U.S. Military HIV Natural History Study and Repository

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Outline

- Brief IDCRP background
- The DoD HIV Natural History Study (NHS)
- NHS Repository: specimen collection and overview
- Opportunities for collaboration
IDCRP Clinical Research Network
IDCRP HIV/STI Working Group

Collaborations

- 1986-present  N. Michael, et al; WRAIR/MHRP*
- 1998-present  S. Ahuja; UT Hlth Sci Cntr San Antonio (UTHSCSA)
- 2003-present  E. Janoff; Univ Colo Health Sci Center
- 2004-09      S. Gange; Johns Hopkins
- 2004-present  C. Thio; Johns Hopkins
- 2004-present  F. Maldarelli; NCI
- 2005-08      M. Silverberg; Kaiser Permanente
- 2005-09      D. Purcell; CDC
- 2005-09      S.J. Gao, UTHSCSA
- 2005-present  C. Lane, J. Mican, I. Sereti, D. Follman; NIAID
- 2005-10      B. Larder, A. Revell; Resistance Database Initiative
- 2006-present  J. Mascola, D. Douek; NIAID/Vaccine Rsrch Cntr
- 2006-present  M. Carrington; SAIC/NCI
- 2007-present  B. Walker, P. de Bakker; Harvard
- 2007-present  D. Goldstein; CHAVI
- 2008-present  S. Letendre; HIV/AIDS Neurobehav Rsrch Cntr
- 2008-present  J. Neaton, F. Gordin; INSIGHT/START
- 2009-present  D. Rimland, V. Marconi; Atlanta VA/Emory
- 2009-present  D. Haas; Vanderbilt
- 2009-present  R. Shaffer, et al; Naval Hlth Rsrch Cntr*
- 2009-present  C. Sessions, A. Eick; AFHSC*
- 2010         J. Eron, S. Cole; UNC
- 2010-present  A. Justice, D. Rimland; Veterans Affairs/VACS
- 2010-present  B. Torbett; Scripps
- 2010-present  J. Ledgerwood; NIAID/VRC
- 2011-present  R. Brinkman, Univ BC
- 2011-present  T. Sanchez, J. Gaydos; DoD GEIS*

*DoD Org.
The Network ID IRB at USU

Crucial to the Success of the IDCRP

- The IDCRP research infrastructure, combined with the Network ID IRB at USU, provide:
  - First large clinical consortium capable of performing multicenter ID research with a single IRB review
  - Rapid initiation of operationally relevant infectious diseases research within the DoD network
  - Ability to generate evidence-based recommendations to leadership with the power of multicenter enrollment
  - Effectively able to leverage the strengths of multiple DoD clinical and research entities
DoD HIV Surveillance

- AD HIV screening program in place since Oct 1985
  - All applicants for military service tested – positives excluded
  - AD tested every 1-5 years, policy now every 2 years and within 6 months of deployment
  - All AD HIV+ must be evaluated at least every six months at Military Treatment Facility (MTF)
Annual No. of Newly Identified HIV-1 Positive Active Duty U.S. Military Personnel, 1985/86 to 2007

U.S. Military HIV Natural History Study

- Ongoing prospective continuous enrollment observational cohort study
  - HIV+ DoD Active Duty & Beneficiaries ≥18 y/o
  - All subjects provide Informed Consent
  - Visits q6 months → clinical data + repositoried blood

- Strengths of the cohort
  - Racial diversity
  - Equal access to healthcare
  - Stable socioeconomic status
  - Educated
  - Minimal substance abuse
  - Excellent follow-up
Approx 5400 enrolled, 3200 dated seroconverters
Median seroconversion window: 1.3 years (IQR 0.8-2.2)
Median time to enrollment: 1.1 years (IQR 0.1-3.3)
Mean age at enrollment: 31.7 years (SD 8.5 yrs)
Active duty at enrollment: 87.3%
Male gender: 90.7%
NHS Data Collected
Record review, CRC interview, Lab

- General Medical Information
  - Demographics
  - Comorbidities and Health Status
    - Medical history, surgeries, ongoing diagnoses
    - Medications
    - Quality of Life, CES-D
    - Vaccinations
  - Co-infections
    - STDs
    - Viral hepatitis
  - Routine labs (chem, lft, lipid, cbc, ua, etc)
- Death (active query of multiple sources)
NHS Data Collected
Record review, CRC interview, Lab

- HIV Disease Information
  - Testing history
  - Transmission risk group (*NEW 2011*)
  - AIDS defining conditions
  - Treatment and treatment complications
  - All CD4 and VL
  - HIV viral resistance testing
NHS Repository
Specimen Processing

- Fasting specimen preferred (flag in DB)
- Serum and plasma via SST and PPT/EDTA tubes
  - Remote sites ship same day as draw
  - Aliquoting done centrally
- PBMC from EDTA (local) or CPT (remote)
- 2 processing/storage sites: Rockville, San Antonio
- -80°C storage of plasma and serum
- LN₂ storage of PBMC
- 100% accountability (aliquot-level inventory DB)
NHS Repository
All Vial Types, All Visits

[Graph showing the number of vials obtained and removed over time, with data extending from 1986 to 2010.]
Some potential areas of collaboration

- Longitudinal HIV outcomes incl AIDS
- Serious non-AIDS events
- HAART outcomes
- Adherence
- Aging
- Alcohol and substance use
- Biomarkers
- Cost effectiveness
- Many more...

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