IDCRP

Uniformed Services University

INFECTIOUS DISEASE CLINICAL RESEARCH PROGRAM

2023

ANNUAL REPORT

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Tribute to Dr. Edmund Tramont, 1939-2023

During the past year, we lost a pioneer in military infectious disease research. Dr. Edmund Tramont not only made significant, groundbreaking contributions to military medicine with regard to vaccine development and HIV military policy, but he also served as a long-time member of our Operational Steering Committee, offering valuable insight and feedback that shaped our research portfolio for the better. He will be deeply missed.

LETTER *from* IDCRP Leadership

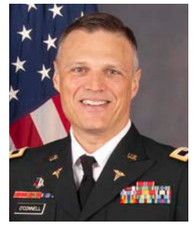
The IDCRP's vision is to eliminate impacts from infectious diseases on military personnel, Military Health System (MHS) beneficiaries, and DoD missions. We seek to realize this vision through conduct of military-relevant, clinical infectious disease research. The ongoing success of the IDCRP is due to the commitment of our personnel and through our vast collaborative relationships established with clinical sites, laboratory partners, academia, and stakeholders.

During the past year, we successfully completed an External Review of our Program. For this review, each research area developed a proposal outlining an initiative to address a high-priority research gap for the MHS and the proposals were critically reviewed by widely respected subject-matter experts. Following extremely valuable feedback, new protocols/initiatives are being developed and include conducting serial immune monitoring to inform correlates of protection against SARS-CoV-2 and influenza, evaluating performance characteristics of diarrheal diagnostic assays to inform recommendations on use in operational settings, identifying host factors predictive of skin and soft-tissue infections to inform clinical prevention trials, and examining prevention, treatment, and impact of sexually-transmitted infections among active-duty personnel using retrospective data and prospective survey methodologies.

The Program hosted our first week-long IDCRP Science Symposium, which featured presentations from trainees, as well as having individual days dedicated to new research findings and high-priority initiatives for our four research areas. The symposium was widely attended (>300) by IDCRP personnel, active-duty investigators, collaborators, and stakeholders with presentations prompting meaningful discussions on the findings and directions of IDCRP research, resulting in a highly successful symposium. The Program also hosted its first two-day Prioritization and Operations Planning Meeting to establish process improvement priorities for the coming year.

During the past year, multiple new initiatives were funded to address critical gaps in combat casualty care, supporting evidence-based management strategies. Enrollment is also underway for clinical trials examining prevention and treatment options for travelers' diarrhea and to assess the effectiveness of the Bexsero® vaccine in reducing risk of gonorrhea, and their findings will help inform guidance recommendations. Studies on Long COVID have informed potential treatment strategies, as well as supporting formal definitions through the National Academy of Sciences. *See Table for more on our measures of success.*

Measures of Success	2023 Accomplishment
Policy Impact	• Updated Joint Trauma System clinical practice guideline on management of invasive fungal wound infections • Supported National Academy of Sciences Long COVID definitions • COVID-19 findings presented to FDA Vaccines and Related Biological Products Advisory Committee to support COVID-19 vaccine boosting decisions • 3 reports to the Defense Health Agency to inform policy and practice recommendations related to active-duty service members with HIV
Capability to Respond to Emergent Infections	• Expanded diversity of individuals involved in Scientific Review Board to increase range of expertise and expedite reviews • New on-the-shelf protocols to support combat casualty care in future conflicts planned
New Protocols / Initiatives	• IDCRP leadership act as Chairs of USU School of Medicine Military Infectious Disease Innovation and Combat Casualty Care hubs, which provide multidisciplinary venues linking researchers across USU and key partners • 6 new protocols were developed and approved by the USU Institutional Review Board • 6 new DoD and academia collaborations established to support new initiatives
Publications / Presentations	• 26 published / accepted manuscripts • 11 submitted manuscripts • 48 presentations at local and national conferences: 14 oral presentations and 34 posters
Stakeholder Satisfaction	• 9 new funding grants
Education	• 57 trainees participating in IDCRP research projects



Robert O'Connell, MD
Colonel, Medical Corps, U.S. Army
Director, IDCRP

Mark P. Simons, PhD, MSPH
Commander, Medical Service Corps, U.S. Navy
Deputy Director, IDCRP

David R. Tribble, MD, DrPH
Science Director, IDCRP

Integral for the successful execution of our clinical research portfolio is the support received from USU leadership, our Operational and Executive Steering Committees, and the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Funding and cooperative partnerships for our clinical research studies and initiatives have also been received from the Defense Health Program, U.S. Army Medical Materiel Development Activity, Military Infectious Diseases Research Program, Navy Bureau of Medicine and Surgery, and the Armed Forces Health Surveillance Division and Immunization Healthcare Division of the Defense Health Agency.

As always, we express our sincerest gratitude to our clinical research and support staff, along with our many active-duty and civilian investigator partners for their dedication and diligence to ensuring the success of the IDCRP's mission. We also thank the military service members and beneficiaries who offer their time to participate in our studies. It is truly a privilege to work with such an outstanding team.

Core values: Compassion and Caring, Ethics and Integrity, Excellence in Scholarship, Innovation, and Selfless Service

Success Is Defined By: 1) Informing military health policy and practice through translation of research findings; 2) Publications and presentations within impactful and relevant peer-reviewed journals/forums; 3) Capability to respond to emergent infection threats and/or high-priority research initiatives; and 4) Key stakeholder satisfaction, including fostering the education of U.S. Armed Forces clinical infectious disease researchers

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), Department of Preventive Medicine and Biostatistics, 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 benefits 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 disease in the military. Study outcomes have far-reaching implications for public health and disease prevention beyond military communities.

PROGRAM ORGANIZATION

Executive Steering Committee

Vice President for Research, USU (Chair)
Dean, School of Medicine, USU
Director, Division of Clinical Research (DCR), NIAID / National Institutes of Health
Director, Research and Development for Health Readiness Policy and Oversight, Defense Health Agency (DHA)
Director, Research and Engineering Directorate, DHA

Operational Steering Committee

Surgeons General Infectious Disease Consultants—Army, Navy, Air Force

Director, Global Emerging Infections Surveillance, Armed Forces Health Surveillance Division

Director, Military Infectious Diseases Research Program, JPC-2

Chief, Collaborative Clinical Research Branch, DCR, NIAID

Chair, Department of Preventive Medicine and Biostatistics, USU

Veterans Affairs Representative (non-voting)

HJF Director of USU Operations (non-voting)

Program Coordination Center

Program Director

Science Directorate
Science Director
- Deputy Science Director
- Associate Science Director
- Research Area Directors

NIAID Liaison

Chair, Scientific Review Board

Deputy Program Director

Director, Center Operations
- Chief, Data Operations
- Head, Regulatory Affairs and Quality Management
- Head, Clinical Research Management
- Head, Site Operations
- Head, Repository and Laboratory Operations
- Head, Finance and Program Management

Partner Organizations

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

VISION

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

MISSION

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

IDCRP RESEARCH AREAS

- **Acute Respiratory Infections (ARI)**—Strategic aims focus on high-priority respiratory pathogens with regard to enhancing detection in military populations, characterizing epidemiology and acute-to-chronic outcomes, predicting risk of severe outcomes and complications, and improving treatment and prevention strategies to reduce morbidity, mortality, and operational readiness loss.

- **Deployment and Travel-Related Infections**—Strategic aims focus on the evaluation of risk and operational impact of deployment and travel-related infectious threats for military personnel, effectiveness of current mitigation strategies, evaluation of knowledge of infectious disease threats and prevention methods, assessment of diagnostic test platforms and patient-reported outcomes, evaluation of novel preventive and treatment strategies for travelers' diarrhea, and assessment of the impact of emerging infectious diseases on U.S. military readiness.

- **Human Immunodeficiency Virus (HIV) and Sexually-Transmitted Infections (STI)**—Strategic aims focus on characterizing the epidemiology and chronic clinical outcomes of priority STIs in U.S. military personnel and beneficiaries, developing and evaluating mitigation strategies related to STI clinical outcomes, supporting development of biomedical countermeasures against STIs in military populations, evaluating care practices and costs related to priority STIs to identify gaps, and assessing novel treatment and prevention strategies for STIs (including HIV) in military populations to inform military policy and practice.

