Disclosures. **All authors:** No reported disclosures.

2800. Pragmatic Assessment of Influenza Vaccine Effectiveness in the DoD (PAIVED): Influenza-Like-Illness Rates in Year 1

Timothy Burgess, MD, MPH[1]; Stephanie Richard, PhD, MHS[2,3]; Limone Collins, MD[4,5,6,7]; Rhonda Colombo, MD, MHS[7,8,9,10]; Anuradha Ganesan, MBBS, MPH[11,12]; Casey Geaney, MD[12]; Tahaniyat Lalani, MBBS[3,8,13]; Ana E. Markelz, MD[14]; Ryan Maves, MD[1,8,16]; Katrin Mende, PhD[8,14,17]; Christina Schofield, MD[7]; Srihari Seshadri, MBBS, MPH[5]; Christina Spooner, MS[5]; Gregory Utz, MD[9,18,19]; Tyler Warkentien, MD, MPH[13]; Christian L. Coles, PhD[3,8]; [1]Infectious Disease Clinical Research Program, Bethesda, Maryland; [2]Infectious Disease Clinical Research Program, Department of Preventive Medicine and Biostatistics, Uniformed Services University of the Health Sciences, Bethesda, Maryland, [3]Henry M. Jackson Foundation, Bethesda, Maryland; [4]Immunization Health Branch, Defense Health Agency, Bethesda, Maryland, [5]Immunization Health Branch, Defense Health Agency, Falls Church, Virginia, [6]Immunization Health Branch, Defense Health Agency, San Diego, California, ; [7]Madigan Army Medical Center, Tacoma, Washington, [8]Infectious Disease Clinical Research Program, Bethesda, Maryland, [9]Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., Bethesda, Maryland, [10]Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., Tacoma, Washington; [11]Infectious Disease Clinical Research Program and the Henry M. Jackson Foundation for the Advancement of Military Medicine, Bethesda, Maryland, [12]Walter Reed National Military Medical Center, Bethesda, Maryland, [13]Naval Medical Center Portsmouth, Portsmouth, Virginia; [14]Brooke Army Medical Center, Fort Sam Houston, Texas; [15]Naval Medical Center at San Diego, San Diego, California, [16]Infectious Disease Clinical Research Program, San Diego, California, [17]The Henry M. Jackson Foundation, Bethesda, Maryland, [14]Brooke Army Medical Center, Fort Sam Houston, Texas, , [18]Naval Medical Center San Diego, Infectious Disease Clinical Research Program, Bethesda, Maryland, [19]Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., San Diego, California,

Session: 281. Viral Respiratory Diseases
Saturday, October 5, 2019: 12:15 PM

Background: Influenza-like illnesses (ILI) are common in military populations due to close living and working conditions, physical exertion, and exposure to novel viruses. The PAIVED trial aims to compare the effectiveness of 3 FDA approved influenza vaccines in active-duty military, retiree, and dependent populations, and will also provide information about the burden, impact, and severity of ILI.

Methods: Participants were enrolled in the 2018–2019 influenza season at 5 geographically diverse military facilities. Active duty, non-recruit military personnel, retirees, and dependents were randomized to receive influenza vaccine (egg-based, recombinant, or cell-culture derived) and then completed weekly electronic surveys throughout the influenza season. If a participant reported ILI symptoms during surveillance, 2 in-person visits with study personnel were scheduled for confirmed ILI. Nasal swabs and blood samples were collected for diagnostic and immunologic testing.

Results: Among the 852 non-recruit participants enrolled in PAIVED, 25% were active military, 36% retired military, and 39% dependents. Almost half (48%) were female, and 72% were white, 15% African American, 6% Asian, 4% multiple races, and 3% unknown or other race. 788 participants (92%) responded to at least one surveillance questionnaire. Participants reported 407 ILIs (Figure 1), of which 160 met the study case definition. Between 12 and 28% of the participants experienced an ILI during the surveillance period, and 12 people experienced 2 ILIs. Most sites reported a median 2–3 days of fever/feverishness or chills and 3–4 days of reduced activity associated with an ILI episode. No viruses were detected in 58% of nasal swabs, 1 virus in 40%, and 2 viruses in 1% of swabs (Figure 2 for pathogen data).

