

# IDCRP



## INFECTIOUS DISEASE CLINICAL RESEARCH PROGRAM



# 2019

## ANNUAL REPORT



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## LETTER from the IDCRP DIRECTOR

The Infectious Disease Clinical Research Program (IDCRP), of the Uniformed Services University of the Health Sciences (USU), is an innovative leader in conducting militarily-relevant, clinical infectious disease research to improve the health of service members and beneficiaries, as well as support advancements in care through the Military Health System (MHS). The IDCRP also connects military public health surveillance of emergent and high-impact pathogens with Department of Defense (DoD) research and development efforts related to materiel solutions, such as vaccines, drugs, and diagnostics. The enduring success of the IDCRP can be attributed to the diverse, clinical research network partnerships established with the National Institute of Allergy and Infectious Diseases (NIAID), Combatant Commands, clinicians in the MHS and biomedical research and development programs, collaborators from the Veterans Affairs Healthcare System, academia, and industry partners. Over the past year, interventional clinical trials have been a substantial focus of the Program with the completion of a *Staphylococcus aureus* vaccine trial and a multi-site travelers' diarrhea rifaximin prophylaxis trial among U.S. and U.K. service members, continuation of the influenza vaccine comparative effectiveness study, and the initiation of new protocols to assess prevention strategies for travelers' diarrhea, refine treatment approaches for travelers' diarrhea (following on the results of the prior IDCRP effort, "TrEAT-TD"), and evaluate the OMV meningitis B vaccine (Bexsero®) for primary prevention of gonorrhea. Overall, each research area made substantial progress in 2019 with significant accomplishments (outlined in the following report). In the coming year, the IDCRP research portfolio will be streamlined as part of an ongoing effort to improve efficiency.

Strong support from USU leadership and the Operational and Executive Steering Committees, and cooperative execution through the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., have been instrumental in enabling IDCRP's success. Funding through, and cooperative partnership with, the Defense Health Program, NIAID, U.S. Army Medical Materiel Development Activity, the Military Infectious Diseases Research Program, the Navy Bureau of Medicine and Surgery, and the Armed Forces Health Surveillance Division and Immunization Healthcare Division of the Defense Health Agency have been essential to IDCRP mission execution, permitting development of needed knowledge products addressing key infectious disease threats.

I also wish to recognize our clinical research and support staff, as well as our active-duty and civilian investigators, for their dedication to the Program. Lastly, the success of the Program would not be possible without the military service members and beneficiaries who volunteer their time to participate in our studies. It is an honor to serve with such an extraordinary team.



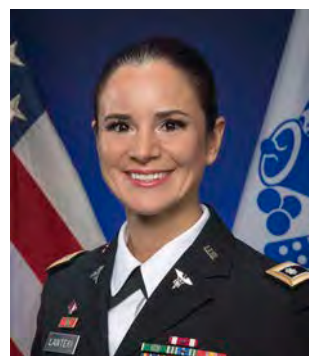
Timothy H. Burgess, MD, MPH  
Captain, Medical Corps, U.S. Navy  
Director, IDCRP

**Core values: Collaboration, Innovation, Quality, Adaptability, Dedication**

*Success is Defined By: Informing military health policy and practice through translation of research findings; Publications and presentations within impactful and relevant peer-reviewed journals/forums; Capability to respond to emergent infection threats and/or high-priority research initiatives; and Key stakeholder satisfaction*



Timothy H. Burgess, MD, MPH  
Captain, Medical Corps, U.S. Navy  
Director, IDCRP



Charlotte Lanteri, PhD  
Lieutenant Colonel, U.S. Army  
Deputy Director, IDCRP  
EIDAR Director



# ABOUT IDCRP

The Infectious Disease Clinical Research Program (IDCRP) was founded in 2005 under an interagency agreement between the Uniformed Services University of the Health Sciences (USU) and the National Institute of Allergy and Infectious Diseases (NIAID) and through a cooperative agreement with The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF). The Program's work is executed through a unique, adaptive and collaborative, international clinical research network. This network directly affects force readiness by advancing clinical practice and informing health policy for military personnel.

In collaboration with partners from the Department of Defense (DoD), academia, government, and industry, IDCRP supports a broad clinical research portfolio within the Military Health System. From observational, longitudinal cohort studies to field-based interventional trials to the evaluation of long-term health outcomes, IDCRP conducts protocols that address critical knowledge gaps in the control and prevention of infectious diseases in the military. Study outcomes have far-reaching implications for public health and disease prevention beyond military communities.

## PROGRAM ORGANIZATION

### Executive Steering Committee

Dean, School of Medicine, Uniformed Services University of the Health Sciences (USU),  
 Chief, Division of Clinical Research (DCR), National Institute of Allergy and Infectious Diseases (NIAID)  
 Director, Research, Development and Acquisition, Defense Health Agency (DHA)

### Operational Steering Committee

Surgeons General Infectious Disease Consultants—Army, Navy, Air Force	Chief, Collaborative Clinical Research Branch, DCR, NIAID
Director, Armed Forces Health Surveillance Division	Chair, Department of Preventive Medicine and Biostatistics, USU
Director, Military Infectious Diseases Research Program, MRMC	Veterans Affairs Representative (non-voting) HJF Representative (non-voting)

### Program Coordination Center

<b>Program Director</b>	<b>NIAID Liaison</b>	<b>Deputy Program Director</b>
Science Directorate	Chair, Scientific Review Board	Research Administration Staff
Science Director		Regulatory Affairs Staff
Deputy Science Director		Chief, Program Operations and Finance
Research Area Directors		Program Management and Finance Staff
Chief, Quality Management		
Clinical Research Managers		

### Data Coordination Center

Chief, DCC  
 Data configuration, management, and programming staff

### Partner Organizations

Military Hospitals  
 Military Research and Development Commands  
 Military Public Health Commands  
 Non-DoD Partners

## VISION

To substantially reduce the impact of infectious diseases in the military population through collaborative clinical research.

## MISSION

To conduct multicenter infectious diseases clinical research, focusing on high-impact cohort and interventional trials, to inform and improve care of the Warfighter.

## IDCRP RESEARCH AREAS

- **Acute Respiratory Infections**—Strategic aims focus on diagnostics, prevention (influenza vaccine), epidemiology (recruit ARI threats), and treatment (severe influenza) of acute respiratory infections among U.S. military personnel and their beneficiaries.
- **Deployment and Travel-Related Infections**—Strategic aims focus on epidemiology of deployment and travel-related infectious threats for military personnel, pre-travel health care and mitigation strategies, novel methodologies for identifying pathogens associated with febrile and diarrheal disease, and improved treatment approaches during deployment.
- **Emerging Infectious Diseases and Antimicrobial Resistance**—Strategic aims focus on emerging infection threat epidemiology along with optimal diagnostic approaches, prevention, and therapeutic interventions.
- **Human Immunodeficiency Virus Infections**—Strategic aims include mitigating specific complications of the virus among military HIV-infected patients; identifying, treating, and preventing HIV-associated neurocognitive disorders; developing and employing predictive models to optimize individual management of HIV; and improving therapeutic outcomes with the ultimate goal of functional cure of infection.
- **Skin and Soft-Tissue Infections**—Strategic aims focus on development of effective strategies for the prevention and control of SSTIs, particularly *Staphylococcus aureus*-related, including vaccine-based interventions, among congregate military personnel in deployment and training settings.
- **Sexually-Transmitted Infections**—Strategic aims focus on development of improved means to diagnose, prevent, and treat sexually-transmitted infections, with particular focus on emergent drug-resistant gonorrhea, among active-duty members and their beneficiaries.
- **Trauma-Related Infections**—Strategic aims focus on addressing knowledge gaps in infection prevention, clinical management, and treatment outcomes in battlefield trauma to inform DoD Joint Trauma System clinical practice, as well as improved understanding of the impact of wound microbiology on clinical outcomes related to high-threat virulent and antimicrobial-resistant pathogens.

Each area's 2019 accomplishments are presented in the following pages, along with information and projections for 2020.

# ACUTE RESPIRATORY INFECTIONS (ARI)

*Seasonal outbreaks of acute respiratory infections (ARI) are a leading cause of morbidity in the Military Health System (MHS), particularly among military trainees and deployed service members. With approximately 400,000 medical encounters and 1,000 hospitalizations per year, ARIs not only affect the health of military personnel, but also greatly impact operational readiness through missed training and lost duty days.*



Christian Coles, PhD,  
ARI Research Area  
Director



Increased virulence of known respiratory pathogens, limited effectiveness of vaccines, diagnostic difficulties, and heightened potential for transmission from crowded, stressful living conditions are all factors contributing to the high prevalence of ARIs in service members. The goal of the ARI Research Area is to substantially reduce the burden of ARIs in military populations by generating evidence needed to inform the development of effective control strategies designed to limit the impact of ARIs on health, performance, and mission readiness.

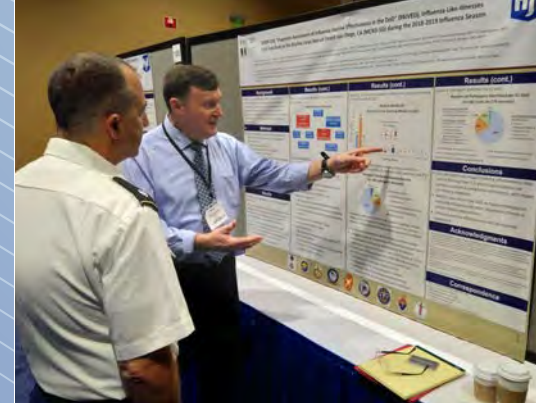
Led by CAPT Timothy Burgess, the multi-site, longitudinal ARI Consortium Natural History Study (ARIC NHS) was initiated in 2009 to collect data on the etiology, epidemiology, and immunology of influenza-like illness (ILI) and severe ARI in the military and provide surveillance reports to the Armed Forces Health Surveillance Division, Global Emerging Infections Surveillance program and Naval Health Research Center. In 2019, data collection for ARIC NHS was suspended so personnel and resources could be dedicated to a new large-scale initiative, the Pragmatic Assessment of Influenza Vaccine Effectiveness in the DoD (PAIVED) clinical trial.

The PAIVED clinical trial (led by CAPT Burgess) is a two-year study designed to determine whether there are clinically meaningful differences in the

effectiveness and immunogenicity between egg-derived, cell-culture-derived, and recombinant licensed influenza vaccines. Enrollment began in October 2018 at five military hospitals. During the first influenza season of the study, >1,600 participants were enrolled with 200 of these subjects also enrolling in the immunogenicity substudy. Due to a low influenza attack rate (1%), the number of enrollment sites was expanded, and the target study size was increased to 15,000 subjects. Enrollment in the second year of the study began in October 2019.

As a result of concerns regarding limited vaccine effectiveness in service members, the impact of repeated immunization on influenza acquisition and severity in the MHS is being assessed in the Impact of Influenza Vaccine Experience on Effectiveness protocol, sponsored by the National Institute of Allergy and Infectious Diseases, Division of Microbiology and Infectious Diseases. Presently, abstraction of electronic medical records is nearing completion and data analysis is expected to be completed in mid-2020.

