

Walter Reed Army Institute of Research (WRAIR)

BIOMEDICAL INNOVATIONS FOR INFECTIOUS DISEASES AND MILITARY PSYCHIATRY AND NEUROSCIENCE

*DEPUTY COMMANDER FOR OPERATIONS
WALTER REED ARMY INSTITUTE OF RESEARCH*



Bottom Line Up Front

Infectious diseases (ID) will continue to represent a threat to the Soldier and global citizen in both conflict and peacetime.

Brain health and behavioral resilience are long term legacy issues of the active Warfighter and veteran.

DoD requires military-oriented biomedical research platforms to develop threat mitigating countermeasures and actionable knowledge products.



NATIONAL SECURITY STRATEGY

FEBRUARY 2015

Now, at this pivotal moment, we continue to face serious challenges to our national security, even as we are working to shape the opportunities of tomorrow. Violent extremism and an evolving terrorist threat raise a persistent risk of attacks on America and our allies. Escalating challenges to cybersecurity, aggression by Russia, the accelerating impacts of climate change, and the outbreak of infectious diseases all give rise to anxieties about global security. We must be clear-eyed about these and other challenges and recognize the United States has a unique capability to mobilize and lead the international community to meet them.

America is the world leader in fighting pandemics, including HIV/AIDS, and in improving global health security. At home, we are strengthening our ability to prevent outbreaks and ensure sufficient capacity to respond rapidly and manage biological incidents. As an exemplar of a modern and responsive public health system, we will accelerate our work with partners through the Global Health Security Agenda in pursuit of a world that is safer and more secure from infectious disease. We will save lives by strengthening regulatory frameworks for food safety and developing a global system to prevent avoidable epidemics, detect and report disease outbreaks in real time, and respond more rapidly and effectively. Finally, we will continue to lead efforts to combat the rise of antibiotic resistant bacteria.

WRAIR Mission and Vision

Mission:

Ensure the health and readiness of the Warfighter by anticipating, mitigating, and/or eliminating future threats to the force by executing strategic and relevant biomedical research, education, and consultation on military infectious disease, psychiatry and neuroscience

Vision:

We are the premier Department of Defense biomedical research enterprise

Broad Spectrum of Competencies

- **Center for Infectious Diseases Research**

- Vaccine development and drug discovery
- Pathogen characterization and repositories
- Diagnostics development and evaluation
- Advanced immunology (immunogenicity and correlates of protection)

- **Center for Military Psychiatry and Neuroscience**

- Psychological Resilience
- Sleep Management
- TBI, Neuroprotection, and Neurorestoration

- **Science and Science Support Capacities and Capabilities**

- Bioproduction
- Clinical trials execution
- Veterinary support services
- Entomology
- Educational Programs

Center for Infectious Disease Research

Military Malaria
Research Program

Military HIV
Research Program

Bacterial Diseases

Translational
Medicine

Viral Diseases

Entomology

Preventive
Medicine

WRAIR CONUS and OCONUS Platforms

Additional Research Sites

- ⊙ Tanzania
- ⊙ Uganda
- ⊙ Cameroon
- ⊙ Nigeria
- ⊙ Mozambique

- ⊙ Cambodia
- ⊙ Vietnam
- ⊙ Philippines
- ⊙ Bangladesh
- ⊙ Bhutan
- ⊙ Nepal
- ⊙ Mongolia



International research capabilities, expertise, and relationships

>2,000 military, civilian, support personnel

Infectious Diseases Research Successes

WRAIR led the first/only HIV vaccine study to show efficacy

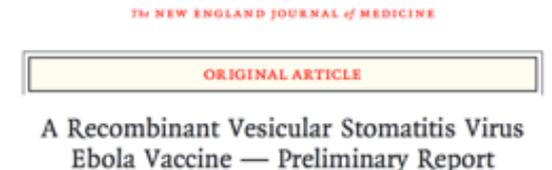
- RV144 in Thailand was international collaboration with 16,000 Thai volunteers
- Showed a preventive vaccine IS possible



Play key roles in leading Dengue and Malaria vaccine candidates

Advancing three Ebola vaccine candidates

- US trial of VSV candidate at WRAIR
- African sites leveraged for Ebola vaccine research
 - Conducted first Ebola vaccine study in Africa
 - Ongoing trials in Uganda and Nigeria