Conclusion: During the period under study, ILIs were common with 1 in 6 participants experiencing a confirmed ILI, many of which were 6–8 days in duration. ILIs resulted in reduced activity, although few individuals reported missing work or school, a situation that could result in greater likelihood of transmission to others. Planned analyses will provide additional information about the pathogens responsible for these illnesses and help guide effective prevention policies in these populations.

Figure 1. Confirmed ILI cases in PAIVED, by site

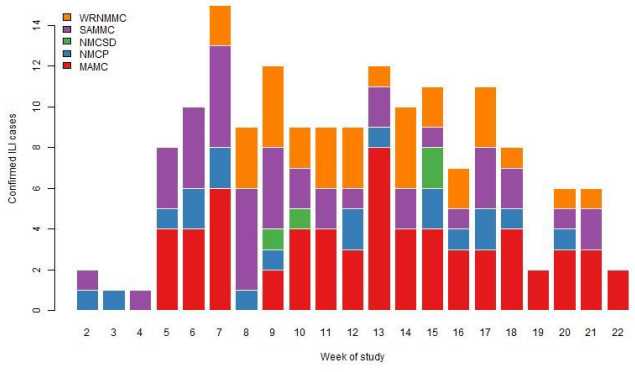
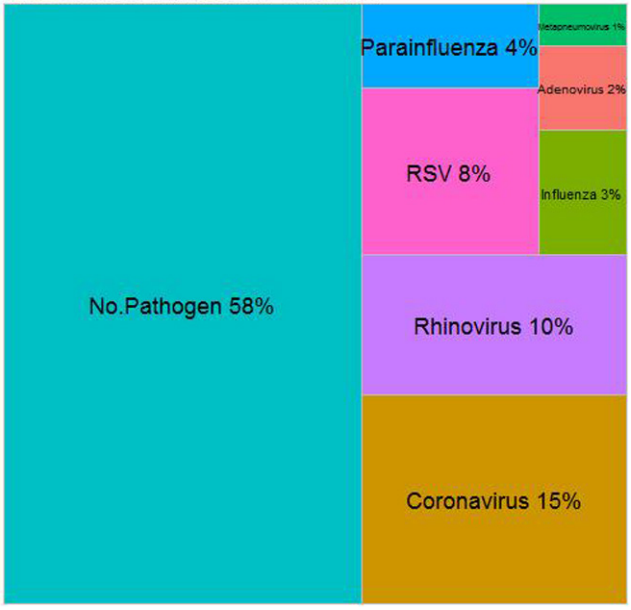


Figure 2. Lab results, non-recruits (N=104 samples)



Disclaimer
This study IDCRP-120 was conducted by the Infectious Disease Clinical Research Program (IDCRP), a Department of Defense (DoD) program executed by the Uniformed Services University of the Health Sciences (USUHS) through a cooperative agreement with The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF). This project has been funded in whole, or in part, with federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health (NIH), under Inter-Agency Agreement (12012-001-07000) and the Defense Health Program.

The contents of this publication are the sole responsibility of the authors and do not necessarily reflect the views, opinions or policies of Uniformed Services University of the Health Sciences (USUHS), The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., the Department of Defense (DoD), or the Departments of the Army, Navy, or Air Force or Brooke Army Medical Center. Mention of trade names, commercial products, or organizations does not imply endorsement by the U.S. Government.

The authors have no conflict of interest to disclose.

The investigators have adhered to the policies for protection of human subjects as prescribed in 45CRF46.

Disclosures. **All authors:** No reported disclosures.