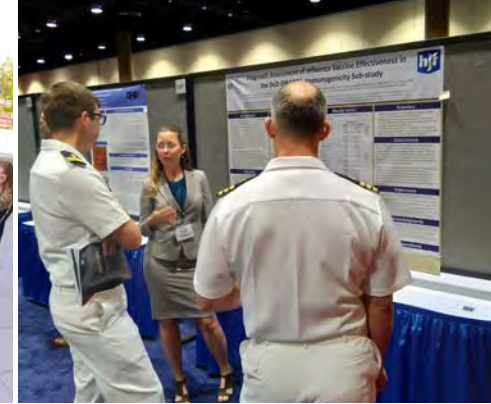
Another protocol is the Flu Breath Study, led by Lt Col Brian White, in collaboration with Menssana Research Inc., to assess the use of exhaled volatile organic compounds in influenza diagnosis. Enrollment was completed with breath samples collected from 250 military trainees experiencing an outpatient ILI. Data analysis is expected to be completed in 2020.



Dr. Gregory Utz presenting at the  
2019 Military Health System Research  
Symposium



IDCRP The Acute Respiratory Infection  
Annual Meeting  
May 7, 2019



Dr. Rhonda Colombo presenting at the  
2019 Military Health System Research  
Symposium

## MILITARY IMPACT

The Study to Address Threats of ARI in Congregate Military Populations (ATARI), led by Dr. Christian Coles, is focused on the assessment of ILI transmission, etiology, and epidemiology among U.S. Army recruits at Fort Benning, GA. Analysis of spatial and temporal patterns of transmission is underway, as well as the genomic sequencing of a sample of coronaviruses and parainfluenza viruses collected from the trainees.

In 2020, enrollment in PAIVED and analysis of the data will continue to be a major focus of the ARI Research Area. Furthermore, a follow-up longitudinal study to ATARI to describe patterns of ILI acquisition and transmission in large trainee populations is being developed. Analyses to expand surveillance of ARIs in the deployed setting, including shipboard and ground force populations, are also planned.

In 2019, the DoD Infectious Disease Threat Prioritization Panel ranked influenza as the second highest infectious disease threat to U.S. Armed Forces. Since inception, findings from ARI Research Area studies have advanced the understanding of the changing distribution, risk factors, and control of ARI in the MHS. Hospital-based surveillance efforts provide valuable data on ARI epidemiology, clinical severity, and disease burden for high-priority pathogens that may directly impact operational readiness. Furthermore, although there is widespread coverage of the influenza vaccine in the MHS, overall vaccine effectiveness varies from 19% in service members to 51% in DoD beneficiaries. Findings from PAIVED and the Influenza Vaccine Experience studies may provide insight to account for the disparities in vaccine effectiveness in military personnel and beneficiaries and support the next generation of influenza vaccinations and vaccine policies in the MHS. Furthermore, ARIs are a frequent occurrence in congregate military populations, such as trainees. Findings from ATARI and anonymous surveys related to transmission patterns and health care seeking behavior may inform educational interventions to reduce the risk of ARI transmission.

## HIGHLIGHTS/KEY FINDINGS

- One out of every 6 non-recruit participants enrolled in PAIVED during the 2018/19 influenza season experienced a confirmed ILI with coronavirus (15%), rhinovirus (10%), and respiratory syncytial virus (8%) being most common. Symptoms lasted 6-8 days in duration with approximately 3-4 days of reduced activity.
- Among recruits at the Marine Corps Recruit Depot San Diego enrolled in PAIVED during the 2018/19 influenza season, 23% reported an ILI with influenza A(H3) being

the most common. Approximately 82% of the ILIs were during the first 3 weeks of training, resulting in a total of 168 days of reduced training and 47 days of missed training.

- Findings from an anonymous survey of >2,400 trainees found that only 40% of trainees who experienced an ILI sought health care, indicating that ILIs are more common during training than what is indicated in medical records. Recruits who are male and over 30 years of age were less likely to seek health care for ILIs.



# DEPLOYMENT AND TRAVEL-RELATED INFECTIONS

*Infectious diseases are not only a significant threat to the health of service members, but also greatly impact the readiness of military wartime operations, as well as peacekeeping and training activities.*



Tahaniyat Lalani, MBBS, MHS, Deployment and Travel-Related Infections Research Area Director



With worldwide deployment of U.S. service members, the improved understanding of the epidemiology of infectious disease threats and identification of optimal preventive and treatment approaches is a high priority of the Military Health System (MHS). The most frequently reported infections include travelers' diarrhea (TD), vector-borne illnesses (e.g., malaria, Dengue virus, Zika virus, and Chikungunya virus), and respiratory diseases. Mitigating the impact of these infections requires comprehensive surveillance efforts and high-quality research. The overarching goal of the Deployment and Travel-Related Infections Research Area is to enhance infectious disease preparedness and Force Health Protection of U.S. military forces prior to and during deployment.

The Deployment and Travel-Related Infectious Disease Risk Assessment, Outcomes, and Prevention Strategies among DoD Beneficiaries (TravMil) cohort study, led by Dr. Tahaniyat Lalani, remains the centerpiece protocol of the research area and has enrolled more than 4,500 travelers and deployed service members. During the past year, infectious disease surveillance efforts focused on deployments to regions considered high-risk for infections by Combatant Commands (COCOMs) and the DoD Global Emerging Infections Surveillance (GEIS) network and enrollment in these populations was successful with 30-50% reporting TD and 10-40% with an influenza-like-illness.

As the occurrence of TD in deployed personnel has a substantial impact on operational readiness,

improved prevention and treatment remains a priority for COCOMs. A significant achievement in 2019 was the completion of enrollment and follow-up for the Trial Evaluating Regimens of Rifaximin for Chemoprophylaxis against Travelers' Diarrhea (Prevent TD), led by CAPT Ramiro Gutierrez, which is a collaborative effort with the United Kingdom Ministry of Defence (U.K. MOD). Overall, 449 subjects were enrolled in the clinical trial and data analysis is expected to be completed in 2020. A difference in the TD incidence between the U.S. and U.K. personnel was observed, likely due to the varying risk of TD at their destinations. For example, the risk of TD is low while the U.K. Army personnel were within the barracks at British Army Training Unit in Nanyuki, Kenya, and increased during exercises in the austere environment at Archers Post and during travel into the local community. This finding is being used to inform the study design for an upcoming placebo-controlled clinical trial, P4TD, which is a collaborative effort with the U.K. MOD to evaluate the clinical efficacy of different nutraceutical products for the prevention of TD (i.e., probiotic, prebiotic, and passive immunoprophylaxis). This clinical study, led by Dr. Lalani and Dr. David Tribble, will also involve a collaboration with the New York Center for Travel and Tropical Medicine.

In 2017, the Trial Evaluating Ambulatory Therapy of Travelers' Diarrhea (TrEAT TD) study was completed and the findings demonstrated that a single high-dose of rifaximin (1650 mg) with loperamide was effective at treating acute watery diarrhea. As a follow-on clinical trial, and in collaboration with the U.K. MOD, TrEAT TD 2.0 will examine the efficacy of rifaximin at a lower dose (550 mg) compared to azithromycin.



COL Patrick Hickey presenting at the 2019 Military Health System Research Symposium



IDCRP Uniformed Services University  
Deployment and Travel Related Infections Research Area  
May 6, 2019



Investigative team visiting the Lightning Academy near Schofield Barracks

## MILITARY IMPACT

Another protocol is the Knowledge, Attitudes, Practice, and Outcomes Study (KAPOS), led by COL Patrick Hickey, which aims to evaluate knowledge of infectious disease threats and prescription practices of travel medicine and deployment health providers. These are critical issues for mitigating infectious disease threats and optimizing Force Health Protection in the expeditionary military. Presently, differences in malaria chemoprophylaxis and TD self-treatment prescription patterns among travel medicine specialists and non-specialists are being evaluated with regards to outcomes.

In 2020, an anonymous post-deployment survey for high-priority infections among Marines serving in the Indo-Pacific Command is planned. Samples will be collected from deployments with high infection rates to identify specific pathogens. A survey-based approach will also be used, along with collection of serum samples, to assess the leptospirosis incidence and operational impact in jungle warfare training settings in Camp Gonsalves, Okinawa, Japan, and Schofield Barracks, Hawaii.

Surveillance of high-priority infectious disease threats and militarily-relevant clinical trials conducted by the Deployment and Travel-Related Infections Research Area add to the evidence base for deployment-related clinical practice guidelines. Findings from TravMil have been used to develop infectious disease threat assessment reports, which are provided to COCOMs, medical support teams of the deployed units, and GEIS. Data from multiple protocols (i.e., Stool Card Validation, TrEAT TD, and TravMil) confirmed the value of filter paper-based stool collection combined with TaqMan® Array Card PCR-based assay as an alternative approach (or supplemental when performed in conjunction with conventional methods) for collection of diarrheal specimens in an austere environment with limited storage and laboratory capabilities. As the research area continues to move forward, the successful partnerships with DoD research laboratories both within and outside of the United States and with the U.K. MOD will be further leveraged to address specific COCOM priority surveillance efforts and utilize findings of clinical trials to improve the practice of deployment and travel medicine within the MHS.

## HIGHLIGHTS/KEY FINDINGS

- **TaqMan® Array Card PCR assay was used to evaluate changes in pathogen detection in stool specimens from subjects who participated in the TrEAT TD clinical trial. Between Day 0 and Day 21, there was a significant decrease in pathogen detection (77% to 25%). Changes in virulence gene profiles for pathogens detected at both time points suggest acquisition of a new strain rather than persistence of the initial pathogen.**
- **P4TD will be the first time there has been a head-to-head placebo-controlled comparison of nutraceutical products (i.e., probiotic, prebiotic, and passive immunoprophylaxis) within a single clinical trial.**
- **Pediatric travelers more frequently reported mosquito bites and contact with wild or domesticated animals than adult military dependent travelers. Also, travelers <10 years old were less commonly prescribed antibiotics and antidiarrheals for TD self-treatment.**
- **Data collected through KAPOS will be used for the FDA-required post-licensure safety surveillance study of Tafenoquine, which was recently approved for malaria chemoprophylaxis and radical cure of Plasmodium vivax in the MHS.**



# EMERGING INFECTIOUS DISEASES AND ANTIMICROBIAL RESISTANCE (EIDAR)

*Outbreaks associated with emerging diseases and high-consequence pathogens constitute a substantial threat to Force Health Protection (FHP) and operational readiness. The prevalence of multidrug-resistant and virulent organisms is also increasing worldwide, putting military personnel at risk for developing difficult-to-treat infections.*



LTC Charlotte Lanteri, PhD, IDCRP Deputy Director and EIDAR Research Area Director



Katrin Mende, PhD, EIDAR Research Area Deputy Director

The Emerging Infectious Diseases and Antimicrobial Resistance (EIDAR) Research Area assesses global emergent infectious disease threats and localized outbreaks through the systematic collection of clinical specimens and evaluation of epidemiology, etiology, and short- and long-term clinical outcomes with the goal of informing FHP policy and designing interventional trials for new preventive or treatment strategies. EIDAR remains responsive to the requirements of the Global Health Security Agenda and National Security Strategy for preparedness and response to infectious disease outbreaks through strategic alliances with the Armed Forces Health Surveillance Division section on Global Emerging Infections Surveillance (GEIS), as well as the USU Center for Global Health Engagement. The research area is also the coordinator of multi-site studies evaluating patterns of antimicrobial resistance and stewardship practices within the Military Health System (MHS) in support of the DoD Combating Antibiotic-Resistant Bacteria initiative.

