension Plan and social assistance in order to reflect the costs faced by people living with HIV/AIDS?
- Do you support regulation of the insurance industry in order to provide adequate insurance coverage to PLWHIV/AIDS?
- If elected, would you provide federal leadership in ensuring provinces subsidize a full range of HIV therapies to remove financial barriers to optimal health care?

4) DISCRIMINATION

The spread of HIV is exacerbated by a social climate which tolerates homophobia, racism and sexism. Discrimination against people with HIV is wide-spread and emotionally and financially devastating. It also shortens lives.

- Do you support amending the Canadian Human Rights Act to specifically prohibit discrimination against gays and lesbians and their relationships, and to strengthen protection for people living with disabilities?

Photo by Jake Peters

Demonstrating outside the Primrose Club, demanding funding for AIDS research on Oct., 10 1993.

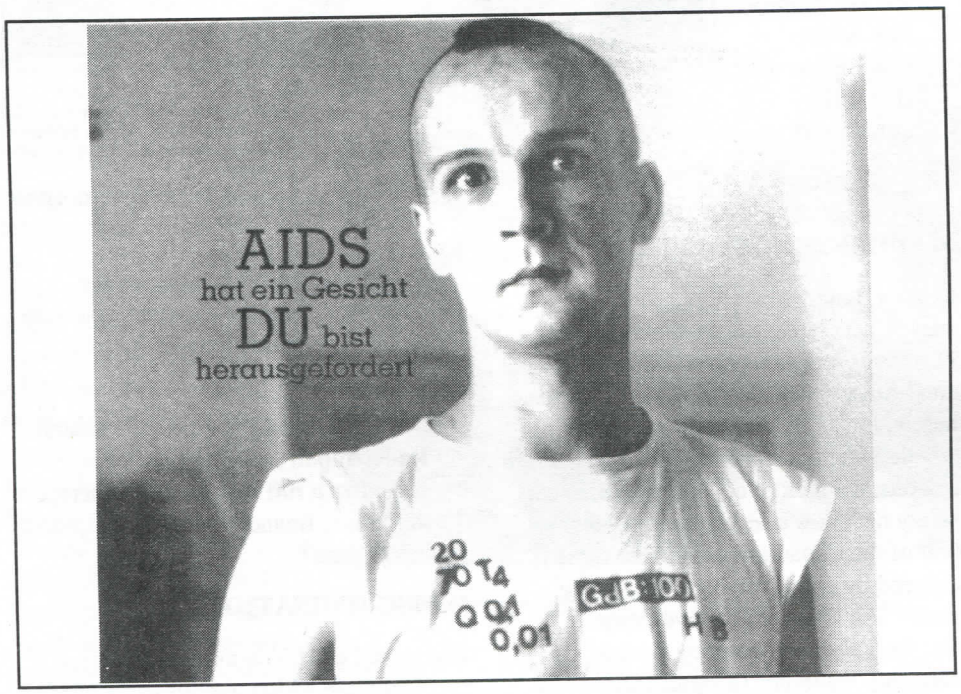
Berlin Highlights continued

geared to reconstituting the lymphatic tissue of lymph nodes and intestines damaged even during the latent stage. Bone marrow transplants or IL-2 infusions might be necessary. The dilemma is the potential overlap of such therapy with harmful immune activation.

Some new approaches to AIDS treatments were presented. One would involve targeting cellular rather than viral components required by HIV, since HIV depends on some cell factors but cells do not mutate to the same extent as HIV. Certain cellular factors and enzymes may be more crucial to HIV than to most cells so interfering with these factors might skirt excessive toxicity. An enzyme known as ribonucleotide reductase is essential for synthesizing nucleotides, the building blocks of DNA. This enzyme is partially inhibited by hydroxyurea. This agent may be particularly effective when the HIV lies dormant in its incomplete resting DNA form inside resting T-cells when it is thought to be heavily dependent on nucleotides.

Another approach would use an innocuous virus like human herpes virus HHV-7 to inhibit HIV replication since this virus uses the same receptor on T-cells as HIV. In competing with the AIDS virus for this binding site, HHV-7 may block HIV infection. Experiments have begun at the NCI to test this hypothesis.

Autoimmunity is recognized as a part of AIDS pathogenesis. It is theorized that the immune system cannot distinguish between gp120 on the HIV envelope and MHC class 2 molecules, which have a controlling role in the response to t helper cells. This may be the mechanism by which so many uninfected T cells become disabled by HIV. The approach to address this problem might be to create an anti-antibody.