2801. Post-Natal Zika Virus Infection and Impact on Neurodevelopment Among a Cohort of Children in Rural Guatemala

Daniel Olson, MD[1]; Molly Lamb, PhD[2]; Amy Connery, PsyD ABPP-CN[3]; Kathryn Colborn, PhD[2]; Muktha S. Natrajan, PhD, MPH[4]; Jesse Waggoner, MD[5]; Alejandra Paniagua-Avila, MD, MPH[6]; Desiree Bauer, MSc[2]; Evan J. Anderson, MD[5]; Mirella Calvimontes, MD[6]; Guillermo Bolanos, MD[6]; Nora Watson, PhD[7]; Hana El Sahly, MD[8]; Flor M. Munoz, MD[9]; Flor M. Munoz, MD[9]; Edwin J. Asturias, MD[3]; [1]School of Medicine, University of Colorado, Denver, Colorado; [2]Colorado School of Public Health, Aurora, Colorado; [3]School of Medicine, University of Colorado - Denver, Denver, Colorado; [4]Emory University Vaccine Center, Atlanta, Georgia; [5]School of Medicine, Emory University, Atlanta, Georgia; [6]Fundacion para la Salud Integral de los Guatemaltecos, Denver, Colorado; [7]The EMMES Corporation, Rockville, Maryland; [8]Baylor College of Medicine, Houston, Texas; [9]Baylor College of Medicine and Texas Children's Hospital, Houston, Texas

Session: 282. Zika Virus Infection
Saturday, October 5, 2019: 12:15 PM

Background: The impact of early post-natal Zika virus (ZIKV) infection on neurodevelopment (ND) is unknown. A prospective study of post-natal ZIKV infection in rural Guatemala (ZIKV study) enrolled a cohort of children ages 1–5 years, including children previously enrolled in a dengue virus (DENV) study during the 2015–2016 ZIKV epidemic. We evaluated ND outcomes by age and ZIKV infection status.

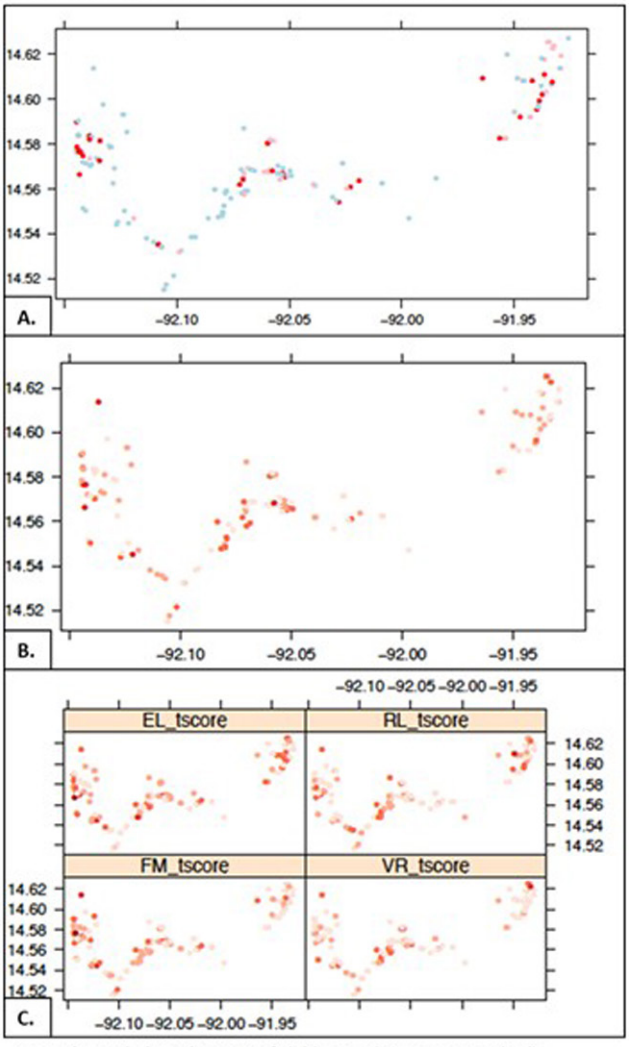
Methods: Subjects enrolled in the ZIKV study June 2017–April 2018 underwent ND testing using the Mullen Scales of Early Learning (MSEL) at baseline and 12 months later. ZIKV/DENV-1/2 FRNT50 was performed on enrollment and on banked serum samples from the 2015 to 2016 subset. ZIKV serostatus and MSEL scores were correlated using multiple linear mixed models, adjusted for age and gender

when appropriate, to evaluate their association. Geolocation was used to explore clustering of ZIKV serostatus and MSEL score.