A unique clinical research capability for military treatment facility (MTF) use directed by EIDAR is the Epidemiology, Immunology and Clinical Characteristics of Emerging Infectious Diseases with Pandemic Potential (EpICC-EID, led by LTC Charlotte Lanteri) contingency protocol, which activates at MTFs when patients are diagnosed with high-consequence infections, allowing the DoD to address clinical questions to inform appropriate treatment and control responses in parallel with a public health response. Presently, the protocol is active at the Walter Reed National Military Medical Center and is being revised to expand capabilities by allowing assessment of biothreat pathogens, along with addition of new strategic sites.

During 2019, EIDAR study teams made significant progress on three GEIS-sponsored infectious disease surveillance efforts. The first study, led by CAPT Ryan Maves, is investigating the seroincidence of *Coccidioides* fungal infections and associated demographic and clinical risk factors through laboratory evaluation of DoD Serum Repository (DoDSR) specimens collected before and after active-duty personnel were stationed at the disease endemic location of Naval Air Station Lemoore, CA. Laboratory analyses of 2,000 specimens at the Naval Health Research Center are complete and data analyses are underway. Another surveillance project involving DoDSR specimens, led by Dr. Steve Dumler, is examining risk for infection with tick-borne *Borrelia* bacteria (responsible for Lyme disease and related infections) among service members at U.S. military training facilities in endemic regions. This is the first study to assess the seroincidence within the MHS of newly identified *Borrelia* species (*B. mayonii* and *B. miyamotoi*) discovered near Fort McCoy, WI, and serological analyses from 920 service members is complete.

The third emerging infectious disease surveillance study is a prospective assessment of Zika-like illness in military populations in Puerto Rico at the Rodriguez Army Health Clinic (RAHC), as part of a collaborative effort with the Walter Reed Army Institute of Research (WRAIR) Viral Diseases Branch to assess the arboviral disease burden and impact on service member fitness for duty. The IDCRP and WRAIR team members conducted a productive site visit to RAHC in October to meet with site leadership and study personnel and assess recruitment and enrollment processes.



Dr. Steve Dumler in his USU Department of Pathology laboratory with LT Steve Capen (USU Capstone medical student), Ms. Katie Hsieh, and LTC Charlotte Lanteri



Dr. Gregory Utz, Mr. Carlos Morales, CAPT Ryan Maves, LTC Charlotte Lanteri, Dr. Katrin Mende, and Ms. Katie Hsieh of the EIDAR Investigative Team



EIDAR site visit at Rodriguez Army Health Clinic, Puerto Rico

The EIDAR team is continuing efforts on the Chikungunya Virtual Cohort Study (led by CAPT Timothy Burgess), which examines the short- and long-term health outcomes, disability, and health care utilization attributable to chikungunya infection in MHS beneficiaries. Cases of chikungunya were identified from data extracted through the Navy and Marine Corps Public Health Center EpiData Center and the MHS Data Repository. In 2020, data analysis will identify rates of arthralgias, myalgias, and neuropsychiatric diagnoses and will examine risk factors.

In response to the largest outbreak of Shiga toxin-producing *Escherichia coli* (STEC) within the U.S. military, EIDAR is examining the long-term health impact of STEC diarrheal disease in U.S. Marines who were stationed at the Marine Corps Recruit Depot San Diego during the outbreak. Due to difficulties with enrollment, the active component of the protocol was closed and data analysis of health assessment responses from 31 enrollees is complete. In the upcoming year, and through GEIS support, the study team will conduct surveillance for post-infectious sequelae by examining electronic health records among STEC cases, asymptomatic carriers, and non-ill controls (~1500 in total study population) twice annually for up to 5 years following the outbreak.

In 2020, the IDCRP portfolio will be restructured to streamline research initiatives. As research efforts under EIDAR align with the aims of other research areas, EIDAR will be closed in the coming year. The valuable work conducted by the EIDAR investigative team will continue with the protocols being transitioned to other research areas, such as Deployment and Travel-Related Infections, Wound Infections, and Acute Respiratory Infections.

## MILITARY IMPACT

The EIDAR Research Area is responsive to both persistent and emerging infectious disease threats impacting the health and operational readiness of the U.S. military. With the goal of providing actionable information to inform FHP guidance, EIDAR includes studies to address clinical knowledge gaps related to the identification and characterization of these infectious disease threats. For example, the STEC protocol supports the U.S. Northern Command regional priorities with respect to characterizing the threat to FHP posed by health consequences of a food-borne enteric pathogen outbreak. Knowledge gained from this study can be applied to mitigate the risk of chronic post-infectious health issues with future outbreaks. Furthermore, EIDAR remains responsive to the threat of arboviral and tick-borne infections, which are also significant MHS concerns.

## HIGHLIGHTS/KEY FINDINGS

- A retrospective study will determine arboviral (Zika and Dengue viruses) seroconversion rates and risk factors among active-duty personnel who deployed to U.S. Southern Command countries with high risk of transmission during the Zika virus outbreak.
- In an effort related to antibiotic stewardship, a study being developed will evaluate effectiveness and potential adverse consequences of antibiotic prophylaxis with low-risk laparoscopic cholecystectomy and inguinal hernia repair.
- Through a retrospective electronic health record review study, the MDRO Bloodstream Infections team is conducting data analyses for ~7,500 cases to characterize prevalence of bacterial species among patient isolates assessed by various demographic and clinical risk factors.
- Through collaboration with the Trauma-Related Infections Research Area, multiple analyses under the TIDOS Multidrug-Resistant and Virulent Organisms Initiative (led by Dr. Katrin Mende) assessing wound microbiology and interaction of wound pathogens are ongoing.



# HUMAN IMMUNODEFICIENCY VIRUS (HIV)

Since 1985, >10,000 active-duty service members have been infected with HIV; however, the number of personnel able to remain on active duty is growing due to earlier diagnosis and successful treatment with antiretroviral therapy. Still, non-AIDS complications, such as neurocognitive impairment, cardiovascular disease, and cancer are becoming more frequent at a younger age, constituting a substantial threat to long-term health. With approximately 350 new active-duty HIV diagnoses yearly, despite ongoing prevention efforts, the lifetime healthcare burden to the Departments of Defense (DoD) and Veterans Affairs (VA) is substantial and growing. The IDCRP HIV Research Area seeks to advance HIV care and treatment to maintain health, function, and readiness.



Brian Agan, MD, Deputy Science Director and HIV Research Area Director



Following introduction of antiretroviral therapy (ART), viral suppression has vastly improved and, as such, death and AIDS have become rare events within the Military Health System (MHS). Nevertheless, non-AIDS complications, sexually-transmitted infections (STIs), and mental health diagnoses remain a source of morbidity among HIV+ service members and beneficiaries. The overarching vision of the HIV Research Area is to inform military HIV policy and clinical practice guidelines and improve the long-term health, function, and readiness of HIV+ active-duty service members, benefiting not only DoD beneficiaries, but also civilian populations.

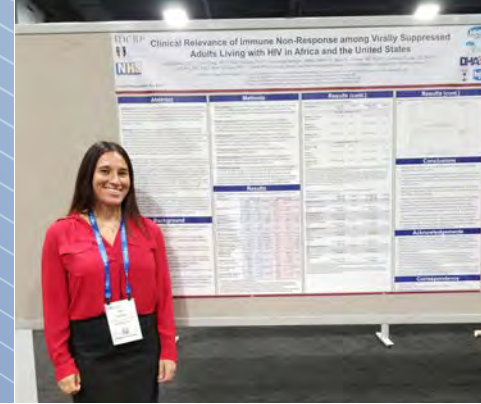
The U.S. Military HIV Natural History Study (NHS), led by Dr. Brian Agan, remains the centerpiece of the HIV Research Area with >6,300 HIV+ active-duty service members and DoD beneficiaries enrolled. During 2019, NHS data were utilized to examine various comorbidities related to HIV infection and ART, including cardiovascular disease, diabetes, eye disease, mental health disorders, and STIs. Analyses found that ART reduced the incidence of eye disease in HIV+ individuals and that disease likely resulted from comorbidities, rather than HIV. Coinfections have also been a research focus, and an elevated incidence of shingles was identified in HIV+ individuals, even those with successful ART. Based on these findings, a randomized controlled trial to evaluate the safety and immunogenicity

of the Shingrix® vaccine in HIV-negative and HIV+ populations is being developed.

As active-duty populations are routinely screened for HIV, resulting in early diagnosis and prompt referrals to care when tests are positive, the cascade of care framework (diagnosis, ART adherence, and viral suppression) can be effectively studied in this population. Research into the cascade of care interconnects with the U.S. Health and Human Services plan to end the HIV epidemic in the United States within 10 years. The NHS population has demonstrated a high-level attainment of the three goals with a large proportion reaching their full cascade of care.

Another major protocol is the DoD HIV Virtual Cohort Study (VCS), also led by Dr. Agan, which is a retrospective study of HIV+ subjects matched to a representative sample of HIV-negative individuals to assess the relationship between HIV and the development of serious non-AIDS events and identify potentially modifiable risk factors. Presently, data have been obtained from the MHS Data Repository and analysis is underway.

HIV-associated neurocognitive disorder (HAND) is a serious non-AIDS comorbidity and remains the primary reason why HIV+ service members are assigned limited duty status. Thus, improved diagnostic methods for the disorder may impact military policy and allow active-duty personnel with HIV to expand job functions and increase rank.



Dr. Adi Noiman presenting at the 2019 IDSA IDWeek



2019 HIV Research Area Annual Investigator Meeting



Discussion panel at the 2019 HIV Research Area Annual Investigator Meeting

Through the HIV-Associated Neurocognitive Disorders (ALLHANDS) protocol, the functional consequences of HAND in a high demand setting are being evaluated. Presently, data collection using the NIH Toolbox is underway and expected to provide new insights into prospective HAND screening. As the diagnosis of HAND is unclear and neuropsychiatric testing alone is inadequate, studies to utilize biomarkers to more objectively identify a population with HAND are being developed in collaboration with the National Institute of Neurological Disorders and Stroke and the National Institute of Mental Health.

A randomized controlled trial, led by Dr. Anuradha Ganesan, to evaluate use of rifaximin to modulate chronic immune activation in HIV+ subjects was completed. Although short-term rifaximin use did not alter CD14 levels or T-cell activation, further analysis is needed to determine if ART interfered with the impact of rifaximin on gut bacterial flora. Regarding the Strategic Timing of Anti-Retroviral Therapy (START) protocol, long-term follow-up through review of electronic medical records is underway. Lastly, through the CD4 Zeta protocol, led by COL (Ret.) Naomi Aronson, analysis is underway to examine the HIV reservoir and persistence of the gene therapy modified cells.

In 2020, we will continue to study the quality and cost of DoD HIV care among active-duty personnel, emphasizing additional performance measures and evaluating the impact of Service differences in HIV policy on these outcomes. Discussions are also

underway to collaborate with the VA to expand understanding of predictors of long-term HIV outcomes, which would enable prospective trials of early interventions to prevent or minimize harm.

## MILITARY IMPACT

The HIV Research Area continues to support the MHS by examining the continuum of HIV care in the DoD and assessing serious outcomes of HIV infection, including HAND. Building on our efforts in 2018 to convene a DoD HIV Quality of Care Interest Group comprised of Service Leaders for HIV and IDCRP investigators, initial analyses to understand the cascade of care among DoD HIV+ active duty and NHS subjects were recently completed. We also provided subject matter expertise to the Defense Health Agency for their development of the active-duty HIV viral suppression measure (now available on CarePoint) in response to the Congressional National Defense Authorization Act of 2017. We have begun to explore the impact of mild and asymptomatic forms of HAND on functional performance, an outcome of significant interest to military duties. Lastly, our study of STIs among HIV+ subjects and our NHS risk behavior questionnaire continues to generate data that may inform policy to improve prevention efforts, diagnosis, and treatment of these infections.