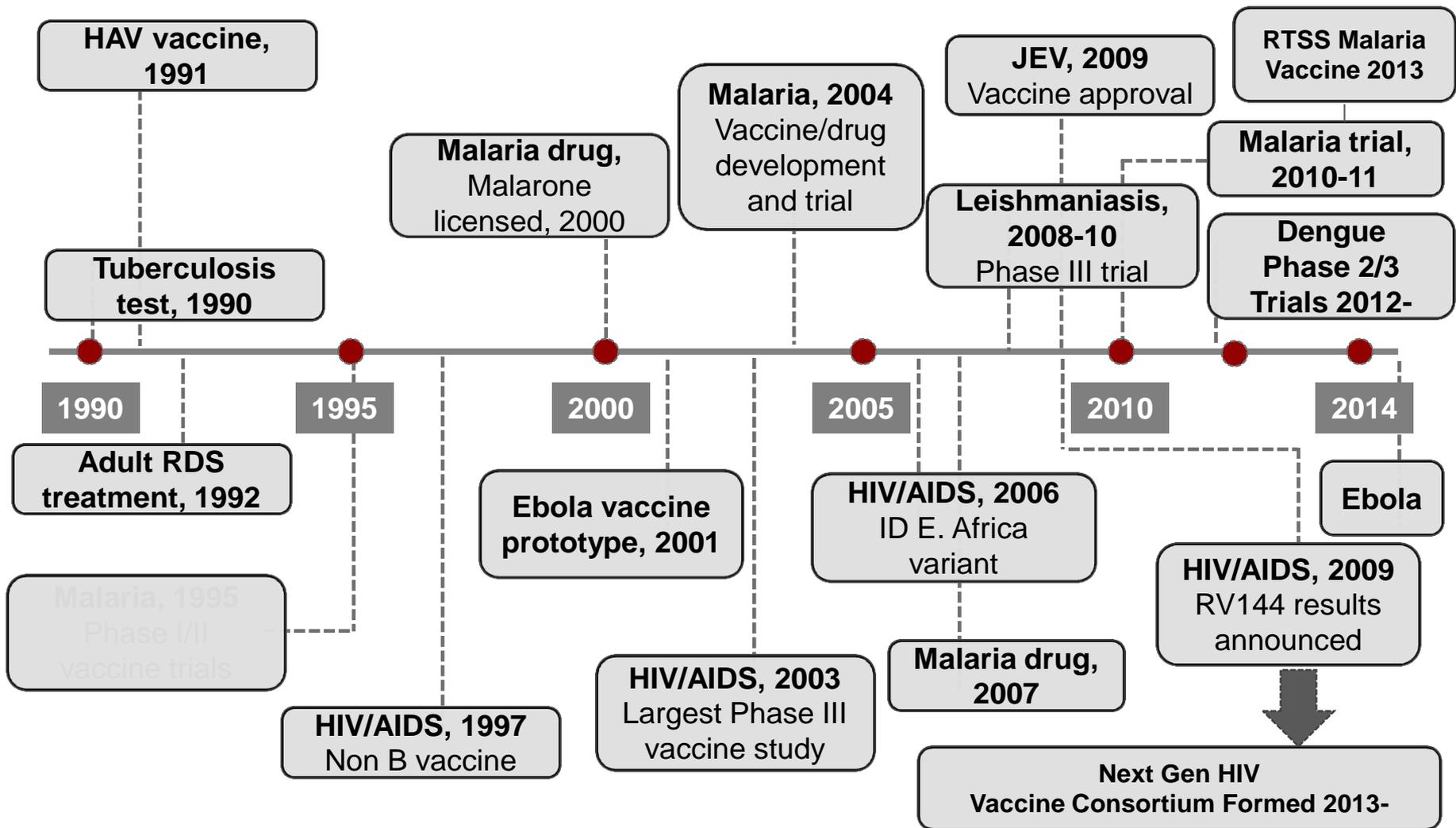
Key capabilities for responding to the next infectious diseases crisis

Battling Drug Resistant infections

One-of-a-kind applied research and surveillance for infections in the U.S.