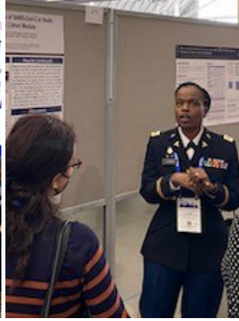
- **Wound Infections**—Strategic aims focus on addressing knowledge gaps in infection prevention, clinical management, microbiologic factors, and treatment outcomes in battlefield trauma infections and community-acquired skin and soft-tissue infections, particularly *Staphylococcus aureus*-related, to inform effective treatment strategies and preventive countermeasures, as well as the evaluation of Military Health System antibiotic stewardship programs to support process improvements.

Each area's 2023 accomplishments are presented in the following pages, along with information and projections for 2024.

ACUTE RESPIRATORY INFECTIONS (ARI)

CAPT (retired) Timothy Burgess presenting at the 2023 Military Health System Research Symposium with COL Robert O'Connell moderating the session

The Acute Respiratory Infections Research Area Day of the 2023 IDCRP Science Symposium



LTC Milissa Jones presenting at the 2023 IDSA IDWeek

Acute respiratory infections (ARIs) are associated with substantial morbidity among military personnel and their beneficiaries. With active-duty service members and military trainees, ARIs may also result in decreased performance of duties and interruptions in training cycles, impacting operational readiness.

Simon Pollett, MBBS, IDCRP Associate Science Director and ARI Research Area Director

Rhonda Colombo, MD, MHS, ARI Research Area Deputy Director

The primary goal of the ARI Research Area is to improve the detection, prediction, treatment, and prevention of higher-priority respiratory pathogens (e.g., SARS-CoV-2, influenza, and adenovirus) and emerging respiratory threats to support Force Health Protection.

During the past year, the new Epidemiology and Prevention of Acute Respiratory Infections at the U.S. Naval Academy (ARIA) study was initiated, led by Dr. Rhonda Colombo. Using multiplex polymerase chain reaction and viral genomic testing with clinical data, ARIA characterizes the epidemiology of respiratory viruses causing medically-attended ARIs in this training setting, including symptoms and illness duration associated with specific pathogens. Findings from ARIA demonstrated the feasibility of utilizing residual self-collected SARS-CoV-2 antigen test swabs for sequencing priority respiratory pathogens. Furthermore, a platform was established to analyze data on licensed ARI treatments and vaccines with virological and clinical outcome data.

Seasonal influenza outbreaks continue to be a source of morbidity among military personnel. Led by CAPT (retired) Timothy Burgess, the open-label, randomized Pragmatic Assessment of Influenza Vaccine Effectiveness in the DoD (PAIVED) clinical trial evaluated the effectiveness of three licensed inactivated influenza vaccine formulations (i.e., egg-based, cell-culture-based, and recombinant) across four influenza seasons. Analysis of relative vaccine effectiveness and immunogenicity was recently completed. Data collected through PAIVED are being utilized to estimate vaccine product effectiveness on other endpoints, such as symptom severity. Further analyses of the immune response to vaccines and influenza are underway.

A major protocol of the ARI Research Area is the Epidemiology, Immunology and Clinical Characteristics of Emerging Infectious Diseases with Pandemic Potential (EPICC) study. Led by Dr. Simon Pollett, EPICC is an observational cohort study of SARS-CoV-2 infections in active-duty service members and Military Health System (MHS) beneficiaries. A focus of EPICC during the past year has been on characterizing chronic outcomes following SARS-CoV-2 infections, including pulmonary and cardiac function, as well as assessing cognitive impairment using an app-based objective neurocognitive module. Findings from EPICC have informed future studies for treating Long COVID and have helped support the establishment of definitions for Long COVID phenotypes and endpoints. Moreover, EPICC is examining clinical and biomarker predictors of acute SARS-CoV-2 complications (e.g., myocarditis) and chronic outcomes, including brain and lung health outcomes. With regard to diagnostics, EPICC assessed the ability of two rapid antigen tests to detect culture-positive (i.e., contagious) cases associated with the highest potential for communicability. Immunological findings from EPICC continue to support the prediction of optimal vaccine booster regimens and to improve the understanding of mechanisms of COVID-19 vaccine protection.

As part of the Prospective Assessment of SARS-CoV-2 Seroconversion (PASS) study, immunogenicity of COVID-19 vaccines toward emerging SARS-CoV-2 variants has been examined; findings on natural killer cell mechanisms of vaccine immunity and reactogenicity led to a provisional patent application related to next-generation COVID-19 vaccines. Utilizing MHS data on SARS-CoV-2 infections collected through the Joint Trauma System COVID-19 Registry, the Military COVID-19 Registry Analysis Project (M-RAP) continues to accumulate real-world data related to the post-licensure effectiveness of COVID-19 vaccines and therapeutic agents and to identify demographic, clinical, and other predictors of chronic post-COVID-19 illness. Factors associated with late uptake of COVID-19 vaccines and boosters have provided insights into vaccine implementation.

For 2024, a new ARI Repository Protocol will pool specimens and clinical data from 10 ARI Research Area protocols to allow comprehensive cross-protocol analyses and future pandemic response activities (e.g., rapid assay development). Additional new protocols being discussed include a new observational pandemic contingency protocol, an extension of the PASS protocol to predict the infection-resistant host, and a serial immune monitoring study to identify correlates of protection against SARS-CoV-2 and influenza infections in congregate settings. The EPICC team is also developing an additional module that will include a cross-sectional survey measuring late post-COVID-19 cognitive impairment and perceptions of Long COVID diagnosis and care in the MHS. Further epidemiological and laboratory-based analyses of the EPICC, M-RAP, PASS, PAIVED, and ARIA protocols are underway.

MILITARY IMPACT

Findings from EPICC, PASS, and M-RAP have bolstered the SARS-CoV-2 evidence base related to detection, prediction, treatment, prevention, and functional illness outcomes. Epidemiologic and surveillance findings from ARIA were shared with leadership at the Naval Health Clinic Annapolis and the Armed Forces Health Surveillance Division (AFHSD) and may be informative for other congregate populations. Findings from COVID-19 observational analyses were utilized to brief senior DoD and other U.S. Government leadership and SARS-CoV-2 genotype data were reported to AFHSD. Using real-world evidence, EPICC has demonstrated the benefits of vaccination and vaccine boosting by reducing the risk of certain post-COVID-19 outcomes, including impaired fitness among active-duty service members. Immunological findings from EPICC and PASS were provided to the U.S. Food and Drug Administration (FDA) Vaccines and Related Biological Products Advisory Committee to support vaccine booster decision-making. Furthermore, EPICC immunological findings were used to validate animal models in support of new global COVID-19 vaccine selection frameworks. Development of salivary assays and evaluation of serodiagnostic platforms for detection of SARS-CoV-2 and influenza infections (and programmable for other ARIs) continue to be supported by the PAIVED and The Observational Seroepidemiologic Study of COVID-19 at the U.S. Naval Academy (TOSCANA) studies. Findings from PAIVED may also inform policy decisions regarding optimal vaccine formulations for use in the DoD to support Force Health Protection.

HIGHLIGHTS/KEY FINDINGS

- **Findings from the EPICC study on machine learning-based Long COVID phenotypes were presented at the National Academies Working Group meeting, which was convened to establish formal definitions for Long COVID.**
- **Extensive antibody analyses from participants in the EPICC and PASS studies with repeated monovalent vaccine and complex hybrid immune profiles were used to support FDA COVID-19 vaccine strain decision making.**
- **ARIA contributed a key proof-of-concept for ARI surveillance, demonstrating the feasibility of detecting and genotyping SARS-CoV-2, influenza, respiratory syncytial virus, and other respiratory pathogens from self-collected nasal swabs previously used in SARS-CoV-2 rapid antigen testing. This finding may support future surveillance approaches in the MHS.**
- **PAIVED showed no significant difference in relative vaccine effectiveness between either the cell-derived or recombinant influenza vaccine and the egg-based vaccine for the prevention of laboratory-confirmed influenza, suggesting all three vaccine types are similarly effective for use in military populations. Further analysis of the immune responses is underway.**
- **The M-RAP study identified correlates of early and late COVID-19 vaccine uptake by active-duty service members, including service branch and demography.**

DEPLOYMENT AND TRAVEL-RELATED INFECTIONS

The Deployment and Travel-Related Infections Research Area Day of the 2023 IDCRP Science Symposium

Dr. David Tribble and COL Robert O'Connell with other attendees of the 2023 Military Infectious Diarrhoea Symposium (MIDAS) meeting, United Kingdom

Infectious diseases constitute a considerable threat to both U.S. military personnel serving overseas in support of combat operations, humanitarian service, and training exercises, and to recruits undergoing military training within the United States. These infections not only affect the health of personnel, but also directly impact operational readiness of deployed U.S. Armed Services.

