INFECTIOUS DISEASE
CLINICAL RESEARCH
PROGRAM

2017
ANNUAL REPORT
As 2017 concludes, the Infectious Disease Clinical Research Program (IDCRP) has begun our second decade providing innovative leadership in military multi-center clinical infectious diseases research to inform and improve the care of the Warfighter. The Program’s sustained success is the product of the robust partnership between the Uniformed Services University (USU), our Department of Defense (DoD) colleagues in the Military Health System (MHS) and biomedical Research and Development commands, the National Institute of Allergy and Infectious Diseases (NIAID), and collaborators from the Veterans Health Administration. This year has seen continued program evolution and production of high-quality evidence for providers and senior leaders in the MHS. Numerous accomplishments from each of our research areas are outlined in the report that follows.

I wish to recognize our USU leadership, our Operational and Executive Steering Committees, the long-standing partnership with and support from NIAID, and the effective implementation of our plans through the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. I also want to thank our DoD funding partners in the Defense Health Program, the Military Infectious Diseases Research Program, the Navy Bureau of Medicine and Surgery, and the Armed Forces Health Surveillance Branch for their support and partnership.

Lastly, our accomplishments are achieved through the hard work and collaboration of active-duty and civilian investigators, the dedicated team of research professionals across IDCRP’s network, and most importantly the military service members and beneficiaries who volunteer to participate as research subjects. It is a privilege to serve with such a great 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
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). 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 evaluation of long-term health outcomes, IDCRP conducts protocols that address critical knowledge gaps in the control and prevention of infectious disease 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), Chair
- 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
- Surgeon General’s Infectious Disease Consultants—Army, Navy, Air Force
- Director, Armed Forces Health Surveillance Branch
- Director, Military Infectious Diseases Research Program, MRMC

Program Coordination Center
- Program Director
- Chief, Division of Clinical Research (DCR), NIAID
- Deputy Program Director
- Chair, Scientific Review Board
- Research Administration Staff
- Regulatory Affairs Staff
- Chief, Research Support and Operations
- Program Management and Finance Staff

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

IDCRP RESEARCH AREAS

- Acute Respiratory Infections—The research area is addressing objectives related to the etiology, immunology, prevention, diagnosis, epidemiology, and treatment of acute respiratory infections among U.S. military personnel and their beneficiaries.
- Deployment and Travel-Related Infections—This research area focuses efforts on describing the epidemiology of deployment and travel-related infectious threats for deploying forces, evaluating pre-travel health care and mitigation strategies, developing novel methodologies for identifying pathogens associated with febrile and diarrheal disease, and improving treatment approaches during deployment.
- Emerging Infectious Diseases and Antimicrobial Resistance—This research area focuses on epidemiology with an overall goal of identifying optimal preventive and therapeutic interventions and diagnostics to result in the most effective response to and management of emerging infectious diseases.
- Human Immunodeficiency Virus Infections—The area’s 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 optimise individual management of HIV, and improving therapeutic outcomes with the ultimate goal of functional cure of infection.
- Skin and Soft-Tissue Infections—The overarching goal of the research area is to identify effective strategies for the prevention and control of the infections (including vaccine-based interventions), a major cause of morbidity among congregate military personnel in deployment and training settings.
- Sexually-Transmitted Infections—This research area seeks to improve the diagnosis, treatment, and prevention of sexually-transmitted infections with particular focus on emergent drug-resistant gonorrhea among active-duty members and their beneficiaries.
- Trauma-Related Infections—This area works to address knowledge gaps in infection prevention, clinical management, and treatment outcomes in battlefield trauma to inform DoD Joint Trauma System clinical practice. Specific focus is improved understanding of wound microbiology management and outcomes related to high-threat virulent and antimicrobial-resistant pathogens.

Each area’s 2017 accomplishments are presented in the following pages, along with information and projections for 2018.

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.
Acute respiratory infections (ARI) remain a Military Health System research priority with seasonal outbreaks posing a substantial threat to operational unit readiness as ARIs contribute to approximately 30% of infectious disease hospitalizations among active-duty service members.

Although the number of ARI cases among active-duty personnel declined in 2016, in part due to the reintroduction of the adenovirus vaccination program for recruits, ~225,000 individuals were still affected with ~360,000 medical visits being attributed to ARI. In general, military personnel are at an increased risk for ARI due to stressful working conditions and crowded training/deployment environments where respiratory infections are endemic.

During the past year, the ARI Research Area launched several new initiatives, including an anonymous survey related to healthcare seeking behavior among military trainees with influenza-like illness (ILI) and the Study to Address Threats of ARI in Congregate Military Populations (ATARI). The purpose of the ATARI pilot study, led by CAPT Timothy Burgess and Dr. Christian Coles, is to assess ILI transmission, and evaluate the effectiveness repeated annual influenza vaccinations. The ATARI study, a follow-up cohort study utilizing a larger trainee population will be developed, which will provide an opportunity to assess and validate novel infection biomarkers and evaluate the effectiveness repeated annual influenza vaccinations.

The centerpiece protocol of the research area recruits developing an ILI requiring medical attention. Analysis of the data is underway. The centerpieces of the research area is the ARI Consortium Natural History Study (ARIC NHS), which is a multisite, longitudinal observational study led by CAPT Burgess and designed to gather data on etiology, epidemiology, and immunology of ILI and severe ARI (SARI) in military populations. Presently, it has enrolled nearly 1,730 ILI cases and 155 SARI cases since initiation in 2009. In 2017, data on ARI epidemiology, etiology, and burden from ARIC NHS were summarized in monthly surveillance reports disseminated to Armed Forces Health Surveillance Branch, Global Emerging Infections Surveillance and Response System (GEIS) and Naval Health Research Center.

The IDCRP is also participating in the NIAD-sponsored, multi-site, FluPlasma 2 trial, which is designed to evaluate the efficacy of hyperimmune anti-influenza plasma for treatment of severe influenza. Nationally, there are 40 participating medical centers, including five ARIC NHS sites. The IDCRP’s effort, which is being led by Dr. Janine Danko at Walter Reed National Military Medical Center, is in its second season and is expected to be completed in 2018. Through collaboration with USU, studies using novel diagnostic platforms for determining ARI etiology are also being conducted. One such analysis is a two-year study to optimize Next Generation Sequencing for pathogen detection using respiratory samples from the ARIC NHS study, which recently identified a class of viruses not typically associated with respiratory infections. Another new initiative is the Flu Breath Test (FBT) study, which is led by Col Patrick Danaher at Fort Sam Houston. The goal of this research is to assess the use of exhaled volatile organic compounds for influenza diagnosis. Enrollment for this study exceeded expectations with 49 patients enrolled in the first four months after its initiation.

In the upcoming year, the ARI Research Area will build on its infrastructure to expand data collection and analysis, particularly with SARI. We will also continue to partner with the GEIS program to conduct ILI surveillance in the high-risk trainee population at Fort Sam Houston and a follow-up survey will be carried out to identify barriers to healthcare seeking in trainees with ILI. Based on findings from the ATARI study, a follow-up cohort study utilizing a larger trainee population will be developed, which will provide an opportunity to assess and validate novel infection biomarkers and evaluate the effectiveness repeated annual influenza vaccinations.

