The Inova Juniper Program is the largest provider of comprehensive medical care for individuals living with HIV/AIDS in northern Virginia. The Inova Juniper Program has seven sites in northern Virginia and provides patients with all aspects of primary medical care, as well as mental health, substance abuse, medical case management, and drug assistance services regardless of insurance status. Patients from a broad range of ethnicities and ages visit the Inova Juniper Program for care, including babies born to mothers who are HIV positive and individuals at risk for contracting HIV. Dr. Michael Serlin is the medical director of the Inova Juniper Program, and he says that the clinic has seen an increased demand for its services in recent years. According to Dr. Serlin, “In the past five years, our clinic population has grown, reflecting increasing HIV testing in the area. We have also seen many at-risk HIV-negative patients as we started providing prevention care, including pre-exposure prophylaxis.”

Support services for patients
Inova Juniper provides critical support to patients newly diagnosed with HIV, which is important for establishing an effective treatment regimen. Dr. Serlin explains that the “nurse case managers and social workers work closely with the patients to help them with a regimented ‘Boot Camp’ when they start medications, and outreach workers help keep patients linked to care. Our mental health providers help manage patients with psychiatric issues.” The availability of clinics in multiple sites across northern Virginia has also been a critical aspect to the success of the Inova Juniper Program. Dr. Serlin says that “having these sites provides many different opportunities for care and enables” patients to be treated near their communities. He adds that Inova Juniper provides “many support services, including community health workers who ensure linkage and retention to care, as well as nurse case managers who manage patients on new medications or who have difficulty with adherence. Mental health and social work services greatly help patients stay in compliance as well.” Support groups are also offered, including groups for Amharic speaking women, young MSM, and older women living with HIV, among others.

Education as part of linkage to care
Inova Juniper has a vibrant education and outreach program that provides services to the Mid-Atlantic region, with education and prevention staff who provide outreach and testing to the community. As a regional partner of the MidAtlantic AIDS Education and Training Center, which is a state and federally funded education center, the Inova Juniper Program provides education to the community and local practitioners to help combat HIV and prevent further transmission. Dr. Serlin notes that the Inova Juniper Program has provided educational opportunities throughout Virginia and also “collaborate[s] with outside facilities to assist with ensuring linkage to care for newly diagnosed HIV patients and other patients who are out of care.”

Dr. Serlin came to Inova Juniper last year after working in New York City for 12 years with patients who have HIV. He says that “NIH has been a great resource for some of our most complicated patients [at Inova Juniper],” adding that “the attitudes here among the patients are much friendlier to clinical research than they were in New York.”

The Inova Juniper Program is a valuable source of care for patients with HIV throughout northern Virginia, and its continued success will help it to support and care for patients well into the future.
**Fostering a Holistic Patient Experience**

Although clinical trials are critical to understanding whether new treatment options will be effective, patient participation in clinical trials has steadily decreased in the United States. Thus, recruiting, enrolling, and maintaining patients in clinical trials has become increasingly important.

In our discussion with Michael and Michelle (pseudonyms), two patients who continue to participate in clinical trials at the NIH, we learned how NIH has created a unique environment that extends beyond patients’ medical needs.

Michelle has participated in several clinical trials at NIH, having first enrolled in the late 1990s. Michael is a more recent participant, beginning his first clinical trial within the past few years. During this time, both Michelle and Michael have been able to observe the benefits and limitations of clinical trials at NIH.

**What makes patients want to participate in clinical trials?**

For Michelle and Michael, access to medications, working with engaged staff, and getting a thorough explanation of the studies were keys to participating in clinical trials.

Michelle recalls that despite medical issues that had initially kept her from qualifying for several clinical trials sponsored by drug companies, one particular physician whom she refers to as “her guardian angel on earth” finally succeeded in helping Michelle enter her first clinical trial at NIH. Since then, Michelle says she has been able to count on the “team, the drugs, and the entire atmosphere.” The staff members “are very honest,” even willing to tell Michelle if they do not know why she is having certain medical problems. She also finds that the flow of information between NIH staff and her primary care physician is very smooth. She is pleased that the transfer of medical records, “keeps [her] in the loop” regarding her medical care.

