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educational offerings

“Report Back from CROI”

Wednesday, February 25, 2004

CPMC – Davies Campus

6:00PM – 8:30 PM

Details to follow....

upcoming conferences

11TH CONFERENCE ON RETROVIRUSES AND OPPORTUNISTIC INFECTIONS (CROI)

FEBRUARY 8 – 11, 2004

MOSCONE WEST, SAN FRANCISCO, CA

[HTTP://WWW.RETROCONFERENCE.ORG/2004/HOME.HTM](http://www.retroconference.org/2004/home.htm)

15TH INTERNATIONAL AIDS CONFERENCE

JULY 11-16, 2004

BANGKOK, THAILAND

[HTTP://WWW.IAS.SE/](http://www.ias.se/)

44TH INTERSCIENCE CONFERENCE ON ANTIMICROBIAL AGENTS AND CHEMOTHERAPY (ICAAC)

OCTOBER 30 – NOV. 2, 2004

WASHINGTON, DC

[HTTP://WWW.ICAAC.ORG/INDEX.HTML](http://www.icaac.org/index.html)

employment opportunities

HIV Experienced Physician Sought

To join primary care practice at 45 Castro Street. Associate sought for clinical and hospital practice. **Contact Stephen Knox, M.D., at 415-863-3366.**

farewell to david macleod, r.n.

David MacLeod, R.N., CPCRA Clinical Research Nurse and our ESPRIT Protocol Specialist, has moved on from his work at the Community Consortium. David accepted the coordinator position at the UCSF main campus. We wish him well and thank him for years of dedicated work at the Consortium!

membership renewal

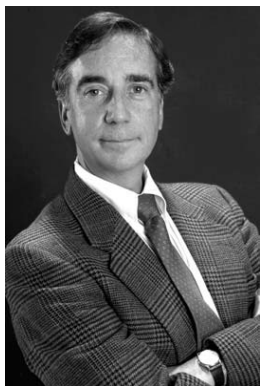
As the New Year quickly approaches, we once again seek your support to assist us in the work that we do for HIV care providers in the Bay Area and beyond. We appreciate the fact that there are many competing demands and requests for our ever shrinking resources, but we hope you will continue to be able to renew your Consortium membership to allow us to accomplish our goals and better serve your needs. We need to keep an accurate updated list of individuals interested in learning of Community Consortium activities; following our research endeavors and gleaning whatever gossip tidbits *Synopsis* may otherwise have to offer. To this end, we ask for you to send back a membership application with the nominal fee that helps us with the printing and mailing of *Synopsis* and some of our other educational brochure materials.

In addition, we have always claimed that our strength is in our numbers. When the Consortium takes a stance on an issue and, for example, writes a letter to an elected official, it behooves us to say that we are an organization of 200 plus HIV care providers in the San Francisco Bay Area. Obviously, the larger the number that fills in the blank, the more clout we have. The Community Consortium has much to be proud of. We have served as an ongoing model for community based clinical trials and provider education in the country. We intend to continue our efforts for as long as they are necessary. We do need and appreciate your support! Please take a moment now to fill out and send back the enclosed membership application. We know there are more providers out there who would be interested in our programs, so feel free to copy your form and share with colleagues! Thanks again for your continued support!

executive advisory board

Meetings of the Community Consortium Executive Advisory Board are slated for April 28th, July 28th, and October 27th in 2004. Meetings take place at 7:30 AM in the Conference room at the Community Consortium. We will commence the New Year with a dinner meeting at an as yet undetermined location on January 28th.

Happy Holidays!



Donald I. Abrams, M.D.,
Editor

**Sandy Schwarcz, M.D.,
M.P.H.**
Guest writer

Could it be true? Another year drawing to a close already? 2004 will mark the 19th anniversary of the Community Consortium. It was wonderful to see so many familiar (note I will not say old) faces at our October 1st “ Report Back from ICAAC” event. We have been on the front lines for quite some time now and can all appreciate how much things have changed for the better since our first meeting in 1985! Our Report Back dinners continue to give us the opportunity to get together, socialize and hear what were the highlights from recent meetings we may have missed. We are most grateful to Steve Becker, Susan Jacobson and Paul Volberding for their excellent summaries of key areas covered at ICAAC. And of course we greatly appreciated the support of our colleagues at Abbott Laboratories, Agouron, Boehringer Ingelheim, Bristol-Meyer Squibb, BTG, GlaxoSmithKline, Merck & Co., Ortho Biotech, Roche, and Solvay. Normally in this issue of Synopsis, we would summarize salient points made by our presenters at the Report Back. Interestingly, many of the studies were already covered in our Report Back from Paris issue and the Report Back from CROI before that! So we took the opportunity to try a new idea. Ken Mills, M.D., former outstanding Consortium Executive Advisory Board member, called to ask if we were aware of how much information was being collected by the City Department of Public Health on newly diagnosed patients with HIV. Especially in this HIPAA happy environment, we thought it would be nice to invite a guest columnist to address the issue. Sandy Schwarcz, M.D., M.P.H., Director of the HIV/AIDS Statistics and Epidemiology Section at the San Francisco Department of Public Health, clearly outlines the facts about HIV tracking. If you have a topic you think we should cover in Synopsis, by all means let us know!