GENE THERAPY OFFERS PROMISE

Gene therapy involves giving new genetic instructions to cells. Its counterpart, antisense, involves cancelling out existing genetic instructions.

There are two approaches to gene therapy. One involves stimulating immunity and the other involves inhibiting the virus. Using the first approach a herpes virus or retrovirus can be used as a delivery vector or in some cases genetic instructions can be injected directly. Using the second approach one must target the gene to the target cell.

A problem with the second approach is that vectors that attach to the stem cells will not attach to T cells. Other vectors will infect T cells but not stem cells. This will be one of the biggest hurdles in developing this approach. Another potential problem is whether escape mutants will develop.

The first approach is more like the way the immune system actually works. It kills cells; it doesn't just block replication. A "booby-trapped" cells approach is being worked on using an HSVI-TK vector. It will not likely be ready for large scale trials for some years.

Things are moving faster with antisense however. Gem (Gene Expression Modulator) 91, an oligonucleotide, binds to RNA before reverse transcriptase and also targets HIV after it emerges from the core of the cell, working on tat, gag and rev genes. Animal studies show a long plasma half life, tolerance at high doses and activity in late stage disease. Hybridon Inc., its manufacturer, has applied to begin Phase I trials in humans in the US and France and it is expected that these will begin in weeks or months. Six other US companies are also working on antisense compounds.

CONTROVERSY ABOUT CURRENT ANTIVIRALS

The Concorde study generated a great deal of discussion. These results indicate that for asymptomatics, taking 1 gram of AZT over 3 years, there is no significant difference in AIDS-free survival or clinical state compared to placebo. French researcher Seligmann says to save AZT for later disease. American clinician Conant believes

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Berlin Highlights continued

that data shows AZT slows disease for the first 12 to 18 months and nobody stays on AZT this long today. Project Inform's Martin Delaney still thinks early intervention is warranted and that combination therapy is best.

The usefulness of CD4 counts as a surrogate marker for assessing the clinical effect of a drug was also challenged by the Concorde study. Participants on AZT had consistently higher CD4 counts but this did not translate into clinical health. While CD4 counts are still useful marker before treatment, they may not mean much for people on antivirals.

Concorde was not the only study to generate controversy. Margaret Fischl reported on ACTG 155 comparing AZT to ddC to AZT/ddC. She segregated her results by T-count and reported that for people with T-counts above 150, the combination of AZT/ddC was best but for people with T-counts below 50 this combination was less effective. She advocated monotherapy for people with low counts and starting combination therapy at an early stage. She neglected to provide results for the whole cohort (without segregating by T count) until activists pressed her for this information. Looking at all participants there was no difference in outcome between any of the arms. A year after regulatory approval for AZT/ddC it is unclear how or if this combination should be used.

Other difficult-to-reconcile results were reported:

• ACTG116A: For antiviral naive patients AZT looks better than ddI until week 16 then ddI looks better

• ACTG 116B/117: ddI looks better than AZT

• CPCRA 002: ddC is equal or better than ddI in AZT intolerant advanced patients

• Euro-Australian Clinical Group 02: For people with CD4 counts above 400, AZT was recommended since it produced a significant difference in progression as defined by CD4 counts.

The end result is confusion. Clinicians are likely to encourage symptomatic patients to take antivirals as monotherapy or in combination. For asymptomatic patients they will likely leave the decision to the patient. The US National Institutes of Health have since issued additional guidelines for the use of AZT, recommending that doctors and asymptomatic patients should decide together whether to start using the therapy. The overall message is that current antivirals, at least as presently used in therapy, are of marginal benefit.

RESISTANCE TO CURRENT ANTIVIRALS

A considerable amount of data on resistance both in vitro and in vivo was presented. In trials of 3TC, resistance was seen in 12 of 42 patients between week 12 and week 60. The quick resistance to nevirapine reported last year may have been dose-related. At a higher dose the results resemble those of AZT.

While resistance to some monotherapies like L661, 3TC, and nevirapine is very rapid there is cross-resistance between drugs, suggesting that alternating, sequencing and combining agents may be beneficial. For example, against a background of AZT resistance, 3TC use may restore some of the efficacy of AZT. Drug companies prefer to do monotherapy studies but they must be encouraged to do combination studies if we are to advance our knowledge in how to use existing agents to maximum benefit.