Results: We enrolled 183 children (43% female, mean age 3.2 years). Of these, 38 (21%) were classified as ZIKV-positive (+), 111 (61%) ZIKV-negative (-), 31 (17%) ZIKV-possible, and 3 (2%) ZIKV-indeterminate. ZIKV(+) cases and higher composite MSEL scores clustered in more densely populated areas (Figure 1). ZIKV(+) serostatus was associated with higher MSEL composite (increase in log score 0.09, $P = 0.003$) and subdomain scores: fine motor (0.13, $P = 0.011$), visual reception (0.15, $P = 0.002$), receptive language (0.09, $P = 0.041$), gross motor (0.14, $P = 0.09$), and expressive language (0.09, $P = 0.058$) (Figure 2). Of the 78 children (43%) with 2015–2016 samples, 46 (59%) remained ZIKV(−), 16 (21%) seroconverted from ZIKV(−) or possible/indeterminate to ZIKV(+), and 16 (21%) were indeterminate when enrolled in the ZIKV study. ZIKV seroconversion was associated with higher composite (0.13, $P = 0.02$) MSEL scores compared with ZIKV(−).

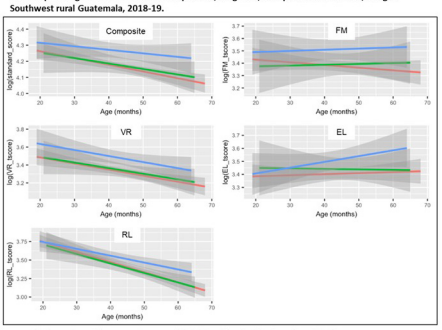
Conclusion: In this exploratory analysis, post-natal ZIKV infection was not associated with adverse ND outcomes in children age 1–5 years. Overall, ZIKV(+) status was associated with higher average ND scores than ZIKV(−), and scores decreased with age for most children, independent of ZIKV status. The correlation of ZIKV(+) status and higher MSEL scores may be confounded by geographic-related factors or other confounders. NIAID Contract HHSN272201300015I Task Order HHSN27200013 (Co-PIs: FMM & EJA).

Figure 1. Distribution of Zika virus serostatus, MSEL composite score, and MSEL sub-domain scores by geolocation, among children 1-5 years in Southwest rural Guatemala, 2018-19.



Legend: Panel A) Geolocation of children with ZIKV-positive (red), -possible (pink), and -negative (blue) serostatus. Panel B) Geolocation of composite MSEL standard score by quintiles (darker = higher quintile). Panel C) Geolocation of sub-domain MSEL T-scores by quintiles (darker = higher quintile), including expressive language (EL), receptive language (RL), fine motor (FM), and visual reception (VR).

Figure 2. Trends in age-based MSEL composite and sub-domain scores from baseline and 12-month follow-up among children with Zika virus-positive, -negative, and -possible serostatus, living in Southwest rural Guatemala, 2018-19.



Legend: When adjusted for age and sex, ZIKV(+) children (blue line) had significantly higher composite MSEL score (log-transformed standard score) as well as higher fine motor (FM), visual reception (VR), expressive language (EL), and receptive language (LR) sub-domain MSEL scores (log-transformed t-scores), compared to children with ZIKV(-) (red line) and ZIKV-possible (green line) serostatus.

Disclosures: Flor M. Munoz, M.D, Biocryst: Grant/Research Support; CDC: Research Grant; Moderna: Other Financial or Material Support, Safety Monitoring Board Member/Chair; NIH: Research Grant; Novavax: Research Grant; UP to Date: Author and Editor - Royalties, Other Financial or Material Support.