HIV Tracking

by Sandy Schwarcz, M.D.,
M.P.H.

The HIV/AIDS Statistics and Epidemiology Section of the San Francisco Department of Public Health is responsible for tracking the HIV/AIDS epidemic in the City. Much of our ability to do so comes from mandated HIV and AIDS case reporting. The California Code of Regulations requires that persons with AIDS and/or HIV infection be reported to the local health department.

Reporting of persons with AIDS differs from the reporting of persons with HIV infection in a couple of important ways. First, persons with AIDS are reported to the local health department using the patient name whereas HIV case reporting is done using a code that is based, in part, on the patient's last name (the Soundex). Second, only health care providers are required to report persons with AIDS

while HIV case reporting is required by both laboratories and health care providers. Case reports may be submitted more than once on a given individual. It is the responsibility of the local health department to un-duplicate cases and forward reports to the California Department of Health Services. Both HIV and AIDS case reports are forwarded using the Soundex

and not the patient's name. The California Department of Health Services forwards statewide AIDS case reports (with Soundex and without patient names) to the Centers for Disease Control and Prevention (CDC). At this time, the California Department of Health Services does not forward HIV case reports to the CDC because the CDC will not accept case reports that were not obtained using the patient name. Note that persons who are initially reported as having HIV infection will be reported again if they progress to AIDS. This allows for counting unduplicated cases of both HIV infection and AIDS.

In San Francisco, we have relied extensively on active surveillance in which the health department staff conducts periodic visits to local hospitals, clinics, and physician offices to investigate and report persons who meet the surveillance case definition for HIV or AIDS. This has allowed us to have AIDS case reporting that is highly complete. HIV reporting has only been in effect since July 2002; consequently, we are not yet able to evaluate the completeness of HIV case reporting. However, we have conducted numerous evaluations of AIDS case reporting and have consistently found reporting to be over 90% complete. This is important to note because it means that any analyses we do with the AIDS case registry is reflective of the San Francisco AIDS population. A full count of persons with HIV infection and AIDS also allows us to maximize Ryan White CARE funds to San Francisco, thereby providing

much needed medical and social services to persons living with HIV infection in our city.

The information we collect for each person reported with HIV or AIDS is derived primarily from the Centers for Disease Control and Prevention (CDC) HIV/AIDS case report form and focuses on sociodemographic, risk, and clinical information. The case report form includes date of birth, race, ethnicity, health insurance status at the time of diagnosis, and AIDS defining opportunistic illnesses. In some situations we collect information that we believe is important locally. This information is retained and used only in San Francisco. For example, the CDC case report form uses a single question to determine use of antiretroviral therapy. We find that this single question is not sufficient to evaluate whether HIV infected persons in San Francisco are receiving therapy because initiating therapy at the time of diagnosis may not be clinically indicated. Consequently we document the start date of the various antiretroviral therapies used by the patients. This allows us to better define HAART use in our analyses and to use the information collected to assess the impact of HAART on survival following AIDS. Another example of a local use variable is the collection of transgender status (male to female and female to male). This was initiated at the request of members of the transgender community who felt that the burden of disease within their community was not adequately ascertained or publicized thereby limiting the resources available to them. In response we created our own local use variables and routinely publish

information on HIV/AIDS in transgender persons in San Francisco.

The information we collect is used to provide information to people in San Francisco who work with the infected or at-risk community. This includes those who provide prevention, social, and clinical services. For example, we are currently working with Jim Kahn, M.D., at the UCSF Institute for Health Policy, to develop a model using HIV/AIDS case data to derive estimates of unmet medical need. This project, funded by HRSA, is designed to identify a model that can be used nationwide for allocation of Ryan White CARE funds. Following a question posed to us by Steven Deeks, M.D., we used our data to examine trends in causes of deaths among persons with AIDS to investigate the possibility that persons using HAART may be dying from complications associated with therapy. Our data are also summarized annually in the HIV/AIDS Epidemiology Report. Copies of the report are available by calling 415-554-9050 and at <http://www.dph.sf.ca.us/php/aidssurvunit.htm>. Copies of our research publications may be obtained by calling 415-554-9050. Note that data are released only in aggregate form and never contain personally identifying information. In addition, we do not release specific health care provider data. Diagnosing facilities are categorized as hospitals, clinics, or private physician offices. Similarly, when analyzing insurance status we usually classify these as private, public, or none.