For Michael, it was particularly important to understand the clinical trial and have all his questions answered thoroughly. Initially encouraged by a member of the PACT team to consider a clinical trial, he made his decision by talking to staff and recalls, “it seems like I talked to everyone here.” He would advise anyone thinking of participating in a clinical trial that “it’s probably not going to be as bad as you think it’s going to be, but check it out before making any decisions.”

Likewise, Michelle felt that by the time she enrolled in her clinical trial, she was so well informed that more information, “would have been helpful, but I [had] already got[ten] information.” Nevertheless, she advises new patients to “read and talk to people. Don’t feel too shy. Talk to folks who have already gone through a clinical trial and talk to the staff.”

Explanations from referring staff at other institutions and staff at NIH are especially important when she contrasts her knowledge of clinical trials before and after her participation. She recounts, “I had not a clue” about what clinical trials involved. “The majority of the folks out in the community think NIH just does research on rats and monkeys, and that was my perception as well.” She was surprised to learn that reality is “completely different.”

With her participation in clinical trials spanning nearly two decades, Michelle has been able to appreciate the volunteer experience as an inpatient and outpatient.

**What makes the experience of a clinical trial at NIH unique from a patient perspective?**

In addition to a patient-centered team, Michelle describes the variety of resources available to patients and their families or caregivers:

“NIH is unlike any other hospital…we are blessed to have a specialized medical pain team, a Patient Advocate, a patient library that is just great, we have a business center, recreation therapy department…a multi-faith chapel…and the food. I was an inpatient quite a few times [at NIH]…the food is unlike any other hospital food, it’s tasty…We have a patient gym [that’s] not just for patients, it’s for the patients’ families as well. If you are a person’s caregiver you won’t get bored here, because through the recreation therapy department there is so much to do to keep you busy.”

The availability of various resources, including an engaging Rehabilitation Medicine and Social Work staff, creates a positive environment for patients to focus on their health. During her own treatment, Michelle recalls, “I had so many procedures when I was an inpatient, that the reward at the end of the tunnel was the relaxation chair, located in the Recreation Therapy Department.”

However, Michelle has noticed changes to her level of access to medical-related resources over the years. She says that, “Although she and Michael are under different protocols, he has a little bit more access.” For Michael, everything is at NIH and he gets “transportation support for his appointments; I don’t.” They used to provide it for me “but over the years they’ve had so many cutbacks.”

Despite these budget restraints, Michelle is impressed by how responsive the staff is to patient feedback. For example, Michelle notes that a benefit of having the library, chapel, and Recreation Therapy Department on the same floor before moving to the new north side of building was that patients and their families or caregivers would also do “a little
As NIH advances in its strategies to develop a whole patient experience, patients like Michelle and Michael continue to find a unique environment that enriches their experience in clinical trials. She reflects that there is “a lot of feedback I’d provided and didn’t realize that they were listening…but they listened.”

The stories that Michelle and Michael shared illustrate how important it is for patients not only to understand the elements of their participation in clinical trials but also to have a voice in their care and environment.

Read more about the NIH Clinical Center.

PATIENT Voice (continued)

bit of socializing.” But, during the transition, the library was moved to another location. Michelle noted that the relocation detracted from the environment that had been fostered for patients within that space. She says, “the clinical director and his staff listened…they moved the library next to the chapel,” thereby restoring the original character of this patient center.

Michelle cites another example that staff made changes directly related to her feedback. She says, “I wrote a letter to the clinical director…regarding the new building not being ADA compliant. According to the builders, it was ADA compliant, but it wasn’t” in practice. After providing her comments, Michelle continually sees many changes that make the building more accessible for every patient.

RESEARCH Corner

NIAID Principal Investigator Spotlight: Michael Sneller, M.D.