MILITARY IMPACT

A greater understanding of the burden and risk factors associated with ARI in military populations is needed to inform the development of effective ARI control strategies to limit the impact of respiratory infections on the health, performance, and mission-readiness of active-duty personnel. Since 2009, findings from the ARI Research Area have advanced understanding of the changing distribution and determinants of ARI in this population. This is achieved through continued military hospital-based surveillance of respiratory infections to provide epidemiology, clinical severity, and burden of disease estimates; surveillance for viral respiratory pathogens with pandemic potential and “routine” respiratory pathogens that might impact operational readiness; contributing operational burden data to allow comparison of the cost-effectiveness of different control measures designed to enhance force health protection; providing performance and detection tools needed to assess impact on routine surveillance for pathogen-specific respiratory infections; and linking clinical syndromes and ILI/SARI etiology to facilitate pathogen-focused monitoring and diagnosis.

HIGHLIGHTS/KEY FINDINGS

- Through use of cross-training with FluPlasma and ARIC NHS, operational efficiency increased, resulting in substantial cost savings
- Number of severe acute respiratory infection cases (SSI) enrolled in 2017 was more than double the average number of cases enrolled annually between 2009 and 2015
- Pilot recruit cohort study (ATARI) study completed with results demonstrating a high frequency of viruses circulating during the first two weeks of training; symptomatic ILI was associated with coronavirus, enterovirus, rhinovirus, and influenza.
- Anonymous survey of healthcare seeking behavior in military trainees found that only 36% of trainees with ILI symptoms sought healthcare with the proportion remaining stable regardless of season; functional impact is currently being assessed
- Infants with vitamin D deficiency had more severe viral respiratory illnesses, requiring increased duration of hospitalization (1.4 days longer than infants with sufficient vitamin D) and oxygen use (2.2 days longer)
Deployment and Travel-Related Infections

Military forces are negatively impacted by a range of infectious threats during deployment, most commonly travelers’ diarrhea (TD), but also vector-borne (malaria, dengue, and more recently, Zika virus) and respiratory spread pathogens. The main goals of the Deployment and Travel-Related Infections Research Area are to 1) provide epidemiologic threat assessment and clinical and operational outcomes, 2) develop rapid diagnostic platforms for pathogen-specific diagnoses in the deployed setting, and 3) execute clinical trials and effectiveness studies to improve prevention and treatment recommendations.

The Deployment and Travel-Related Infectious Disease Risk Assessment, Outcomes, and Prevention Strategies among DoD Beneficiaries (TravMil) cohort study, led by Dr. Tahaniyat Lalani, is the centerpiece protocol of the Deployment and Travel-Related Infections Research Area Director. A manuscript with findings from the Trial Evaluating Treatment of Ambulatory Travelers’ Diarrhea (TREAT TD) study, led by CAPT Mark Riddle, was also published in Clinical Infectious Diseases. The results of this randomized trial demonstrated that single-dose regimens of azithromycin, levofloxacin, and rifaximin with loperamide were comparable for treatment of acute watery diarrhea. As part of TREAT TD, IDCRP sponsored development of a TD TaqMan PCR assay in collaboration with the University of Virginia for detection of pathogens associated with TD. Based on analysis of the utility of the assay, use has become widespread within several national and international surveillances and research settings. In another laboratory analysis, assessment of the impact of TD treatment on gut microbiome and host-pathogen interaction during Escherichia coli infections is expected to be complete by late 2019.

During the past year, enrollment at U.S. sites continued for the Trial Evaluating Regimens of Rifaximin for Chemoprophylaxis Against Travelers’ Diarrhea (Prevent TD), led by CDR Ramiro Gutierrez at NMRC. In addition, we received approval from the U.K. Ministry of Defence to enroll British military personnel in the study. We anticipate all enrollments to be completed by mid-2018.

The Knowledge, Attitudes, Practice, and Outcomes Study (KAPOS) study, led by COL Patrick Hickey, is evaluating military health system providers’ fund of knowledge and practice patterns related to prevention of infectious diseases in the pre-travel and pre-deployment settings, critical issues for optimizing threat mitigation and maximizing force health protection in the expeditionary military. Currently, data collection is in process with analysis and presentation planned for 2018.

A Peer-Reviewed Medical Research Program proposal was submitted related to a TD prevention clinical trial, which will evaluate the efficacy of three over-the-counter “nutraceutical” products in preventing TD compared with a placebo (P4TD) by Drs. Tahaniyat Lalani and David Tribble. Another new project, led by Dr. Tribble, aims to provide pathogen-specific diarrhea incidence among military beneficiaries stationed in Oahu with assessment of Pacific region-specific risk based on travel history. This work will expand understanding of clinical, microbiological, and immunological outcomes and was awarded funds through a Global Emerging Infections Surveillance and Response System (GEIS) proposal.

MILITARY IMPACT

The Deployment and Travel-Related Infection Research Area focus on disease surveillance and randomized trials has provided an evidence base to develop deployment-related clinical practice guidelines for TD management. In addition, several protocols in the research area (TREAT TD, TravMil, Prevent TD and the Stool Card Validation study) evaluate the use of field expedient diagnostics for determining the pathogen-specifc epidemiology of illnesses, which will inform the development of effective preventive and treatment measures. Multiple TravMil substudies are evaluating the incidence of resistant Gram-negative organism acquisition, exposure to mosquito vectors, and associated infections during deployment. Looking forward, the research area will focus on collaborative efforts with GEIS and Center for Global Health Engagement to best address COCOM-specific priority support surveillance efforts, as well as using data-driven guidelines to improve the practice of deployment and travel medicine through our knowledge, attitudes and practices initiatives.

HIGHLIGHTS/KEY FINDINGS

- Clinical practice guideline for TD management in deployed service members developed through an expert consensus panel comprised of IDCRP investigators and subject-matter experts was published in a special supplement of Military Medicine, along with evidence-based reviews of data supporting the recommendations. IDCRP investigators also contributed to the development of guidelines for TD prevention and treatment, which were published in the Journal of Travel Medicine.

- IDCRP-sponsored 2017 American Society of Tropical Medicine and Hygiene symposium included four presentations with findings related to the TaqMan Array Card PCR assay, military TD clinical practice guidelines, biomarkers of mosquito exposure, and KAPOS preliminary results.

- In a TravMil study on self-reported mosquito exposure, 64% of travelers to Chikungunya-outbreak regions reported seeing mosquitos and 53% reported at least one bite.

- TREAT TD TaqMan PCR analysis demonstrated sensitive and specific detection of diarrheagenic E. coli, a leading cause of diarrhea among deployed troops, making it a promising alternative to conventional methods for diarrheal specimen collection and testing.

