

EXHIBIT A

Remington Nevin, MD, MPH, DrPH

Consultant Physician Epidemiologist

Board Certified in Public Health & General Preventive Medicine and in Occupational Medicine by the American Board of Preventive Medicine and Certified in Public Health by the National Board of Public Health Examiners

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Curriculum Vitae

June 24, 2019

Education and Professional Training

2016-2017	Johns Hopkins University Bloomberg School of Public Health Baltimore, MD	Postdoctoral Fellowship in Occupational and Environmental Medicine
2012-2016	Johns Hopkins University Bloomberg School of Public Health Baltimore, MD	DrPH in Mental Health
2012-2014	Johns Hopkins University Bloomberg School of Public Health Baltimore, MD	Certificate in Pharmacoepidemiology and Drug Safety
2003-2005	Walter Reed Army Institute of Research, Washington, DC	Residency in Public Health and General Preventive Medicine
2003-2004	Johns Hopkins University Bloomberg School of Public Health Baltimore, MD	MPH
2002-2003	Womack Army Medical Center Ft. Bragg, NC	Internship in Family Medicine
1998-2002	Uniformed Services University of the Health Sciences Bethesda, MD	MD
1995-1998	University of Toronto University College Toronto, Ontario, Canada	BSc (Hon) with High Distinction Majors in Physics & Physiology, Minor in Mathematics

Faculty Appointments

2019	Johns Hopkins University Bloomberg School of Public Health Baltimore, MD	Faculty Associate (Part-Time) Department of Mental Health
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Professional Licensure

2017-	Medicine	Vermont License 42.0013908
2012-	Medicine and Surgery	Maryland License D73583
2003-	Medicine and Surgery	New York License 229259 (Inactive)

Medical Board Certifications

2018-	Occupational Medicine	American Board of Preventive Medicine
2006-	Public Health and General Preventive Medicine	American Board of Preventive Medicine

Other Board Certifications

2015-	Certified in Public Health	National Board of Public Health Examiners
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Academic Awards, Honors, and Scholarships

2014	Outstanding Recent Graduate Award Johns Hopkins University Alumni Association Dr. Ali Kawi Scholarship, Department of Mental Health Johns Hopkins University, Bloomberg School of Public Health Gordis Teaching Fellowship Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences
2013	Dr. Ali Kawi Scholarship, Department of Mental Health Johns Hopkins University, Bloomberg School of Public Health Gordis Teaching Fellowship Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences
2012	Dr. Ali Kawi Scholarship, Department of Mental Health Johns Hopkins University, Bloomberg School of Public Health
2011	Alumni Inductee, Delta Omega Honor Society, Alpha Chapter Johns Hopkins University, Bloomberg School of Public Health
2005	George Miller Sternberg Medal in Preventive Medicine Walter Reed Army Institute of Research
2002	Captain Richard R. Hooper Award in Preventive Medicine Uniformed Services University of the Health Sciences
2000	Distinguished Academic Performance Award in Preventive Medicine Uniformed Services University of the Health Sciences
1997	R. L. Burton Scholarship in Mathematics and Physical Sciences University of Toronto, University College

Teaching

- 2019 Johns Hopkins University, Bloomberg School of Public Health
Current Issues in Military Mental Health. PH.330.659 (Summer Institute).
Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences
Public Health and U.S. Military Policy. AS.280.213 (Winter Intersession).
- 2018 Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences
Public Health and U.S. Military Policy. AS.280.213 (Winter Intersession).
- 2017 Johns Hopkins University, Bloomberg School of Public Health
Current Issues in Military Mental Health (with Peter Zandi).
PH.330.659 (Summer Institute).
Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences
Public Health and U.S. Military Policy. AS.280.213 (Winter Intersession).
- 2016 Johns Hopkins University, Bloomberg School of Public Health
Current Issues in Military Mental Health (with Peter Zandi).
PH.330.659 (Summer Institute).
Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences
Public Health and U.S. Military Policy. AS.280.213 (Winter Intersession).
- 2015 Johns Hopkins University, Bloomberg School of Public Health
Current Issues in Military Mental Health (with Peter Zandi).
PH.330.659 (Summer Institute).
- 2014 Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences
U.S. Military Policy and Public Health. AS.280.406 (Fall Term).
Johns Hopkins University, Bloomberg School of Public Health
Current Issues in Military Mental Health (with Peter Zandi).
PH.330.659 (Summer Institute).
Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences
U.S. Military Policy and Public Health. AS.280.406 (Spring Term).
- 2013 Johns Hopkins University, Zanvyl Krieger School of Arts and Sciences
U.S. Military Policy and Public Health: The Consequences of Conflict.
AS.280.406 (Fall Term).

Military and Non-Profit Service

- 2018- **Executive Director**
The Quinism Foundation, White River Junction, VT.
- 2010-2012 **Preventive Medicine Physician**
Bayne-Jones Army Community Hospital, Fort Polk, LA.
- 2008-2009 **Preventive Medicine Officer**
360th Civil Affairs Brigade, United States Africa Command, Combined
Joint Task Force Horn of Africa (CJTF-HOA), Camp Lemonier, Djibouti.
- 2008 **Preventive Medicine Officer and Deputy Chief of Staff (Acting), Force
Health Protection**
18th Medical Command, US Army Garrison Yongsan, Seoul, Korea.

- 2007-2008 **Preventive Medicine Officer and Program Manager (Acting), Defense Medical Surveillance System**
Armed Forces Health Surveillance Center, Silver Spring, MD.
- 2007 **Preventive Medicine Officer**
International Security and Assistance Force (ISAF) Regional Command East, Combined Joint Task Force 82 (CJTF-82), Bagram Airfield, Afghanistan.
- 2005-2006 **Preventive Medicine Officer**
Army Medical Surveillance Activity, Directorate of Epidemiology and Disease Surveillance, US Army Center for Health Promotion and Preventive Medicine, Washington, DC.

Invited Public Testimony

- 2019 Canadian Parliament. Standing Committee on Veterans Affairs. *Effects of Mefloquine Use Among Canadian Veterans*. Wednesday, May 1, 2019. The Wellington Building Room 420, Ottawa, Canada.
- 2018 Australian Senate. Foreign Affairs, Defence and Trade References Committee. *Use of the Quinoline Anti-malarial Drugs Mefloquine and Tafenoquine in the Australian Defence Force*. Thursday, October 11, 2018. Committee Room 2S1, Parliament House, Canberra, Australia. (By Video Teleconference).
- 2016 Canadian Parliament. Standing Committee on Veterans Affairs. *Mental Health and Suicide Prevention Among Veterans*. Tuesday, October 25, 2016. The Valour Building Room 228, Ottawa, Canada.
- 2015 UK Parliament. Defence Committee. *An Acceptable Risk? The Use of Lariam for Military Personnel*. Tuesday, December 8, 2015. The Wilson Room, Portcullis House, London, UK.
- 2012 U.S. Senate. Appropriations Defense Subcommittee. *Outside Witnesses: Mefloquine Research*. Wednesday, June 6, 2012. Dirksen Senate Office Building Room 162, Washington, DC.