Whether triple combination therapy will give multiple resistance is a question which needs to be studied. In vitro the combination of AZT, ddI and L661 does give low level resistance. In fact, the Harvard researcher whose "Nature" publication caused interest in convergent combination therapy last fall stated that he regretted the publicity and exaggerated enthusiasm his story had created. However if triple combination significantly delays high level resistance, this may be an important step forward. ACTG 241 is now studying the triple combination of AZT, ddI and nevirapine.

The technology now exists to determine viral load and resistance levels in patients. We do not have 100% confidence in how to interpret the results. The tests are now commonplace in clinical trials and should become common in clinical practice in the near future. For example, 10 to 15% of patients are AZT resistant before they have ever taken an antiviral. A patient who knew this might decide to start antiviral therapy with another agent. And patients vary considerably in how quickly they develop resistance to a drug. Test results showing the level of resistance would help patients to determine when to change therapy and to what. Many of the clinical trial results at Berlin suggest that we must do a better job of tailoring treatment regimens to individual patients. Current antivirals can significantly help some patients. General rules of thumb have not worked for most patients. We have to take advantage of these tests to make better informed decisions.

NEW ANTIVIRALS

There were many reports on new antivirals.

• 3TC was shown to give transient improvements in surrogate markers. 3TC is available through the EDRP and a compassionate arm is available .

• Disappointingly, Ro24-7429 tat gene inhibitor Phase I/II showed no antiviral activity at the doses tested.

• A-77003 a PhaseI/II protease inhibitor showed inconclusive results.

• Ro31-8959, a protease inhibitor, showed good results including CD4

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Berlin Highlights continued

counts and p24 decline in French, English and Italian studies. Phase II studies have been ongoing for several months.

Several other protease inhibitors are in the works (Du Pont/Merck, Merck, Ciba-Geigy and Bayer and Hoechst) and it is felt that this is the most promising antiviral approach today.

IMMUNE-BASED THERAPIES

The good news was that for the first time at these conferences there was a session on this topic. The bad news was that there was little to report. Salk claims to have enough data to approach the FDA for approval of a therapeutic vaccine but the data only shows a decrease in the increase in viral load. The biggest need is to develop a better adjuvant which presents the immugen to cells.

GASTRO-INTESTINAL PROBLEMS AND WASTING

It is now recognized that the GI tract is a preferred reservoir for HIV and may be an important area for loss of CD4 cells. An American researcher, D. Kotler, reported that inflammatory bowel disease is a common problem in intermediate disease and should be treated like colitis with asacole. He believes such treatment can significantly prolong survival.

Malabsorption and weight loss can be due to decreased calorie intake, endocrine dysfunction and cachexia and it is important to thoroughly investigate its cause. Tests which measure xylose, l-rhamnose and glucose were cited in this regard.

In a PAAC (Physicians Association for AIDS Care) session it was reported that two studies of megace showed no increase or a decrease in lean body muscle at the same time as overall weight increased by fat. Growth hormones were indicated as promising for increasing muscle. Other approaches include anabolic agents such as oxandrolone, anti-cytokine agents such as fish oil, anti-catabolic agents and exercise. In another session a low fibre/high calorie diet with liquid supplements was said to be helpful, and periodic intravenous hyperalimentation needs to be considered.

OPPORTUNISTIC INFECTIONS

There was little new information on prophylaxis and treatment of opportunistic infections. Just as there is resistance to antivirals, resistance develops over time to these drugs. Resistance can be detected to agents like fluconazole. Such tests may be used to determine whether to increase your dose or change medication.

There remains no prophylaxis with proven efficacy for CMV. High-dose acyclovir and weekly infusions of ganciclovir were reported in clinical use. Standard treatment remains ganciclovir, foscarnet or a combination of the two and survival is measured in months in cases where the treatment is deemed to be effective.

Risk for MAI increases exponentially with a decline in CD4s, with one expert reporting half of his cases arising in people with counts below 10. While rifabutin does give a statistically significant difference in survival, the difference is not an enormous. Alternate prophylaxis regimens including clarithromycin are under study. Because resistance to clarithromycin is seen in treatment after 10 to 12 weeks, standard practice is to use it in combination with one, two or three other agents.

A Canadian researcher reported on Mepron as a second line treatment of PCP. It is a less effective agent than septra with low bioavailability and 17% of patients have no response. The current formulation is not very effective for patients with diarrhoea. Mepron is currently being studied as a prophylaxis for PCP in a formulation with improved bioavailability.