2802. Occupational Exposure to the Ugandan Strain of Zika Virus in a Laboratory Worker in the United States: Clinical Presentation, Viral Persistence, and Antibody Response

Paola Lichtenberger, MD[1]; Mike Ricciardi; Dalhila Solorzano; Patricia Raccamarich; Ana R. Leda, PhD[2]; Mark Sharkey; David Walkins; Mark Mulligan, MD, FIDSA[3]; Susanne Doblecki-Lewis, MD, MSPH[4]; Mario Stevenson, PhD[4]; Maria L. Alcaide, MD[4] [1]Miller School of Medicine, University of Miami, Miami, Florida; [2]University of Miami, Miami, Florida; [3]New York University, New York, New York; [4]University of Miami Miller School of Medicine, Miami, Florida

Session: 282. Zika Virus Infection
Saturday, October 5, 2019: 12:15 PM

Background: A laboratory worker suffered an accidental needle stick resulting in infection with the Ugandan strain (MR766) of Zika virus (ZIKV), a strain that has rarely been studied in humans. We report the clinical presentation and outcomes, molecular and serological diagnostic results, and immunological response. A 34-year-old Brazilian-born female laboratory researcher, presented with malaise, skin rash, myalgia and joint pain 10 days after an accidental needle stick while inoculating a mouse with ZIKV-MR766. On physical examination she had bilateral maculopapular rash on the cheeks, and tender effusions at the metacarpal and proximal interphalangeal joints and ankles. Symptoms and signs resolved within 3 weeks. ZIKV infection was confirmed by Nucleic Acid Amplification Test (Lab Corp®) in urine. Serological testing using the ZIKV IgM ELISA test from Lab Corp®, and a confirmatory plaque reduction neutralization test (PRNT) in accordance with the Centers for Disease Control and Prevention (CDC), results were negative.

Methods: Whole blood, plasma, urine, saliva, and a vaginal swab were collected from day (D) 14 post exposure (PE) to D104 PE. A novel, antibody competition-based ZIKV diagnostic test (highly specific for ZIKV antibodies) was performed in serum, and detection of ZIKV-MR766 genomic RNA was performed in all body fluids longitudinally.

Results: Antibody response revealed broad IgM response to both ZIKV-Paraiba (strain from the 2015 outbreak) and ZIKV-MR766 during the acute phase of the infection, suggesting cross-reactivity. There was no cross-reactivity against dengue or yellow fever viruses. An IgG response was detected against both ZIKV strains and increased until D104 PE. ZIKV RNA was detected in whole blood, saliva, urine, and the vaginal swab at D14 PE. At D20 PE, virus was only detectable in whole blood at a value of less than 37 copies per mL. At D23 PE, there was no detectable virus. (figure).

Conclusion: This case highlights the potential for ZIKV occupational exposure. Findings may be useful for the development of diagnostic tests against ZIKV as we were able to accurately determine time of exposure, presence of virus in body fluids, development of symptoms, and antibody responses after a well-documented infection.

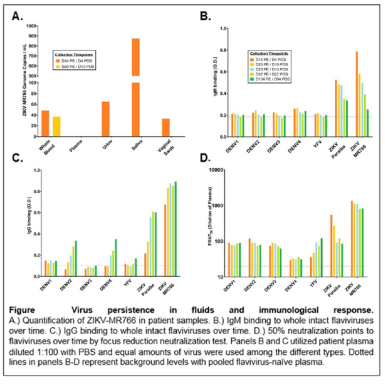


Figure Virus persistence in fluids and immunological response. A.) Quantification of ZIKV-MR766 in patient samples. B.) IgM binding to whole intact flaviviruses over time. C.) IgG binding to whole intact flaviviruses over time. D.) 50% neutralization points to flaviviruses over time by focus reduction neutralization test. Panels B and C utilized patient plasma diluted 1:100 with PBS and equal amounts of virus were used among the different types. Dotted lines in panels B-D represent background levels with pooled flavivirus-naïve plasma.

Disclosures. **All authors:** No reported disclosures.