

The **HAVACS (HIV Atlanta VA Cohort Study)** was initiated in 1982 to clinically care for and study all HIV+ veterans seeking care at the Atlanta VA Medical Center. To date, over 3,000 patients have been entered into this cohort and database. The prospective collection of data was begun in 1982 and includes the full HIV history of patients including any care they received for their HIV disease before receiving care at the AVAMC. The database provides the physicians and other health care providers with an individual's summary of current pertinent patient information. Additionally, this database is used for surveillance and research analyses and aids in the identification of patients eligible for research protocols. The Veterans Affairs (VA) population is unique in that these patients are likely to receive all treatment and care in the VA system. Only 1.8% have been lost to follow-up since 1982. Therefore, unlike many large clinical and research databases, loss to follow-up or missing clinical information is not a source of bias.

Information collected on standardized forms includes demographic characteristics, clinical symptoms, HIV-related diagnoses, prophylaxes, antiretroviral regimens, vaccinations, inpatient visits and diagnoses and laboratory measurements. These data are updated for every patient contact with the AVAMC including inpatient and clinic visits. Pharmaceutical data are also collected from the computerized pharmacy database. All data are kept in a secured and centralized database. If the patient has left care from the VA system, outcome data are collected from active sources such as family members and passive sources such as National Death Index and the National Veterans Benefits Database. The database is routinely checked for quality of data during other analyses and routine use of the patient summary sheets.

The patient population is 99% male, 69% African American, 29.5% Caucasian and 1.5% Hispanic. MSM is the primary risk factor for 50% of the cohort; IV drug abuse accounts for an additional 19% and heterosexual contact 4% of the HIV risk factor. Twenty-two percent of the patients are naïve to antiretrovirals; 30.7% were naïve before starting HAART. Co-infection with hepatitis C is common with 35% of the cohort being dual infected. Mean age is 47 years.

Multiple studies recently have been published from the HAVACS database. These studies include two recent manuscripts on the impact of hepatitis C coinfection on survival, adverse events of protease inhibitors and response of HIV+ patients to hepatitis A vaccine. Most recently, Drs. Guest and Rimland have been part of a Department of Health and Human Services grant entitled "Protease inhibitor-induced hyperlipidemia in AIDS" that has resulted in two manuscripts to date. In these cross-sectional studies of both men and women, both protease inhibitors and non-nucleoside reverse transcriptase inhibitors were found to be associated with elevated apolipoproteins, specifically apoc-III. In the women, an additional association was found with elevated total cholesterol level that was not seen with the men. However, an elevation was seen in triglyceride levels for the men but not the women. These data add to the growing evidence of gender-related differences in the natural history, pharmacokinetics and toxicity of antiretroviral therapy.

A subset of patients from HAVACS are currently enrolled in VACS (n=500), SMART, OPTIMA, and FRAM 1 and 2.

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## HAVACS publications:

1. Stroud L, Srivastava P, Culver D, Bisno A, Rimland D, et al: Nosocomial infections in HIV-infected patients: preliminary results from a multicenter surveillance system (1989-1995). *Inf Control and Hospital Epidemiol*, 1997; 18:479-485.
2. Stuyver L, Wyseur A, Rombout A, Louwagie J, Scarcez T, Verhofstede C, Rimland D, Schinazi RF, Rossau R: Line probe assay (LiPA) for the rapid detection of drug-selected mutations in the HIV-1 reverse transcriptase gene. *Antimicrob Agents Chemother*, 1997; 41:284-291.
3. Ward TT, Rimland D, Kauffman C, Huycke M, Evans TG and Heifetz L: Randomized, open label trial of azithromycin plus ethambutol versus clarithromycin plus ethambutol therapy of Mycobacterium avium complex bacteremia in patients with human immunodeficiency virus infection. *Clin Inf Dis* 1998; 27:1278-85.
4. Staples CT, Rimland D, Dudas D: Hepatitis C in HIV Atlanta VA Cohort Study (HAVACS): The effect of co-infection on survival. *Clin Inf Dis* 1999; 29:150-4.
5. Edge MD, Rimland D: Reasons for failure of prophylaxis for Pneumocystis carinii pneumonia. *AIDS* 1999; 13:1991-2.
6. Navin TR, Rimland D, Lennox JL, Jernigan J, Cetron M, Hightower A, Roberts JM, Kaplan J: Risk factors for community-acquired pneumonia among persons infected with human immunodeficiency virus. *J Inf Dis* 2000; 181:158-164.
7. Chapman LE, Green TA, Parekh BS, Ahmed F, Rimland D, Kaplan JE, Thompson M, Folks TM. Effect of clinical events on plasma HIV-1 RNA levels in individuals with CD4 above 500. *AIDS* 2000; 14:1135-46.
8. Nicholson JKA, Browning SW, Hengel RL, Lew E, Gallagher LE, Rimland D, McDougal JS. CCR5 and CXCR4 expression on memory and naïve T cells in HIV-1 infection and response to highly active antiretroviral therapy. *JAIDS* 2001; 27:105-115.
9. Lew E, Gallagher L, Kuehnert M, Rimland D, Hubbard M, Parekh B, Zell E, Jarvis W, Jason J. Intracellular cytokines in the acute response to highly active antiretroviral therapy. *AIDS* 2001; 15:1665-1670.
10. Lasker BA, Elie CM, Lott TJ, Espinel-Ingroff A, Gallagher L, Kuykend-Kellum ME, Pruitt WR, Wamock DW, Rimland D, McNeill MM, Reiss E. Molecular epidemiology of Candida albicans strains isolated from the oropharynx of HIV-positive patients at successive clinic visits. *Med Mycology* 2001; 39:341-52.
11. Paddock C, Folk SM, Shore GM, Machado LJ, Huycke MM, Slater LN, Liddell AM, Buller RS, Storch GA, Monson TM, Rimland D et al. Infections with Ehrlichia chaffeensis and Ehrlichia ewingii in persons coinfecting with human immunodeficiency virus. *Clin Inf Dis* 2001; 33:1586-94.
12. Rimland D, Navin TR, Lennox J, Jernigan J, Kaplan J, Erdman D et al: Prospective study of etiologic agents of community-acquired pneumonia in patients with HIV infection. *AIDS* 2002; 16:83-95.
13. Cannon MJ, Dollard SC, Black JB, Edlin BR, Hannah C, Hogan SE, Patel MM, Jaffee HW, Offermann MK, Spira TJ, Pellett PE, Gunthel CJ. Risk factors for Kaposi's sarcoma in men seropositive for both human herpesvirus 8 and human immunodeficiency virus. *AIDS* 2003;17:215-222.
14. Justice AC, McGinnis KA, Atkinson JH, Heaton R, Young C, Sadek J, Madenwald T, Becker JT, Conigliaro J, Brown ST, Rimland D, Crystal S, Simberkoff M for the VACS 5 Project Team. Neurocognitive and psychiatric disorders among HIV positive and negative veterans in care: Veterans Aging Cohort 5 Site Study. *AIDS* 2004; 18:S49-S60.
15. Volberding PA, Levine AM, Dieterich D, Mildvan D, Mitsuyasu R, Saag M. Anemia in HIV Working Group\* (JL Guest, member). Anemia in HIV infection: clinical impact and evidence-based management strategies. *Clin Infect Dis* 2004; 38:1454-1463.
16. Guest JL, Ruffin C, Tschampa JM, DeSilva KE, Rimland D. Differences in rates of diarrhea in patients with human immunodeficiency virus receiving lopinavir/ritonavir or nelfinavir. *Pharmacotherapy* 2004; 24:727-735.
17. Anderson KB, Guest JL, Rimland D. Hepatitis C coinfection increases mortality in HIV-infected patients in the highly active antiretroviral therapy era: data from the HIV Atlanta VA Cohort Study. *Clin Infect Dis* 2004; 39: 1507-13.
18. Guest JL, Anderson KB, Rimland D. The hepatitis C and HIV coinfecting patient, pre- and post-HAART differences in survival in the HAVACS cohort. *Contagion* 2005;2:360-364.