## HIGHLIGHTS/KEY FINDINGS

- In a collaborative study with the Military HIV Research Program and National Institute of Allergy and Infectious Diseases, immune reconstitution inflammatory syndrome (IRIS) occurred in 19% of HIV+ individuals who started ART with a CD4 count <100 cells/μL. Within 6 months, 6.5% died and IRIS was significantly associated with an increased risk of death.
- A low incidence of complications (7.6%) was reported following refractive eye surgery in HIV+ patients. In the unadjusted model, AIDS was identified as a risk factor

for complications, indicating that ophthalmologists should consider ART status, history of AIDS, and viral load before performing the surgery.

- In a population of active-duty and retired male service members with HIV, 19% were diagnosed with neurocognitive impairment. Assessment of mental health disorders identified lifetime history of post-traumatic stress disorders as an independent predictor of neurocognitive impairment.



# SKIN AND SOFT-TISSUE INFECTIONS (SSTI)

*Skin and soft-tissue infections (SSTIs), typically caused by Staphylococcus aureus, are a significant source of morbidity among congregate military personnel, such as trainees and deployed service members. As SSTIs not only result in a high utilization of healthcare resources, but also may directly affect operational readiness, prevention and control of these infections remain a top priority of the Military Health System.*



Eugene Millar, PhD,  
SSSI Research Area  
Director

Recognizing the substantial healthcare and operational burden associated with SSTIs, the primary objective of the SSSI Research Area is to identify effective strategies for the prevention and control of SSTIs in the military. A strong and expansive knowledge base is imperative to develop a successful approach for infection management. Thus, the research area's investigative team has focused analyses on epidemiology, microbiology, and immunology of SSTIs, particularly those associated with *Staphylococcus aureus*.

A major accomplishment in 2019 was the completion of a Phase 2 trial of a *S. aureus* vaccine candidate (NDV-3A; NovaDigm Therapeutics, LLC), which was funded through the U.S. Army Medical Materiel Development Activity. Led by LTC Jason Bennett (WRAIR), the safety, immunogenicity, and efficacy of the vaccine candidate against nasal acquisition of *S. aureus* was evaluated among U.S. Army Infantry trainees at Fort Benning, GA. The Clinical Study Report is scheduled for release in early 2020. Not only does this represent an advance for the first *S. aureus* vaccine candidate with a targeted indication for SSSI prevention, the success of the trial also demonstrated that investigational product trials can be conducted in the highly structured and regimented framework of the military training setting.

Another significant achievement over the past year was the successful leveraging of the vast number of isolates collected through the research area's observational studies at Fort Benning (led by LTC Bennett and Dr. Eugene Millar). These microbiological analyses have focused largely on the genomic characterization of *S. aureus* isolates, both methicillin-resistant (MRSA) and

methicillin-susceptible (MSSA), and have greatly expanded our collaborative relationships. As one example, in collaboration with the Johns Hopkins Applied Physics Laboratory (APL), whole genome sequencing of colonizing and infecting *S. aureus* isolates collected through the SSSI Epidemiology and the SSSI Prevention Trial indicated that intrahost reservoirs are common among those with recurrent SSTIs, suggesting that targeted decolonization after initial infections may be beneficial. Through collaboration with the Harvard T.H. Chan School of Public Health, whole genome sequencing was utilized to describe MRSA transmission dynamics and the relatedness of MRSA colonization and infection strains. As part of a collaboration with the Naval Medical Research Center (NMRC) Biological Defense Research Directorate, assessment of the genomics of MRSA isolates collected through the Epidemiology, Etiology, and Immunology of SSSI study indicated an epidemiologic link between MRSA colonization and purulent infections. Lastly, examination of the genomics of MSSA isolates (contributes ~40% of *S. aureus* SSTIs) is underway in collaboration with the Walter Reed Army Institute of Research (WRAIR) Multidrug-Resistant Organism Repository and Surveillance Network (MRSN).

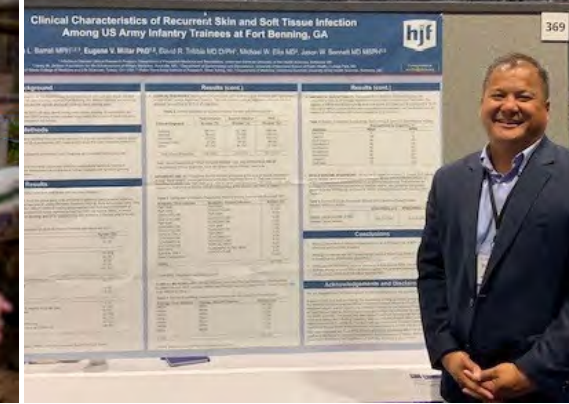
The assessment of the human microbiome is another focus of the research area. Leveraging isolates collected through the SSSI Cohort Study, two analyses in collaboration with the USU Department of Microbiology are underway to evaluate the host microbiome among trainees with and without *S. aureus* SSTIs and examine host microbiome changes among individuals in a congregate setting. In collaboration with Johns Hopkins APL, host microbiome changes following receipt of Bicillin as prophylaxis against Group A



LTC Jason Bennett presenting at 2019  
IDSA IDWeek



U.S. Army Infantry Trainee at Fort Benning



Dr. Eugene Millar presenting at the 2019  
Military Health System Research Symposium

streptococcal disease among military trainees are being assessed. With regards to immunology, analyses to re-examine the cellular and humoral immune response to SSTIs are being developed.

In 2020, the outcome of the *S. aureus* NDV-3A vaccine trial, as well as strategic decisions by the vaccine manufacturer and other industry partners, will help determine the next course of action regarding preventive efforts, including assessment of other vaccine candidates in the pipeline. In addition, the large repository of specimens and data that has been built over the last decade will continue to be utilized to better understand the epidemiology, immunology, and microbiology/pathogenesis of *S. aureus* SSTIs.

Lastly, in 2020, the SSSI Research Area will merge with the Trauma-Related Infections Research Area to form the Wound Infections Research Area. Through 10+ years of effort in clinical research of these militarily-relevant infectious diseases, both research areas have amassed specimen and data repositories that are unparalleled in DoD and non-DoD circles. This invaluable resource will give rise to a host of laboratory-based efforts which, when tied to clinical and epidemiologic data, will help inform future clinical research efforts, especially in the area of disease prevention.

## MILITARY IMPACT

Substantial operational and healthcare-associated burdens are associated with SSTIs in congregate military populations, particularly among military trainees. Investigations through the SSSI Research Area have assessed SSSI epidemiology and evaluated strategies to prevent SSTIs in high-risk military populations. Specifically, research initiatives are focused on (1) generating epidemiological, clinical, immunological, microbiological, and genomic data; (2) incorporating whole genome sequencing in the characterization of MRSA and MSSA isolates to identify individual- and group-level factors that contribute to transmission in congregate settings; and (3) evaluating the efficacy of an investigational vaccine in preventing *S. aureus* nasal colonization. Through our efforts, we have contributed to the larger scientific and medical community in its collective pursuit of an effective *S. aureus* vaccine and/or other strategies for the prevention of SSTIs, which will likely have a similar impact among non-military populations (e.g., athletes, inmates, and children attending daycare) who are also at increased risk for SSTIs.

## HIGHLIGHTS/KEY FINDINGS

- **The Phase 2 *S. aureus* NDV-3A vaccine trial at Fort Benning, GA, vaccinated 382 U.S. Army Infantry trainees with 352 completing follow-up. Processing of specimens for microbiology and immunologic evaluation was completed. Future interventional trials in high-risk military training populations will benefit from the lessons learned in the successful execution of this trial.**
- **Collaboration with investigators in the USU Department of Microbiology and Immunology determined that *S. aureus*, as well as *Staphylococcus epidermidis*, were able to acquire resistance to antiseptics/biocides (e.g., chlorhexidine) via transfer of conjugate plasmids containing biocide-resistance genes (e.g., *qacA*). The finding of this novel mechanism suggests that antiseptic-tolerant staphylococci strains may increase in settings where widespread use of hygiene-based antiseptics is common.**
- **Entire repository of *S. aureus* isolates (>10,000) collected through the research area was transferred to WRAIR MRSN for full characterization, including whole genome sequencing.**
- **Genomic characterization of MRSA colonizing and infecting isolates collected from military trainees with purulent SSTIs indicated a high degree of strain relatedness. Limited intrahost diversity also suggests that persistent colonization may contribute to risk of recurrent infections.**

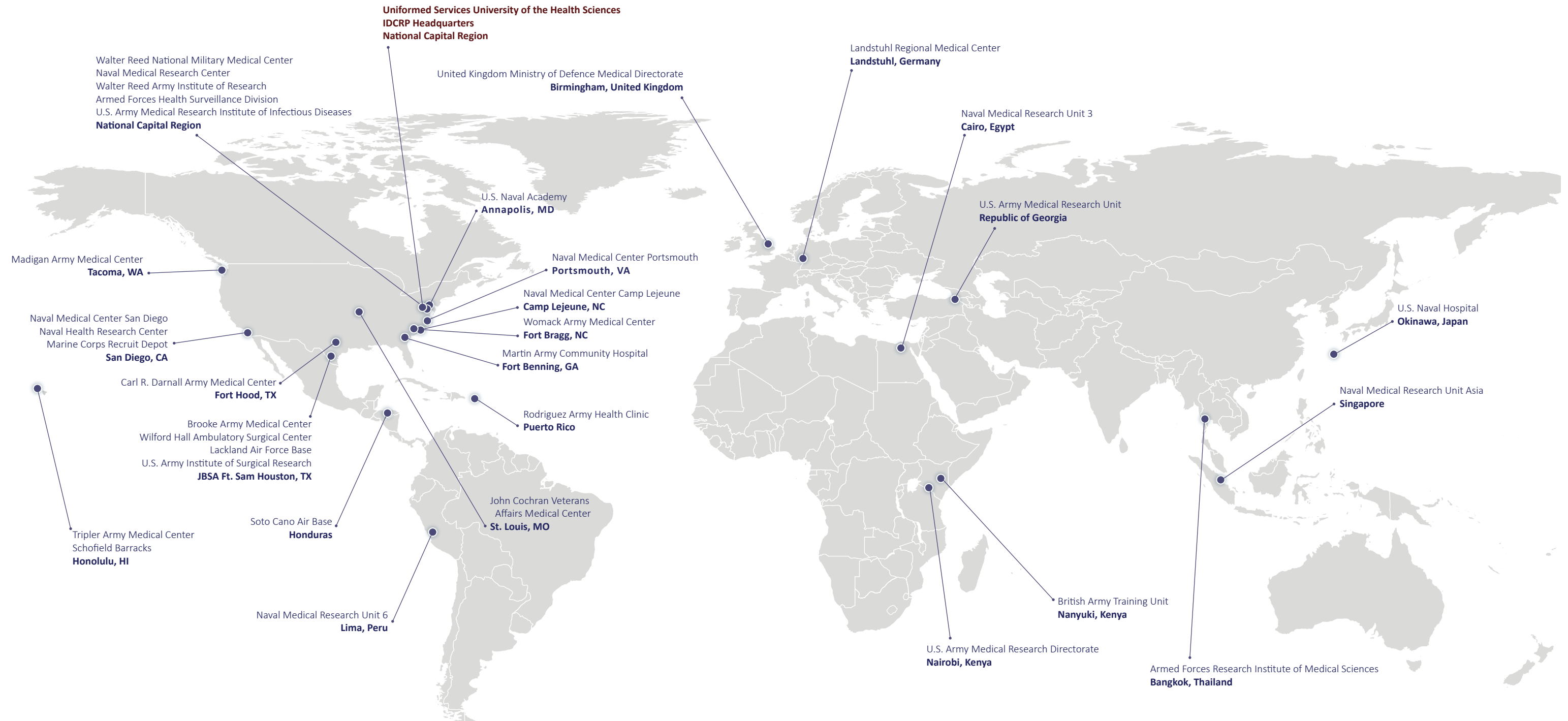


# IDCRP PARTNER NETWORK

**34**  
PARTNER SITES

**120+**  
EMPLOYEES

**71**  
ACTIVE PROTOCOLS





# SEXUALLY-TRANSMITTED INFECTIONS (STIs)

*Rates of sexually-transmitted infections (STIs) continue to increase within the Military Health System. Improved prevention and treatment approaches are critical to reduce the burden of STIs on Force Health Protection and medical readiness, as well as limit the contribution of deployed service members to the growing global dissemination of emerging and resistant STIs.*