Protecting the confidentiality of persons reported with HIV/AIDS is a high

priority for our section. The confidentiality of HIV/AIDS surveillance data is protected by strict regulations that forbid disclosing identifiable information outside of limited, specified public health uses. All San Francisco Public Health HIV/AIDS surveillance staff members are carefully screened prior to hire, sign oaths of confidentiality, and receive training on our confidentiality and security procedures at the time they are hired and annually thereafter. The surveillance staff works in a secure area of the AIDS Office to which access is restricted. Personally identifying data from persons with HIV/AIDS is maintained in locked file cabinets secured with heavy U-bars with padlocks housed within a restricted room that is located in the secure area of the building. This room is further protected by lock to which only selected personnel have access and by a motion detector that is linked to the 24-hour security guard who patrols the building. Data maintained on computers does not include personally identifying information.

Collecting reliable and complete information on persons with HIV infection and AIDS in San Francisco has been successful in large part because of the collaboration between the health department staff and health care providers. The ability of the surveillance staff to gather surveillance information from a large number of health care facilities and health care providers has allowed us to collect, maintain, analyze, and disseminate important information on the

HIV/AIDS epidemic in San Francisco. If you have any questions regarding the health department HIV/AIDS surveillance activities, please feel free to call me at 415-554-9134.

Clinical Trials Update

SMART (CPCRA 065)

Strategies for Management of AntiRetroviral Therapy is a trial for subjects with CD4+ cell counts greater than 350/mm³ currently on or naïve to antiretroviral therapy. There are two strategies to which patients are randomized in the study. In the Viral Suppression (VS) arm the goal is to use antiretroviral therapy to maintain viral load as low as possible throughout the anticipated six to nine years of study follow-up. In the Drug Conservation (DC) arm, antiretroviral therapy is stopped (or deferred) until the CD4+ cell count drops to less than 250/mm³, at which time episodic antiretroviral therapy is initiated to increase the CD4+ cell count to greater than 350/mm³. Three thousand participants are required per arm for a total target sample size of 6000. Thus far the Community Consortium has enrolled 75 of the 1331 study participants.

A special thank you to Robert Scott, M.D., and Paula Pell, R.N., for inaugurating the trial and enrolling 8 patients in the last two months! We have also established a new relationship with clinician/investigators at UCSF Fresno and are delighted to report that Simon

Paul, M.D., and Jill Langford, R.N., have already randomized their first participant. Congratulations!

A number of additional SMART substudies are in development. Currently we are participating in two substudies. One is evaluating the risk of HIV transmission in participants in the VS vs. the DC arm. The second substudy is investigating quality of life and cost of care differences between the two arms of the trial. The three studies that are currently being developed will take advantage of the initial strategic randomization to compare the rates of development of 1) atherosclerosis, 2) anal dysplasia and 3) neurologic complications in the VS and DC arms. It is hoped that these additional substudies will be available for enrollment by early in the New Year.

If you or your patients might be interested in participating in the SMART study, please contact Pierre Crouch, R.N., at (415) 476-9554, ext. 333, for further information, or visit the SMART Study website at: <http://www.smart-trial.org/>

ESPRIT

Enrollment into ESPRIT (The Evaluation of Subcutaneous Proleukin in a Randomized International Trial) closed on May 30, 2003, with 4150 participants randomized in this 25-nation international trial. This makes ESPRIT the largest randomized HIV treatment intervention trial to date! The

Community Consortium enrolled 42 of our target goal of 50 subjects, with the majority coming from our Emory University “satellite” site in Atlanta. The study is designed to assess the clinical benefit of IL-2 and hence will follow the 4150 patients worldwide for disease progression events for a minimum of five years. Participants randomized to the IL-2 arm will repeat cycles of therapy to maintain their CD4+ cell counts at twice baseline or above 1000 cells/mm³. Now that the study is fully enrolled our focus shifts to maintaining participants in follow-up as well as making sure that those individuals randomized to the IL-2 intervention receive cycles of therapy to maintain their CD4+ cell counts at the target level. Information about your patients enrolled in ESPRIT and whether or not they are at their goal can be found on the ESPRIT website <http://www.espritstudy.org/>