Grants and Research Funding

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| 2019 | \$18K | Royal Canadian Legion, Mefloquine Long-Term Effects |
| 2010 | \$264K | Department of Defense Fiscal Year 2010 Defense Medical Research Development Program, MDR1 Polymorphisms and Risk of Anxiogenic Mefloquine Adverse Events. MRMC #D61-I-10-J5-121 |
| 2006 | \$1.919M | Department of Defense Global Emerging Infectious Disease Surveillance and Response System (DoD-GEIS), Pandemic Influenza Surveillance Supplemental Funding. |
| | \$20K | Department of Defense Military Vaccine Agency, Measles/Mumps/Rubella Immunity Concordance. |
| 2005 | \$4.5K | Department of Defense Military Vaccine Agency, Mumps Screening Cost-Effectiveness. |
| | \$20K | Department of Defense Military Vaccine Agency, Hepatitis A Seroprevalence. |

Peer Review

- 2019 **Journal Reviewer:** American Journal of Public Health; Clinical Case Reports; Federal Practitioner; Military Medicine. **Abstract Reviewer:** American College of Preventive Medicine, 2019 Annual Meeting.
- 2018 **Journal Reviewer:** American Journal of Tropical Medicine & Hygiene; BMJ Case Reports; Clinical Case Reports; Federal Practitioner; Journal of Medical Case Reports; Journal of Travel Medicine; Military Medicine.
- 2017 **Journal Reviewer:** American Journal of Infection Control; American Journal of Tropical Medicine and Hygiene; American Journal of Psychiatry; Biomedicine and Pharmacotherapy; BMJ Case Reports; Federal Practitioner; Journal of Medical Case Reports; Journal of Travel Medicine; Military Medicine. **Abstract Reviewer:** American College of Preventive Medicine, 2018 Annual Meeting.
- 2016 **Journal Reviewer:** American Journal of Tropical Medicine and Hygiene; Australasian Medical Journal; Disaster Medicine and Public Health Preparedness; PLOS ONE; Journal of Medical Case Reports; Military Medicine. **Abstract Reviewer:** American College of Preventive Medicine, 2017 Annual Meeting.
- 2015 **Journal Reviewer:** American Journal of Infection Control; American Journal of Preventive Medicine; American Journal of Public Health; American Journal of Tropical Medicine and Hygiene; Clinical Case Reports; Journal of Cerebral Blood Flow & Metabolism. **Abstract Reviewer:** American College of Preventive Medicine, 2016 Annual Meeting; International Society for Pharmacoepidemiology 2016 Mid-Year Meeting.
- 2014 **Journal Reviewer:** American Journal of Bioethics Neuroscience; American Journal of Infection Control; American Journal of Public Health; Military Medicine. **Abstract Reviewer:** American College of Preventive Medicine, 2015 Annual Meeting.
- 2013 **Journal Reviewer:** American Journal of Infection Control; American Journal of Tropical Medicine and Hygiene; Military Medicine; Paediatrics and International Child Health. **Abstract Reviewer:** American College of Preventive Medicine, 2014 Annual Meeting.
- 2012 **Journal Reviewer:** American Journal of Infection Control; American Journal of Public Health; Journal of the Neurological Sciences; Military Medicine. **Abstract Reviewer:** American College of Preventive Medicine, 2013 Annual Meeting.
- 2011 **Journal Reviewer:** American Journal of Infection Control; Journal of Infection and Public Health.
- 2010 **Journal Reviewer:** American Journal of Infection Control; American Journal of Tropical Medicine and Hygiene; BMC Medical Research Methodology; Emerging Infectious Diseases; The Lancet; Lancet Infectious Diseases.
- 2009 **Journal Reviewer:** American Journal of Public Health; American Journal of Tropical Medicine and Hygiene; Clinical Nursing Research; Military Medicine.

- 2008 **Journal Reviewer:** American Journal of Infection Control; American Journal of Public Health; American Journal of Tropical Medicine and Hygiene; Military Medicine.
- 2007 **Journal Reviewer:** American Journal of Public Health; Journal of Adolescent Health.
- 2006 **Abstract Reviewer:** International Society of Pharmacoeconomics and Outcomes Research, 11th International Meeting.

Publications

- 2018 Langston ME, Pakpahan R, **Nevin RL**, De Marzo AM, Elliott, DJ, Gaydos CA, Isaacs WB, Nelson WG, Sokoll LJ, Zenilman JM. Sustained influence of infections on prostate-specific antigen concentration: An analysis of changes over 10 years of follow-up. Prostate. 2017;78(13):1024-1034.
- 2017 **Nevin RL**, Bernt J, Hodgson M. Association of Poultry Processing Industry Exposures with Reports of Occupational Finger Amputations: Results of an Analysis of OSHA Severe Injury Report (SIR) Data. J Occup Environ Med. 2017;59(10):e159.
- Milbrandt M, Winter AC, **Nevin RL**, Pakpahan R, Bradwin G, De Marzo AM, Elliott DJ, Gaydos CA, Isaacs WI, Nelson WG, Rifai N, Sokoll LJ, Zenilman JM, Platz EA, Sutcliffe S. Insight into infection-mediated prostate damage: contrasting patterns of C-reactive protein and prostate-specific antigen levels during infection. Prostate. 2017;77(13):1325-1334.
- Nevin RL.** A serious nightmare: psychiatric and neurologic adverse reactions to mefloquine are serious adverse reactions. Pharmacol Res Perspect. 2017;5(4):e00328.
- Summers MR, **Nevin RL.** Stellate Ganglion Block in the Treatment of Posttraumatic Stress Disorder: A Review of Historical and Recent Literature. Pain Pract. 2017;17(4):546-553.
- Nevin RL.** Screening for Symptomatic Mefloquine Exposure among Veterans with Chronic Psychiatric Symptoms. Fed Pract. 2017;34(3):12-14.
- Nevin RL**, Leoutsakos JS. Identification of a Syndrome Class of Neuropsychiatric Adverse Reactions to Mefloquine from Latent Class Modeling of FDA Adverse Event Reporting System Data. Drugs R D. 2017;17(1):199-210.
- 2016 Jain M, **Nevin RL**, Ahmed I. Mefloquine-associated dizziness, diplopia, and central serous chorioretinopathy: a case report. J Med Case Rep. 2016;10(1):305
- Nevin RL**, Ritchie EC. FDA Black Box, VA Red Ink? A Successful Service-Connected Disability Claim for Chronic Neuropsychiatric Adverse Effects from Mefloquine. Fed Pract. 2016;33(10):20-24.
- Nevin RL**, Anderson J. The Timeliness of the U.S. Military Response to the 2014 Ebola Disaster: a Critical Review. Med Confl Surviv. 2016;32(1):40-69.