- **Unique Repository and Capabilities**
 - Multidrug-resistant Organism and Repository Network (MRSN) is the largest, most comprehensive such surveillance system and repository in the world
 - Recognized by the White House's *National Action Plan (NAP) for Combating Antibiotic-resistant Bacteria* and model for newer civilian programs
- **Health Care and Combat Associated Infections**
 - Improve clinical care by performing real time sequencing and analysis of suspect infections
- **Outbreaks at Army, Navy Air Force and Affiliated hospitals**
 - Informs clinical practice, healthcare policy and enhanced infection control

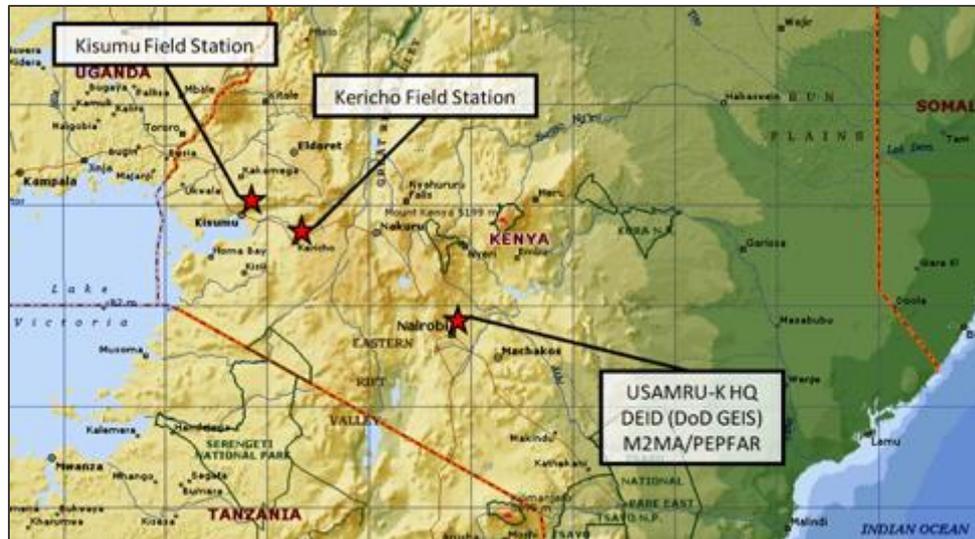
Contributions to Infectious Diseases Research



WRAIR Operations in Africa



- U. S. Army Medical Research Unit-Kenya – Nairobi
 - ~40-year partnership with the Kenyan Government
 - >14 USG employees, > 300 local employees
 - Support ASAALT programs, GEIS, public health responses



Kondele Research Center, Nyanza Province

WRAIR Operations in Africa

- Military HIV Research Program (MHRP)
 - Kenya, Nigeria, Mozambique
Tanzania, and Uganda
 - PEPFAR program execution
 - Clinical trial execution
- Military to Military Collaboration
 - Nigerian, Kenyan, and Tanzanian militaries
 - Key element in AFRICOM medical engagement strategy



*Nigerian Ministry of Defense delegation
visits MHRP in Rockville, Maryland*

WRAIR Operations in the Caucasus Region



U. S. Army Medical Research Unit-Georgia (USAMRU-G), Tbilisi, Georgia

- Conducts bench science, surveillance, and infectious disease characterization and diagnostics
- Origins with DTRA mission and at the request of the Georgian Prime Minister

Current Focus

- CBEP (capacity building)
- GEIS (biosurveillance)

Future Directions

- ASAALT S&T and AD DEV
- DHP, GEIS, CARB, GHSA



WRAIR Operations in Southeast Asia



Armed Forces Research Institute of the Medical Sciences, Bangkok, Thailand

- >25 USG personnel, >400 local employees
- >50-year partnership with the Royal Thai Army
- AAALAC-accredited animal facility with >600 nonhuman primates, breeding colony
- BSL-3 laboratory, CAP certified
- Expansive regional presence