DEPLOYMENT AND TRAVEL-RELATED INFECTIONS

Deployment and travel-related infections account for substantial morbidity with direct negative consequences on military operations and readiness.
Emerging infectious diseases and increasing prevalence of multidrug-resistant infections are persistent global health threats that may result in substantial morbidity and mortality among military personnel deployed to disease-endemic regions.

The Emerging Infectious Diseases and Antimicrobial Resistance (EIDAR) Research Area supports clinical studies to characterize the etiology, epidemiology, and patient outcomes associated with emerging pathogens and resultant impact on the health and readiness of the U.S. military with the goal of supporting force health protection (FHP) directives. The diverse EIDAR research portfolio addresses a variety of infectious disease threats, such as multidrug-resistant organism (MDRO) wound/trauma-related infections, vector-borne pathogens, and other infectious diseases encountered during military operations worldwide.

A unique capability of EIDAR, the Epidemiology, Immunology and Clinical Characteristics of Emerging Infectious Diseases with Pandemic Potential (EICC-EID) protocol, allows the DoD to be responsive to infectious disease outbreaks. The recent Ebola outbreak highlighted U.S. hospital emergency response challenges in providing appropriate care of affected patients, while preventing spread of this highly contagious disease. The EPICC-EID protocol was designed to fill critical needs by providing military hospitals with a plan to rapidly respond to public health crises/outbreaks by obtaining clinical outcomes and epidemiologic data critical to informing effective patient care. The EPICC-EID protocol also provides the foundation for executing interventional trials with collaborative research partners to evaluate new diagnostic assays, drugs, or vaccines in Military Health System (MHS) patients.

This past year, the EIDAR team established strategic partnerships with the Global Emerging Infections Surveillance and Response System (GEIS) section at the Armed Forces Health Surveillance Branch and the USU Center for Global Health Engagement (CGHE) to facilitate alignment of EIDAR research efforts with Combatant Command (COMCOM) FHP needs. Consultation at the GEIS Business Optimization Meeting resulted in COMCOM Surgeons’ endorsement of IDCRP’s plans for establishing new research initiatives to address the Zika virus (ZIKV) threat. Although military service members deploy extensively to areas with ZIKV transmission, current U.S. and DoD policy precludes testing of asymptomatic men for ZIKV infection diagnosis. As only 20% of ZIKV infected individuals are symptomatic, the risk could be relatively high for asymptomatic male service members to unknowingly transmit ZIKV to sexual partners. In 2017, the EIDAR team was awarded GEIS funding to conduct a risk for non-vector (presumably sexual) transmission of ZIKV from service members post-deployment to their non-traveling spouses. The EIDAR team also established a collaboration with the Walter Reed Army Institute of Research (WRAIR) Viral Diseases Branch on a GEIS-sponsored study investigating ZIKV and related illnesses at the Rodriguez Army Health Clinic in Puerto Rico, an operationally important location as it is the origin of nearly 50% of all active-duty ZIKV cases. This study will be launched in 2018, expanding the IDCRP’s clinical research network to include a new site in the Caribbean.

The EIDAR research portfolio includes GEIS-funded retrospective studies that leverage the DoD Serum Repository with the goal of investigating the impact emerging infectious diseases have on U.S. military service member health and operations. One of these serological surveys will examine the risk for military populations to be exposed to tick-borne infections with Borrelia bacteria and development of Lyme disease or related pathologies as a result of outdoor training operations at military installations in disease-endemic areas. Another retrospective study in development will evaluate the incidence of coccidioidomycosis among military personnel stationed at installations within disease-endemic areas, including the Pacific Naval Air Station Lemoore, where there is anticipation of increased risk for Coccidioides fungus exposure in MHS beneficiaries in future years due to forthcoming expansion of the station. During 2017, the EIDAR team was highly engaged in various efforts addressing clinical questions related to military relevant antimicrobial resistance (AMR) issues. In collaboration with the Trauma-Related Infections Research Area and led by Dr. Karin Mendez (EIDAR Deputy), the Multidrug-Resistant and other Virulent Organisms Trauma Infections (TIDOS MDR/VO) Initiative continued investigations on combat-related wound infections and associated microorganisms. Furthermore, the EIDAR team received IRB protocol approval for a USU medical student Capstone research project to evaluate the impact of bacterial drug resistance and patient co-morbidities on outcomes in MDRO bloodstream infections within the MHS. The EIDAR team is also promoting DoD Combating Antimicrobial Resistant Bacteria (CARB) Initiatives to enhance MHS antimicrobial stewardship programs (ASP). In 2017, the EIDAR team initiated an ASP/IDCRP Clinical Research Consortium at military sites worldwide to conduct research addressing knowledge gaps in best practices to promote antimicrobial stewardship.

**MILITARY IMPACT**

The EIDAR Research Area is responsive to the persistent and ever-evolving infectious disease threats impacting the health and readiness of the U.S. military. EIDAR clinical studies address the Global Health Security Agenda and the National Security Strategy requirements for preparedness and response to infectious disease outbreaks. In response to the recent ZIKV outbreak, the EIDAR team is addressing the unique and challenging FHP issue concerning the risk of sexual transmission of ZIKV to spouses of active-duty service members returning from deployments. In 2018, the team will lead new studies examining the impact of emerging pathogens in the U.S., such as Coccidioides fungus and tick-borne Borrelia bacterial species, on the health and readiness of service members engaged in outdoor training activities at disease endemic military installations. The EIDAR team is also conducting microbiological investigations to support development of improved clinical practices to prevent emergence and transmission of difficult-to-treat, multidrug-resistant bacterial and fungal wound infections. Lastly, EIDAR serves as the central coordinator of multi-site studies investigating key clinical knowledge gaps essential for promoting appropriate stewardship practices to prevent the emergence and spread of antimicrobial resistance within the MHS.

**HIGHLIGHTS/KEY FINDINGS**

- The EIDAR team established strategic partnerships with GEIS and CGHE to align IDCRP operational infectious disease surveillance and research efforts with COMCOM FHP needs.
- In support of the CARB Initiative, the EIDAR team established an ASP/ Clinical Research Consortium to identify best clinical practices to promote antimicrobial stewardship and is presently developing a survey to understand behavior driving antibiotic prescribing practices amongst MHS healthcare providers.
- With continued Military Infectious Disease Research Program support of the TIDOS MDR/VO Initiative, high impact molecular analyses of antimicrobial resistance patterns are underway to help guide appropriate treatment guidelines for trauma-related infections.
- The USU Department of Pathology is developing serologic and molecular methods to improve detection of recently identified emerging Borrelia species that are suspected to cause an under-reported burden of disease.
Within the DoD, approximately 350 new HIV infections are diagnosed each year with more than 10,000 active-duty service members diagnosed since the beginning of the epidemic. In spite of successful lifelong antiretroviral therapy, long-term impacts of chronic HIV infection may include cognitive decline, renal insufficiency, cardiovascular disease, cancer, and mortality.