Novel Neutralizing Antibody at the Center of New HIV Trial

A new clinical trial at NIH will feature a novel broadly neutralizing antibody (bNAb) that has the potential to disrupt HIV infection and improve HIV treatment. Dr. Michael Sneller, a clinician in the Clinical and Molecular Retrovirology Section of the Laboratory of Immunoregulation at NIAID/NIH is the principal investigator of a new clinical study examining the effectiveness of this bNAb, called VRC01, in HIV patients.

The immune system generates antibodies against the vast array of pathogens that cause infection, and these antibodies are often extremely effective at stopping infection and providing long-term immunity. Humans make antibodies against HIV during infection, but in most individuals, these antibodies do not neutralize HIV and do not contribute to long-term protection against HIV/AIDS.

Several years ago, VRC01 was identified as a bNAb that targets the viral gp120 envelope glycoprotein, which binds to CD4 molecules on the surface of host cells and mediates infection. Sneller explained, “VRC01 binds to a highly conserved CD4-binding site on the envelope protein of HIV-1. Binding of VRC01 to this site prevents the envelope protein of a wide range of HIV-1 isolates from binding to the CD4 molecule on T cells, thus preventing new infection of CD4 T cells by HIV.”

Only two broadly neutralizing antibodies against HIV have ever been tested in humans, and these small studies have focused primarily on the safety of infusing these antibodies into human subjects. This new study will investigate whether multiple doses of VRC01, given for up to six months, can control HIV infection in subjects who have temporarily interrupted their anti-HIV combination antiretroviral therapy (cART). This study will enroll patients who are currently taking cART and have stable CD4 cell counts greater than 450 cells/µl along with documented suppression of HIV in the blood for at least 3 years. Patients must also be free of other chronic active infections such as hepatitis B or C.

CD4 T cell counts and HIV levels will be monitored closely throughout the study in order to determine the effectiveness of VRC01 treatment. The results of this trial should reveal if VRC01 is effective at suppressing HIV infection in the absence of cART. If HIV levels go up during VRC01 treatment, the rebounding viruses will be examined to see if they have become resistant to VRC01 but may still be susceptible to neutralization by other bNAbs. This study should provide insight into the potential use of VRC01 or similar bNAbs during HIV infection and may pave the way for future studies examining the use of a combination of bNAbs.

At present, HIV patients on cART are often able to manage their HIV infection, but this course of treatment is not without problems. Sneller explained, “Despite the success of combination therapy with anti-HIV drugs in suppressing HIV infection, the burden of taking daily medication for life, potential long-term toxicity of these drug regimens, and resistance to anti-HIV drugs necessitates a continued search for effective alternatives for the treatment of HIV infection. It is conceivable that infrequent administration of one or more bNAbs such as VRC01 could result in control of HIV infection without the use of standard HIV medications. Our study is an important first step in determining whether bNAb might offer a better tolerated and more convenient alternative to current anti-HIV medications.”

This study is now open for enrollment. For more information, contact: Cassie Seamon RN 301-402-3481
NIAID Study Reference Kit app is now available for download.

The NIAID Study Reference Kit is a free mobile application (app) that provides health care professionals with information on NIAID clinical research studies being conducted at the NIH Clinical Center in Bethesda, Maryland.

The app allows you to search for studies, find study-related resources, save pages as favorites, and share information via email.

Click here to download the app.

The PACT program develops educational materials for use in the community. Printed copies of materials are distributed to patients at the PACT partner clinics and at community events. We encourage you to order materials to use at your office.

PACT Materials Are Available Free of Charge

Drugs That Fight HIV-1

This 8.5” x 11” brochure shows the several different kinds of antiretroviral drugs currently being used to treat HIV infection. Available in English and Spanish online in PDF: http://www.niaid.nih.gov/volunteer/hivandinfectious/resources/Pages/healthResources.aspx

Health Information Record Booklet

This handy, pocket-sized booklet allows patients to record health information such as lab results and physicians’ names and contact information. It can be conveniently taken to all medical appointments. Text appears in both English and Spanish.