19. Fisk TL, Lundberg BE, Guest JL, Ray S, Barrett TJ, Holland B, Stamey K, Angulo FJ, Farley MM. Invasive infection with multidrug-resistant *Salmonella enterica* serotype Typhimurium definitive type 104 among HIV-infected adults. *Clin Infect Dis* 2005;40:1016-1021.
20. Rimland D, Guest JL. Response to hepatitis A vaccine in HIV patients in the HAART era. *AIDS* 2005;19:1702-1704.
21. Rimland D, Guest JL, Hernandez I, del Rio C, Le NA, Brown WV. Increased apoCIII to triglyceride ratios in HIV positive men on antiretroviral therapy. *HIV Med*, 2005; 6:326-333.
22. Fultz SL, Goulet JL, Weisman S, Rimland D, Leaf D, Gibert C, Rodriguez-Barradas MC, Justice AC. Differences between HIV and general medical providers in comfort with providing primary care. *Clin Infect Dis* 2005; 41:738-43.
23. Rimland D, Guest JL, Hernandez I, del Rio C, Le NA, Brown WV. Antiretroviral therapy in HIV positive women is associated with increased ApoC-III, triglycerides and total cholesterol. *J Acquir Immune Defic Syndr* 2006;42:307-313.
24. Osborn M, Guest JL, Rimland D. Hepatitis B and HIV coinfection: relationship of different serologic patterns on survival and liver disease. *HIV Med (in press)*

### **Selected HAVACS abstracts:**

1. Guest JL, Rimland D. Decreased incidence of CMV disease unrelated to use of HAART: data from HAVACS (HIV Atlanta Veterans Affairs Cohort Study). Presented at the Society for Epidemiologic Research 32<sup>nd</sup> Annual Meeting, Baltimore, 1999.
2. Guest JL, Clark WS, Rimland D, Curran J, Liff J. Prognostic indicators beyond CD4+ thresholds to assess risk of *Pneumocystis carinii* pneumonia and disseminated *Mycobacterium avium* complex in HIV+ patients: data from HAVACS (HIV Atlanta Veterans Affairs Cohort Study). Presented at the Society for Epidemiologic Research 32<sup>nd</sup> Annual Meeting, Baltimore, 1999.
3. Guest JL, Hamilton DT, Rimland D. The effect of the use of protease inhibitors on immunologic factors in HIV+ patients: data from HAVACS (HIV Atlanta Veterans Affairs Cohort Study). Presented at the Society for Epidemiologic Research 33<sup>rd</sup> Annual Meeting, Seattle, 2000.
4. Gallagher L, Le Flore DB, Guest JL, DeSilva KE, Marston BJ, Rimland, D. The CARDS panel: a collaborative approach to complicated antiretroviral decisions. Presented at the 12<sup>th</sup> Annual ANAC Conference, San Juan, PR, 2000.
5. Rimland D, Guest JL, Smith R. Incidence of herpes Zoster in HIV disease: no evidence for increase after introduction of potent antiretroviral therapy. Presented at the 1<sup>st</sup> IAS Conference on HIV Pathogenesis and Treatment, Buenos Aires, Argentina, 2001.
6. DeSilva KE, Guest JL, Flaherty TD, Marston BJ, Rimland D. Tolerability of Efavirenz in patients with a history of mental health disorder. Presented at the American College of Clinical Pharmacy 2001 Conference, Tampa, Florida, 2001. (*Pharmacotherapy* 2001, 21:1273.)
7. Guest JL, Rimland D, Stolfus SA. Prognostic value of immunologic and virologic markers in late-stage HIV-1 disease: data from HAVACS (HIV Atlanta Veterans Affairs Cohort Study). Presented at the 9<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, Seattle, Washington, 2002. (#268-T)
8. Rimland D, Guest JL, Anderson KB. The effect of hepatitis C coinfection on survival in the HIV Atlanta Veterans Affairs Cohort Study (HAVACS) in the post HAART era. Presented at the 9<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, Seattle, Washington, 2002. (#658-M)
9. Guest JL, DeSilva KE, Le Flore DB, Flaherty TD, Rimland D. Incidence of CNS effects in patients with a history of mental health disorders and/or substance abuse starting an Efavirenz-containing regimen: data from HAVACS. Presented at the International AIDS 2002 Conference, Barcelona, Spain, 2002.
10. Guest JL, Ruffin C, DeSilva KE, Tschampa JM, Rimland D. Rates of treated diarrhea in patients on either a Kaletra- or a Nelfinavir-containing regimen: data from HAVACS. Presented at the 40<sup>th</sup> Annual Meeting of Infectious Disease Society of America Conference, Chicago, 2002. (#476)
11. Mildvan D, Creasgh T, Leitz G and the Anemia Prevalence Study Group (J. Guest, member). Greater prevalence of anemia in women and African Americans with HIV/AIDS in the HAART era: a study of about 10,000 patients. Presented at the 40<sup>th</sup> Annual Meeting of Infectious Disease Society of America Conference, Chicago, 2002. (#475)
12. Guest JL, Rimland D, Tschampa JM, DeSilva KE, Robinson M. Comparison of diarrhea in patients on Nelfinavir-containing regimen followed by a lopinavir/ritonavir-containing regimen: data from HAVACS. Presented at HIV DART 2002: Frontiers in Drug Development for Antiretroviral Therapy, Naples, Florida, 2002. (#070)
13. Guest JL, Rimland D, Hernandez I, del Rio C, Le N-A, Brown WV. Elevated ApoC-III levels are associated with hyperlipidemia in men and women on PI or NNRTI regimens. Presented at 2<sup>nd</sup> Annual Meeting for Lipodystrophy in HIV/AIDS Symposium and Retreat, Davis, California, 2003.