Although there has been substantial progress related to improved understanding of HIV in the Military Health System, data gaps still exist, including how to best ensure survival, minimize the development of non-AIDS comorbidities, and maximize fitness for those who are infected. Further data are also needed to enhance HIV and sexually-transmitted infection prevention efforts, potentially through novel methods, such as antiretroviral pre-exposure prophylaxis (PrEP). These critical issues constitute the scientific strategic aims of the HIV Research Area, which is focused on ensuring and restoring the long-term health and function of HIV-infected military personnel and beneficiaries.

Since its inception in 1986, the U.S. Military HIV Natural History Study (NHS), led by Dr. Brian Agan, has been the centerpiece protocol of this research area, and continues to prove to be an invaluable resource for advancing the understanding of HIV both within the military and more broadly in civilian patients. The NHS has enrolled over 6,000 individuals and provides a wealth of data and specimens for analysis of this disease among military active-duty and beneficiaries. During 2017, efforts to increase the engagement of multiple lead investigators were successful, with growth to over 20 active analyses. New collaborations were also developed with DoD investigators at USU, the U.S. Military HIV Research Program (MHRP), and the Naval Postgraduate School, as well as with academic collaborators. A new area of investigation this year focused on patient centered outcomes, particularly health-related quality of life (HRQoL), which demonstrated that addressing modifiable mental and medical comorbidity factors may improve quality of life of HIV-infected patients. Moreover, HRQOL was found to be predictive of subsequent hospitalization. Additional analyses are ongoing in separate collaborations with Emory University and Atlanta Veterans Affairs, as well as with the Naval Postgraduate School.

Over the past several years, we have made substantial efforts to increase repository-based collaborations with the goal of fully leveraging this unique resource of the NHS. This was successful in 2017 with new grant applications, increased publications, and new collaborations. In one of the repository-based analyses, the immunological response of HIV-infected individuals to hepatitis B vaccine was examined; extending past NHS work in this area. Individuals who responded to the hepatitis B vaccine had an immune profile consistent with a better Type 1 T helper cell (adaptive immunity) response. In addition, two new repository-based collaborations with investigators at the National Institute of Neurological Disorders and Stroke are in protocol development. One will utilize cerebrospinal fluid to investigate biomarkers for HIV-associated neurocognitive disorders (HAND) and HIV-associated dementia, while the other will evaluate the effect of antiretroviral drugs on human endogenous retrovirus K, which is a presumed cause of amyotrophic lateral sclerosis, including among HIV-infected individuals.

This past year also saw progress with other protocols in the HIV Research Area. In particular, the HIV Associated Neurocognitive Disorders (ALLHANDS) protocol continued enrollment of HIV-infected individuals and recruitment of the HIV+ cohort and HIV- controls was completed. Approximately half of the subjects have already completed their second annual visit. Preliminary baseline data from the cohort were presented at the NIH NeuroHIV Retreat, which is a conference that brings together scientists and program officers from at least seven NIH Institutes.

The HIV Virtual Cohort Study is moving forward following approval from the USA IRB, as well as for data sharing agreement with the Defense Health Agency. Initial abstraction of data through the Military Health System Data Repository for the analysis is forthcoming. For the Rifaximin study, led by Dr. Anuradha Ganesan, data collection for the randomized control trial was completed and analysis of the data is underway. This completed the analysis related to the study’s primary objective, the Strategic Timing of Anti-Retroviral Therapy (START) protocol was modified to simplify visits and extend follow-up beyond 2017. Lastly, an amendment to collaborate with MHRP on the CD4 Zeta protocol, led by COL Naomi Aronson, to examine the HIV reservoir and persistence of the gene therapy modified cells has been approved and is underway.

We anticipate the coming year to be successful in our expanding areas of HIV research. Non-AIDS outcomes, including the study of HAND, remain a priority. With the possibility of a functional cure, we are also working with MHRP to initiate a trial of a therapeutic HIV vaccine.

MILITARY IMPACT

Our current HIV research portfolio is designed with military impact as a central goal. Through our investigations, we continue to support the Military Health System by evaluating clinical care and serious outcomes among people with HIV.

The HIV Virtual Cohort Study seeks identifiable or modifiable risk factors for adverse effects of HIV that may enable early diagnosis, treatment, or prevention. Our current work to evaluate the ‘cascade of care’ among active-duty found to be newly HIV positive will identify potential areas for military care improvement and is a first step in the evaluation of very high care quality in the DoD. We anticipate that the ALLHANDS study may have policy implications to allow active-duty members with HIV to expand job roles and increase rank. Lastly, our work with sexually-transmitted infections among HIV-infected subjects continues to generate data that may inform policy to improve diagnosis and treatment of these infections, as well as improve understanding of transmission to support prevention efforts in the military.

HIGHLIGHTS/KEY FINDINGS

• First year that National Institutes of Health Research Project R01 funding for HIV research was awarded to the ICDRP
• Reached target of 200 consented subjects for ALLHANDs protocol and a higher than expected proportion of subjects elected to participate in optional procedures critical to addressing research aims
• Evaluation of patient centered outcomes determined that highly active antiretroviral therapy (HAART) was not associated with HRQOL; however, the presence of medical and mental comorbidities was negatively associated with physical functional health. This work resulted in a PhD being awarded to a trainee.
• As part of collaboration with the UNAIDS Working Group collecting seroconverter data from multiple cohorts, the NHS supplied data from 3053 NHS subjects as part of the development of a model describing the CD4+ cell decline following HIV-1 infection; data demonstrated regional and age-specific differences which will support future HIV models
Skin and soft-tissue infections (SSTIs), most frequently caused by Staphylococcus aureus, are a common occurrence among military personnel, particularly trainees, resulting in a significant operational and healthcare burden.

Staphylococcus aureus, including methicillin-resistant S. aureus (MRSA), is well-recognized as a major contributor of SSTIs. As personal hygiene-based measures have only limited success and an effective S. aureus vaccine has not yet been identified, the primary objective of this research area is to identify effective strategies for the prevention and control of SSTIs among military populations.

During the past year, the SSTI Cohort Study at Fort Benning completed enrollment and follow-up specimen/data collection in over 600 U.S. Army Infantry trainees. The focus of the study was not only on the evaluation of the natural history, clinical characteristics, and risk factors of SSTIs, but also on the transmission of S. aureus in this setting. Preliminary findings indicate that the trainees experience an intense and prolonged exposure to S. aureus over the course of the training cycle, with colonization of different anatomic sites by multiple strains of S. aureus being a common occurrence. Enrollment and follow-up specimen/data collection were also completed for the Submarine MRSA Study, which evaluated the prevalence of S. aureus colonization and incidence of SSTIs in the submariner population at Kings Bay, GA. In addition, analysis of data collected through a case-control study conducted at Fort Benning (Epidemiology, Etiology, and Immunology of SSTI) is underway. Findings from these detailed observational studies (all led by LTC Jason Bennett at USU) will expand the knowledge base of SSTI epidemiology, clinical characteristics, and risk factors, as well as provide further information on the epidemiology of S. aureus colonization and infection with inclusion of advanced immunology, microbiome, and microbial genetic analyses.