We’re Taking Care of You—A Helpful Guide to HIV and Metabolic Complications

This book is written for individuals with HIV who are at risk for developing metabolic complications that could lead to heart disease. Available in English and Spanish. English version available online in PDF: http://www.niaid.nih.gov/volunteer/hivandinfectious/resources/Pages/healthResources.aspx

A Patient’s Guide to NIAID Clinical Trials

This brochure provides general information about clinical trials and answers such questions as, “What is a clinical trial?” and, “Do I still see my regular doctor?” Text appears in both English and Spanish.

A pocket-sized version of the brochure is also available in Spanish, French, and Amharic. Each brochure also includes the same text in English.

PACT Brochure

This tri-fold brochure provides information about the NIAID PACT program, which includes staff trained to work with health professionals at community clinics to recruit patients for clinical studies at NIH. Available in English and Spanish.

To order or find out more about these materials, ask a PACT team member or call Karen Davison at (301) 348-1606. Some materials are also available online.
ACTIVE Clinical Studies

The following are select NIAID clinical trials that are open. These studies are conducted by NIAID and the NIH Clinical Center in Bethesda, Maryland. To learn more about specific studies, call (301) 348-1606.

Some studies provide compensation for time and travel.

HIV Studies

An Exploratory, Open-label Study of VRC-HIVMAB060-00-AB (VRC01) in Subjects with Chronic HIV Infection Undergoing Analytical Treatment Interruption
(bNAb – Protocol #15-I-0140)
- HIV+ and taken HIV medications continuously for at least 3 years
- CD4 (t-cell) count of 450 or more at screening
- Undetectable HIV viral load for at least 3 years
- Agree to stop HIV medications for 6 months
- No hepatitis infection of any type
- No history of heart problems
- No difficulty having blood drawn
- If female, not currently pregnant or breast feeding

Tesamorelin Effects on Liver Fat and Histology in HIV
(TESLA – protocol # 15-I-0036)
- HIV+ and on HIV medications for at least 6 months, with no changes in the regimen
- Diagnosed with or suspected to have non-alcoholic fatty liver disease (NAFLD)
- No cirrhosis (end stage liver disease)
- Willing to undergo study procedures including MRI, DEXA scan, liver ultrasound and liver biopsy, among others
- Willing to inject study medication/placebo daily for 18 months
- Elevated AST and/or ALT liver enzymes
- No active or ongoing infection with hepatitis A, B, or C
- Do not take insulin
- Do not drink alcohol excessively
- Have a primary care physician

Elite Controller and ART-Treated HIV+ Statin versus ASA Treatment Intervention Study
(ECSTATIN-Protocol #14-I-0039)
- HIV+ patients considered long-term non-progressors or elite controllers
- Never taken HIV medications, with a stable CD4 count for the past 5 years and undetectable viral load OR a person who has taken HIV medications continuously for the past 5 years, with an undetectable viral load for the past 3 years or more
- Never been diagnosed with heart disease or high cholesterol
- Has not taken a statin or daily aspirin therapy in the past 6 months

PET Imaging and Lymph Node Assessment of IRIS in Persons with AIDS
(PANDORA-Protocol #14-I-0124)
- HIV+ patients with absolute CD4 t-cell count < 100 within the past 8 weeks
- Never taken HIV medications or used HIV medications for less than 3 months in total at least 6 months ago
- Patient must agree to allow the NIH to do genetic testing

Clinical Outcomes of Patients with HIV Acquired in Early Life
(COPE – Protocol #12-I-0157)
- HIV infection in the first 10 years of your life
- Participants must be able to travel and to undergo study procedures

Characterization and Management of Patients With HIV-1 Infection Who Experience Virologic Failure Despite Combination Antiretroviral Therapy
(DOTCOM– Protocol #14-I-0009)
- HIV+ patients who have not responded well to at least two ARV medications and have been taking the second ARV medication for at least 6 months (HIV RNA >1,000 copies/mL)
- Participant must be willing to undergo genetic testing and be able and willing to be hospitalized for the inpatient DOT
ACTIVE Clinical Studies (continued)