MDR (CPCRA 064)

The initial results of the Multi-Drug Resistant (MDR) study were published in the August 28, 2003 *New England Journal of Medicine*, with Dr. Jody Lawrence as the lead author. A new version of the study, defining exact length of follow up and new study endpoints, should be coming to the field shortly. The study has definitely set the mark for current views on managing drug resistance with STI's and the further need for evaluation of STI's in patients with significant drug resistance. All participating care providers and patients for this study deserve a big thank you for helping to make MDR the largest randomized study of its kind. To

view the NEJM articles on MDR go to the following link:
http://communityconsortium.org/research/research_closed.html

FIRST (CPCRA 058)

The CPCRA's Flexible Initial Retroviral Suppressive Therapies (FIRST) trial, the entry point into the CPCRA's menu of strategic antiretroviral studies for naïve patients, closed to further enrollment on January 13, 2002. The study surpassed its target enrollment and continues to follow subjects already accrued. Stay tuned for further information to be made available as the study matures. Results from the FIRST NRTI substudy comparing ddi/d4T to ABC/3TC as baseline nucleosides in the HAART regimen were released on May 13, 2003. Although we did not have any patients participating in this substudy, you may find the results of interest. Go to http://communityconsortium.org/research/research_closed.html and see the section under FIRST to view the NRTI substudy results and Executive Summary documents.

LTM (CPCRA 060)

Do you have patients who have chosen to remain antiviral naïve or who have been long-term non-progressors? The CPCRA Long Term Monitoring team is looking to enrich follow-up of such patients in the LTM database. If you have individuals who may be interested to contributing to the general knowledgebase regarding naïve and LTNP patients and you are currently a collaborating Consortium clinician/investigator, please let your

clinical research nurse know. Such individuals are often eager to participate in observational studies so that their experience can be counted! To date, 3,180 patients are being followed on LTM nationwide, including 153 from our site.

Marijuana for HIV Neuropathy (RCT)

The pilot study of smoked marijuana for patients with painful peripheral neuropathy has been completed. Analysis of the 16 patients enrolled revealed that a significant number had relief of their pain resulting in the design of the follow-on randomized placebo-controlled trial. The sample size for the randomized trial was calculated at 50 participants. To date, 11 subjects have completed the RCT. Eligible patients need to have persistent pain of greater than 3/10 for the week prior to randomization. Participants are admitted for 7 days to the General Clinical Research Center at San Francisco General Hospital. After a two-day lead-in period, they are randomized to smoke one marijuana or placebo cigarette three times daily for the next five days. Individuals are compensated \$650 for completion of the study. This is our first attempt to conduct a randomized placebo-controlled trial investigating smoked cannabis. We need your patients with persistent pain from peripheral neuropathy secondary to HIV, antiviral therapy, or both. Please have potential participants contact Hector Vizoso, R.N., at 415-476-9554, ext. 366, for more information.

Marijuana for Cancer Pain

We are now studying the effects of smoked marijuana in patients with persistent cancer pain despite opioid analgesics. The study investigates the potential synergy between the cannabinoids and opioids, the potential decrease of opioid side effects by the cannabis and the pharmacokinetic interaction between the two drug classes. Eligible subjects should have persistent cancer pain of any origin greater than 3/10 despite opioid analgesics. In this open label pilot study, 16 subjects will be enrolled for a 9 day admission to the General Clinical Research Center at San Francisco General Hospital. After a two-day lead-in period, they will smoke three marijuana cigarettes daily for seven days. Individuals are compensated \$600 for completion of the trial. To date, only one patient has completed this study. If you know of patients who may be interested in participating in this trial, or have any ideas on how to increase enrollment, please contact Hector Vizoso, R.N., at 415-476-9554, ext. 366.

Both of our marijuana studies are supported by funding from the University of California San Diego Center for Medicinal Cannabis Research (<http://www.cmcrc.ucsd.edu/>).

DHEA

We recently completed enrollment of our study of dehydroepiandrosterone (DHEA) and its effects on latent HIV replication and host immunity. Data will be analyzed and results

forthcoming later in the year. Thanks to everyone who referred participants to this trial!

Observational Cohort Study

The Community Consortium has an ongoing observational cohort study that involves 927 patients being followed predominantly at 8 local sites. As follow-up matures, this OCS is becoming a valuable resource of information. Here's a breakdown of OCS enrollments by Community Consortium site:

<u>Site</u>	<u>Provider</u>	<u>Enrollments</u>
010	EBAC	388
021	MNHC	243
005	CMHC	189
038	VAMC	60
009	Milton Estes	42
007	CPMC - CA	8
008	Ken Mills	3
012	Robert Scott	2
	<u>Total Enrollments</u>	927

Stay tuned for future analyses from this incredible local registry!