Center For Military Psychiatry & Neuroscience

Applied Neurobiology

Behavioral Biology

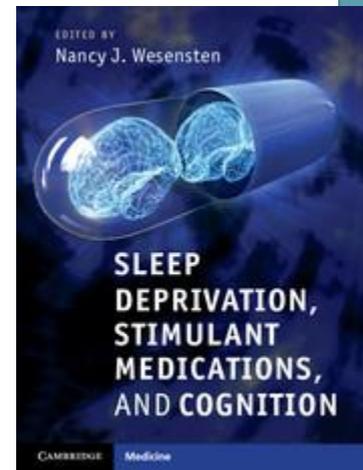
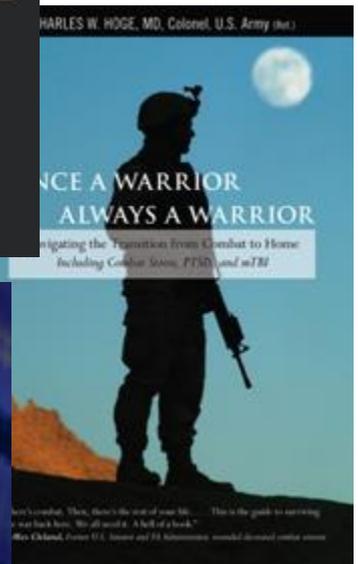
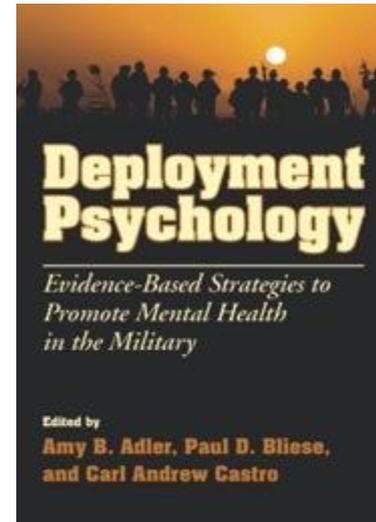
Closed Head Injury and
Neuroprotection

Military Psychiatry

Military Psychiatry & Neuroscience

Develop tools to:

Diagnose, prevent, and mitigate the effects of psychological demands, continuous operations, and brain trauma on the health and well-being of our Service Members.



Military Psychiatry

Mission:

- Improve psychological functioning
- Reduce the impact of mental disorders
- Enhance the resilience of Soldiers, leaders, and families.
- Improve diagnoses, treatment and management across the continuum of TBI



Products:

- Comprehensive survey-based mental health assessments for Army and DoD
- Responsible for staffing and implementing in-theater Mental Health Advisory Teams (MHATs)
- Validated psychological resiliency programs



Brain Health, Neuroprotection & Neurorestoration

Mission:

- Reduce death and the chronic residual disability caused by brain injury
- Focus on improved diagnostics and the discovery of novel therapeutic strategies
- Study mechanisms for restoration of function during chronic states



Products:

- Identifying molecular biomarkers of brain injury and treatment efficacy
- Developing and evaluating novel neuroprotective and neurorestorative mechanisms and treatment modalities