- Anderson J, **Nevin RL**. Prohibiting Direct Medical Care by U.S. Military Personnel in Foreign Disaster Relief: Arguments from the Ebola Disaster. *Med Confl Surviv*. 2016;32(1):14-20.
- Nevin RL**, Byrd AM. Neuropsychiatric Adverse Reactions to Mefloquine: A Systematic Comparison of Prescribing and Patient Safety Guidance in the US, UK, Ireland, Australia, New Zealand, and Canada. *Neurol Ther*. 2016;5(1):69-83.
- Nevin RL**, Croft AM. Psychiatric Effects of Malaria and Anti-Malarial Drugs: Historical and Modern Perspectives. *Malar J*. 2016;15:332.
- Sutcliffe S, **Nevin RL**, Pakpahan R, Elliot DJ, Langston ME, De Marzo AM, Gaydos CA, Isaacs WB, Nelson WG, Sokoll LJ, Walsh PC, Zenilman JM, Cersovsky SB, Platz EA. Infectious Mononucleosis, Other Infections, and Prostate-Specific Antigen Concentration as a Marker of Prostate Involvement During Infection. *Int J Cancer*. 2016;138(9):2221-2230.
- Wicken C, **Nevin RL**, Ritchie EC. U.S. Military Surveillance of Mental Health Disorders, 1998-2013. *Psychiatr Serv*. 2016;67(2):248-251.
- 2015 **Nevin RL**. Rational Risk-Benefit Decision-Making in the Setting of Military Mefloquine Policy. *J Parasitol Res*. 2015;2015:260106.
- Maxwell N, **Nevin RL**, Stahl S, Block J, Shugarts S, Wu A, Dominy S, Solano M, Kappelman-Culver S, Lee-Messer C, Maldonado J, Maxwell A. Prolonged Neuropsychiatric Effects Following Management of Chloroquine Intoxication with Psychotropic Polypharmacy. *Clin Case Rep*. 2015;3(6):379-387.
- Chase R, **Nevin RL**. Population Estimates of Undocumented Incident Traumatic Brain Injuries Among Combat-Deployed U.S. Military Personnel. *J Head Trauma Rehabil*. 2015;30(1):E57-64.
- 2014 **Nevin RL**. A Memoir of Mefloquine Amnesia: A Review of "The Answer to the Riddle is Me" by David Stuart MacLean. *AJOB Neurosci*. 2014;s5(4):88-91.
- Nevin RL**. Idiosyncratic Quinoline Central Nervous System Toxicity: Historical Insights into the Chronic Neurological Sequelae of Mefloquine. *Int J Parasitol Drugs Drug Resist*. 2014;4(2):118-125.
- 2013 Cosby MT, Pimentel G, **Nevin RL**, Ahmed SF, Klena JD, Amir E, Younan M, Browning R, Sebeny P. Outbreak of H3N2 influenza at a US military base in Djibouti during the H1N1 pandemic of 2009. *PLOS One*. 2013;8(12):e82089.
- Ritchie EC, Block J, **Nevin RL**. Psychiatric Side Effects of Mefloquine: Applications to Forensic Psychiatry. *J Am Acad Psychiatry Law*. 2013;41(2):224-235.
- 2012 Sutcliffe S, Pakpahan R, Sokoll LJ, Elliot DJ, **Nevin RL**, Cersovsky SB, Walsh PC, Platz EA. Prostate-Specific Antigen Concentration in Young Men: New Estimates and Review of the Literature. *BJU Int*. 2012;110(11):1627-1635.
- Nevin RL**. Mefloquine Gap Junction Blockade and Risk of Pregnancy Loss. *Biol Reprod*. 2012;87(3):65,1-9.

- Nevin RL.** Mass administration of the antimalarial drug mefloquine to Guantánamo detainees: A critical analysis. Trop Med Int Health. 2012;17(10):1281-1288.
- Nevin RL.** Limbic encephalopathy and central vestibulopathy caused by mefloquine: A case report. Travel Med Infect Dis. 2012;10(3):144-151.
- 2011 Eick AA, Faix DJ, Tobler SK, **Nevin RL**, Lindler LE, Hu Z, Sanchez JL, MacIntosh VH, Russell KL, Gaydos JC. Serosurvey of Bacterial and Viral Respiratory Pathogens among Deployed U.S. Service Members. Am J Prev Med. 2011;41(6):573-580.
- Scher AI, Wu H, Tsao JW, Blom HJ, Feit P, **Nevin RL**, Schwab KA. MTHFR C677T Genotype as a Risk factor for Epilepsy Including Post-Traumatic Epilepsy in a Representative Military Cohort. J Neurotrauma. 2011;28(9):1739-1745.
- Ollivier L, **Nevin RL**, Darar HY, Bougère J, Saleh M, Gidenne S, Maslin J, Anders D, Decam C, Todesco A, Khaireh BA, Ahmed AA. Malaria in the Republic of Djibouti, 1998-2009. Am J Trop Med Hyg. 2011;85(3):554-559.
- Sutcliffe S, **Nevin RL**, Pakpahan R, Elliott DJ, Cole SR, De Marzo AM, Gaydos CA, Isaacs WB, Nelson WG, Sokoll LJ, Zenilman JM, Cersovsky SB, Platz EA. Prostate involvement during sexually transmitted infections as measured by prostate antigen concentration. Br J Cancer. 2011;105(5):602-605.
- 2010 Ollivier L, Decam C, Pommier de Santi V, Darar HY, Dia A, **Nevin RL**, Romand O, Bougère J, Deparis X, Boutin J. Gastrointestinal illnesses among French forces deployed to the Republic of Djibouti: French military health surveillance, 2005-2009. Am J Trop Med Hyg. 2010;83(4):944-950.
- Eick A, Ticehurst J, Tobler S, **Nevin R**, Lindler L, Hu Z, MacIntosh V, Jarman RG, Gibbons RV, Myint KSA, Gaydos J. Hepatitis E Seroprevalence and Seroconversion among U.S. Military Service Members Deployed to Afghanistan. J Infect Dis. 2010;202(9):1302-1308.
- Nevin RL.** Mefloquine prescriptions in the presence of contraindications: prevalence among U.S. military personnel deployed to Afghanistan, 2007. Pharmacoepidemiol Drug Saf. 2010;19(2):206-210.
- 2009 **Nevin RL.** Low validity of self-report in identifying recent mental health diagnosis among U.S. service members completing Pre-Deployment Health Assessment (PreDHA) and deployed to Afghanistan, 2007: a retrospective cohort study. BMC Public Health. 2009;9:376.
- Nevin RL.** Epileptogenic potential of mefloquine chemoprophylaxis: a pathogenic hypothesis. Malar J. 2009;8:188.
- Nevin RL**, Means GE. Pain and discomfort in deployed helicopter aviators wearing body armor. Aviat Space Environ Med. 2009;80(9):807-810.
- Bobo WV, **Nevin R**, Greene E, Lacy TJ. The effect of psychiatric third-year rotation setting on academic performance, student attitudes, and specialty choice. Acad Psychiatry. 2009;33(2):105-111.