Building on the foundation of these observational studies, the research area was awarded funding by the U.S. Army Medical Material Development Activity in 2017 for a phase 2a trial of a S. aureus vaccine candidate (NDV-3A; NovaDigm Therapeutics, LLC) to study the safety, immunogenicity, and efficacy of vaccination against nasal acquisition of S. aureus among trainees at Fort Benning. This vaccine candidate has shown great promise for S. aureus prevention through a series of preclinical and clinical studies leading up to this proof of concept field trial. Conducting a vaccine trial in a high-risk population of U.S. Army Infantry trainees represents a major advance in strategies related to the prevention of a common cause of infectious disease morbidity in military populations.

One reason for the success of this research area is the effective collaborations with various military laboratories, including Wound Infections Department at the Naval Medical Research Center (NMRC), Department of Microbiology and Immunology at the Uniformed Services University, and Biological Defense Research Directorate at NMRC. In addition, substantial operational, healthcare, and economic costs are associated with the burden of SSTI in military populations. Efforts under this research area support the development of preventive efforts by (1) generating epidemiological, clinical, immunological, microbiological, and genomic data related to SSTIs associated with S. aureus and other etiologic agents; (2) detailing the epidemiological and economic burden of SSTI in military training settings; (3) assessing the effectiveness of personal hygiene-based efforts on other common communicable diseases, such as acute respiratory infections; (4) examining transmission dynamics of MRSA in SSTI clusters among trainees; and (5) securing funding to conduct S. aureus vaccine trial among military trainees.

**HIGHLIGHTS/KEY FINDINGS**

- Results from an observational, longitudinal study of S. aureus colonization and SSTI among 600 Infantry trainees revealed a 10% attack rate for SSTI and high rates of S. aureus and MRSA acquisition at multiple body sites
- Genomic characterization of MRSA from clusters of SSTI among trainees found patterns of both inter- and intra-class transmission, suggesting that an environmental reservoir may contribute to persistence of MRSA in the training setting
- Novel pathogens, such as Rhodanobacter spp., were frequently identified from cases of non-purulent cellulitis, while abscesses are typically associated with S. aureus
- Awarded funding for a Phase 2 trial of a S. aureus vaccine candidate among infantry trainees at Fort Benning to be executed in 2018

**MILITARY IMPACT**

Substantial operational, healthcare, and economic costs are associated with the burden of SSTI in military populations. Efforts under this research area support the development of preventive efforts by (1) generating epidemiological, clinical, immunological, microbiological, and genomic data related to SSTIs associated with S. aureus and other etiologic agents; (2) detailing the epidemiological and economic burden of SSTI in military training settings; (3) assessing the effectiveness of personal hygiene-based efforts on other common communicable diseases, such as acute respiratory infections; (4) examining transmission dynamics of MRSA in SSTI clusters among trainees; and (5) securing funding to conduct S. aureus vaccine trial among military trainees.
Sexually-transmitted infections (STIs) are among the most common infections in military populations and represent a threat to medical readiness, and force health protection, as well as contributing significant morbidity with the potential to introduce clinically problematic infections into civilian communities.

Although the U.S. military is largely comprised of the same risk groups described in civilian populations, multiple studies have shown higher rates of STIs in the military. In recent years, interest in STIs and their relevance to the military intensified with the inclusion of Neisseria gonorrhoea (GC) by the Centers for Disease Control and Prevention as one of the top three urgent drug-resistant U.S. threats. The intersection of deployment health and STIs became even more apparent with the demonstration of sexual transmission of the Zika virus along with ongoing research into long-term genital carriage of Ebola virus.

The GC Resistance Study and Repository, led by LTC Eric Garges and Dr. Ann Jense, remains the backbone of the research portfolio with 77 new GC isolates added to the repository. The domestic GC surveillance program was maintained at four U.S. military hospitals and inclusion/reengagement of additional sites are being planned for the upcoming year. We have also continued to develop a role in support of the Global Emerging Infections Surveillance and Response System (GEIS) global GC surveillance effort, largely as a coordinating center for the newly established DoD Gonococcal Reference Laboratory and Repository at USU (located in the lab of Dr. Jense). Upcoming analyses will incorporate whole genome sequencing to provide genetic epidemiologic data to compare determinants of resistance to phenotypes from GC isolates from around the globe.

With the goal of examining prevalence and risk factors for GC and chlamydia (CT) infections, two additional protocols are underway. The 3 Site GC/CT Testing Among HIV+ DoD Beneficiaries study, led by Dr. Anuradha Ganesan, has enrolled 450 HIV-infected subjects and the self-testing portion of the study was completed. Findings indicate that self-testing is a feasible and acceptable method for collection of extra-genital samples within the Military Health System. Molecular testing of the CT specimens is forthcoming, which will provide information on transmission networks and support preventive efforts. Risk factors for extragenital CT and GC infections among asymptomatic active-duty women is the focus of the second protocol (3 Site GC/CT Testing Among Women study), led by CAPT Mary Bavaro and Dr. Robert Deiss. Presently, the study has completed enrollment and data analysis is underway.

In the upcoming year, we will see the further expansion of the domestic GC surveillance program and extra-genital testing in high-risk HIV-negative populations. Additionally, we will begin screening clinical samples collected from our CT studies for Mycoplasma genitalium, which is prevalent in civilian populations, but surveillance efforts in military populations have been limited. The Sexual and Social Network Study, led by LTC Garges, recently completed a pilot study and the protocol is being refined based on the findings. Enrollment will start in early 2018 at four sites with the potential to expand to any clinical site currently enrolling in the GC Resistance Protocol. This study will be used to identify risk reduction targets for interventions beyond traditional individual risk factors. Research concepts in development include a multi-component approach to evaluating sexual transmission of Zika virus, as well as conducting studies to evaluate a Meningitis B vaccine (4cMenB, Bexsero) for prevention efficacy and host response against GC.

**MILITARY IMPACT**

The IDCRP is uniquely positioned to address sexually-transmitted threats to service member health from clinical prevention through therapy. Our goal is to support DoD STI prevention, diagnosis, and treatment to reduce STIs among active-duty members and beneficiaries. In our role as the GC Resistance Coordinating Center, providing support and standardization across all sites involved in efforts in this area, we have demonstrated regional resistance patterns from locations with no other available data. This information is valuable to the DoD for mission planning, but is also critical in assessing the global antimicrobial resistance risk for GC. Ongoing surveillance efforts have also monitored the resistance patterns at U.S.-based treatment facilities, directly affecting force health.

Looking forward, a new strategic plan is being developed for the research area, which will outline the current disease trends within the military population, define unique advantages and disadvantages of STI study within the DoD, and identify clinical research targets that are (1) relevant to the DoD, (2) appropriate for burden and risk assessment and, (3) support clinical research goals of our stakeholders, collaborators, and the global community. We will also continue to maintain a comprehensive survey of new STI vaccines and diagnostic platforms that may be of interest to the DoD, with the long-term goal of planning prevention studies, including behavioral interventions and STI vaccines.
Infections following battlefield trauma remain one of the most military-specific and highest DoD priorities for improved prevention and clinical management. Complex blast-injured patient management is further challenged by emerging virulent and multidrug-resistant pathogens.