LTC Eric Garges, MD,  
STI Research Area  
Director

There is currently an epidemic of STIs in the United States, with sustained national increases in chlamydia, gonorrhea, and syphilis. What is notable is that the rates of select bacterial STIs in military service members are regularly 2-3 times higher than those seen in civilian counterparts, demonstrating the impact of this national epidemic within the Department of Defense (DoD). With the emergence of multidrug-resistant *Neisseria gonorrhoeae* (GC) and high levels of antimicrobial resistance of *Mycoplasma genitalium*, the STI Research Area aims to evaluate high-risk sexually-transmitted pathogens, support the development of biomedical countermeasures against STIs in military populations, and evaluate novel treatment strategies and test prevention efforts among active-duty personnel to support policy decisions and improved practice patterns.

The GC Resistance Study (led by LTC Eric Garges) and the DoD GC Reference Laboratory and Repository (coordinated by the IDCRP and led by Dr. Ann Jerse, USU) continue to be the backbone of the STI Research Area with >900 subjects enrolled. A concern for the Military Health System has been the acquisition of resistant GC during deployment; however, GC isolates collected within the health system have demonstrated similar levels of resistance to commonly used antibiotics compared to national data reported by the Centers for Disease Control and Prevention (CDC) Gonococcal Isolate Surveillance Project for the corresponding regions. Further identification of network clustering of GC isolates is underway in collaboration with informaticists at the Walter Reed Army Institute of Research (WRAIR) Multidrug-Resistant Organism

Repository and Surveillance Network (MRSN), which may include classification of isolates from remote non-DoD networks.

Led by Dr. Anuradha Ganesan, the 3 Anatomic Site GC/CT Testing Among HIV+ and HIV- high-risk DoD Beneficiaries study aims to examine the prevalence of and risk factors for gonorrhea and chlamydia at multiple anatomic sites. Findings from this study have provided valuable information on the incidence of extragenital disease in high-risk groups within the Military Health System, as well as data on the antimicrobial resistance of GC. In addition, the study validated the value of self-collected versus provider-collected swabs for STI testing and demonstrated the viability of early-stream urine for culture of GC. Enrollment in the second phase of the study involving a high-risk HIV-negative population (DoD pre-exposure prophylaxis users) was completed in 2019.

During the past year, a new protocol was initiated to evaluate use of the OMV meningitis B vaccine (Bexsero®) for primary prevention of gonorrhea. Led by LTC Garges, the study utilizes serum collected through the DoD Serum Repository from service members vaccinated with Bexsero® to study the host response to the vaccine and surrogate markers of protection against GC *in vitro*. Findings from this study will lay the groundwork for a clinical trial presently being developed to evaluate the efficacy of Bexsero® against gonorrhea (trial sponsored by National Institute of Allergy and Infectious Diseases (NIAID), Division of Microbiology and Infectious Diseases).



The IDCRP STI Research Area Investigative Team with collaborators from USU and NIAID at the 2019 STI & HIV World Congress



IDCRP STI Research Area Annual Meeting 2019



Dr. Adriana Le Van and Mr. Nelson Dozier of the DoD GC Reference Laboratory and Repository at the 2019 STI & HIV World Congress

In the upcoming year, the GC Resistance Study protocol will be amended to allow for comprehensive surveillance of bacterial STIs other than GC, including genital mycoplasma and chlamydia. In addition, the modified GC Resistance Study will include the evaluation of antimicrobial resistance, infection persistence, and patient-derived clinical outcomes for these bacterial STIs, which will provide new opportunities for partnerships with academia.

## MILITARY IMPACT

The overall goal of the STI Research Area is to support the prevention, diagnosis, and treatment of STIs to eliminate STI transmission among active-duty members and beneficiaries and improve Force Health Protection. Findings from the GC Resistance Study provide valuable up-to-date information on the geographic distribution of isolates connected to antimicrobial susceptibility patterns, which are used for operational planning

by the DoD. Susceptibility testing and advanced molecular characterization of isolates collected from within the United States and at overseas sites are assessed through the DoD GC Resistance Laboratory and Repository. Epidemiologic data on increasing resistance to azithromycin among GC isolates in the Western United States also continues to be provided to Combatant Commands through the Global Emerging Infections Surveillance (GEIS) Data to Decision Initiative for situational awareness and response, as needed. Furthermore, engagement with partner militaries for GC surveillance is active in Ghana, Thailand, Peru, and the Republic of Georgia, which provides not only valuable local Force Health Protection data, but also supports improvements in the technical capabilities and laboratory methods for our host nation partners.

## HIGHLIGHTS/KEY FINDINGS

- Among active-duty servicewomen in the U.S. Navy with endocervical chlamydia infections, there was a high rate of concurrent anorectal infections. The findings indicate a need for extragenital screening among high-risk patients, as well as increased education and behavioral interventions (use of condoms). This article was included in the evidence review for the revision of the U.S. Sexually-Transmitted Disease Treatment Guidelines at the CDC Treatment Guidelines 2019 meeting.
- The value of the GC Resistance Study and the DoD GC Reference Laboratory and Repository was recognized as the DoD (represented by LTC Garges) was invited to be a stakeholder and participate in a World Health Organization 2019 protocol planning meeting related to GC surveillance.
- The Survey of Social Networks and STI Risk study completed enrollment (>700 subjects) and is the first time a dedicated sexual network risk study will address formation of sexual partnerships and risk of STIs among active-duty personnel.



# TRAUMA-RELATED INFECTIONS

*Improving the prevention and clinical management of infections complicating battlefield injuries, particularly with blast trauma, continues to be a high priority of the Military Health System. Research to further the understanding of the care of complex wounds with virulent and multidrug-resistant pathogens is also crucial.*



David Tribble, MD, DrPH, Science Director and Trauma-Related Infections Research Area Director



The four scientific aims of the Trauma-Related Infections Research Area are strategically focused on research priorities of the Military Health System (MHS) to address knowledge gaps in the prevention and clinical management of combat-related infections in relation to blast injuries, multidrug-resistant bacterial infections, long-term outcomes, quality of life, Joint Trauma System clinical practice guidelines, and antibiotic stewardship. The centerpiece protocol of the research area is the Trauma Infectious Disease Outcomes Study (TIDOS), which is led by Dr. David Tribble. From June 2009 through December 2014, TIDOS systematically collected information on the medical and surgical management, microbiology, and infectious outcomes from military personnel wounded during deployment (i.e., battle and non-battle injuries). For patients who enrolled in the TIDOS follow-up cohort, information on trauma-related infections diagnosed after hospital discharge continues to be captured through the MHS Data Repository. For cohort enrollees who left military service and entered Veterans Affairs (VA) healthcare, information was collected through our collaboration with the VA St. Louis Health Care System (led by Dr. Jay McDonald), which included mental and social health factors (e.g., depression, post-traumatic stress disorder, and opioid use).

Each year, the Department of Defense (DoD) Blast Injury Research Program Coordinating Office includes one chapter in their Annual Report to the DoD Executive Agent, highlighting a specific research program or initiative. For the FY2018 report, Dr. Tribble was invited to write a chapter on the TIDOS research efforts on blast-related wound

infections. Extremity trauma, often involving severe polytrauma due to blasts, is the most frequent type of battlefield injury and remains a focus of multiple analyses through the research area. Presently, TIDOS analyses examining effectiveness of specific antimicrobial regimens related to the treatment of deep soft-tissue infections are nearing completion. These findings, coupled with literature review, will support future guidance on treatment.

Osteomyelitis is another complication of serious orthopedic trauma, which is generally characterized by multiple surgical procedures, extended use of antibiotics, and lengthy hospitalizations and ambulatory care. The Trauma-Associated Osteomyelitis protocol, led by Dr. Tribble, evaluated risk factors for the development of osteomyelitis among combat casualties with open fractures of the tibia, femur, and upper extremities. Through our collaboration with the VA St. Louis Health Care System, the long-term outcomes for patients in this study are currently being assessed.

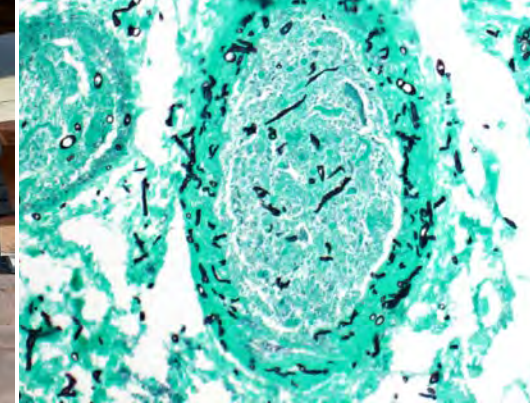
Invasive fungal wounds infections (IFIs) are associated with substantial morbidity among blast casualties and effective management and improved clinical outcomes are dependent on early diagnosis. As a follow-on to the assessment of a polymerase chain reaction (PCR)-based diagnostic assay for IFI identification, led by Dr. Anuradha Ganesan, additional evaluation is underway to support applications of the PCR-based assay in future conflicts. Furthermore, comprehensive examination of patients with laboratory evidence of a fungus isolated from wounds led to the development of a refined IFI classification scheme based on degree of certainty of diagnosis (i.e., IFI, High Suspicion of IFI, and Low Suspicion of IFI). This classification scheme provides a framework to support clinical decision making and reduce practice variation.



MAJ Joseph Petfield (former site Principal Investigator [PI]) and Lt Col Charla Geist (current site PI) at Landstuhl Regional Medical Center



2019 Annual Trauma-Related Infections Investigator Meeting



Necrotic tissue with fungal angioinvasion (image courtesy of Dr. Mary Klassen-Fischer)

Although not as frequent as orthopedic injuries, non-extremity wound infections are also being evaluated. One recent analysis examined characteristics of abdominal surgical site infections among trauma patients who underwent downrange exploratory laparotomy and infection risk factors are currently being assessed. Analyses to examine infectious complications following pelvic fractures and penetrating central nervous system injuries are in development.

During 2019, analyses continued under the TIDOS Multidrug-Resistant and Virulent Organisms (MDR/VO) Trauma Infections initiative, which is led by Dr. Katrin Mende and involves a collaborative effort across multiple DoD laboratories (Walter Reed Army Institute of Research, Naval Medical Research Center, U.S. Army Institute of Surgical Research, and Brooke Army Medical Center) to maximize the understanding of complex polymicrobial wounds using clinical data from TIDOS connected to isolates in the TIDOS Microbiology Repository. Ongoing analyses will further examine the interaction of common wound bacteria, as well as assess clinical outcomes with regards to wound microbiology and biofilm formation.

