



TravMil

Deployment and Travel Related Infectious Disease Risk Assessment, Outcomes, and Prevention Strategies Among Department of Defense Beneficiaries Executive Summary – Non-Deployment Travel



Purpose:

- Describe the clinical features and outcomes of high-impact, militarily relevant infectious diseases among deployed US Department of Defense (DoD) active duty and other beneficiaries traveling outside the continental United States.
- Focus on four key infectious disease areas of interest: i) travelers' diarrhea, ii) malaria and other vector-borne febrile illnesses, iii) influenza-like illness; and iv) emerging infectious diseases.
- Evaluate current and new risk reduction and self-treatment strategies with regard to compliance, efficacy, effectiveness, cost-effectiveness, and side effect profile

Inclusion Criteria:

Pre-travel enrollment:

1. Age \geq 18 years
2. Planned travel outside of the continental United States within 3 months of the pre-travel visit
3. Ability to follow-up within 8 weeks after return from travel.

Post-travel (ill-subject enrollment):

1. Completed travel outside of the continental United States within 2 months of clinic visit.
 - Infectious diseases of interest include: malaria, chikungunya, travelers' diarrhea with an extensive microbiological workup or associated with irritable bowel syndrome, and serious travel-related infections necessitating hospitalization

Exclusion Criteria:

1. Planned or completed travel is limited to Western or Northern Europe, Canada, or New Zealand
2. Planned or completed travel time is $>$ 6.5 months

Study Procedures:

Pre-Travel Enrollment:

1. A pre-travel survey completed by participants
2. Blood samples obtained prior to travel and up to 8 weeks after return to evaluate for potential infectious disease exposures (e.g. dengue, chikungunya etc.).
3. A 1 page diary to record episodes of diarrhea and fever that occur during travel as well as the severity of symptoms and treatment used.
4. A self-collected stool smear obtained on a filter paper card prior to travel, and either during an episode of diarrhea during travel or towards the end of travel if no diarrhea occurs
5. A post-travel survey completed within 2 months of return from travel.
6. An extended follow-up survey for symptoms of functional bowel disorders at 3 and 6 months after return from travel.

Post-travel Enrollment:

1. A post-travel enrollment survey
2. Blood samples obtained during the acute illness and 3-8 weeks later
3. Participants with a diarrheal illness will be asked to provide a stool smear.
4. An extended follow-up survey for symptoms of functional bowel disorders at 3 and 6 months after return from travel

Primary Objectives:

- 1) Describe the clinical features, impact and outcomes of travelers' diarrhea (TD), febrile illness, influenza-like-illness, and emerging infectious diseases during deployment and travel.
- 2) Estimate the effectiveness of selected risk-reduction and self-treatment strategies using serological surrogates of exposure, PCR testing and post-travel surveys that assess utilization, compliance, side effects, and preventive and/or therapeutic effectiveness, for the following:
 - a. Traveler's Diarrhea (antibiotics and anti-diarrheal agents)
 - b. Vector borne febrile illness including
 - i) Malaria (personal protective measures [PPM] and antimalarial chemoprophylaxis);
 - ii) Arboviral/ rickettsial infections (PPMs);
 - iii) Leptospirosis
 - c. Influenza like Illness
 - d. Emerging infectious disease (e.g. chikungunya)
- 3) Utilize the TravMil cohort as a platform for conducting observational studies and clinical trials (through companion protocols).
- 4) Evaluate the utility of the self-collected stool smears combined with molecular assays for detection of enteropathogens associated with travelers' diarrhea

Study Sites:

- Naval Medical Center Portsmouth, VA
- Naval Medical Center San Diego, CA
- Walter Reed National Military Medical Center, MD
- Madigan Army Medical Center, WA
- San Antonio Military Medical Center, TX
- Landstuhl Regional Medical Center, Germany

Laboratory Sites/Collaborators:

- Research Lab, Naval Medical Center Portsmouth
- Naval Medical Research Center, Silver Spring, MD
- Leptospirosis Center of Excellence, San Antonio, TX

Study coordination:

- Infectious Disease Clinical Research Program/Uniformed Services University of the Health Sciences, Bethesda, MD

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Infectious Disease Clinical Research Program (IDCRP)/National Institute of Allergy and Infectious Disease (NIAID)

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