14. Hernandez I, del Rio C, Folch E, Lennox J, Le N-A, Rimland D, Guest JL, Brown WV. Lipid abnormalities among PI-treated women may be due to excess production of ApoC-III. Presented at the 10<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, Boston, Massachusetts, 2003. (#751)
15. Guest JL, Rimland D, Hernandez I, del Rio C, Le N-A, Brown WV. Elevated ApoCIII levels are Associated with Elevated Cholesterol and Triglycerides in HIV Positive Men on PI or NNRTI Regimens. Presented at the 10<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, Boston, Massachusetts, 2003. (#749)
16. Rimland D, Guest JL. Mortality in the HIV Atlanta VA Cohort Study (HAVACS): A 22-Year Analysis. Presented at the 11<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, San Francisco, CA, 2004. (#873)
17. Rimland D, Guest JL. Response to hepatitis A vaccine in HIV patients in the HAART era. Presented at the International AIDS 2004 Conference, Bangkok, Thailand, 2004. (#MoPeB 3299)
18. Guest JL, Ataher QS, Rimland D. Racial Differences in Response to EFV-Containing vs. LPV/r-Containing Regimens. Presented at the 44<sup>th</sup> ICAAC, Washington DC, 2004. (#H-579)
19. Rimland D, Guest JL. Decreasing incidence of all pneumonias in the HAART era. Presented at the 12<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, Boston, MA, 2005. (#879)
20. Guest JL, Rimland D, Patterson B, DeSilva KE. Tenofovir induced nephrotoxicity in the first year of therapy: Data from HAVACS (HIV Atlanta VA Cohort Study). Presented at the 13<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, Denver CO, 2006. (#778)
21. Osborn M, Guest JL, Rimland D. Hepatitis B and HIV coinfection: relationship of different serologic patterns on survival and liver disease. Presented at the 13<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, Denver CO, 2006.
22. Guest, JL, Rimland D, Ataher Q. Characterization of lipid changes associated with lopinavir/ritonavir (LPV/r) vs. efavirenz (EFV) with and without stavudine (d4T) in HIV-infected patients. Presented at the XVI International AIDS Conference, Toronto Canada, 2006. (#CDB0727)
23. Guest JL, Rimland D, Powell K, Patel A. Choice of first HAART regimen impacts survival: data from HAVACS. Presented at the XVI International AIDS Conference, Toronto Canada, 2006. (#CDB0477)
24. Rimland D, Guest JL. Increasing incidence of prostate cancer in the Atlanta VA Cohort Study (HAVACS). Presented at the 14<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, Los Angeles CA, 2007. (#Q-105).