In 2020, the Trauma-Related Infections Research Area will merge with the Skin and Soft-Tissue Infections Research Area to form the Wound Infections Research Area. The long-standing clinical research initiatives of the two research areas have resulted in comprehensive databases of clinical factors and substantial microbiological specimen repositories that will continue to be the foundation of both epidemiologic and laboratory-based studies needed to improve infection prevention and management.

## MILITARY IMPACT

The research area's aims and objectives continue to be responsive to priorities of the DoD Joint Trauma System and MHS and provide essential information during inter-war periods by improving the understanding and best practices of infection-related issues following battlefield injury. The strengths and opportunities presented by this research area present a robust platform to support development and refinement of evidence-based clinical practice guidelines for the management of combat trauma-related infections during future conflicts.

## HIGHLIGHTS/KEY FINDINGS

- Patients with open upper extremity fractures characterized by substantial soft-tissue damage (i.e., extensive degloving) are at high risk of developing osteomyelitis.
- Among trauma patients who received vancomycin and piperacillin-tazobactam combination therapy, 13% met criteria for acute kidney injury.
- Patients meeting criteria for an IFI classification were more likely to have fungi from the order Mucorales isolated from their wounds (39%) compared to patients classified as High or Low Suspicion of IFI (22% and 9%, respectively).
- There is substantial variation in antibiotic prescribing patterns for combat-related extremity wound infections with 72% of patients receiving at least three different antibiotics.



## THE IDCRP STAFF

*The vast clinical research accomplishments and successes of the IDCRP are the direct result of its highly skilled employees, who demonstrate a remarkable commitment and enthusiasm to the advancement of clinical infectious disease research with the goal of improving the health of military service members.*

In 2019, over 120 research and program-support personnel were employed by the Program. These exceptional individuals meet the challenge of supporting the diverse IDCRP portfolio, which includes clinical research spanning retrospective observational studies to prospective clinical trials.

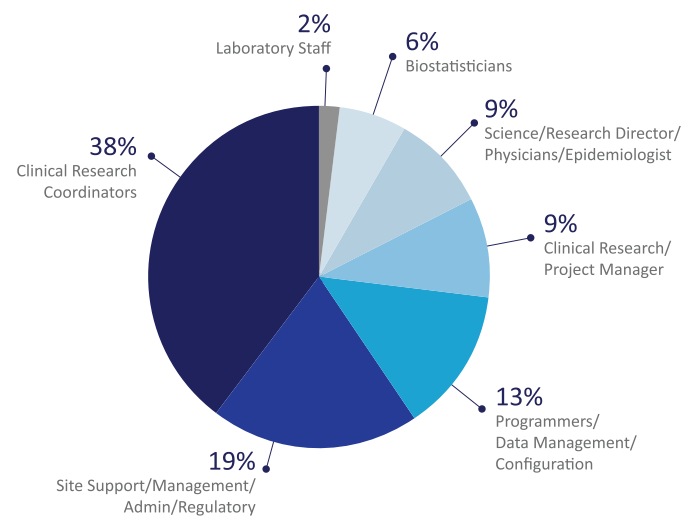
More than half of the personnel directly interact with research study subjects at clinical sites within the military hospital/clinic network. As depicted in the figure, clinical research coordinators comprise the majority of these professionals. Additional members of the IDCRP staff include clinical investigators based at military clinical sites and USU and protocol-support personnel, such as clinical research and site managers, program and data managers, laboratory staff, and biostatisticians.

The expertise of IDCRP staff members includes infectious diseases, epidemiology, preventive medicine, public health, microbiology, data programming, statistical analysis, finance, program management, and regulatory affairs. Staff members are distributed within DoD medical treatment facilities, USU, and operational clinics within the United States, as well as at overseas locations. More than half of IDCRP personnel have earned at least two degrees and everyone within the team adds to the wealth of knowledge and experience that has led to the success of the IDCRP.

We wish to thank our employees for their continued distinction and hard work to support the IDCRP.



The IDCRP Team at the 2019 IDCRP Leaders Meeting



IDCRP Personnel Distribution by Occupation, 2019

## DATA COORDINATION CENTER

*The Data Coordination Center (DCC) is the central hub of the IDCRP's research efforts and provides high-quality, efficient data collection, processing, management, and access.*

Led by Edward Parmelee, DCC Chief, the team includes data system designers, data managers, data entry staff, and SAS / Oracle programmers. The DCC team supports IDCRP research by providing Principal Investigators with expertise regarding the conceptualization, design, collection, management, cleaning, analysis, and publication of study data. These essential resources are provided for all research studies where the IDCRP is the primary data collector or repository. During the past year, 31 IDCRP studies were supported by the DCC, which includes 4 studies that entirely used data obtained from the Military Health System (MHS) Medical Data Repository.

In 2018, a browser-based electronic data capture system and workflow methodology for the design and execution of clinical research databases (i.e., REDCap) was employed for two IDCRP protocols: 1) Shiga Toxin-producing *Escherichia coli* (STEC) Outbreak Investigation in the EIDAR Research Area and 2) the Pragmatic Assessment of Influenza Vaccine Effectiveness in the DoD (PAIVED) trial in the ARI Research Area. Throughout 2019, the DCC team learned how to more effectively utilize the capabilities of REDCap, thereby decreasing resource needs for the start-up of new studies and increase programmatic capabilities.

During 2019, data continued to be acquired from the MHS Medical Data Repository to support research studies under the HIV and Trauma-Related Infections Research Areas, as well as collect data for retrospective cohorts (e.g., Chikungunya Virtual Cohort under EIDAR Research Area and HIV Virtual Cohort under the HIV Research Area). As the DCC team gains experience with the MHS Medical Data Repository, new ways to utilize this valuable resource are being examined.

In the upcoming year, the DCC will continue to build processes around the REDCap system with the goal of supporting interventional studies, as well as transferring long-term studies from the older, legacy systems into REDCap. The registry hosted by the IDCRP to store protected health information and personally identifiable information about subjects enrolled in IDCRP studies no longer meets the evolving needs of the Program. Thus, a new registry workflow based in the REDCap system to host this information is under development and is expected to be implemented in 2020. Lastly, as the IDCRP moves toward more interventional clinical studies, DCC processes and procedures will be comprehensively examined to assess compliance with federal (i.e., FDA) and international standards.



Edward Parmelee, MS  
Chief, Data Coordination Center

### HIGHLIGHTS

- Employed a new software tool called Remark OMR, which allows for the scanning of standard-bubble sheets used to collect information from a large group of subjects and/or in situations when electronic capture of data is not possible.
- National Institutes of Health toolkit for cognitive assessment was implemented as part of the ALLHANDS study in the HIV Research Area with the toolkit application downloaded and tested on iPads and distributed to relevant clinical sites for data collection.
- Templates for standardized case report forms (CRFs) were developed and integrated into the REDCap system to be used by any IDCRP research study, increasing efficiency and reducing costs for system development.
- Initiated the intensive process of transitioning IDCRP long-term studies from the currently used, legacy electronic data capture systems (e.g., ClinPlus) to the more efficient REDCap system.



# PROGRAM OPERATIONS AND FINANCE

*A solid operational and financial foundation are core elements crucial for the ongoing success of the IDCRP and, particularly, the Program's capability to accomplish high-quality clinical research.*



Samuel Davis, PhD, Chief, Program Operations and Finance

Led by Dr. Samuel Davis (Chief of Program Operations and Finance), the Program Management and Finance (PM&F) team continued to improve overall efficiency and productivity of the Program over the past year. Specifically, the PM&F team oversaw the evolving clinical research portfolios of the research areas, processed numerous funding awards, and conducted complex financial analyses to augment resource management.

An intensive effort over the past year has been the development of a Clinical Trials Finance System (CTFS) to standardize the reporting of budgetary and expense data. Furthermore, with the goal of strengthening communication with stakeholders and increasing transparency, monthly meetings were held over the past year with USU and HJF finance and program management representatives to discuss details related to incoming funding.



The IDCRP Program Management and Finance Team

The backbone of these meetings was the Master External Funds Report, which provides up-to-date information related to the status of funding requests (e.g., expected timing of receipt of the awards by USU).

In 2020, additional comprehensive financial planning and resource management tools will be developed, which includes the use of a cloud-based software (Adaptive Insights) for budget building, management, and analysis.

The Research Support Group (RSG) provides invaluable administrative support for IDCRP leadership and research area teams. In particular, the RSG team is responsible for the submission and tracking of clearance requests for deliverables, organization of annual leadership and investigator meetings, and coordination of travel requests for multiple protocols.



LTC Charlotte Lanteri and the IDCRP Research Support Group

# QUALITY MANAGEMENT & CLINICAL RESEARCH OPERATIONS

*The Clinical Research Operations team oversees the daily management for all research protocols within the IDCRP and quality management is critical for the successful execution of these studies.*

In 2019, Ms. Christina Fox was hired to fill the newly created IDCRP position of Chief of Quality Management to provide centralized quality management oversight of IDCRP protocols, ensure regulatory compliance, and increase standardization of practices and reporting across clinical sites. Over the past year, Ms. Fox accompanied IDCRP leadership on site visits to gain insight into clinical operations, met with stakeholders, and conducted a landscape review of IDCRP protocol quality control and assurance reports to identify areas for potential process improvements. Ms. Fox also serves as the IDCRP liaison with the USU Human Research Protection Program Office.

To enhance communications with IDCRP clinical study teams, Ms. Fox leads the twice monthly Clinical Operations Management Meeting, which provides a forum to review topics focused on quality management and regulatory affairs and make standardized decisions for dissemination throughout the IDCRP.

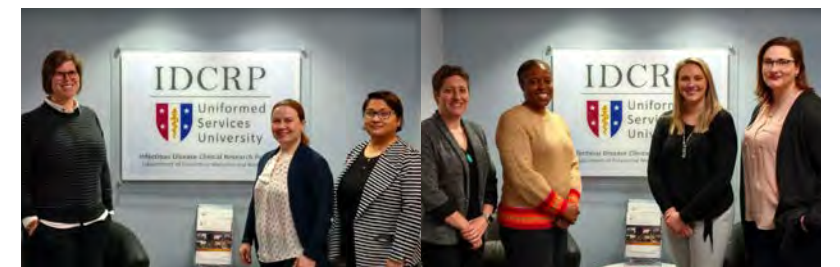
Also vital for the successful execution of the clinical research portfolio is the USU-based IDCRP team of Clinical Research Managers, as well as the military treatment facility-based Site Managers (and lead Clinical Research Coordinators), who support Principal Investigators, Data Coordination Center,

and protocol teams with protocol development and study execution. During the past year, the completion of enrollment and follow-up for the Prevent Travelers' Diarrhea protocol under the Deployment and Travel-Related Infections Research Area and the *Staphylococcus aureus* vaccine study through the Skin and Soft-Tissue Infections Research Area would not have been possible without the hard work of the entire study teams.

In 2020, an IDCRP-wide Quality Management Plan and Manual will be developed following an intensive review of study documentation, site practices, external monitoring, and regulatory requirements. Furthermore, IDCRP Standard Operating Procedures related to quality management and regulatory affairs will also be produced.