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

The primary mission of the Deployment and Travel-Related Infections Research Area is to enhance infectious disease preparedness and Force Health Protection of U.S. Armed Services prior to and during deployment with a focus on prevalent and re-emerging infectious disease threats (e.g., bacterial diarrhea, norovirus, and arboviruses) that are priorities of the Military Health System (MHS).

Diarrheal disease remains a frequent occurrence among deployed service members with substantial impacts on operational readiness. In collaboration with the United Kingdom Ministry of Defence, two clinical trials evaluating travelers' diarrhea (TD) mitigation strategies are underway. Led by Dr. David Tribble, the first clinical trial is a continuation of the Trial Evaluating Ambulatory Therapy of TD (TrEAT TD) clinical trial, which initially evaluated the effectiveness of single-dose (1,650 mg) rifaximin for treating acute watery diarrhea compared to azithromycin and levofloxacin. The objective of TrEAT TD 2.0 is to examine the efficacy of a lower dose of rifaximin (550 mg) for treating moderate/severe acute watery diarrhea compared to azithromycin (both used with adjunct loperamide). The second is the P2 clinical trial, which is a randomized placebo-controlled trial to assess the effectiveness of enterotoxigenic *Escherichia coli* passive immunoprophylaxis (Travelan®) for maintaining gut health of personnel during short (10-20 days) travel/deployment.

A critical gap in the management of TD in deployed settings is the lack of guidance related to use of culture-independent diagnostics. To address this gap, a new initiative being developed will evaluate performance characteristics of polymerase chain reaction (PCR)-based assays, such as the BioFire® Gastrointestinal (GI) Panel Assay, to support the development of consensus-driven, evidence-based clinical practice guidelines (CPGs) related to indications, sampling strategies, testing, and interpretation of diarrheal PCR-based diagnostic testing.

Force Health Protection infectious disease threat assessments are dependent on regional estimates of the incidence of infectious diseases, such as TD, acute respiratory infections, and febrile illness. During the past year, surveillance studies have expanded to include additional overseas locations and operational environments to further the understanding of the operational and health impacts of highly prevalent and priority infectious diseases, as well as identifying the risk of re-emerging infectious disease threats. Enrollment is currently underway for the Deployment Infection Threat Assessment and Outcomes Survey among U.S. Marines (MARSID) study. In collaboration with Preventive Medicine investigators of the III Marine Expeditionary Force, responses to the survey completed by U.S. Marines returning from military exercises in the Indo-Pacific Command region will be used to estimate the incidence, trends, and operational impact of infectious diseases. Enrollment in the Leptospirosis in Jungle Warfare Training Environments study is planned to begin in early 2024 at training sites in Okinawa (Japan) and Hawaii to determine the military impact of leptospirosis in personnel undergoing jungle warfare training. Expansion of infectious disease surveillance to include deployments and exercises in regions other than the Indo-Pacific Command region is planned through a new protocol being developed, the Enhanced Infectious Disease Surveillance for U.S. Military Operations (MilOpsID) study.

For 2024, enrollment and follow-up will be completed for the TrEAT TD 2.0 and P2 clinical trials. Data will also be collected from the MHS Data Repository in the coming year for the Gut Microbiome and Guillain-Barré Syndrome (GBS) Study with assessment of corresponding sera from the DoD Serum Repository to evaluate associations with antecedent evidence of antiganglioside antibody and development of GBS. For the Tripler Army Medical Center Diarrhea Case Cohort Study, data will be abstracted from medical records and laboratory collaborators will perform genotype and phenotype analysis of isolates and examine host immunologic responses to inform *Campylobacter* vaccine candidates. The Arboviral Serosurveillance protocol was also recently modified to include evaluation of immunity to Americas Yellow Fever Virus strains in military personnel who were vaccinated.

MILITARY IMPACT

The clinical trials executed through the Deployment and Travel-Related Infections Research Area are generating findings on the effectiveness of prevention and management strategies for TD to support evidence-based recommendations. Specifically, if the lower dose of rifaximin is found to be effective at treating TD, those findings will support refinement of the DoD CPG for the management of acute watery diarrhea in the deployed setting. Similarly, if Travelan® is shown to be effective at maintaining gut health of deployed personnel, those findings may also be used to support development of a CPG for preventing TD in deployed settings. Data from these trials will also support development of a new initiative aimed at evaluating the clinical performance characteristics of the BioFire® GI Panel Assay and developing a CPG regarding use of TD diagnostics in austere settings to reduce the time to full recovery for personnel and improve operational readiness. Findings from surveillance protocols (MARSID and MilOpsID) will support infectious disease threat assessment reports for dissemination to unit leadership and Combatant Command surgeons. Drs. Lalani and Tribble also serve on the GEIS Enterics Steering Committee, offering input on the GEIS Enterics Roadmap. Assessment of provider-knowledge and prescription practice patterns for travel-related infectious disease mitigation is also an important aim of the research area. Lastly, translational research efforts are focused on refining culture-independent diagnostics for diarrheal pathogen detection on stool smears in austere environments and evaluating the impact of travel, antibiotic use, and diarrheal disease on the gut microbiome and resistome.

COL Robert O'Connell, Capt Connor Wakefield, and LCDR Terrel Sanders at Camp Lemonnier, Djibouti, in support of the TrEAT TD 2.0 clinical trial

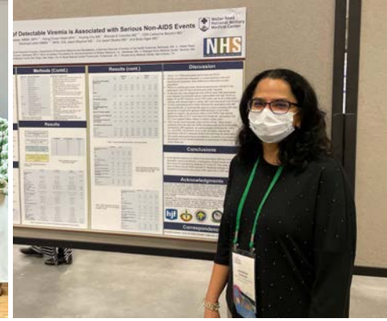
HIGHLIGHTS/KEY FINDINGS

- **In a survey-based assessment of 1,822 military personnel returning from overseas deployment, military training exercises, or short-term military travel, 36% had ≥1 infectious disease with 26% reporting ≥50% reduction in activity level due to the infection. Eating street vendor food, inability to sanitize hands prior to meals, and environmental exposures (e.g., exposure to rodents) were identified as risk factors.**
- **Among the 1,822 military personnel surveyed, the incidence of TD was 9.3 per 100 person-months with a median duration of decreased activity of 3 days. The incidence of influenza-like illness was 3.7 per 100 person-months (median of 4 days of decreased activity), while it was 3.3 per 100-person months for febrile illness (median of 3 days of decreased activity).**
- **In a review of arboviral infections among MHS beneficiaries (2012-2019), Dengue virus contributed the greatest burden with 2.2 cases per 100,000 MHS beneficiaries. Occurrence of pretravel counseling was low (13% of those with arboviral infections).**

HUMAN IMMUNODEFICIENCY VIRUS (HIV) AND SEXUALLY-TRANSMITTED INFECTIONS (STI)

The HIV/STI Research Area Day of the 2023 IDCRP Science Symposium

The MAGI team at the Armed Forces Research Institute of Medical Sciences in Thailand



Dr. Anuradha Ganesan presenting at 30th Conference on Retroviruses and Opportunistic Infections (CROI)

The Military Health System (MHS) has achieved early diagnosis and rapid viral suppression for active-duty service members (ADSM) with HIV; however, non-AIDS complications (e.g., neurocognitive impairment) remain a concern.

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

To eliminate the occurrence and prevent adverse impacts of sexually-transmitted infections (STIs) among ADSMs and MHS beneficiaries, the HIV/STI Research Area focuses on characterizing high-priority STIs, supporting development of STI biomedical countermeasures, evaluating care practices and costs to inform practice recommendations, and assessing STI treatment and prevention strategies to inform military policy.