- 2008 **Nevin RL**, Carbonell I, Thurmond V. Device-specific rates of needlestick injury at a large military teaching hospital. *Am J Infect Control.* 2008;36(10):750-752.
- Nevin RL**, Shuping EE, Frick KD, Gaydos JC, Gaydos CA. Cost and effectiveness of chlamydia screening among male military recruits: Markov modeling of complications averted through notification of prior female partners. *Sex Transm Dis.* 2008;35(8):705-713.
- Nevin RL**, Silvestri JW, Hu Z, Tobler SK, Trotta RF. Suspected pulmonary tuberculosis exposure at a remote U.S. Army camp in northeastern Afghanistan, 2007. *Mil Med.* 2008;173(7):684-688.
- Nevin RL**, Pietrusiak PP, Caci JB. Prevalence of contraindications to mefloquine use among U.S. military personnel deployed to Afghanistan. *Malar J.* 2008;7:30.
- Eick AA, Hu Z, Wang Z, **Nevin RL**. Incidence of mumps and immunity to measles, mumps and rubella among U.S. military recruits, 2000-2004. *Vaccine.* 2008;26(4):494-501.
- 2007 Knapik JJ, Jones SB, Darakjy S, Hauret K, **Nevin R**, Grier T, Jones B. Injuries and injury risk factors among members of the United States Army Band. *Am J Ind Med.* 2007;50(12):951-961.
- Hsu L, **Nevin RL**, Tobler SK, Rubertone MV. Trends in overweight and obesity among 18-year-old applicants to the U.S. military, 1993-2006. *J Adolesc Health.* 2007;41(6):610-612.
- Nevin RL**, Niebuhr DW. Rising hepatitis A immunity in U.S. military recruits. *Mil Med.* 2007;172(7):787-793.
- 2006 Grabenstein JD, **Nevin RL**. Mass immunization programs: principles and standards. *Curr Top Microbiol Immunol.* 2006;304:31-51.
- Nevin R**, Niebuhr D, Frick K, Grabenstein J. Improving soldier care through outcomes research: The Accession Screening and Immunization Program. *U.S. Army Medical Department Journal.* 2006;30-38.
- 2000 Norwich KH, **Nevin R**. The information of a welcher Weg experiment. *Il Nuovo Cimento.* 2000;115B:1137-1147.

Book Chapters

- 2019 **Nevin RL**. Neuropsychiatric Quinism: Chronic Encephalopathy Caused by Poisoning by Mefloquine and Related Quinoline Drugs. In: Ritchie EC, Llorente M, eds. *Veteran Psychiatry in the US.* Cham, Switzerland: Springer; 2019:315-331.
- 2018 **Nevin RL**, Ritchie EC. Ethical Dilemmas in the Forensic Psychiatric Evaluation of Guantánamo Detainees Mass-Administered Mefloquine. In: Griffith EEH, ed. *Ethics Challenges in Forensic Psychiatry and Psychology Practice.* New York, NY: Columbia University Press; 2018:223-236.
- 2017 **Nevin RL**. To Squander the Fighting Strength? Personal Experiences with Preventive Psychiatry and the Dilemma of Wartime Public Mental Health. In: Ritchie EC, Warner CH, McLay R, eds. *Psychiatrists in Combat.* Cham, Switzerland: Springer; 2017:145-155.

- Nevin RL**, Ritchie EC. Toxic Exposures from Service in the US Military: Effects on Reproductive and Sexual Health. In: Ritchie EC, ed. *Intimacy Post-Injury: Combat Trauma and Sexual Health*. London, England: Oxford University Press; 2017:165-178.
- 2015 **Nevin RL**, Ritchie EC. The Mefloquine Intoxication Syndrome: A Significant Potential Confounder in the Diagnosis and Management of PTSD and Other Chronic Deployment-Related Neuropsychiatric Disorders. In: Ritchie EC, ed. *Post-Traumatic Stress Disorder and Related Diseases in Combat Veterans*. Basel, Switzerland: Springer; 2015:257-278.
- Nevin RL**. Mefloquine and Posttraumatic Stress Disorder. In: Ritchie EC, ed. *Forensic and Ethical Issues in Military Behavioral Health. Textbook of Military Medicine*. Washington, DC: Borden Institute Press; 2015:275-296.
- Nevin RL**. Issues in the Prevention of Malaria Among Women at War. In: Ritchie EC, Naclerio AL, eds. *Women at War*. London, England: Oxford University Press; 2015:93-119.
- 2006 Engler RJM, Martin BL, **Nevin RL**, Grabenstein JD. Immunizations for military trainees. In: DeKoning B, ed. *Textbook of Military Medicine: Recruit Medicine*. Washington, DC: Borden Institute Press; 2006:205-226.
- Grabenstein JD, **Nevin RL**. Mass immunization programs: Principles and standards. In: Plotkin SA, ed. *Mass-Vaccination: Global Aspects – Progress and Obstacles*. Berlin, Germany: Springer-Verlag; 2006:31-51.

Letters

- 2019 **Nevin RL**. Unexpectedly Low Rates of Neuropsychiatric Adverse Effects Associated with Mefloquine Repurposed for Treatment of Glioblastoma. Cancer. 2019;125(8):1384-1385.
- Nevin RL**. Threats to the validity of studies of PTSD from unmeasured symptomatic exposure to mefloquine. *Br J Psych*. 2019;214(4):237.
- Nevin RL**. Bias and Confounding in Studies of Chronic Mental Health Effects from Mefloquine Exposure. *Am J Trop Med Hyg*. 2019;100(2):476-477.
- 2018 **Nevin RL**. Measurement of mefloquine exposure in studies of veterans' sleep disorders. *J Clin Sleep Med*. 2018;14(7):1273–1274
- Nevin RL**. Considerations in the repurposing of mefloquine for prevention and treatment of osteoporosis. *Bone*. 2018;114(9):304-305.
- Nevin RL**. Re: “A Decade of War: Prospective Trajectories of Posttraumatic Stress Disorder Symptoms Among Deployed US Military Personnel and the Influence of Combat Exposure”. *Am J Epi*. 2018;187(7):1573-1574.
- Nevin RL**. Confounding by Symptomatic Mefloquine Exposure in Military Studies of Post-Traumatic Stress Disorder. *Behav Med*. 2018;44(2):171-172.
- Nevin RL**. A Rearguard Defence: Mefloquine, Tafenoquine, and the Australian Army Malaria Institute. *J Mil Vet Health*. 2018;26(1):6-7.