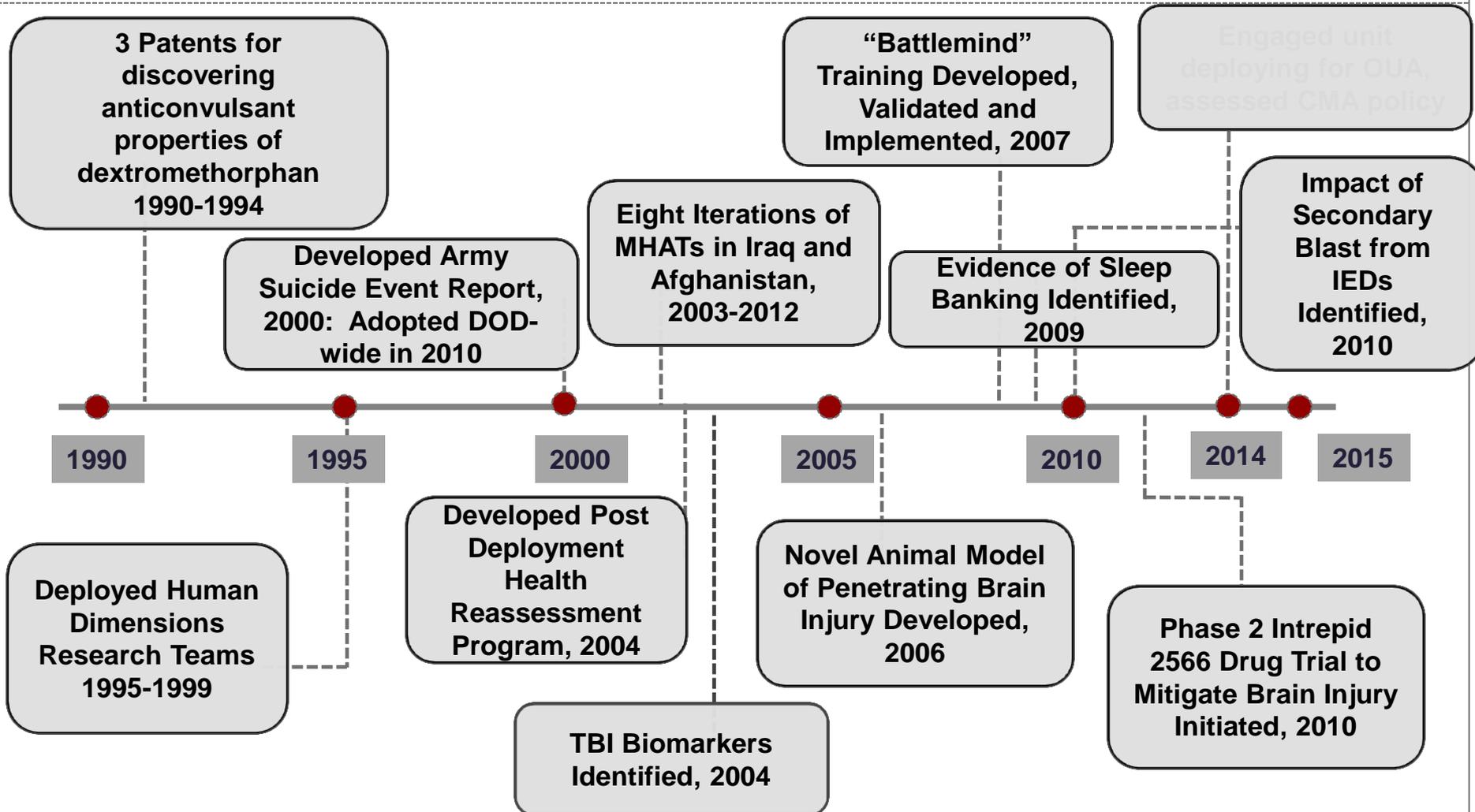
USAMRU-E → USAMRU-W

Sembach, Germany → Tacoma, Washington

- 30+ year EUCOM partnership
- 13 staff, 10 scientific
- The Army's behavioral health (BH) research asset co-located with operational units
- Addresses emerging BH issues and develops information products while providing rapid response to senior leaders
- Expertise conducting studies with operational units and complex randomized trials in the field



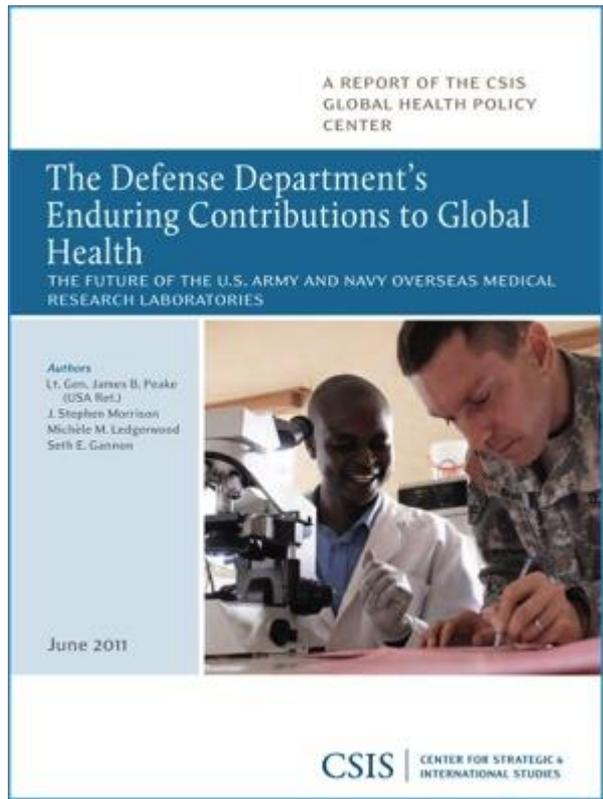
US Military Contributions to Military Psychiatry and Neuroscience