Leukapheresis Procedures to Study HIV-Specific Immunity  
(LTNP – Protocol #02-I-0086)

- Study includes blood collection, genetic testing, and tissue sampling from HIV+ patients who are suppressing HIV without medications (long-term non-progressors or elite controllers)

A Double Blind Randomized Placebo Controlled Study Examining the Effects of a Non-absorbable (Rifaximin) Antibiotic on the Chronic Immune Activation Observed in HIV-infected Subjects  
(GUTCHEK – Protocol #13-I-0062)

- HIV+ patients currently taking HIV medications
- Viral load undetectable (<50) for at least the past 3 years
- No hepatitis B or hepatitis C
- No history of inflammatory bowel disease, such as Crohn’s disease, ulcerative colitis, or C diff
- Not on antibiotics or taking probiotics (Probiotics in yogurt is allowed)

Effect of Early Antiretroviral Therapy on Maintenance of Immune Cell Function  
(RPHI – Protocol #02-I-0202)

- HIV+ patients not on HAART; either chronically infected or who have acquired HIV within the past three months

A Pilot Study of Hepatic Fibrosis in HIV/AIDS Patients with Chronically Elevated Transaminases on Antiretroviral Therapy  
(TRANSAM – Protocol #06-CC-0153)

- HIV+ patients on HAART who have chronically elevated transaminases, but who do not have HBV or HCV
- Study includes abdominal CT, liver biopsy, and possible specialized ultrasound procedure

Losartan to Reduce Inflammation and Fibrosis Endpoints in HIV (LIFE-HIV) Trial  
(LIFE-HIV – Protocol #14-CC-0179)

- HIV+ patients age 50+ taking HIV medications continuously for at least 2 years
- CD4 (t-cell) count < 600 and viral load < 200
- If on daily aspirin therapy or a statin, no plans to stop in the next 12 months; if not on either of these, no plans to start in the next 12 months
- Systolic blood pressure over 120
- Not treated for hepatitis C in the past 6 months with the drugs interferon or ribavirin
- Not currently taking rifampin, an ACE Inhibitor or an angiotensin receptor blocker (ARB)

Healthy Volunteer Studies

A Phase I Randomized, Double-Blind Pilot Study of Respiratory Syncytial Virus Human Challenge in Healthy Adult Volunteers  
(RSV-Protocol #15-I-0148)

- 18–50 years old
- Healthy and non-smoking
- Willing to use birth control
- Living within 300 miles of the NIH Clinical Center in Bethesda, Maryland

Phase I Study of the Safety of Replication-Defective Herpes Simplex Virus-2 Vaccine, HSV529, in Adults Aged 18 to 40 Years With or Without HSV Infection  
(HSV529 – Protocol #13-I-0172)

- Age 18-40 years
- Are healthy or have been infected with the herpes simplex virus

Phase 1 Study of Safety and Immunogenicity of Ad4-HIV Vaccine Vectors in Healthy Volunteers  
(NACHO – Protocol #14-I-0011)

- Age 18-49 years for vaccines; age 18-65 years old for household and intimate contacts
- Negative FDA-approved HIV test
The Partnership for Access to Clinical Trials (PACT) program brings together Washington, D.C.-area community-based health care providers, their patients, and research clinicians from NIAID. The focus of the program is to increase access to research for people who may be underrepresented in clinical studies.

The PACT team includes multicultural health care professionals with skills in phlebotomy, case management, health promotion, and data processing and who have knowledge of the Washington, D.C., area and its diverse population and varied health needs. Project staff members assist community providers in identifying appropriate studies and facilitating the study referral process.

Contact PACT:
pacthivstudies@mmgct.com
Para español — pacthivstudiesespanol@mmgct.com
To learn more, visit www.niaid.nih.gov/volunteer/hivandinfectious/pages/pact.aspx.

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