- 2017** Nevin RL. Mefloquine Exposure May Confound Associations and Limit Inference in Military Studies of Posttraumatic Stress Disorder. Mil Med. 2017;182(11/12):1754.
- Nevin RL. Implications of Changes to the Mefloquine Product Monograph. Can J Hosp Pharm. 2017;70(4):323-324.
- Nevin RL. Misclassification and Bias in Military Studies of Mefloquine. Am J Trop Med Hyg. 2017;97(1):305.
- 2016** Nevin RL. Considerations in the Repositioning of Mefloquine for Anesthetic Indications. Anesthesiology. 2016;125(1):253-254.
- Nevin RL. Bias in Military Studies of Mefloquine. J. Travel Med. 2016;23(2):tav028.
- 2015** Nevin RL. Unexpected Pharmacological and Toxicological Effects of Tafenoquine. Occup Med. 2015;65(5):417.
- Nevin RL. Organic Depersonalization as a Chronic Sequela of Mefloquine Intoxication. Psychosomatics. 2015;56(1):103.
- 2013** Nevin RL, Ritchie EC. Suicides Among Military Personnel. JAMA. 2013;310(23):2563-2564.
- Nevin RL. Letter to the Editor regarding: The Incidence of and Risk Factors for Emergence Delirium in U.S. Military Combat Veterans. J Perianesth Nurs. 2013;28(6):334-336.
- Nevin RL, Caci J. Letter to the Editor regarding: Medical evacuations from Afghanistan during Operation Enduring Freedom, active and reserve components, U.S. Armed Forces, 7 October 2001-31 December 2012. MSMR. 2013;20(8):24.
- 2012** Nevin RL. Confounding and Bias in Studies of DMSS Vaccination Data. Vaccine. 2012;30(50):7146.
- Nevin RL. Falling Rates of Malaria Among U.S. Military Service Members in Afghanistan Substantiate Findings of High Compliance with Daily Chemoprophylaxis. Am J Trop Med Hyg. 2012;87(5):957-958.
- Nevin RL. Neuropharmacokinetic Heterogeneity of Mefloquine in Treatment of Progressive Multifocal Leukoencephalopathy. Intern Med. 2012;51(16):2257.
- Nevin RL. Limitations of Post-Marketing Surveillance in the Analysis of Risk of Pregnancy Loss Associated with Maternal Mefloquine Exposure. Clin Infect Dis. 2012;55(8):1167-1168.
- Nevin RL. Pharmacokinetic considerations in the repositioning of mefloquine for treatment of progressive multifocal leukoencephalopathy. Clin Neurol Neurosurg. 2012;114:1204-1205.
- Nevin RL. Hallucinations and persecutory delusions in mefloquine-associated suicide. Am J Forensic Med Pathol. 2012;33(2):e8.
- Nevin RL. Investigating Channel Blockers for the Treatment of Multiple Sclerosis: Considerations with Mefloquine and Carbenoxolone. J Neuroimmunol. 2012;243(1-2):106-107.
- Nevin RL. Biased Measurement of Neuropsychiatric Adverse Effects of Pediatric Mefloquine Treatment. Ped Infect Dis J. 2012;31(1):102.

- Nevin RL.** Mefloquine Blockade of Connexin 36 and Connexin 43 Gap Junctions and Risk of Suicide. Biol Psych. 2012;71(1):e1-2.
- 2011 **Nevin RL.** Mefloquine Neurotoxicity and Gap Junction Blockade: Critical Insights in Drug Repositioning. Neurotoxicology. 2011;32(6):986-987.
- Nevin RL.** Mefloquine Blockade of Connexin 43 (Cx43) and Risk of Pregnancy Loss. Placenta. 2011;32(9):712.
- Nevin RL.** Mental Health Standards for Combat Deployment. Psychiatr Serv. 2011;62(7):805.
- Nevin RL,** Ollivier L. In Reply to: Acute Diarrheas Among French Soldiers in Djibouti. Am J Trop Med Hyg. 2011;84(1):175.
- 2010 **Nevin RL.** Reply to Authors: Active Tuberculosis and Recent Overseas Deployment in the U.S. Military. Am J Prev Med. 2010;39(6):e39-40.
- 2008 **Nevin RL,** Silvestri JW, Hu Z, Tobler SK, Trotta RF. Reply to Authors: Suspected Pulmonary Tuberculosis Exposure at a Remote U.S. Army Camp in Northeastern Afghanistan, 2007. Mil Med. 2008;173(12):xviii.
- 2005 Pablo KR, Rooks PD, **Nevin RL.** Benefits of Screening for Hepatitis B Immunity in Military Recruits. J Infect Dis. 2005;192(12):2180-2181.

Technical Publications

- 2005 **Nevin RL.** The U.S. Army Accession Screening and Immunization Program. Edgewood, MD: U.S. Army Center for Health Promotion and Preventive Medicine; November 18, 2005. Technical Guide #310.

Presentation and Poster Awards

- 2007 Finalist, TRICARE Innovations Awards. Demonstrating the feasibility and cost-effectiveness of serologic screening for recruit immunizations: The U.S. Army Accession Screening and Immunization Program General Leonard Wood Army Community Hospital (GLWACH) pilot implementation. 2007 TRICARE Conference; January 29, 2007; Washington, DC.
- 2006 Finalist, Captain Gregory Gray Award for Military Operational Research. An economic analysis of serologic screening prior to immunization of Navy enlisted accessions. 45th Navy Occupational and Preventive Medicine Workshop; March 18 to March 23, 2006; Norfolk, VA.

Posters

- 2018 **Nevin RL.** Historical insights into the neurotoxicity of the 8-aminoquinolines: Implications for effective post-marketing surveillance of adverse effects associated with tafenoquine. Poster presented at: Johns Hopkins 2018 World Malaria Day Conference; April 25, 2018; Baltimore, MD.
- 2014 **Nevin RL.** Historical insights into the neurotoxicity of the 8-aminoquinolines: Implications for the development of tafenoquine and for global malaria control efforts. Poster presented at: Johns Hopkins 2014 World Malaria Day Conference; April 25, 2014; Baltimore, MD.