Christina Fox, CCRC, CCRP, Chief, Quality Management



The IDCRP Clinical Research Operations team

## HIGHLIGHTS

- The potential of integrating ORACLE data directly into the CTFS to expand its capabilities is being examined. If successful, the directly-integrated CTFS platform will become an important resource for the financial management of protocols.
- The PM&F team tracked, processed, and managed 15 separate funding awards received by the IDCRP in 2019.
- RSG team members supported Clinical Research Operations by assisting with enrollment in two large-scale IDCRP-led clinical trials: the *Staphylococcus aureus* vaccine study and the Pragmatic Assessment of Influenza Vaccine Effectiveness in the DoD (PAIVED) protocol.

## HIGHLIGHTS

- Quality management site visits were conducted at six military hospitals as part of a review of the Acute Respiratory Infections Research Area, Pragmatic Assessment of Influenza Vaccine Effectiveness in the DoD (PAIVED) protocol with the findings being used to develop IDCRP-wide quality management tools.
- A Quality Management Manual, in support of the IDCRP Investigator Handbook, will be produced to achieve consistency in clinical research protocol design, site selection, execution, and management in accordance with Good Clinical Practice guidelines and other applicable DoD regulations.
- An IDCRP-wide metrics module in REDCap was developed for IDCRP staff to provide detailed updates on ongoing research studies using standardized metrics.



## SCIENTIFIC REVIEW BOARD

*The IDCRP Scientific Review Board (SRB) executes independent, comprehensive, and efficient scientific reviews of clinical research protocols and protocol amendments prior to submission to the USU Institutional Review Board (IRB).*



John Powers, MD, Chair, Scientific Review Board

The central purpose of the SRB, chaired by Dr. John Powers (National Institute of Allergy and Infectious Diseases Liaison) and Vice Chair LTC Charlotte Lanteri, is to meticulously review protocol submissions (and amendments) to determine if the research questions, hypotheses, aims and objectives, and methods are scientifically valid and meaningful. Before a new protocol is submitted to the SRB for review, a research concept is first evaluated by the Concept Scoring Panel, Senior Science Group, and Operational Steering Committee, who discuss the programmatic and military relevance, uniqueness, and scientific validity of the proposed study, culminating in a recommendation regarding whether the concept should move forward with protocol development. In brief, the SRB reviews all new protocol submissions, including studies that involve participants already enrolled in approved protocols. This foundational review is intended to augment the scientific quality of all new IDCRP protocol submissions prior to review by the USU IRB.

The SRB process includes three separate review pathways to maintain efficiency, with the level of review required for each submission determined by the SRB Chair (or the Vice Chair when the Chair is recused or unavailable). Standard review typically occurs within 35-45 days, Low Resource reviews are 28 days, and Chair Reviews are accomplished in 14 days. The composition of SRB review panels correspond to the focus of the specific protocol or amendment under review and generally include subject matter experts,

biomedical scientists, statisticians, and scientific review panel members affiliated with IDCRP research networks (as appropriate).

During 2019, the SRB continued to be productive with review of 8 submissions. There are also three new protocols that are expected to be submitted for review in the coming months. During the past year, the efficiency of SRB reviews improved by discussing study design elements with Principal Investigators prior to protocol development and submission.

For the upcoming year, the SRB Chair will continue to streamline the review process by encouraging further communication with the Principal Investigators, standardizing timelines related to SRB submissions, mentoring new investigators on protocol development, and providing new reviewers with training to improve the quality of reviews. The SRB Chair or Vice Chair will review protocols prior to SRB submission to confirm the scientific quality. These efforts will improve the productivity of the SRB, as well as maintaining high-quality reviews.

SRB Reviews and Approvals	Numbers
<b>Submission to the SRB</b>	<b>8</b>
New protocols	5
Protocol amendments	3
<b>SRB disposition</b>	
Approved	6
Under Review	2

## REGULATORY AFFAIRS

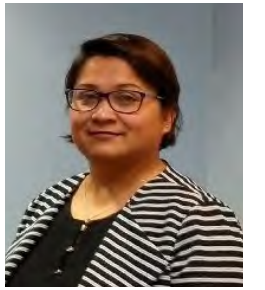
*The IDCRP Regulatory Affairs team supports investigators in preparing new research protocols and assisting with the execution of existing protocols by ensuring ethical and regulatory compliance, as well as establishing agreements necessary for the conduct of protocols. The Regulatory Affairs team also functions as an invaluable liaison between the IDCRP and USU, Defense Health Agency (DHA), Department of Defense (DoD) partners, National Institute of Allergy and Infectious Diseases, collaborators, and other regulatory agencies.*

The IDCRP presently has 71 active (open) protocols, of which 56 are nonexempt studies and 15 are exempt studies. Over the past year, the burden of administrative tasks increased as the result of the required conversion of studies to a multi-site Electronic Institutional Review Board (eIRB) format, mandated by the DHA Regulatory Oversight Office. Specifically, Ms. Luca Illinik (IDCRP Regulatory Affairs Specialist) and IDCRP staff processed 437 eIRB submission in 2019, including 5 closures, 44 continuing reviews, 6 initial review submissions, 170 protocol modifications, 107 site-specific protocols, and 105 miscellaneous protocol actions. To facilitate the eIRB conversion, a portfolio of regulatory affairs operations management tools was developed, and multiple informative training sessions were hosted by Ms. Illinik.

Collaborations and partnerships with military, government, and civilian research institutions and laboratories, as well as academia are a core component of the IDCRP. As such, various official agreements are required for each collaboration

(e.g., Cooperative Research and Development Agreements, Data Sharing Agreements, and Materiel Transfer Agreements). Presently, Ms. Stephanie Cammarata, IDCRP Agreements Officer, has a portfolio containing more than 145 active agreements with 43 agreements related to either a new collaboration or a renewal of an existing agreement submitted for review in 2019.

A significant achievement in 2019 was the implementation of a cloud-based Regulatory Affairs Workspace at central DoD participating sites, designed to support the management of regulatory tasks across IDCRP. The benefits of this new system are already evident as it promotes regulatory compliance through the standardization of metrics and the tracking of regulatory requirements (including pending reviews and post-IRB approval tasks). In the coming year, the Regulatory Affairs team will assist the Quality Management Chief with the development of an IDCRP-wide Quality Management program.



Luca Illinik, MPH, CIP, CCRP, Regulatory Affairs Specialist

### HIGHLIGHTS

- IDCRP Regulatory Affairs team successfully supported the conversion of 32 multi-center protocols to the new eIRB multi-site format.
- A Regulatory Affairs Smartsheet Workspace designed to assist with IDCRP regulatory task management was established.
- Two new Institutional Agreements for IRB Review (IAIR) were established between the USU IRB and Carl R. Darnall Army Medical Center and the U. S. Naval Hospital Okinawa, while the Brooke Army Medical Center IAIR and the 59th Medical Wing IAIR were renewed.



## EDUCATION / MENTORSHIP

*Fostering the training and development of the next generation of infectious disease clinical researchers in the United States military remains a high priority of the IDCRP. To support this goal, the IDCRP utilizes mentored research projects, as well as research engagement.*



CPT Kathryn Lago presenting at 2019 AFIDS

As part of the mentored research project initiative, medical and public health students, residents, and infectious disease (ID) fellows in the Armed Forces are provided opportunities to participate on or lead IDCRP-mentored projects at USU, as well as at military hospitals within the IDCRP Partner Network, such as Brooke Army Medical Center, Walter Reed National Military Medical Center (WRNMMC), Naval Medical Center San Diego, and Madigan Army Military Center. These mentored research projects provide trainees with valuable, practical experience pertaining to the design of research studies, data collection, statistical analysis, and data interpretation. In addition, IDCRP investigators support the development of the clinical ID research Capstone curriculum for medical students offered through USU.

During the past year, 24 residents (across multiple specialties, including Internal Medicine, Pediatrics, Preventive Medicine, and Surgery) and ID Fellows either began or finished their IDCRP-mentored research projects, which resulted in 22 oral and poster presentations at local and national infectious diseases conferences. A USU DrPH candidate is also utilizing data from the TravMil and TrEAT TD studies in support of her degree and a USU MPH student used data from Social and Sexual Networks Study for his Capstone project. In addition, data from the EIDAR *Borrelia* serosurvey is being used by a USU medical student for his Capstone project. During 2019, six manuscripts with findings from IDCRP-mentored research projects were either published or accepted for publication with additional manuscripts either submitted for journal consideration or in development. The Armed Forces Infectious Diseases Society (AFIDS) annual Spring meeting and continuing graduate medical education efforts at WRNMMC are also supported by the IDCRP. During 2019, trainees who participated in



CPT Grant Justin presenting at the 2019 HIV Research Area Annual Investigator Meeting

IDCRP-mentored research projects also received award recognition at local conferences, as well as for their manuscripts developed from their mentored analyses (see IDCRP Awards and Honors, page 28).

As part of research engagement, IDCRP investigators, mentored trainees, and USU faculty continued to work over the past year to increase awareness about ID clinical research in the Armed Services beyond publishing and presenting clinical research findings. Specifically, IDCRP investigators attended public health student practicum and project fairs, met with ID fellows and medical residents to discuss training opportunities, and corresponded with medical training Program Directors about IDCRP mentored research opportunities. Infectious disease consultants and USU faculty, particularly individuals who graduated from military training programs, were also invited to meet with trainees to discuss how research plays an important role in their respective practices.

Overall, the IDCRP education mission has successfully supported the growth of active-duty ID clinical researchers in the U.S. Armed Forces.



Maj Dana Blyth and Dr. Katrin Mende with their trainees (MAJ Kiley, Capt Yabes, Capt Schall)

## SELECT IDCRP TRAINEE EDUCATION PUBLICATIONS AND PRESENTATIONS

### PUBLICATIONS

**Gilbert L**, Wang X, Deiss R, Okulicz J, Maves R, Schofield C, Ferguson T, Whitman T, Kronmann K, Agan B, Ganesan A. Herpes Zoster Rates Continue to Decline in People Living With Human Immunodeficiency Virus but Remain Higher Than Rates Reported in the General US Population. *Clinical Infectious Diseases*. 2019; 69(1): 155-158.

**Carney B**, White J, Xu X, Sunil T, Daniels C, Byrne M, Ganesan A, Deiss R, Macalino G, Agan BK, Okulicz JF. Relationship Between Depression and Risk Behaviors in a US Military Population with HIV Infection. *AIDS Care*. 2019; 31(9): 1152-1156.

### PRESENTATIONS

#### 48th Critical Care Congress, 17-20 February 2019

**McCarthy S**, Stewart L, Shaikh F, Carson ML, Merritt T, Whitman TJ, Petfield JL, Murray CK, Tribble DR, Blyth DM. Application of the Sequential Organ Failure Assessment Score to Combat-Injured Patients from OEF/OIF.

#### American Society of Cataract and Refractive Surgery and American Society of Ophthalmic Administrators (ASCRS ASOA) Annual Meeting, 3-7 May 2019

**Justin G**, Wang X, Chu X, Agan B, Legault G. Refractive Surgery: Complications and Risk Factors in the US Military HIV Natural History Cohort.

#### 2019 Texas Infectious Diseases Society Annual Meeting, 7-9 June 2019

**Kiley JL**, Mende K, Beckius M, Kaiser SJ, Carson ML, Lu D, Whitman TJ, Petfield JL, Tribble DR, Blyth DM. Clinical Characteristics and Outcomes of *Klebsiella pneumoniae* Infection in Service Members Who Sustained Trauma in Iraq and Afghanistan.