To address knowledge gaps in the prevention and clinical management of combat-related infections, the aims of the research area were refined emphasizing blast injuries, multidrug-resistant bacterial infections, long-term outcomes and quality of life, and Joint Trauma System (JTS) clinical practice guideline initiatives and antibiotic stewardship. Within the research area, the centerpiece protocol is the Trauma Infectious Disease Outcomes Study (TIDOS), which is led by Dr. David Tribble. TIDOS systematically collected infection-related medical management and clinical outcomes from military personnel wounded during deployment from 2009 through 2014. Follow-up data continues to be captured from cohort enrollees through the military, as well as veterans healthcare through a collaboration with the St. Louis Veterans Affairs (VA) Health Care System under the leadership of Dr. Jay McDonald.

Extremity wounds are the most common injury sites and are frequently complicated by infections. During 2017, comprehensive analyses of extremity wound infection data collected from the first three years of TIDOS regarding epidemiology, wound microbiology, risk factors, and antibiotic practice patterns were completed. Furthermore, an analysis to examine the effectiveness of specific antimicrobial regimens related to the treatment deep soft-tissue infections is underway.

Invasive fungal wounds infections (IFIs) are a serious complication of blast trauma with high morbidity and mortality and early diagnosis is crucial for optimal management. As a result, Dr. Anuradha Ganesan led the IFI Molecular Diagnostics Protocol, funded under the Defense Medical Research and Development Program, to critically assess molecular diagnostics methods to support earlier and more accurate diagnosis. In preparation for the analysis, a large-scale review of the TIDOS database was conducted to refine the TIDOS IFI Case Registry and develop new classifications for patients with laboratory evidence of a fungal infection. During 2017, 363 archived formalin-fixed wound tissue specimens collected during surgical procedures were examined using a polymerase chain reaction (PCR)-based assay. A technical report with the findings of the analysis was presented to a panel of subject-matter experts in November for a roundtable discussion of the utility of the assay and incorporation of the findings into clinical practice guideline recommendations. In the upcoming year, a brief of the findings and recommendations will be provided to the JTS for consideration in the review of the JTS IFI practice guidelines.

Osteomyelitis is a serious, often chronic, complication that frequently recurs in multiple surgeries, prolonged use of antibiotics, and extended hospitalization and ambulatory care. Thus, one of the research area’s protocols, the Trauma-Associated Osteomyelitis study, led by Dr. Tribble, evaluated risk factors for the development of osteomyelitis among combat casualties with open fractures of the tibia, femur, and arm long bones. Presently, all analyses have been completed and the first manuscript with findings of the tibia case-control risk factor analysis was submitted for journal consideration. Through collaboration with the St. Louis VA Health Care System, collection of data is nearing finalization, which will extend follow-up beyond a decade in many cases.

During the past year, multiple analyses were also completed under the TIDOS Multidrug-Resistant and Virulent Organisms (MDR/VO) Trauma Infections initiative, which is a collaborative effort across DoD laboratories (Walter Reed Army Institute of Research, Naval Medical Research Center, U.S. Army Institute of Surgical Research, and San Antonio Military Medical Center) led by Dr. Katrin Mende to maximize understanding of complex polymicrobial wounds through use of the TIDOS Microbiology Repository. Additional analyses are being planned or are underway to evaluate the bacterial microbiome, antimicrobial resistance emergence, interaction of common wound bacteria (e.g., Enterococcus spp., coagulase-negative staphylococci, and other ESKAPE pathogens), and biofilm dispersal agents.

During 2017, two proposals submitted to the Military Infectious Disease Research Program were selected for funding. The first will fund an expansion of analyses under the MDR/VO Initiative and the second is focused on conducting analyses to support JTS clinical practice guideline refinement and antibiotic stewardship.

**MILITARY IMPACT**

The research area’s aims and objectives continue to be responsive to priorities of the DoD JTS and provide significant clinical relevance during inter-war periods by improving the understanding of ongoing issues among wounded personnel. Overall, the strengths and opportunities presented by the 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**

- Following detailed review of the TIDOS database, 13% of combat casualties from Afghanistan with open extremity wounds admitted to U.S. hospitals and had tissue specimens or wound cultures collected met the criteria for an IFI.
- IFI Molecular Diagnostics PCR-based assay had high specificity (99%) and sensitivity (83%) in tissues with documented angiogenesis or priority pathogens (Mucorales order).
- In a MDR/VO Trauma Infections Initiative analysis, 1107 Pseudomonas aeruginosa isolates were examined, of which 7% were multidrug-resistant and 38% were recovered from wound cultures.
- The DoD Blast Injury Research Program proceedings of their 2016 International State-of-the-Science Meeting on “Minimizing the Impact of Wound Infections Following Blast-Related Injuries.”
- Recommendations highlight critical need for DoD to preserve and sustain TIDOS project and valuable integration with the DoD Trauma Registry and Joint Trauma System.
- Key recommendations were highlighted at the 126th Annual AMSUS Meeting, Force Health Protection: From Battleground to Homefront.
- Multidrug-resistant Gram-negative bacteria were isolated from 56% of first infections involving Gram-negative bacteria.
The backbone of any successful organization is its employees. The IDCRP is comprised of dedicated, highly skilled, well-educated individuals with sincere dedication to issues related to military health and the clinical study and treatment of infectious diseases.

In 2017, the IDCRP employed over 130 research and administrative personnel who work diligently to execute a complex workload servicing the broad areas of infectious disease research within the program. The IDCRP staff supports the program through designing, conducting, and maintaining a diverse clinical research portfolio. Over half of the staff is composed of professionals interacting directly with study subjects at clinical sites. The majority of these individuals are clinical research coordinators. The many types of staff positions are outlined in the figure.

The IDCRP staff is personally and professionally diverse. Expertise ranges from health and medical specialties to statistical analysis and data programming. More than half of the staff is composed of individuals with sincere dedication to issues related to military health.

Throughout the United States and in overseas settings, IDCRP employees are found in offices, laboratories, medical facilities, and operational bases. Over half of the staff members possess at least two degrees and all share an abundance of experience related to various areas of infectious disease research.

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research Coordinators</td>
<td>38%</td>
</tr>
<tr>
<td>Admin/Regulatory</td>
<td>16%</td>
</tr>
<tr>
<td>Microbiologist/Lab</td>
<td>6%</td>
</tr>
<tr>
<td>Lab Support/Management</td>
<td>3%</td>
</tr>
<tr>
<td>Microbiology/Sci. Phys.</td>
<td>9%</td>
</tr>
<tr>
<td>Physicians/Epidemiologist</td>
<td>9%</td>
</tr>
<tr>
<td>Clinical Research/Project Manager</td>
<td>10%</td>
</tr>
<tr>
<td>Information Systems/Configuration</td>
<td>19%</td>
</tr>
</tbody>
</table>

Over the past year, multiple efforts were undertaken to improve efficiency and efficacy of the team and their processes. In particular, the DCC created a set of standardized data collection subject matter domains and Case Report Forms (CRFs) to produce consistency of data elements across different studies. In addition, we improved our data cleaning processes, reducing the number of queries being sent to sites and, thus, decreasing site staff time needed to respond to queries.