- 2013 Maxwell NM, **Nevin RL**, Stahl T, Block J, Shugarts S, Wu A, Dominy S, Blanco M, Kappelman-Culver S, Lee-Messer, C, Maldonado J. A 16 Year old Girl with Acute and Prolonged Mental Status Changes following Chloroquine Toxicity and Polypharmacy: Utility of Personalized Pharmacogenetic Testing. Poster presented at: 2nd International Congress on Personalized Medicine; July 25 to July 28, 2013; Paris, France.
- 2011 **Nevin R.** Subcortical Encephalopathy and Central Vestibulopathy Associated With Prophylactic Mefloquine Use: A Case Report. Poster presented at: 60th Annual Meeting of the American Society of Tropical Medicine and Hygiene; December 4 to December 8, 2011; Philadelphia, PA.
- Scher A, Wu H, Tsao J, Blom H, Feit P, **Nevin R**, Schwab K. MTHFR C677T Genotype as a Risk Factor for Epilepsy in a Representative Military Cohort. Poster presented at: 63rd Annual Meeting of the American Academy of Neurology; April 9 to April 16, 2011; Honolulu, HI.
- 2009 Jordan N, **Nevin R**, Allen A, Irish V, Gaydos J. Review of sexual health visits and well-woman exams among female military members deployed to Afghanistan. Poster presented at: 18th International Society for STD Research Meeting; June 28 to July 1, 2009; London, UK.
- Jacobs Muhlen T, Gaydos C, Meyers M, Gaydos J, **Nevin R**, Foster A. Surveillance for Chlamydia trachomatis among female military personnel newly assigned to U.S. Forces Korea. Poster presented at: 18th International Society for STD Research Meeting; June 28 to July 1, 2009; London, UK.
- 2008 Eick A, Hu Z, **Nevin R**, Tobler S. Seroprevalence of influenza H1 and H3 antibody among U.S. military accessions. [Poster 32]. Presented at: 2008 International Conference on Emerging Infectious Diseases; March 16 to March 19, 2008; Atlanta, GA.
- 2007 **Nevin RL**, Carbonell IS, Miller SN, Thurmond VA, Tobler S. Device-specific rates of needlestick injury at Walter Reed Army Medical Center: Establishing baseline metrics for process improvement. Poster presented at: 10th Annual Force Health Protection Conference; August 7 to August 10, 2007; Louisville, KY.
- Nevin RL**, Means GE, Tobler S. Longer flight times as a risk factor for increased pain among deployed rotary-wing aviators. Poster presented at: 10th Annual Force Health Protection Conference; August 7 to August 10, 2007; Louisville, KY.
- Nevin RL**, Hu Z, Tobler S. Suspected pulmonary tuberculosis exposure at a remote U.S. Army camp in northeastern Afghanistan, 2007. Poster presented at: 10th Annual Force Health Protection Conference; August 7 to August 10, 2007; Louisville, KY.
- Hsu LL, Martin CB, **Nevin RL**, Tobler S. Trends in overweight and obesity among 18-year-old applicants for U.S. military service, 1995-2006. Poster presented at: 10th Annual Force Health Protection Conference; August 7 to August 10, 2007; Louisville, KY.
- Eick AA, Wang Z, Hu Z, **Nevin R**, Tobler SK. Serosurveillance for H5N1: Large-scale serological testing for H5N1 exposure among U.S. military

service members deployed to Thailand, Indonesia, or Vietnam. Poster presented at: Options for the Control of Influenza VI Conference; June 17 to June 23, 2007; Toronto, Canada.

Knapik JJ, Jones SB, Darakjy S, **Nevin R**, Hauret KG, Canham-Chervak M, Jones BH. Musical athletes: Injuries and injury risk factors in the United States Army Band. Abstract in: Med Sci Sports Exerc. 2007;39(5 Supplement):S395. Poster presented at: 54th Annual Meeting of the American College of Sports Medicine; May 30 to June 2, 2007; New Orleans, LA.

Eick A, **Nevin RL**, Hu Z, Hughes H, Ford SM. Measles, mumps, and rubella immunity and concordance among U.S. military recruits, 2000-2004. Poster presented at: 46th Annual NEHC Occupational Health and Preventive Medicine Conference; March 17 to March 22, 2007; Norfolk, VA.

Hughes H, **Nevin RL**, Ford SM, Anderson RG. An economic analysis of the U.S. Army Accession Screening and Immunization Program (ASIP). [Poster 152]. Presented at: 41st National Immunization Conference (NIC); March 5 to March 8, 2007; Kansas City, MO.

Eick A, Wang Z, Hu Z, Tobler S, **Nevin R**, Rubertone M. Serosurveillance for avian and pandemic influenza: Utilizing the resources of the DoDSR and AMSA. Poster presented at: 2007 Seasonal and Pandemic Influenza Conference; February 1 to February 2, 2007; Crystal City, VA.

Nevin RL. First-time episodes of mental health specialty care resulting from Post-Deployment Health Reassessments (PDHRA): Analysis of health care utilization following screening and referral. Poster presented at: 2007 TRICARE Conference; January 29, 2007; Washington, DC.

Nevin RL, Hughes H, Rooks P, Pablo K. Demonstrating the feasibility and cost-effectiveness of serologic screening for recruit immunizations: The U.S. Army Accession Screening and Immunization Program General Leonard Wood Army Community Hospital (GLWACH) pilot implementation. Poster presented at: 2007 TRICARE Conference; January 29, 2007; Washington, DC.

2006

Nevin RL, Hughes H, Ford SM, Anderson R, Eick A. Risk of mumps in foreign-born U.S. military recruits deferred MMR vaccination following serologic confirmation of measles and rubella immunity. [Poster 841]. Presented at: 44th International Meeting of the Infectious Diseases Society of America (IDSA); October 15, 2006; Toronto, Canada.

Nevin RL, Green DJ. Mental health specialty clinic referrals generated during the Post-Deployment Health Reassessment process: Numbers of referrals, referral completion rates, and resultant first-time use among active duty soldiers. Poster presented at: 9th Annual Force Health Protection Conference; August 5 to August 12, 2006; Albuquerque, NM.

Nevin RL, Agnew RP. Numbers of Post-Deployment Health Reassessment forms outstanding among deployed soldiers: Cost estimates and estimated credentialed health care provider time required for resolution. Poster presented at: 9th Annual Force Health Protection Conference; August 5 to August 12, 2006; Albuquerque, NM.

Nevin RL, Kong V, Taubman S, Ford SM. Rates of influenza-like illness among active duty servicemembers receiving live attenuated influenza virus vaccine-trivalent versus trivalent inactivated influenza vaccine during the 2005-2006 influenza season. Poster presented at: 9th Annual Force Health Protection Conference; August 5 to August 12, 2006; Albuquerque, NM.

Nevin RL, Gustave J, Ford SM. Mumps cases reported in the military healthcare system during the 2006 epidemic: Geospatial comparison of counts against historical baselines among active duty servicemembers and beneficiaries. Poster presented at: 9th Annual Force Health Protection Conference; August 5 to August 12, 2006; Albuquerque, NM.

Nevin RL. Economic analysis of Latent Tuberculosis (LTBI) screening in military recruits: QuantiFERON-TB Gold In-Tube (QFT-GIT) versus Tuberculin Skin Testing (TST). [Poster PIN4]. In: Contributed Poster Presentations. Value in Health. 2006;9(3):A154. Presented at: 11th International Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR); May 21, 2006; Philadelphia, PA.

Rooks P, Pablo K, **Nevin R.** Demonstrating the feasibility and cost-effectiveness of serologic screening for recruit immunizations: The U.S. Army Accession Screening and Immunization Program General Leonard Wood Army Community Hospital pilot implementation. Poster presented at: 34th Annual Meeting of the Society of Armed Forces Medical Laboratory Scientists; March 26 to March 30, 2006; Reno, NV.

Nevin RL. An economic analysis of serologic screening prior to immunization of Navy enlisted accessions. Poster presented at: 45th Annual NEHC Occupational Health and Preventive Medicine Conference; March 18 to March 23, 2006; Norfolk, VA.

Nevin RL, Rubertone MV. Enabling improved DoD pandemic influenza preparedness: Capabilities of the proposed Armed Forces Health Surveillance Center (AFHSC). Presented at the 45th Annual NEHC Occupational Health and Preventive Medicine Conference; March 18 to March 23, 2006; Norfolk, VA.