Distant Healing

The study of distant healing and HIV, in which the Consortium continues to assist our collaborators at CPMC, was closed to enrollment in December 2002. The study was enrolled in cohorts of 15 patients, each randomized to one of 3 arms. In each cohort, five patients received DH efforts by professional "healers," five patients received DH

attempts by nurses, and five patients received no special intervention beyond usual medical treatments. The study is double-blind: neither the patients nor their doctors nor the researchers knew who was receiving the healing treatments. Outcomes included clinical course, psychological course, and medication use; HIV RNA, CD4/CD8 cell, and NK cell levels; metabolic measures and antiretroviral toxicities. The study enrolled a total of 155 HIV-positive individuals, each on a stable antiretroviral regimen and each with a history of having had a CD4+ cell count <200/mm³. Patients who did not speak English or were unable or unwilling to fill out questionnaires were excluded, as were patients with non-HIV related life-threatening disease. Study procedures took place at CPMC. Following their baseline evaluations, patients returned for month 6 and month 12 visits, which included follow-up questionnaires and blood work. The research assistant extracts the remaining data from clinic charts. Patient follow-up in this trial will end in December. Study results should be forthcoming.

Future Studies

Oyster Mushrooms

The Community Consortium recently received funding from the National Center on Complimentary and Alternative Medicine (NCCAM) to study oyster mushrooms. The study is a single-arm, 8-week, 20 patient pilot

study evaluating the short-term safety and potential efficacy of oyster mushrooms for treatment of hyperlipidemia in HIV-infected patients who are taking Kaletra. Stay tuned for more details and study inclusion and exclusion criteria.

Volcano Vaporizer

The Community Consortium has successfully competed for funding from the Center for Medicinal Cannabis Research (CMCR) to perform another marijuana study. This study, which will enroll 20 healthy individuals, will evaluate the use of a vaporization system as a “smokeless” delivery system for inhaled marijuana and compare plasma levels of delta-9-tetrahydrocannabinol (THC) to those obtained from smoking an identical amount of marijuana from a cigarette using the standardized Foltin puff procedure over a range of THC doses. The study will also attempt to determine if there is a difference in the subjective and objective evidence of cannabis effects between the two delivery systems. Stay tuned for more details regarding this exciting study.

Screening for Long Term Nonprogressors

In order to understand how the immune system controls HIV replication, the NIAID, NIH Laboratories of Dr. H. Clifford Lane, are currently seeking patients who maintain very low plasma viral loads without antiretroviral therapy to participate in research focusing on long-term non-progression

(LTNP) of HIV Infection. The research project entitled "Leukapheresis procedures to obtain plasma or lymphocytes for research studies of HIV-infected patients, including long-term nonprogressor", is being conducted under Mark Connors, M.D., at the National Institute of Allergy and Infectious Disease (NIAID). Inclusion criteria include: adult (at least 18 years of age) HIV-1-infected patient, stable plasma viral loads <5000 copies/mL for a minimum of 3 years, CD4 counts >350 cells/mL for a minimum of 3 years, return visits to NIH at approximately 6-month intervals and willingness to provide informed consent for HLA testing and the storage of blood or tissue samples. Exclusions are pregnant women and antiretroviral therapy (within the previous 3 years). If you have patients who may qualify for this study and are interested in being screened, please contact the Study Coordinator, Mary McLaughlin, at 1-800-772-5464, extension 58001.

Supreme Court and Prop. 215

On October 14, the United States Supreme Court refused to hear the Federal Government’s request to appeal the prior lower court decision in favor of Conant vs. McCaffery. By deciding not to hear the case, the Supreme Court sends a clear message that they believe that the states have the right to protect medical marijuana patients under the law and that physicians have the right to discuss the use of medical marijuana with their patients. It is considered rare for the Supreme Court to refuse to hear federal government appeals of lower court decisions. The case was filed against the government by Marcus

Conant, M.D., pioneer AIDS physician, and other local providers and patients including Dr. Arnold Leff, Dr. Neil Flynn, Dr. Stephen Follansbee, Dr. Robert Scott III, Dr. Stephen O’Brien, Dr. Milton Estes, Dr. Virginia Cafaro, Dr. Howard Maccabee, Dr. Donald Northfelt and Dr. Debasish Tripathy. The Consortium applauds Dr. Conant and our Consortium provider colleagues for their courage and perseverance!