There is still no specific treatment for cryptosporidiosis but paromomycin, pentamidine and letrazuril are used experimentally with little response in those with T counts below 50.

KAPOSI'S SARCOMA

Results of several studies were reported, including:

- Intralesional vinblastine for intraoral KS gave a 72% complete resolution. It causes pain in 73% of patients with 36% requiring an analgesic.

- A Phase I study of CD8 expansion confirmed the safety of this therapy with 50% of participants having a 50% or greater reduction in tumours. A Phase II study is underway. This therapy may have application in CMV retinitis and Epstein-Barr virus infection.

- A phase II study of daunorubicin concluded the agent was effective with 20 of 22 participants having a partial response. (The FDA's advisory committee has since rejected Vestar's NDA for second line treatment of advanced KS due to insufficient data.)

- A study of liposomal doxorubicin showed an 85% partial response and a 7.5% complete response in 40 patients.

One expert recommended that sotradecol (a 3% sodium tetracycline solution) be used on oral KS before other therapies are used. It eliminates or reduces the lesion, eliminating the need for other therapies or making them less traumatic.

- Researchers from Lynx Therapeutics and Hybridon are collaborating with the US National Cancer Institute on the development of antisense sequences against basic fibroblast growth factor for use in KS.

-Brian Farlinger

TREATMENTS IN THE NEWS

—Peptide T will no longer be available through the Toronto Western HIV Clinic for new patients. The US manufacturer has decided to cut off supplies, except for patients currently receiving it who will continue to be able to access it for as long as they wish.

—Phase II/III trials of 3TC, a nucleoside analogue manufactured by Glaxo, began to enroll participants in Toronto, Montreal and Ottawa in May. One study is for the AZT naive (4 weeks or less of AZT use) with T counts between 200 and 500; and the other is for the AZT experienced (24 weeks or more) with t counts between 100 and 300. In response to activist demands, a compassionate arm will be available for those with T counts of 300 or less who have failed other therapies and are not eligible for any other parallel track. Materials towards the compassionate arm have been filed in Ottawa and the compassionate arm should be available in mid-October. EDRP access is supposedly now available. For further information contact Barbara Dawson at 416-819-3020.

—Dr. Chris Tsoukas of the Montreal General Hospital recently received a grant from the NHRDP to conduct a CD8 expansion trial. We are attempting to learn more about the parameters of the Canadian trial. A Phase II trial of CD8 expansion began in San Francisco for 20 patients about 6 months ago. This therapy for Kaposi's Sarcoma involves removal of white blood cells(CD8) from the patient's bloodstream, their treatment and incubation during three weeks, and then reinfusion into the patient. Three participants have withdrawn due to IL-2 toxicity, three have withdrawn because their cells would not grow and one withdrew for unknown reasons. The principal investigator continues to be unwilling to meet activist demands to expand eligibility by including people with t counts below 50.

—In August Hoffman-LaRoche announced the termination of their development program for the tat gene inhibitor Ro-24-7429. The absence of antiviral effects, severe toxicities, and evidence that the tat gene is not as crucial for HIV replication as once thought were the principal reasons given for this decision. This will likely mean the end of investigation for the whole tat gene inhibitor class of compounds.

— The NIH recently completed a pharmacokinetics study of NAC, an antioxidant believed to be able to raise intracellular levels of glutathione. Of the 24 participants 23 had normal intracellular glutathione levels, contradicting current belief that these levels are low in PHA's. Stanford University researchers believe that NIH researchers used the wrong method to measure intracellular glutathione levels and began to enroll a trial in September to study the effects of NAC on these levels and markers of viral activity in 44 participants.

—A US court in July ruled that there was no basis for the challenge to Burroughs-Wellcome's patent on AZT since government scientists merely served as the company's technicians in testing the compound against cultured HIV. The case has been appealed.

—Aztec(AZT Efficiently Controlled) is a sustained release form of AZT being developed by Verex Labs which releases AZT more gradually to achieve better intracellular levels of the active form of the drug. They have received FDA permission to begin Phase III trials.

—U-90 will enter two new Phase II/III clinical trials in October in the US. One trial is for AZT-naive patients with counts between 300 and 500 and tests AZT in combination with U-90: the other is for people intolerant of AZT with counts less than 300 and tests U-90 in combination with ddI. U-90 is a non-nucleoside reverse transcriptase inhibitor. Upjohn claims it will open trial sites, extensions of the US trials, in Toronto, Montreal, Vancouver and Ottawa this winter.