2005

Nevin RL, Niebuhr DW. Incremental cost-benefit of screening for Anti-HAV in mass screening and immunization programs: Results of a 2004 U.S. Army seroprevalence study. [Poster 176]. In: Abstracts. Am J Trop Med Hygiene. 2005;73(6 Supplement):59. Presented at: 54th Annual Meeting of the American Society of Tropical Medicine and Hygiene (ASTMH); December 13, 2005; Washington, DC.

Bennett JW, **Nevin RL**, Polhemus ME, Ogutu BR. Cost-effectiveness of empiric antimalarial treatment among febrile children aged 0-4 years in areas of high malaria endemicity. Poster presented at the DC Chapter of the American College of Physicians Meeting; November 4, 2005; Bethesda, MD.

Nevin RL, Niebuhr DW. Seroprevalence of hepatitis A antibodies among new enlisted accessions to the U.S. military in 2004. [Poster 1026]. Presented at: 43rd Annual Meeting of the Infectious Diseases Society of America (IDSA); October 8, 2005; San Francisco, CA.

Nevin RL, Niebuhr DW. Hepatitis A seroprevalence among young adults: Effects of ACIP immunization recommendations. [Poster #LB01]. In:

Abstracts. Annals of Epidemiology. 2005;15(8):660. Accepted for presentation at: 2005 Meeting of the American College of Epidemiology (ACE); September 19, 2005; New Orleans, LA. (cancelled).

Nevin RL, Niebuhr DW, Frick KD. Mathematical modeling of occupational needlestick injury reduction in a U.S. Army mass immunization program through universal serologic screening for pre-existing immunity. [Poster 50443]. In: Poster Abstracts. American Journal of Infection Control. 2005;33(5):e139-140. Poster presented at: 32nd Annual Educational Conference and International Meeting of the Association for Professionals in Infection Control and Epidemiology (APIC); June 19, 2005; Baltimore, MD.

Nevin RL, Niebuhr DW, Frick KD. Cost-minimization analysis of serologic screening policy options for U.S. Army accession immunizations. [Poster PHP47]. In: Contributed Poster Presentations. Value in Health. 2005;8(3):436. Poster presented at: 10th International Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR); May 16, 2005; Washington, DC.

1999 Norwich KH, **Nevin R**. The information of simple physical events. In: Proceedings of the 25th Canadian Medical and Biological Engineering Conference. London, Ontario, Canada; June 1999; p 72. Poster presented at: 25th Canadian Medical and Biological Engineering Conference; June 1999; London, Ontario, Canada.

Presentations

2018 **Nevin RL**, Ritchie EC. A Clinician's Guide to Screening for Symptomatic Mefloquine Exposure and Evaluating Claims of Chronic Neuropsychiatric Effects from Mefloquine Poisoning. Presented at: 2018 Annual Meeting of the Association of Military Surgeons of the United States; November 29, 2018; National Harbor, MD.

2017 **Nevin RL**, Ritchie EC. A Clinician's Guide to Distinguishing Chronic Neuropsychiatric Effects from Mefloquine from Symptoms of PTSD/TBI. *Presentation 9825*. Presented at: 126th Annual Meeting of the Association of Military Surgeons of the United States; November 28, 2017; National Harbor, MD.

Nevin RL. Industry Sources of Population Risk Associated with Reports of Occupational Finger Amputations: Results of an Analysis of OSHA Severe Injury Report Data. *Abstract 138*. Presented at: 2017 American Occupational Health Conference; April 24, 2017; Denver, CO.

2015 **Nevin RL**, Ritchie EC. Mefloquine Intoxication In Clinical And Forensic Psychiatry. *Workshop 1763*. Presented at: 168th Annual Meeting of the American Psychiatric Association; May 20, 2015; Toronto, Canada.

2014 **Nevin RL**, Ritchie EC. Mefloquine and the U.S. Military. Presented at: 2014 Annual Continuing Educational Meeting of the Association of Military Surgeons of the United States; December 3, 2014; Washington, DC.

Nevin RL. Controversies Abound Around PTSD. *Workshop 5576*. Presented at: 167th Annual Meeting of the American Psychiatric Association; May 6, 2014; New York, NY.

- Nevin RL.** Anabolic Steroid and Supplement Use in the Military. *Workshop 5054.* Presented at: 167th Annual Meeting of the American Psychiatric Association; May 4, 2014; New York, NY.
- Nevin RL.** The Mefloquine Toxidrome in Clinical and Forensic Psychiatry. *Workshop 5072.* Presented at: 167th Annual Meeting of the American Psychiatric Association; May 3, 2014; New York, NY.
- 2013 **Nevin RL.** Mefloquine Neurotoxicity Plausibly Contributes to the Burden of PTSD, TBI, Suicide, and Violence within the U.S. Military. *Workshop 57.* Presented at: 166th Annual Meeting of the American Psychiatric Association; May 20, 2013; San Francisco, CA.
- Nevin RL.** Steroid Use and Consequences in the Military. *Workshop 83.* Presented at: 166th Annual Meeting of the American Psychiatric Association; May 20, 2013; San Francisco, CA.
- Nevin RL.** Controversies Around Posttraumatic Stress Disorder. *Workshop 73.* Presented at: 166th Annual Meeting of the American Psychiatric Association; May 20, 2013; San Francisco, CA.
- Nevin RL.** Violence and the American Soldier. *Workshop 40.* Presented at: 166th Annual Meeting of the American Psychiatric Association; May 19, 2013; San Francisco, CA.
- 2009 Jacobsmuhlen T, Gaydos C, Meyers M, Gaydos J, **Nevin R**, Foster A. Surveillance of chlamydia among female soldiers assigned to U.S. Forces Korea. Presented at: 2009 Force Health Protection Conference; August 18 to August 21, 2009; Albuquerque, NM.
- Sutcliffe S, **Nevin RL**, Pakpahan P, Bruzek DJ, Cole SR, DeMarzo AM, Gaydos CA, Issaacs WB, Nelson WG, Sokoll LJ, Zenilman JM, Cersovsky SB, Platz EA. Prostate involvement during sexually transmitted infections as measured by prostate specific antigen concentration. In: *J.Urol* 2009;181 Apr (4 Supplement 1):64. Presented at: 2009 Annual Meeting of the American Urological Association; April 25 to April 30, 2009; Chicago, IL.
- 2008 **Nevin RL**, Shuping EE, Frick KD, Gaydos JC, Gaydos CA. Cost-effectiveness of chlamydia screening policies among male military recruits. Presented at: 2008 International Conference on Emerging Infectious Diseases; March 16 to March 19, 2008; Atlanta, GA.
- 2007 Eick A, Wang Z, Hu Z, **Nevin RL**, Tobler S. Seasonal and avian influenza: Seroprevalence among deployed servicemembers and new accessions. Presented at: 10th Annual Force Health Protection Conference; August 7 to August 10, 2007; Louisville, KY.
- Nevin RL**, Eick A, Tobler S. Biobanking and biosurveillance: The biologic foundation for the future of armed forces health surveillance. Presented at: 10th Annual Force Health Protection Conference; August 7 to August 10, 2007; Louisville, KY.
- Nevin RL**, Tobler S, Caci J, Johnson J. Hepatitis E outbreak in eastern Afghanistan, 2007: Risk of seroconversion among U.S. personnel and implications for vaccine development. Presented at: 10th Annual Force Health Protection Conference; August 7 to August 10, 2007; Louisville, KY.