**Joya C**, Won SH, Schofield C, Lalani T, Maves RC, Kronmann, Deiss R, Okulicz J, Agan BK, Ganesan A. Persistent Low-Level Viremia while on Antiretroviral Therapy is an Independent Risk Factor for Virologic Failure. *Clinical Infectious Diseases*. 2019; 69(12): 2145-2152.

Tisdale CS, **Justin GA**, Wang X, Chu X, Carlton DK, Okulicz JF, Schofield C, Maves RC, Agan BK, Legault GL. Refractive Surgery in the HIV-Positive U.S. Military Natural History Study Cohort: Complications and Risk Factors. *Journal of Cataract & Refractive Surgery*. 2019; 45(11): 1612-1618.

#### IDSA IDWeek, 2-6 October 2019

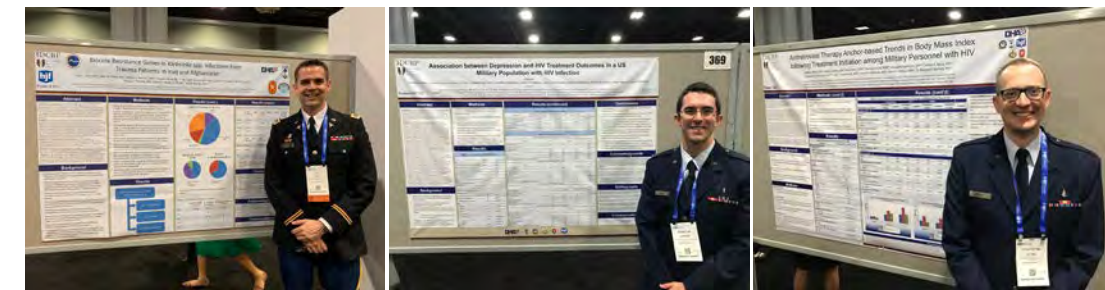
**Carney B**, Daniels C, Xu X, Sunil T, Ganesan A, Blaylock JM, Kronmann K, Schofield C, Tahaniyat T, Agan B, Okulicz J. Association between Depression and HIV Treatment Outcomes in a US Military Population with HIV Infection.

**Kline D**, Daniels C, Xu X, Sunil T, Ganesan A, Agan B, Colombo R, Kronmann K, Blaylock JM, Okulicz J, Markelz AE. Antiretroviral Therapy Anchor-based Trends in Body Mass Index following Treatment Initiation among Military Personnel with HIV.

**Kiley JL**, Mende K, Beckius M, Kaiser SJ, Carson ML, Lu D, Whitman TJ, Petfield JL, Tribble DR, Blyth DM. *Klebsiella variicola* Infections in Service Members who Sustained Trauma in Iraq and Afghanistan.

**Kiley JL**, Blyth DM, Beckius M, Kaiser SJ, Carson ML, Lu D, Whitman TJ, Petfield JL, Tribble DR, Mende K. Biocide Resistance Genes in *Klebsiella spp.* Infections from Trauma Patients in Iraq and Afghanistan.

**Manley M**, Lalani T, Telu T, Tribble D, Tilley H, Ganesan A, Kunz A, Geist C, Fraser J, Mitra I, Yun H, Lindholm DA. TravMil Surveillance of Travel-Related Illness in a Prospective Cohort of US Military Beneficiaries, 2010-2018.



Trainee presentations at 2019 IDSA IDWeek.

From left, MAJ John Kiley, Capt Brandon Carney, and Capt David Kline



# IDCRP AWARDS AND HONORS

During 2019, multiple Infectious Disease Fellows and residents received awards or honors for their mentored IDCRP-related research studies.

In addition, LTC Eric Garges, STI Research Area Director, was awarded the “A” Proficiency Designator Award by the U.S. Army Surgeon General, which is bestowed on individuals who have attained full professional status and national prominence in their field. LTC Garges also received the William Gorgas Preventive Medicine Award and one of

the USU 2019 School of Medicine Dean’s Impact Awards for Associate Professors for recognition of his contributions as a transformative leader in sexually-transmitted infectious disease research within and outside of the DoD. Furthermore, Dr. Ann Jerse, who oversees the DoD *Neisseria gonorrhoeae* Reference Laboratory and Repository, also received one of the USU School of Medicine Dean’s Impact Award for full professors in recognition of research leadership success and contributions to graduate education and service.

Name	Award/Honor	Awarding Organization
LTC Eric Garges	“A” Proficiency Designator Award	Office of the U.S. Army Surgeon General
LTC Eric Garges	William Gorgas Preventive Medicine Award	Association of Military Surgeons of the United States
LTC Eric Garges	School of Medicine Dean’s Impact Award	USU
Dr. Ann Jerse	School of Medicine Dean’s Impact Award	USU
CPT Mary Ford	John L. Carpenter Department of Medicine Outstanding Resident Paper award for graduating internal medicine residents	San Antonio Uniformed Services Health Education Consortium
Capt Joseph Yabes	2 <sup>nd</sup> Place in Commander’s Research Paper award for fellows	San Antonio Uniformed Services Health Education Consortium
CPT Kathryn Lago	2 <sup>nd</sup> Place for Trainee presentation	Armed Forces Infectious Diseases Society
MAJ John Kiley	1 <sup>st</sup> Place for research podium presentation	Texas Infectious Diseases Society
MAJ Shannon Wood	Robert A. Phillips award	National Capital Region Military Research Competition
CPT Grant Justin	2 <sup>nd</sup> Place in clinical research paper competition	Military Refractive Surgery and Safety Standards Symposium

Left: LTC Eric Garges being congratulated by CAPT Timothy Burgess for his receipt of the USU School of Medicine Dean’s Impact Award

Middle: CPT Mary Ford with her John L. Carpenter award

Right: Capt Joseph Yabes with his Commander’s Research Paper award



# IDCRP COLLABORATORS AND PARTNERS

## Department Of Defense Sites

### U.S. Military Hospitals and Clinics

Brooke Army Medical Center, JBSA Fort Sam Houston, TX  
 Carl R. Darnall Army Medical Center, Fort Hood, TX  
 Landstuhl Regional Medical Center, Germany  
 Madigan Army Medical Center, Joint Base Lewis McChord, WA  
 Martin Army Community Hospital, Ft. Benning, GA  
 Naval Medical Center Camp Lejeune, Jacksonville, NC  
 Naval Medical Center Portsmouth, VA  
 Naval Medical Center San Diego, CA  
 Rodriguez Army Health Clinic, Puerto Rico  
 Schofield Barracks Health Clinic, Tripler Army Medical Center, Oahu, HI  
 Soto Cano Air Base, Honduras  
 Troop Medical Clinic, Fort Sam Houston, TX  
 U.S. Naval Academy, Annapolis, MD  
 U.S. Naval Expeditionary Base, Camp Lemonnier, Djibouti  
 U.S. Naval Hospital Okinawa, Japan  
 Walter Reed National Military Medical Center, Bethesda, MD  
 Wilford Hall Medical Center, JBSA Fort Sam Houston, TX  
 William Beaumont Army Medical Center, El Paso, TX  
 Womack Army Medical Center, Ft Bragg, NC

### U.S. Military Research Commands

Naval Medical Research Center (NMRC)  
 • Biological Defense Research Directorate  
 • Enteric Disease  
 • Viral and Rickettsial Diseases  
 • Wound Infections  
 NMRC—Subordinate Commands  
 • Naval Health Research Center, San Diego, CA  
 • Naval Medical Research Unit No. 6 Lima, Peru  
 • Naval Medical Research Unit No. 2, Singapore  
 • Naval Medical Research Unit No. 3, Cairo, Egypt  
 • Naval Submarine Medical Research Laboratory  
 U.S. Army Institute of Surgical Research  
 U.S. Army Medical Research Institute of Infectious Diseases  
 Walter Reed Army Institute of Research  
 • Military HIV Research Program  
 • Multidrug Resistant Organism Repository and Surveillance Network  
 • Specimen Processing Laboratory  
 • Wound Infections  
 • Viral Diseases  
 • Overseas Research Detachments  
 – Armed Forces Research Institute of Medical Sciences, Bangkok, Thailand  
 – U.S. Army Medical Research Directorate, Nairobi, Kenya  
 – U.S. Army Medical Research Unit, Tbilisi, Georgia  
 – U.S. Army Medical Materiel Development Activity

### Other U.S. Military Commands/Programs

Defense Health Agency  
 • Armed Forces Health Surveillance Division (AFHSD)  
 – Global Emerging Infection Surveillance (GEIS) Program  
 • Immunization Healthcare Division  
 Bureau of Medicine and Surgery, Department of Navy (BUMED)  
 Congressional Defense Medical Research Program (CDMRP)  
 Defense Advanced Research Projects Agency (DARPA)  
 Military Infectious Diseases Research Program (MIDRP)  
 Navy Marine Corps Public Health Center (NMCPHC)  
 San Antonio Uniformed Services Health Education Consortium

### United States Government Health Agencies

Centers for Disease Control and Prevention  
 Food and Drug Administration  
 National Institutes of Health

- National Institute of Allergy and Infectious Diseases
  - Division of AIDS
  - Division of Clinical Research
  - NIAID Flu Networks
  - Division of Microbiology and Infectious Diseases
  - Vaccine Research Center
- National Institute of Mental Health
- National Institute of Neurological Disorders and Stroke
- National Institute of Health Clinical Center
- U.S. Department of Veterans Affairs
  - Atlanta Veterans Affairs Medical Center
  - James J. Peters VA Medical Center, Bronx, NY
  - South Texas Veterans Health Care System
  - St. Louis Veterans Affairs Medical Center
  - Veterans Aging Cohort Study
  - Veterans Affairs Connecticut Healthcare System

### Foreign Health Agencies and Organizations

National Institute for Public Health and the Environment (RIVM), The Netherlands  
 Thai Red Cross AIDS Research Centre  
 United Kingdom Ministry of Defence
 

- Royal Centre for Defense Medicine, Birmingham, UK
- Camp Bastion, Afghanistan
- British Army Training Unit, Nanyuki, Kenya
- Defence Medical Directorate, Birmingham, UK
- Defence Statistics (Health) MOD Abbey Wood

### Academia

Bryant and Stratton College  
 Columbia University  
 Drexel University  
 Duke University  
 Emory University  
 Harvard T. H. Chan School of Public Health  
 Johns Hopkins Applied Physics Laboratory  
 Johns Hopkins Bloomberg School of Public Health  
 Johns Hopkins School of Medicine  
 New York University School of Medicine  
 University of California-Los Angeles  
 University of California-San Diego  
 University of Maryland-Baltimore  
 University of Minnesota  
 University of Nebraska  
 University of North Carolina  
 University of Pennsylvania  
 University of Pittsburgh  
 University of Texas Health Science Center at San Antonio  
 University of Texas Medical Branch  
 University of Texas-San Antonio  
 University of Toledo College of Medicine and Life Sciences  
 University of Vermont  
 University of Virginia  
 University of Washington  
 University of Wuerzburg Medical Center, Germany  
 Vanderbilt University  
 Yale University

### Research Organizations and Industry Partners

Cherokee Nation Technology Solutions  
 Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.  
 Leidos Biomedical Research, Inc.  
 Menssana Research, Inc.  
 NovaDigm Therapeutics, LLC.  
 Scripps Research Institute





**Infectious Disease Clinical Research Program**

Uniformed Services University of the Health Sciences  
 Department of Preventive Medicine & Biostatistics

[www.idcrp.org](http://www.idcrp.org)