The Data Coordination Center (DCC) is an essential component of IDCRP’s scientific research efforts by providing high-quality data collection, management, processing, and access.

The DCC team of data system designers, data managers, data entry staff, and SAS / Oracle programmers (led by Edward Parmelee, Chief) supports research investigations by providing expertise related to the conceptualization, design, collection, management and cleaning, analysis, and publication of study data. These resources are used for every IDCRP study where the Program is the primary data source (collector or repository). The DCC utilizes multiple systems to receive data in either paper format or through electronic means (e.g., electronic data capture using laptops or tablets, web-based survey tools, and form scanning). Use of these diverse systems allows the IDCRP to collect data from and about subjects at the time of medical treatment within the United States and at other facilities around the world.

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The backbone of any successful organization is its employees. The IDCRP is comprised of dedicated, highly skilled, well-educated individuals with sincere dedication to issues related to military health and the clinical study and treatment of infectious diseases.
The IDCRP RS&O team includes the Program Management and Finance Team (PM/F), which is led by Dr. Samuel Davis (Chief), and the Research Support Group (RSG), led by MAJ (P) Charlotte Lanteri. Over the past year, the RS&O team continued to improve program processes and implemented enhanced communications and reports. The PM/F team improved work flow between program management, clinical research management, and site teams. In the coming year, the RS&O team will focus on further enhancing program efficiencies.

In an effort to improve efficiency and promote standardization, it was decided that the Program needed to utilize a Clinical Trial Management System approach for the creation of budget and expense reports. Use of the database system will allow the development of a financial architecture in 2018, providing comprehensive financial reports associated with project accomplishments. A new approach to budget planning was also implemented in 2017. Following a thorough examination of the research portfolios for the IDCRP seven research areas, site managers were asked to create independent protocol-specific budgets based on expense data provided by the PM/F. These estimated budgets were extensively reviewed by the research area directors, clinical research managers, program managers, Chiefs, PM/F, and program directors to identify potential issues.

Overall, these improvements with the RS&O team will ensure that the IDCRP continues to be a successful program with the ability to adapt to a changing infectious disease environment.

The IDCRP Clinical Research Management group is responsible for coordinating and managing the day-to-day operations for all research studies within the IDCRP.

The clinical research managers (CRMs), led by Mr. Daniel Rosenberg (Chief), provide guidance to principal investigators, the Data Coordination Center, site personnel, and lab personnel related to the development, preparation, and conduct for the entire IDCRP research portfolio. In 2017, the CRMs supported the development of approximately 20 new approved research study projects and continued management of an additional 60 protocols in the active data collection or analysis phase.

As part of an overall effort to optimize processes, requirements for a Clinical Trials Management System were developed during the past year for integration into the existing IDCRP infrastructure. Following completion of the various modules of the system in 2018, the CRMs will be able to increase their efficiency with monitoring and managing protocols through generation of instant reports.
The IDCRP Scientific Review Board (SRB) is designed to provide independent rigorous and timely reviews of clinical research protocols and related amendments prior to submission to the USU Institutional Review Board (IRB).

The purpose of the SRB (chaired by NIAID liaison Dr. John Powers and Vice Chair MAJ (P) Charlotte Lanteri) is to ensure the scientific validity of each protocol, which includes determining whether the research questions, hypothesis, aims and objectives, and methods are both meaningful and achievable based on the protocol. The comprehensive scientific review occurs following an assessment of the research concept and discussion of recommendations by the Concept Scoring Panel, Senior Science Group, and Operational Steering Committee. All new protocol submissions are reviewed by the SRB, including retrospective and prospective studies that involve participants already enrolled in existing protocols. Overall, this comprehensive review is intended to improve the scientific quality of IDCRP protocols prior to the submission to the IRB.

In order to maintain the efficiency of the SRB process, there are three review pathways:
1) standard review;
2) low resource review; and
3) chair review

Although requests from Principal Investigators and the Senior Science Group are taken into consideration, the level of review for each protocol and amendment is determined by the SRB Chair or the Vice Chair when the Chair is recused or unavailable. For the SRB review process, a panel is identified based on the specific protocol or amendment to be reviewed. In general, the scientific review panels include subject-matter experts, biomedical scientists and statisticians and additional scientific review panel members affiliated with IDCRP research networks, as appropriate.

During 2017, the SRB continued to be productive with approval of eight new protocols and six amendments. There are also two additional protocols currently under review. For 2018, efforts will continue to streamline the review process by creating a standardized SRB cover sheet for submissions to guide protocol development and providing new reviewers with training to improve the quality of reviews. These efforts will not only improve efficiency, but also shorten the review timeline process, while still maintaining a standard of high quality reviews.

The IDCRP Regulatory Affairs team assists investigators in the development and review of new research protocols, as well as ensuring compliance with ongoing research and serving as liaisons between the IDCRP and USU, NIAID, and other regulatory agencies.

Over the past year, the IDCRP conducted 46 active nonexempt studies and 13 active exempt studies. In addition, the Regulatory Affairs team supported the submission of 79 protocol amendments and 37 continuing reviews to the USU Infectious Disease Institutional Review Board. In collaboration with the Chiefs of the Data Coordination Center and Clinical Research Management, several standard operating procedures (SOPs) were developed to increase efficiency, promote uniformity, and streamline the process related to compliance audits.

Part of the success of the IDCRP is due to its partnerships and collaborations with multiple military and civilian research laboratories and organizations, which necessitate various types of official agreements and documentation.

During the past year, a new position of Agreements Officer was created to coordinate the management of this vital documentation. Ms. Stephanie Cammarata has successfully taken on this role and created a comprehensive agreements database for the IDCRP. Furthermore, an agreements SOP was developed and an in-service training session was held with the Clinical Research Management team to review the procedures.

Use of the Electronic Institutional Review Board system (EIRB), which was launched in 2016 has eliminated redundancies related to protocol and amendment submission, as well as standardizing processes across the different Military Health System sites.

HIGHLIGHTS

• Creation of IDCRP agreements officer position, leading to development of a comprehensive agreements database
• Development of new SOPs related to general protocol procedures, conducting site visits, and compliance tracking to increase efficiency and optimize processes
• Coordinated activities for a renewal of the overarching Memorandum of Understanding establishing scientific and ethical review and approval of IDCRP research
The IDCRP is proud to continue a long-standing commitment to cultivating the development of future infectious disease clinical researchers in the U.S. military.

The IDCRP education mission is achieved through use of three strategies 1) mentored research, 2) didactic learning, and 3) research engagement.