WRAIR Global Laboratory Enterprise

- SME, competencies, capabilities, relationships
- U.S. military focused
- Product/Acquisitions focused
- Infectious diseases and military psychiatry & neuroscience
- CONUS and OCONUS Assets (Asia, Africa, Caucuses)
- Support programs allowing “bench to bedside”
 - AAALAC- Accredited Animal Facilities (US & Thailand)
 - Pilot Bioproduction Facility—a Strategic DoD Asset
 - Clinical trials centers
 - CAP certified and BSL 3 laboratories

DoD OCONUS Laboratories



Center for Strategic International Studies (CSIS) provided independent evaluation of DoD OCONUS laboratories. Report found that DoD labs:

- Protect deployed forces
- Develop vaccines and therapies
 - Strengthen the scientific community in the host country
 - Leverage partnerships with other U.S. government agencies
 - Labs are a “critical partner” for NIH
- Cost-effective with clear ROI

Extensive Collaborations



- Strong ties with international government, ministries of health, militaries
- Strategic partnership with NIAID/NIH
- Broad pharmaceutical company partnerships (Sanofi, J&J, Crucell, Novartis, GSK)
- Collaborative relationship with the Bill & Melinda Gates Foundation
- Extensive engagements with international normative bodies (WHO, UNAIDS) and Non Government Organizations

Science Support Capacities and Capabilities

Clinical Trials

Veterinary Services

Educational Programs

Bioproduction



Human Clinical Trials

- Highly experienced
 - Since 2011 26 trials, 842 volunteers
 - 10 human malaria challenge studies
- Full spectrum of services for clinical trial execution
 - Idea → Execution → FDA reporting
- Co-located with numerous research assets
 - Animal research facilities and Insectary
 - Product manufacturing facility (GMP)
 - Basic and applied science labs



Veterinary Services

- 38 Military, 6 Government, 35 Contract personnel
- AAALAC accredited, 155,000 sq. ft. vivarium, housing 18,000 animals
- Full spectrum of protocol support
 - Procure & house animals
 - Veterinary consultation & animal model development
 - Surgery support
 - Diagnostic & comparative pathology
- Unique capabilities:
 - BSL-3 Laboratory
 - Nonhuman primate colony
 - Training program
- Laboratory Animal Medicine Post Doctoral Residency Program



Bioproduction

- Diverse experience and production portfolio
 - Vaccines, therapeutics, diluents, adjuvants
- Full spectrum manufacturing and fill process
- Process development and technology transfer expertise
- Assay development supporting regulatory compliance



Educational Programs

- Hands-on programs across diverse ages
 - Near Peer Mentors (NPM)
 - College Qualified Leaders (CQL)
 - National Research Council (NRC)
 - US Army Education Outreach Programs
 - Engineering Apprentice Program (SEAP)
 - Oak Ridge Institute for Science and Education (ORISE)
 - Science Technology Engineering and Mathematics (STEM)
 - Gains in the Education of Mathematics and Science (GEMS)
- Developing the scientists who will meet our global health challenges



Operational Clinical Infectious Disease Course

WRAIR helps improve medical providers' ability to identify, diagnose, and treat infectious diseases of significance to deploying and re-deploying U.S. Service Members

Five-day course at WRAIR

- Hands-on for medical providers and medical support personnel with requirements to identify, diagnose, and treat infectious diseases threatening military personnel or travelers

Three-day on-site course

- Units can request this course
- Infectious disease and preventive medicine experts provide classroom and hands-on training directed at geographic region-specific disease threats



WRAIR: Strategic Focus

- Advance research and accelerate product development to optimize care and disease prevention for our Service Members
 - Increase collaborations with USG and non-USG collaborators
 - Expand and diversify funding streams
 - Transition from program based assets into enterprise-wide competencies
- Ensure WRAIR's relevance, positive impact, and support for the U.S. Military
 - Further develop agile organization to anticipate future threats and respond to new challenges
 - Optimize operations to ensure efficiency and effectiveness
 - Enhance ongoing communications with external research partners, other government agencies and military commands
- Provide long-term expertise for Army by developing next generation of military focused researchers and leadership
 - Guarantee no gaps in knowledge and experience
 - Retain critical talent and knowledge at WRAIR, OCONUS sites and within US Military



WRAIR

Walter Reed Army
Institute of Research

Soldier Health • World Health

Committed to innovation and excellence, with military-specific focus to protect the health and readiness of the Warfighter