—A new MAI prevention trial has begun in the US for 1000 particpants with T counts under 100. It has three arms: rifabutin alone, clarithromycin alone and a combination. The rationale of the study is to assess whether a two-drug regimen in more effective than rifabutin alone, since mycobacteria can develop resistance to a single agent.

—We are told that the trial comparing low dose acyclovir, high dose acyclovir and the prodrug valacyclovir(BW 256) as a prophylaxis for CMV has been stopped since one arm gave significantly better results than the others. Burroughs-Wellcome has not disclosed which arm gave the best result. Toronto was one of the sites of this trial. Syntex has agreed to a head to head comparison study of oral ganciclovir and valacyclovir, but Burroughs-Wellcome may not have adequate supplies of this drug for this trial for up to a year.

If you are interested in monitoring developing AIDS therapies and research, or working with drug companies, researchers and government authorities on access issues, clinical trial design, research priorities and licensing, consider joining the Treatment Access and Research Committee of AIDS Action Now! We'd like your help and we'll show you how to get started.

AIDS ACTION NOW! - Committees - Get Involved!

The work of AIDS ACTION NOW! gets done by members - there is no staff, no consultants, and no per diems. There's just people determined to fight for the rights of people living with HIV. Here's a quick summary of the active components of AAN! If you'd like to get involved, there is always work to be done. If you'd like to help but can't decide where you'd best fit in, call the AAN! answering machine at (416) 928-2206 and someone will get in touch.

General Meeting

AIDS ACTION NOW! meets on the second and forth Tuesdays of each month at 8:00pm at 519 Church Street. Meetings are always open. These meetings include reports of committee activities, and discussions and strategy on current issues.

Provincial Issues

The provincial committee takes on issues such as: drug funding; standards of health care; social service and housing policies; hospital and clinic services; homecare; primary care doctors; and service delivery. The committee meets about every two months, but has many smaller working groups which meet more often on specific areas. Contact Bob at 531-0867.

Treatment, Access and Research

This committee tackles issues like clinical trials, access to drugs, drug licensing, pharmaceutical companies and community research. This committee is also our federal watchdog, monitoring such issues as the AIDS Treatment Information Service and the "National AIDS Strategy." This committee meets about every three weeks, and has lots of homework. Contact Darien Taylor at 324-8703.

Prisons

AIDS ACTION NOW! initiated and is an active participant in the Prisoners with AIDS Support and Action Network. PASAN will continue to push provincial and federal governments to take action on prison HIV/AIDS issues. Contact Julia Barnett at 926-0744 during office hours.

Media & Outreach

The media committee produces this newsletter, and works on broader education efforts: pamphlets, posters, media stories, press releases, letters to the editor, etc. This committee also organizes orientation sessions for new members. Contact Glen Brown at 920-9633.

Fundraising

The committee coordinates fundraising activities such as bar nights, bake sales, and theatre benefits to pay for all the above activities. Contact Michael McGaughrity at 929-6422.

Activist Brigade

The Activist Brigade organizes the phone tree & demonstrations for AAN!, delivers flyers for postering, leaflets street corners, props & banner making. Please contact David Chu at 960-8266 or Susan at 533-8349.

AIDS ACTION NEWS! IS BROUGHT TO YOU FOUR TIMES A YEAR BY THE AIDS ACTION NOW! MEDIA COMMITTEE. CONTRIBUTORS THIS ISSUE INCLUDE: PETER AMENTA, GLEN BROWN, DAVID CHU, BRIAN FARLINGER, BOB GARDNER, LINDA GARDNER, TIM MCCASKELL, CLARE MERIDEW, BRENT PATTERSON, JAKE PETERS, DARIEN TAYLOR. PLEASE CONTACT DAVID CHU (960-8266) IF YOU HAVE COMMENTS OR SUGGESTIONS.

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AIDS ACTION NOW! WAS FOUNDED IN 1988. AAN! IS A TORONTO-BASED ACTIVIST GROUP FIGHTING FOR IMPROVED TREATMENT, CARE AND SUPPORT FOR PEOPLE LIVING WITH HIV AND AIDS. AAN! IS ENTIRELY VOLUNTEER AND RECEIVES NO GOVERNMENT FUNDING.

AIDS ACTION NOW! CAN BE REACHED AT SUITE 321 - 517 COLLEGE STREET, TORONTO, ONTARIO M6G 1A8. TELEPHONE (416) 928-2206.

LE GROUPE D'ACTION-SIDA

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