The U.S. Military HIV Natural History Study (NHS), led by Dr. Brian Agan, has collected clinical data and blood specimens from >6,400 HIV+ ADSMs and MHS beneficiaries. Through collaboration with the University of California San Francisco and Emory University, HIV NHS data and specimens are being utilized in a large-scale evaluation of cardiovascular disease genetics. Moreover, in collaboration with the University of Texas Health Science Center at San Antonio, analyses to further understand the host immune responses to HIV and other antigenic exposures have been completed. A new collaboration with the National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Research Center, as well as the U.S. Military HIV Research Program, related to large-scale screening and characterization of broadly neutralizing antibody responses among NHS subjects is also underway.

Collaboration with the Department of Veterans Affairs (VA) Veterans Aging Cohort Study to develop a DoD-VA Overlap Cohort Study has advanced. This new protocol will result in multiple analyses focused on HIV-associated comorbidities, long-term treatment outcomes, immune responses, co-infections, STIs, and quality and utilization of care. The evaluation of differences in care and utilization among service member and MHS beneficiaries with HIV between direct and purchased care systems was recently assessed using data obtained from the MHS Data Repository through the HIV Virtual Cohort Study.

As HIV-associated neurocognitive disorders (HAND) remains a substantial concern for people with HIV, include ADSMs, the goal of the ALLHANDS study is to examine the functional consequences of HAND in a high-demand military setting. Led by Dr. Agan, ALLHANDS is collaborating with the National Institute of Neurological Disorders and Stroke, National Institute of Mental Health, and five other institutes through the National Institutes of Health to examine HAND biotypes and the impact of the central nervous system on imaging.

As part of the efforts to support preventive strategies, and in collaboration with the University of Alabama at Birmingham and GlaxoSmithKline plc, a Phase II randomized, placebo-controlled, observer-blinded clinical trial of the group B Meningococcal (Bexerso®) Vaccine for Gonococcal Infection (MAGI Trial) is currently enrolling individuals at Walter Reed National Military Medical Center, two DoD-associated sites in Thailand, and civilian academic sites. The primary goal of the trial is to assess the effectiveness of the Bexsero® vaccine as a potential interim prevention strategy against *Neisseria gonorrhoeae* (gonococcus, GC) in high-risk populations with the resulting findings informing DoD clinical practice. Enrollment is expected to be completed by mid-2024 with a one-year follow-up period. Furthermore, as part of a new collaborative effort with multiple USU departments, the pre-clinical evaluation of a combined GC/*Chlamydia trachomatis* (CT) vaccine is underway.

Led by CDR Mark Simons, revisions to the GC Resistance Study to expand surveillance efforts and clinical outcome evaluation to include CT and *Mycoplasma genitalium*, as well as to assess antimicrobial resistance (AMR) and the impact of high-priority STIs on operational readiness and patient-reported outcomes is nearing approval. During the past year, deployment-relevant surveillance GC isolates received from overseas military sites (e.g., Republic of Georgia and Kenya) are being assessed by the USU GC Reference Laboratory and Repository, which is led by Dr. Ann Jerse (USU), funded by the DoD Global Emerging Infections Surveillance (GEIS) program, and coordinated by the IDCRP.

For 2024, a new protocol funded by the Defense Health Agency (DHA) Immunization Healthcare Division is being established to investigate the durability of response and reactogenicity of the recombinant zoster vaccine (RZV) among people with HIV, focused on those under the age of 50. These findings will inform potential vaccine safety concerns and DoD clinical practice following recent recommendations by the Advisory Committee on Immunization Practices for immunocompromised individuals (≥19 years of age) to receive the vaccine to prevent herpes zoster (shingles) and related complications. Another new initiative in development will examine STI (GC and CT focus) prevention, treatment, and impact among ADSMs using retrospective data from the MHS Data Repository and the Defense Manpower Data Center, along with prospective qualitative and survey methodologies.

MILITARY IMPACT

The HIV/STI Research Area objectives are responsive to clinical HIV and STI-related research requirements, as detailed by the DHA, including GEIS, the Tri-Service Infectious Diseases Working Group, and the Military Infectious Diseases Research Program. During the past year, reports on recommendations for in-person and virtual care delivery for ADSMs with HIV and changes to the U.S. Air Force HIV evaluation policy to inform the current revision of the DoD HIV policy implementation guidance were provided to DHA. Additional technical reports in development will help inform implementation of the SECDEF June 2022 memo, eliminating most duty restrictions for ADSMs with HIV. Evaluation of the Bexsero® vaccine to reduce GC risk and assessment of the RZV vaccine may also inform military practice. Analyses through the ALLHANDS protocol are furthering the evidence base on HAND among ADSMs with HIV related to impact, predictors, and function to inform military policy. Findings from the GC Resistance Study and the GC Repository on isolate geographic distribution and susceptibility patterns continue to be provided to GEIS to inform operational planning and a member of the investigative team also serves on the GEIS AMR Working Group.

HIGHLIGHTS/KEY FINDINGS

- **The Department of Health and Human Services 2023 update to the Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV cited Dr. Anuradha Ganesan's IDCRP study (Clin Infect Dis. 2015; 60: 653-60) to support single-dose benzathine penicillin to treat syphilis among people with HIV.**
- **Compared to HIV-negative controls, despite successful treatment, people with HIV on antiretroviral therapy for ≥15 years were more likely to report more cognitive difficulties in everyday life, depressive symptoms, general anxiety, and use of psychiatric medications.**
- **Examination of combinations of in-person and virtual care for ADSMs with HIV resulted in recommendations for annual in-person visits at a Center of Excellence plus interim in-person or virtual visits at the nearest military treatment facility with an infectious disease physician. This model had a high quality of care plus also the highest incremental net monetary benefit of the models of care assessed.**

WOUND INFECTIONS

Battlefield-related wound infections significantly impact the health and recovery of wounded warriors, potentially for years after the trauma. Military personnel living in close quarters, such as trainees, are also at risk of developing skin and soft-tissue infections (SSTIs). The worldwide increase in multidrug-resistant (MDR) pathogens, as well as emergence of novel pathogens, further complicate the management of wound infections.

Katrin Mende, PhD, Wound Infections Research Area Director

The primary mission of the Wound Infections Research Area is to decrease the impact of battlefield-related infections and community-associated SSTIs among military personnel through development of improved evidence-based clinical practice guidance and identification of effective prevention and treatment strategies.

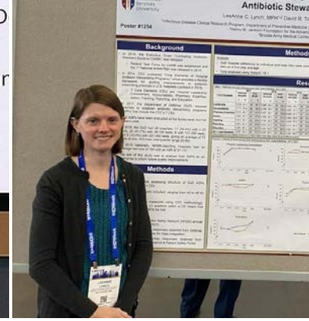
Infectious complications and outcomes following battlefield trauma have largely been evaluated through the Trauma Infectious Disease Outcomes Study (TIDOS). Led by Dr. David Tribble, TIDOS collected detailed information on injury and clinical characteristics, medical and surgical management, infections, and microbiology from military personnel wounded during deployment through the Joint Trauma System (JTS) DoD Trauma Registry (DoDTR) and the TIDOS Infectious Disease (ID) Module of the DoDTR. A longitudinal cohort also allowed for collection of data on infections that occurred during follow-up through DoD and Veterans Affairs (VA) electronic medical records. During the past year, analyses related to burn infections, complications of cranial injuries, battlefield-related infection healthcare costs, invasive fungal infection (IFI) molecular diagnostics, and mental and physical health quality of life following battlefield-related trauma were completed. In collaboration with Dr. Jay McDonald of the VA St. Louis Health Care System, further analysis of indicators of social and mental health (e.g., opioid use and post-traumatic stress disorder) collected from TIDOS cohort enrollees who received VA healthcare is planned. The complex microbiology of wounds and wound infections is also examined through the TIDOS MDR and Virulent Organisms (MDR/VO) Trauma Infections Initiative, which is a collaborative effort with multiple DoD laboratories led by Dr. Katrin Mende. In collaboration with USU investigators, TIDOS wound isolates are being utilizing to assess the activity of lysozymes against biofilms and evaluate nimbolide, a novel antimicrobial.