Mentored research opportunities on IDCRP-led projects are provided to medical and public health students, residents, and infectious disease (ID) fellows in the armed forces at USU, as well as military hospitals, such as San Antonio Military Medical Center, Walter Reed National Military Medical Center (WRNMMC), Naval Medical Center San Diego, and Madigan Army Medical Center. In addition, IDCRP investigators assist in the development of a clinical ID research capstone curriculum for USU medical students. The mentored research projects are designed to provide hands-on experience in research study design, data collection, and analysis. During the past year, more than a dozen trainees conducted research with IDCRP mentors and these efforts resulted in 5 published manuscripts, and 13 oral and poster presentations at national infectious diseases conferences. The education program also supports the Armed Forces Infectious Disease Society (AFIDS) annual Spring meeting.

In the fall of 2015, IDCRP investigators launched a new course to teach ID fellows about the fundamentals of conducting clinical research by providing background knowledge and tools necessary to conduct ID clinical research. Currently, the course is taught to ID fellows at WRNMMC; however, making these lectures available in an online setting to military medical trainees at other sites is planned.

A critical element for the success of the IDCRP’s education mission is raising awareness about ID clinical research in the armed services. Along with publications and presentations, IDCRP investigators also attend public health grand rounds at Tripler Army Medical Center. In the fall of 2015, IDCRP investigators launched a new course to teach ID fellows about the fundamentals of conducting clinical research by providing background knowledge and tools necessary to conduct ID clinical research. Currently, the course is taught to ID fellows at WRNMMC; however, making these lectures available in an online setting to military medical trainees at other sites is planned.

The continuing success of this program supports the expansion of the number of active-duty ID clinical researchers in the U.S. armed services.

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The continuing success of this program supports the expansion of the number of active-duty ID clinical researchers in the U.S. armed services.
During 2017, members of the IDCRP investigative team received awards, honors, or recognition for their work. Here are some highlights:

**IDCRP AWARDS, HONORS, AND RECOGNITION**

<table>
<thead>
<tr>
<th>Name</th>
<th>Award/Honor/Recognition</th>
<th>Awarding Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anuradha Ganesan, MD</td>
<td>Graduate Medical Education (GME) Mentor Award</td>
<td>Walter Reed National Military Medical Center</td>
</tr>
<tr>
<td>Multiple IDCRP staff contributing authors</td>
<td>Major General Joyce Award for most outstanding manuscript by a member of clinical staff/faculty at Madigan Army Medical Center</td>
<td>Madigan Army Medical Center</td>
</tr>
<tr>
<td>Multiple IDCRP staff contributing authors</td>
<td>Recognition of HIV Research Area article being among the top 25% most cited PLoS One articles as of June 2017</td>
<td>International Society for Pharmacoeconomics and Outcomes Research</td>
</tr>
<tr>
<td>Multiple IDCRP staff contributing authors</td>
<td>“Evaluation of the Performance Properties of the Influenza Patient-Reported Outcomes Instrument (FluPRO) in Patients with Influenza-like Illness (ILI)”</td>
<td></td>
</tr>
<tr>
<td>Multiple IDCRP staff contributing authors</td>
<td>Top 10% of Scores for Poster Research presentation</td>
<td></td>
</tr>
</tbody>
</table>

**IDCRP COLLABORATORS AND PARTNERS**

- **Department Of Defense Sites**
  - U.S. Military Hospitals and Clinics
  - Brooke Army Medical Center, JBSA Fort Sam Houston, 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
  - Schofield Barracks Health Clinic, Tripler Army Medical Center, Oahu, HI
  - Soto Cano Air Base, Honduras
  - Trumc Medical Clinic, Fort Sam Houston, TX
  - U.S. Naval Expeditionary Base, Camp Lemonnier, Djibouti
  - 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 (NMIIC)
  - - BioDefense Research
  - - Wound Infections
  - - Subordinate Commands
  - - Naval Health Research Center, San Diego, CA
  - - Naval Medical Research Unit No. 2, 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 Material Development Activity
  - U.S. Army Medical Research Institute of Infectious Diseases
  - Walter Reed Army Institute of Research
  - U.S. Army HIV Research Program
  - - Multidrug Resistant Organism Repository and Surveillance Network
  - - Specimen Processing Laboratory
  - - Wound Infections
  - - Overseas Research Detachments
  - - Armed Forces Research Institute of Medical Sciences, Bangkok, Thailand
  - - U.S. Army Medical Research Unit, Nairobi, Kenya
  - - U.S. Army Medical Research Unit, Thessaloniki, Greece

- **Other U.S. Military Commands/Programs**
  - Defense Health Agency
  - - Armed Forces Health Surveillance Branch (AFHSB)
  - - Global Emerging Infection Surveillance and Response System (GEISS) Program
  - - Immunization Healthcare Branch, Bureau of Medicine and Surgery, Department of Navy (BUMED)
  - - Congressional Defense Medical Research Program (CDMRP)
  - - Defense Advanced Research Projects Agency (DARPA)
  - - Military Infectious Disease 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

- **Foreign Health Agencies and Organizations**
  - Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Mexico City
  - Instituto Nacional de Enfermedades Respiratorias Ismael Cosío Villagómez, Mexico City
  - 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 Defence Medicine, Birmingham, UK
  - - Defence Medical Directorate, Birmingham, UK
  - - Defence Statistics (Health) MOD Abbey Wood
  - - British Army Training Unit, Nanyuki, Kenya
  - - Camp Bastion, Afghanistan

- **Academia**
  - Academia
  - - Bryant and Strout College
  - - Columbia University
  - - Drexel University
  - - Duke University
  - - Emory University
  - - Harvard University School of Public Health
  - - Johns Hopkins University, Bloomberg School of Public Health
  - - New York University
  - - University of California-Los Angeles
  - - University of California-San Diego
  - - University of Maryland-Baltimore
  - - University of Michigan
  - - University of Minnesota
  - - University of Nebraska
  - - University of Pennsylvania
  - - University of Pittsburgh
  - - University of Tennessee
  - - University of Texas Medical Branch
  - - University of Texas Health Science Center at San Antonio
  - - University of Texas-San Antonio
  - - University of Virginia
  - - United Kingdom Ministry of Defence
  - - Royal Centre for Defence Medicine, Birmingham, UK
  - - Defence Medical Directorate, Birmingham, UK
  - - Defence Statistics (Health) MOD Abbey Wood
  - - British Army Training Unit, Nanyuki, Kenya
  - - Camp Bastion, Afghanistan

- **Research Organizations and Industry Partners**
  - Cherokee Nation Technology Solutions
  - - Daimera Laboratories, LLC
  - - Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.
  - - Lesco Biomedical Research, Inc.
  - - Novagen Inc.
  - - Scripps Research Institute

- **Division of Clinical Research**
  - - NIAID Flu Networks
  - - 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
  - - - South Texas Veterans Health Care System
  - - - St. Louis Veterans Affairs Medical Center
  - - - Veterans Aging Cohort Study
  - - - Veterans Affairs Connecticut Healthcare System