To further advance combat casualty care research, a new protocol is being developed to answer critical research questions on outcomes related to different injury patterns and management approaches occurring during the wars in Iraq and Afghanistan. Data from TIDOS and the Trauma-Associated Osteomyelitis Study will be incorporated into this new protocol and will also support the collaboration with the Universities of Minnesota and Michigan Medicine to conduct analyses on data from military and civilian trauma patients related to the management of deep soft-tissue wound infections. Findings from these analyses, bolstered by a complex intervention systematic review, will provide the evidence base to support refinement of existing and development of new JTS clinical practice guidelines (CPGs) for the prevention and management of battlefield -related wound infections.

With the substantial morbidity associated with high-consequence battlefield-related infections, wartime preparedness is a priority of the JTS. In collaboration with the U.S. Army Institute of Surgical Research (USAISR), U.S. Army's Telemedicine and Advanced Technology Research Center (TATRC), and USU Surgical Critical Care Initiative (SC2i), machine learning is being utilized to support development of a clinical decision support tool to aid with infection risk stratification in the prehospital setting, particularly with

The Wound Infections Research Area Day of the 2023 IDCRP Science Symposium

Dr. Jay McDonald presenting at the Wound Infections Research Area Day of the 2023 IDCRP Science Symposium



LeeAnne Lynch presenting at the 2023 IDSA IDWeek

prolonged field care, and provide diagnostic support with greater precision following hospital admission. As part of another new initiative, technical recommendations and scientific/regulatory frameworks will be developed to support a next-generation DoDTR ID Module, Wartime Specimen/Isolate Repositories, and 'on-the-shelf' adaptive clinical trial protocols (collaboration with the George Washington University Biostatistics Center) focused on wound infection prevention/treatment for activation during future conflicts.

Community-associated SSTIs, primarily attributed to *Staphylococcus aureus*, have been the focus of multiple IDCRP protocols conducted in military trainees and deployed populations. Through the new SSTI Repository Protocol, the massive amount of clinical data and specimens collected from these prior studies are being pooled to become a comprehensive resource for conducting analyses to answer priority research questions with the goal of informing eventual clinical trials focused on SSTI prevention. Presently, data management efforts are underway to merge datasets from three prior SSTI studies. Data analyses are also nearing completion for the Evaluation of DoD Antimicrobial Stewardship Programs (ASP) study, which is assessing DoD ASPs in relation to the CDC's Core Elements for Hospital and Outpatient Antibiotic Stewardship, and the Antibiotic-Resistant Bloodstream Infections (BSI) study, which is examining the epidemiology and longitudinal trends of BSIs in MHS beneficiaries over a 10-year period.

For 2024, the focus will be on the new collaborative initiatives designed to address gaps in combat casualty care. This includes providing support for wound infection research efforts in Ukraine. Discussions will also continue with the United Kingdom Ministry of Defence for collaborative analyses to compare outcomes between U.S. and U.K. wounded military personnel.

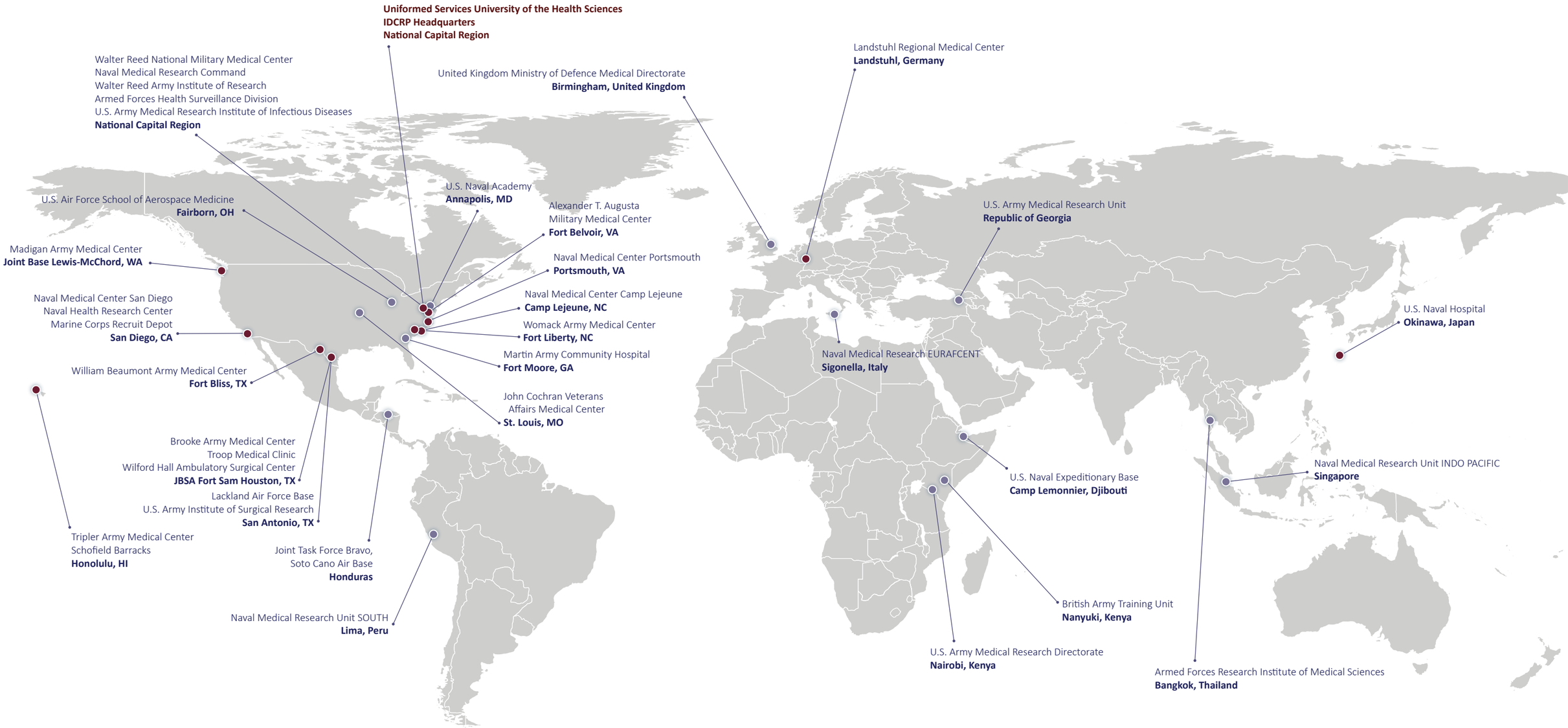
MILITARY IMPACT

The strategic aims of the Wound Infections Research Area remain responsive to priorities of the Military Infectious Diseases Research Program, DoD JTS, and the MHS. New collaborative initiatives are focused on addressing gaps in combat casualty care by creating an evidence base to support JTS CPG refinement/development, supporting development of a clinical decision support tool to aid triage, en-route care, and prioritization of medical evacuation, and developing technical recommendations to advance wartime preparedness for future conflicts. A knowledge, attitudes, and practices questionnaire being developed will provide an assessment of familiarity of frontline providers with wartime infection control, prevention, and treatment. The TIDOS team is also providing support for prospective, observational studies of Ukraine war-related wound infections. The SSTI Repository Protocol will be leveraged to utilize a systems biology approach to inform SSTI prevention strategies with the eventual goal of utilizing the findings to conduct clinical trials. Through the DoD ASP study, areas where DoD ASPs could be improved are being identified. Overall, the Wound Infections Research Area is a robust research platform, focused on supporting evidence-based prevention and management of militarily-relevant wound infections

HIGHLIGHTS/KEY FINDINGS

- **Findings from TIDOS IFI studies were used to support the 2023 update of the JTS CPG on management of IFIs in war wounds (CPG 28).**
- **Multiple new DoD, government, and academic collaborations were established to support initiatives developed in 2023.**
- **A new initiative being developed will leverage the SSTI Repository Protocol to identify host factors predictive of SSTI risk to inform future clinical trials related to SSTI prevention in congregate military populations.**
- **Combat casualties with penetrating cranial injuries who developed ≥1 central nervous system infection had lower presenting Glasgow Coma Scale scores and more retained fragments in the cranial injury than patients without infections.**

IDCRP PARTNER NETWORK



CENTER OPERATIONS

Essential for the ongoing success of the IDCRP's mission to conduct high-quality, high-impact clinical research is a robust, well-organized, and cohesive operational foundation.

Matthew Pearl, MS
Director, Center Operations

Todd Stroberg, RN, BSN
Head, Clinical Research Management

Susan Chambers, RN, BSN, CCRC
Head, Site Operations

Led by Mr. Matthew Pearl (Director, Center Operations), Center Operations is a fully integrated unit dedicated to the planning, coordination, and oversight of the IDCRP to ensure effective protocol development and execution with regard to Program Management, Clinical Research Management, Site Operations, Repository and Laboratory Operations, Regulatory Affairs and Quality Management, and Data Operations. The central mission of Center Operations is to improve communication, standardization, and synergy across the Program's clinical research portfolio to support timely execution of protocol milestones and the development of high-quality, evidence-based knowledge products.

A robust operational and financial foundation is a crucial component for the successful execution of the Program's clinical research portfolio. During the past year, the Program Management team continued to enhance protocol execution through improved communication and coordination with Research Area Directors and other Center Operations teams. The Program Management team oversaw 34 funding awards in support of more than 70 protocols, as well as coordinating proposal submissions, budget development, agreement and contract approvals, purchase orders, hiring and personnel actions, and reports to stakeholders. In addition, the Program Management team worked with the Research Support Group to centralize purchasing for the Program and coordinated with HJF to develop new methods for providing payments to study participants.

The Clinical Research Management team supports investigative teams and Data Operations with the development, execution, and management of protocols to ensure that the projects accomplish their objectives within the allotted timelines. Led by Mr. Todd Stroberg, the Clinical Research Management team includes eight USU-based IDCRP Clinical Research Managers (CRM) and four Research Area Coordinators. During the past year, the team worked to update and revise the IDCRP Protocol Handbook, which provides the framework for key processes spanning the protocol lifecycle (i.e., development through execution to close-out). In addition, the first Protocol Operation Readiness Review, a new process that occurs prior to the activation of protocols, was performed for the Acute Respiratory Infections (ARI) Research Area Epidemiology and Prevention of ARIs at the U.S. Naval Academy (ARIA) protocol. This new process includes a detailed readiness review of operational procedures, regulatory documents, data quality management plans, and laboratory procedures. New Smartsheet protocol development and management toolkits were created and executed to improve communication, key metric tracking, performance indicators, budget reports, and overall progress.

The mission of Site Operations is to provide centralized oversight to ensure standardization, efficiency, and quality across the broad IDCRP Partner Network. Led by Ms. Susan Chambers, the Site Operations team includes site operational managers and >50 highly trained clinical research professionals who support the investigative teams with site selection, population engagement, resource utilization, and data collection and quality. During 2023, Site Operations supported clinical trials being conducted by the Deployment and Travel-Related Infections Research Area by providing enhanced, remote research execution support in austere forward-deployment environments. New IDCRP personnel were also embedded at Okinawa, Japan, to enhance research capabilities for a new study on leptospirosis among personnel undergoing jungle warfare training. Furthermore, Site Operations team members hosted site visits at core clinical sites for IDCRP Program and Research Area Directors, providing a platform to advance critical collaborations and enhance sustainment with military and non-military clinical partners.

Led by Mr. Scott Merritt, the Repository and Laboratory Operations team provides laboratory-related oversight and guidance for the development and support of new and existing research studies, bridging gaps between IDCRP investigative teams, laboratory partners, and specimen biorepositories. During the past year, a priority was the updating of existing laboratory manuals and manuals of operation, as well as the development of manuals for two new protocols. Moreover, a new Specimen Tracking System (STS) is being developed to provide a digital framework for specimen/data management to reduce redundancies across study sites, enhance visibility with the IDCRP Partner Network, and identify specimen/data issues in real-time. Commercial biorepositories to augment capacities and capabilities of existing IDCRP specimen repositories are also being explored.

Led by Mr. Mark Fritschlanski, the Regulatory Affairs and Quality Management teams are responsible for ensuring that the development and implementation of IDCRP clinical research protocols are compliant with regulatory and ethical standards. In addition, Regulatory Affairs team members serve as the liaison between the Program and regulatory officials at USU, the Defense Health Agency, DoD partners, and the National Institute of Allergy and Infectious Diseases. During 2023, the Regulatory Affairs team supported investigative teams and CRMs by reviewing and providing regulatory consultations for 158 protocols and protocol-related materials prior to submission to the USU Institutional Review Board. The Quality Management team focuses on enabling excellence across all IDCRP sites participating in clinical research, implementing best practices, and validating the quality of work being performed. During the past year, the Quality Management team ensured that all newly executed IDCRP protocols were initiated with *a priori* defined quality management procedures following a risk-based approach focused on known risks to participant rights and data integrity. Furthermore, together the Regulatory Affairs and Quality Management teams prioritized the program-wide implementation of the Florence electronic Trial Master File system to support development and tracking of essential clinical research study documents and facilitate regulatory compliance for all IDCRP protocols. A web-based platform for quality management documentation using Smartsheet was also implemented to further communication and understanding of the elements related to quality management.

Led by Mr. Edward Parmelee, Data Operations are managed through the Data Coordination Center (DCC), which includes highly experienced data managers/developers and SAS/Oracle programmers. The primary focus of the DCC is to ensure the highest quality of data collection, management, processing, and access for the IDCRP clinical research portfolio. During 2023, the DCC provided support services for 44 IDCRP protocols, including the creation or modification of data collection workflows, provision of analysis data and reports, and the acquisition of Military Health System (MHS) Data Repository data. To improve standardization, new standard operating procedures (SOPs) for the handling of data for discontinued subjects and processes for extracting data from the MHS Data Repository were developed to facilitate acquisition and retention of high-quality data, while minimizing

Scott Merritt
Head, Repository and Laboratory Operations

Mark Fritschlanski
Head, Regulatory Affairs and Quality Management

Edward Parmelee, MSc
Chief, Data Coordination Center

CENTER OPERATIONS *(Continued)*

risk of acquiring data incorrectly. The DCC team also created guidance documents related to applying for an account with the IDCRP electronic data capture system (REDCap) and acquiring data using the Joint Longitudinal Viewer, which is an essential tool used by site staff to obtain research data from historic MHS data sources. During the past year, data management efforts were initiated for the Wound Infections Research Area Skin and Soft-Tissue Infection Repository Protocol. As this protocol is merging data from multiple prior protocols into one resource, it is a complex undertaking to correctly identify, associate, and aggregate clinical and specimen data across the different studies.

For the coming year, priorities for Center Operations will be to standardize data management practices, processes, and tools to include integration of quality management documentation throughout the protocol process and quality checks to streamline data queries, clearly define roles and responsibilities for all protocol team members, standardize project management processes through use of the Smartsheet toolkits, develop methods for measuring protocol health, and improve the Program's internal communication practices and file-sharing methods. A goal of the Program Management team for the coming year will be to work with Research Area Directors and other research team members to improve protocol spending and integrate budget development with protocol development and project management. For the Clinical Research Management team, one goal for 2024 is to participate in a Project Management training series related to the new Smartsheet toolkits and subsequently implement the toolkits to improve workflow for protocol development, execution, oversight, and communication. For Site Operations, objectives for 2024 include improving operational efficiencies and resource utilization in the execution of research portfolios through site-specific assessment, leveraging of site-specific strengths, alignment of operational resources to research priorities, and training research professionals on newly developed standardization platforms and processes. Plans for Repository and Laboratory Operations in 2024 include continued development of the STS and expansion of biorepository capacities and capabilities to include specimen processing and storage. For 2024, the Regulatory Affairs team plans to continue process improvements with development/revision of SOPs and continuing training of personnel on applicable regulations and new policies. In addition, the Quality Management team plans to further integrate quality management and data management processes across the Program to improve efficiency and ensure processes are meeting stringent quality standards. For 2024, Data Operations will continue to work toward standardizing data management practices, processes, and tools across protocols, as well as integrate and document quality management through the protocol lifecycle and use risk management principles to streamline data cleaning practices.

HIGHLIGHTS

- **The first two-day Annual Prioritization and Operations Planning Meeting was held in July 2023 and attended by IDCRP personnel and federal clients with the focus on enhancing team communication, developing an overarching plan for IDCRP operations into 2024, discussing operational objectives (e.g., identifying priorities and barriers), and establishing working groups to address priority objectives.**
- **The Research Support Group coordinated and supported the first week-long IDCRP Science Symposium, which focused on highlighting new research and initiatives for the four IDCRP research areas, as well as showcasing mentored research conducted by trainees. The symposium was attended by >300 IDCRP personnel, active-duty investigators, collaborators, government personnel, and stakeholders.**

SCIENTIFIC REVIEW BOARD

The objective of the IDCRP Scientific Review Board (SRB) is to conduct independent, efficient, and comprehensive scientific reviews of clinical research protocols and protocol amendments in preparation for their submission to the USU Institutional Review Board (IRB).

The thorough reviews performed by the IDCRP SRB are focused on assessing whether the scientific content (e.g., research questions, hypotheses, aims/objectives, and methods) of protocols and protocol amendment submissions are scientifically valid, clinically meaningful, and feasible. The SRB, chaired by Dr. John Powers (National Institute of Allergy and Infectious Diseases liaison) and supported by CDR Mark Simons (IDCRP Deputy Director and SRB Vice Chair), reviews each new IDCRP protocol, as well as protocol amendments that can result in substantive changes to the associated protocol.

The SRB review panels are comprised of subject-matter experts who are selected according to the focal areas of the research questions described in the protocol or protocol amendment being reviewed and include biomedical scientists, statisticians, and other scientific review panel members affiliated with the IDCRP Partner Network. A precursor evaluation of each submission is performed by the SRB Chair (or Vice Chair when the Chair is recused or unavailable), who then assigns the submission to one of the three potential review pathways that is the most appropriate and efficient pathway. The most rapid pathway is the Chair Review, which is completed within 14 days of submission and usually used for protocol amendments that do not ask new research questions. The Low Resource Review is generally completed within 28 days of submission, while completion for the Standard Review occurs within 35-45 days of submission.

During the past year, the SRB reviewed five new protocols and four protocol amendments; two submissions are pending. Dr. Powers and members of the IDCRP SRB also published a correspondence in *Nature* during 2023 on strengthening the scientific review of research protocols based on the experiences of the SRB. As part of efforts to streamline the review process and improve productivity, Principal Investigators and the SRB Chair would meet prior to submission to discuss elements of the protocol's study design that may facilitate review. Investigators were also asked to provide a tentative timeline of steps leading to their SRB submission. As SRB reviews may not be initiated until the review panels are fully staffed, investigators suggested subject-matter experts as potential reviewers prior to submission, allowing for advanced communications with the experts to confirm their availability and willingness to participate on the panels prior to the submission.

John Powers, MD, Chair, Scientific Review Board

In 2024, the SRB Chair will continue to maintain the efficiency of the Standard Review pathway, while upholding the scientific rigor of the reviews. Training and mentorship of junior investigators with regard to the process for developing a protocol and appropriately linking research question(s) to the study design and statistical analysis will continue to be offered in the year.

SRB Reviews and Approvals	Numbers
Submission to the SRB	**9**
New protocols	5
Protocol amendments	4
SRB disposition	
Approved	9
Pending review / projected submissions	2

EDUCATION/MENTORSHIP

A fundamental aim of the IDCRP is to foster the growth of the next generation of clinical infectious disease (ID) researchers in the U.S. Armed Services.

Dr. Anuradha Ganesan (mentor [right]) with Dr. David Tribble (left) and her trainee, LCDR Graham Ellis (middle) at the 2023 IDSA IDWeek.

2LT Ketrah Dekanich presenting at the 2023 IDSA IDWeek

Capt Connor Wakefield presenting at the 2023 San Antonio Uniformed Services Health Education Consortium Research Day

In support of the education mission of the IDCRP, residents, ID fellows, and medical/graduate students in the U.S. Armed Services are provided opportunities to conduct research projects under the mentorship of IDCRP investigators and to participate in ongoing research studies led by investigators. These opportunities are made available at USU and military clinical sites within the IDCRP Partner Network, including Brooke Army Medical Center, Madigan Army Medical Center, Naval Medical Center Portsmouth, Naval Medical Center San Diego, Tripler Army Medical Center, and Walter Reed National Military Medical Center (WRNMMC). In addition, trainees from the National Institutes of Health (NIH), University of Maryland, Emory University, University of California San Diego, and San Diego University are also participating in IDCRP research projects. These mentored research projects allow trainees to experience real-world, hands-on clinical research, providing them with greater understanding related to how research studies are conducted, including study design, data collection, analysis, and publication/presentation of findings. Furthermore, the IDCRP supports the clinical ID research capstone curriculum for USU medical students, as well as continuing GME activities at WRNMMC and the Defense Health Agency-ID Working Group Subcommittee (previously the Armed Forces ID Society).

During 2023, 52 residents (across multiple specialties, including Internal Medicine, Preventive Medicine, Pulmonary and Critical Care Medicine, Surgical, and Neurosurgical), medical/graduate students, ID Fellows, MPH students, and 5 post-doctoral trainees either began or completed their IDCRP-mentored research projects. Data from the Acute Respiratory Infections Research Area EPICC and PASS protocols, as well as protocols through the HIV/Sexually-Transmitted Infections Research Area, are being utilized to support MPH projects, PhD dissertations, and post-doctoral projects. A Public Health PhD candidate is also conducting a mentored research project in support of her degree on the evaluation of DoD antimicrobial stewardship programs through the Wound Infections Research Area.

Seventeen oral and poster presentations involving trainees were presented at local and national conferences during the past year. Moreover, 13 manuscripts co-authored by trainees were published or accepted for publication. Trainees who participated in IDCRP-mentored research projects also received award recognition in 2023 (see IDCRP Awards and Honors, page 20).

Along with mentored research projects, research engagement remains a crucial element for the success of the IDCRP's education mission. In 2023, IDCRP investigators attended public health student practicum and project fairs, met with medical students and ID Fellows to discuss opportunities, and engaged medical training program directors in regular communications about available IDCRP-mentored research opportunities. Medical school graduates, USU faculty, and ID consultants were encouraged to share with trainees the impact of clinical research has had on their respective paths to further kindle interest in participating in research opportunities.

Overall, the IDCRP remains successful in meeting the aims of the Program's education mission to cultivate high-quality clinical ID research in the Military Health System through mentoring the growth of active-duty researchers.

SELECTED IDCRP TRAINEE EDUCATION PUBLICATIONS AND PRESENTATIONS

PUBLICATIONS

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Boatwright MA, Kuo H, Lindholm DA, Griffith T, Colombo RE, Tribble DR, Lalani T. The Impact of Infectious Disease Syndromes on Activities during Military Travel. *Open Forum of Infectious Diseases*. 2023; 10(9): ofad461.

Topal S, Richard P, Young J, Ganesan A, Gleeson T, Blaylock J, Okulicz JF, Chu X, Agan B. Mandated Checkups, Knowledge of Own Health Status, and Chronic Care Utilization: The Effect of HIV Medical Evaluation Mandates on Healthcare Quality and Expenditure in a US-Single Payer System. *Health Economics*. 2024; 33(1): 59-81.

PRESENTATIONS

2023 Military Health System Research Symposium, 14-17 August 2023, Kissimmee, FL

Goertzen SM, Lindholm D, Walter RJ, Huprikar N, Ganesan A, Richard S, Mende K, Murillo C, Harrell TE, Peterson P, Simons M, Tribble D, Agan B, Burgess TH, Pollett S, Morris MJ. Clinical, Radiographic, and Physiological Correlates of Post-COVID-19 Respiratory Symptoms: Results from the Chronic Impairment with Pulmonary Symptoms (ChIPS) Sub-study.

Graydon E, Epsi N, Lindrose AR, Jackson-Thompson BM, Conner T, Coggins SA, Goguet E, Tribble DR, Hollis-Perry M, Sanchez-Edwards M, Kosh L, Mohammed R, Wang G, Alcorta Y, Wong MA, Shipmon T, Kobi P, Haines H, Moser M, Samuels EC, Tso M, Saunders D, Burgess TH, Broder CC, Laing ED, Mitre E, Pollett S. Non-workplace SARS-CoV-2 Exposure Risk is Associated with Incident COVID-19 among Vaccinated Healthcare Workers in a Tertiary-level Military Treatment Facility.

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Wakefield CJ, Geringer MR, Stewart L, Shaikh F, Carson ML, Lu D, Cancio LC, Gurney JM, Tribble DR, Kiley JL. Time Until Definitive Grafting of Battlefield-Related Burn Injuries Is Associated with Burn Wound Infection.

2023 IDSA ID Week, 11-15 October 2023, Boston, MA

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Goertzen SM, Lindholm D, Walter RJ, Huprikar N, Ganesan A, Richard S, Mende K, Murillo C, Harrell TE, Peterson P, Simons M, Tribble D, Agan B, Burgess TH, Pollett S, Morris MJ. Clinical, Radiographic, and Physiological Correlates of Post-COVID-19 Respiratory Symptoms: Results from the Chronic Impairment with Pulmonary Symptoms (ChIPS) Sub-study.

Dekanich K, Smith K, Laing E, Wang W, Weiss C, Samuels E, Swafford I, Proulx DP, Currier J, Parsons E, Richard SA, Jones MU, Rozman J, Colombo RE, Huprikar N, Lindholm DA, Mende K, Ganesan A, Larson D, Ewers E, Flanagan R, Simons MP, O'Connell R, Tribble D, Agan BK, Burgess TH, Hickey PW, Pollett SD, Malloy A. Maternal Antibody and Placental Transfer Increases with Hybrid Immunity Against SARS-CoV-2 But Antibody Transferred Is Qualitatively Different.

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IDCRP AWARDS AND HONORS

During the past year, investigators and trainees have received recognition for their IDCRP research studies by various organizations. The editors of *Military Medicine* unanimously selected the 2022 article by MAJ Mary Ford on her IDCRP mentored analysis on *Pseudomonas aeruginosa* infections among combat casualties as the Article of the Year 2022. We sincerely congratulate MAJ Ford and her co-authors on this recognition. We would also like to congratulate LCDR Graham Ellis for being one of the 10 trainees who received an IDSA Kass Award and CPT Madeline Fleit for receiving an IDWeek Trainee Award for their IDSA IDWeek abstracts to support travel-related expenses. In addition, Ms. Danielle Ali was awarded 2nd place in the poster competition at the 2023 Military Health System Research Symposium.

We also congratulate CDR Mark Simons (IDCRP Deputy Director) who was recognized with a USU School of Medicine Dean's Impact Award for his efforts with the IDCRP when he served as the Acting Director in 2022, ensuring seamless transition to the new leadership.

Name	Award/Honor	Awarding Organization
Academic or General Award/Honor		
CDR Mark Simons	School of Medicine Dean's Impact Award	USU
Research-Related Award for IDCRP-Related Research Study		
MAJ Mary Ford	Article of the Year 2022	Military Medicine
LCDR Graham Ellis	Kass Award	Infectious Diseases Society of America
CPT Madeline Fleit	IDWeek Trainee Award	Infectious Diseases Society of America
Danielle Ali	2nd place in Poster Session	Military Health System Research Symposium

Ms. Danielle Ali receiving her award at the 2023 Military Health System Research Symposium

LCDR Graham Ellis (Kass award winner) presenting at the 2023 IDSA IDWeek

CPT Madeline Fleit (IDWeek Trainee Award winner) with her poster at the 2023 IDSA IDWeek

IDCRP COLLABORATORS & PARTNERS

Department Of Defense Sites

U.S. Military Hospitals and Clinics

- Alexander T. Augusta Military Medical Center, Fort Belvoir, VA
- Brooke Army Medical Center, JBSA Ft Sam Houston, TX
- Joint Task Force Bravo, Soto Cano Air Base, Honduras
- Landstuhl Regional Medical Center, Germany
- Madigan Army Medical Center, Joint Base Lewis-McChord, WA
- Martin Army Community Hospital, Ft Moore, GA
- Naval Medical Center Camp Lejeune, Jacksonville, NC
- Naval Medical Center Portsmouth, VA
- Naval Medical Center San Diego, CA
- Schofield Barracks Health Clinic, Oahu, HI
- Tripler Army Medical Center, Oahu, HI
- Troop Medical Clinic, Ft Sam Houston, TX
- U.S. Air Force School of Aerospace Medicine (USAFSAM)
- 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 Ambulatory Surgical Center, JBSA Fort Sam Houston, TX
- William Beaumont Army Medical Center, Ft Bliss, TX
- Womack Army Medical Center, Ft Liberty, 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 INDO PACIFIC, Singapore
  - Naval Medical Research Unit EURAFCENT, Sigonella, Italy
  - Naval Medical Research Unit SOUTH, Lima, Peru
- U.S. Army Institute of Surgical Research
- U.S. Army Medical Research Institute of Infectious Diseases
- U.S. Army Telemedicine & Advanced Technology Research Center
- Walter Reed Army Institute of Research
  - Emerging Infectious Diseases Branch
  - Military HIV Research Program
  - Multidrug Resistant Organism Repository and Surveillance Network
  - Specimen Processing Laboratory
  - Wound Infections
  - Viral Diseases Branch
  - Global Research Network
    - Armed Forces Research Institute of Medical Sciences, Bangkok, Thailand
    - U.S. Army Medical Research Directorate-Georgia, Tbilisi, Georgia
    - U.S. Army Medical Research Directorate-Africa, Nairobi, Kenya
    - U.S. Army Medical Research Directorate-West, WA, USA
  - Global Research Network

Other U.S. Military Commands/Programs

- Defense Health Agency
  - Armed Forces Health Surveillance Division (AFHSD)
    - Global Emerging Infection Surveillance (GEIS) Program
  - Immunization Healthcare Division (IHD)
- Bureau of Medicine and Surgery, Department of Navy (BUMED)
- Congressionally Directed Medical Research Program (CDMRP)
- Defense Advanced Research Projects Agency (DARPA)
- Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense
- Military Infectious Diseases Research Program (MIDRP)
- Navy Marine Corps Public Health Center (NMCPHC)
- San Antonio Uniformed Services Health Education Consortium (SAUSHEC)

United States Government Health Agencies

- Biomedical Advanced Research and Development Authority
- Centers for Disease Control and Prevention
- Food and Drug Administration
- Lawrence Livermore National Laboratory
- National Institutes of Health
  - National Cancer Institute
  - 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
  - St. Louis Veterans Affairs Medical Center
  - Veterans Aging Cohort Study
  - Veterans Affairs Connecticut Healthcare System
  - Veterans Affairs Sierra Nevada HealthCare System

Foreign Health Agencies and Organizations

- International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b)
- National Institute for Public Health and the Environment (RIVM), The Netherlands
- Royal Thai Army Clinical Research Center
- SEARCH Research Foundation and Innovation (IHRI) clinic
- United Kingdom Ministry of Defence
  - Royal Centre for Defense Medicine, Birmingham, UK
  - British Army Training Unit, Nanyuki, Kenya
  - Defence Medical Directorate, Birmingham, UK
  - Defence Statistics (Health) MOD Abbey Wood

Academia

- Broad Institute
- Children's Hospital of Philadelphia
- Cornell University
- Emory University
- George Washington University
- Harvard T. H. Chan School of Public Health
- Icahn School of Medicine at Mount Sinai
- Johns Hopkins Applied Physics Laboratory
- Johns Hopkins School of Medicine
- Johns Hopkins Bloomberg School of Public Health
- Michigan State University
- San Diego University
- University of California-San Diego
- University of California-San Francisco
- University of Colorado
- University of Georgia, Athens, Georgia
- University of Glasgow, Scotland
- University of Maryland
- University of Michigan Medicine
- University of Minnesota
- University of Nevada, Reno
- University of Pennsylvania
- University of Pittsburgh
- University of Texas Health Science Center at San Antonio
- University of Texas-San Antonio
- University of Toledo College of Medicine and Life Sciences
- University of Vermont
- University of Virginia
- University of Washington
- Washington University in St. Louis
- Yale University

Research Organizations and Industry Partners

- AstraZeneca plc
- Antigen Discovery, Inc.
- GlaxoSmithKline plc
- Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.
  - Austere Environments Consortium for Enhanced Sepsis Outcomes (ACESO)
- Integrated Biotherapeutics, Inc.
- Janssen Pharmaceuticals, Inc.
- Leidos Biomedical Research, Inc.

National Institute of Allergy and Infectious Diseases

IDCRP
Uniformed Services University

hjf

Infectious Disease Clinical Research Program

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

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