Ford S, Hughes H, Nevin RL. Outcomes research for military vaccination policy: The U.S. Army Accession Screening and Immunization Program. Presented at: 12th International Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR); May 21, 2007; Arlington, VA.

2006

Nevin RL, Shuping EE, Frick KD, Gaydos JC, Gaydos CA. Cost-effectiveness of chlamydia screening among male military recruits. In: Chlamydial Infections: Proceedings of the Eleventh International Symposium on Human Chlamydial Infections. International Chlamydia Symposium; San Francisco, CA; pp 477-480. Presented at: 11th International Symposium on Human Chlamydial Infections; June 18 to June 23, 2006; Niagara-on-the-Lake, Canada.

Nevin RL, Rubertone MV. Numbers and frequencies of specimens in the Department of Defense serum repository. Presented at: 2006 Annual Meeting of the International Society of Biologic and Environmental Repositories; May 1, 2006; Bethesda, MD.

Nevin RL. The U.S. Army Accession Screening and Immunization Program at Army training centers. Presented at: U.S. Army Training and Doctrine Command Initial Entry Training Soldier Care Conference; April 11, 2006; Hampton, VA.

Nevin RL. Improving the efficiency of accession medical processing: The MEPCOM role in screening. Presented at: 2nd Annual Joint Accessions Research & Best Practices Symposium; April 6, 2006; San Antonio, TX.

Nevin RL. An economic analysis of serologic screening prior to immunization of Navy enlisted accessions. Presented at: 45th Annual NEHC Occupational Health and Preventive Medicine Conference; 8th Operational Research Competition; March 18, 2006; Norfolk, VA.

2005

Bennett JW, **Nevin RL**, Polhemus ME. Cost-effectiveness of empiric antimalarial treatment among febrile children aged 0-4 years in areas of high malaria endemicity. Presented at: Army American College of Physicians Meeting; November 19, 2005; San Antonio, TX.

Nevin RL. The U.S. Army Accession Screening and Immunization Program: Implementation and directions for future research. Presented at: U.S. Army Accessions Command Accessions Research Consortium; October 20, 2005; Hampton, VA.

Nevin RL. Cost-effectiveness modeling of serologic screening policy options for U.S. Army accession immunizations: Implications for improving the efficiency of accession medical processing. Presented at: 1st Annual Accessions Training Research & Best Practices Symposium; August 25, 2005; Lincolnshire, IL.

Nevin RL, Niebuhr DW, Frick KD. Implementing cost-effective serologic screening for recruit immunizations: The U.S. Army Accession Screening and Immunization Program (ASIP) business plan. Presented at: 8th Annual U.S. Army Center for Health Promotion and Preventive Medicine Force Health Protection Conference; August 12, 2005; Louisville, KY.

Nevin RL. Improving the efficiency of military accession immunization programs through centralized screening for pre-existing immunity among Department of Defense applicants at military entrance processing

stations: Variable cost modeling of policy options. Presented at: 8th Annual U.S. Army Center for Health Promotion and Preventive Medicine Force Health Protection Conference; August 12, 2005; Louisville, KY.

Invited Talks and Grand Rounds

- 2019 **Nevin RL.** Identifying and Evaluating Sources of Evidence of Quinism: A Novel Disease Affecting U.S. Veterans. Presentation to the National Academies of Sciences, Engineering, and Medicine Committee on Long-Term Health Effects of Antimalarial Drugs; January 28, 2019: Washington, DC.
- 2017 **Nevin RL.** The New “Great Imitator”: Chronic Neuropsychiatric Adverse Effects from Mefloquine. Mental Health Grand Rounds, Washington DC VA Medical Center; October 12, 2017: Washington, DC.
- Nevin RL.** The New “Great Imitator”: Chronic Neuropsychiatric Adverse Effects from Mefloquine. Grand Rounds Presentation to the Department of Medicine, Washington DC VA Medical Center; May 31, 2017: Washington, DC.
- 2014 **Nevin RL.** Central Nervous System Toxicity of Antiparasitic Quinolines. Presentation to the Johns Hopkins University School of Medicine, Department of Clinical Pharmacology; April 2, 2014: Baltimore, MD.
- 2013 **Nevin RL.** An Antimalarial Toxidrome? New Insights into the Psychiatric Adverse Effects of Mefloquine (Lariam®). Presentation to the Veterans Health Administration Northwest Mental Illness Research Education & Clinical Center; December 18, 2013. Online.
- Nevin RL.** Mefloquine and Special Forces: An Update. Presentation to the Green Beret Foundation Annual Board Meeting; November 9, 2013: Fayetteville, NC.
- Nevin RL.** Mefloquine limbic encephalopathy: a model of impulsive suicidality. Presentation to the James Kirk Bernard Foundation Science Planning Meeting; March 18, 2013: Denver, CO.
- Nevin RL.** Mefloquine neurotoxicity. Presentation to Food and Drug Administration, Office of the Commissioner/Office of Special Health Issues (OSHI); January 11, 2013: White Marsh, MD.
- 2011 **Nevin RL.** Neuropsychiatric adverse events associated with mefloquine. Presentation to the Special Operations Medical Association 2011 Annual Meeting; December 12, 2011; Tampa, FL.
- Nevin RL.** Neuropsychiatric adverse events associated with mefloquine. Presentation to the U.S. Army Special Operations Command Preventive Medicine Symposium; April 20, 2011. Fayetteville, NC.
- 2010 **Nevin RL.** Neuropsychiatric adverse events associated with mefloquine. Presentation to the Special Operations Medical Association 2010 Annual Meeting; December 16, 2010; Tampa, FL.
- Nevin RL.** The epidemiology of weaponized disease agent outbreaks. Presentation to the Uniformed Services Academy of Family Physicians 2010 Annual Meeting; February 24, 2010; New Orleans, LA.

- 2006 **Nevin RL.** Uses of the Department of Defense serum repository in support of vaccine-related studies: Case-control, cohort, and cross-sectional study designs. Presentation to the Johns Hopkins Bloomberg School of Public Health Department of International Health; October 5, 2006; Baltimore, MD.
- Nevin RL.** The U.S. Army Accession Screening and Immunization Program. Presentation to the Military Vaccine Agency (MILVAX) Annual Meeting; June 6, 2006; Arlington, VA.
- Nevin RL.** Advancing research in seroepidemiology: Visions for the future of the Department of Defense serum repository. Presentation to the National Institutes of Health Autoimmune Diseases Coordinating Committee, NIH; February 24, 2006; Rockville, MD.
- 2005 **Nevin RL.** The Department of Defense serum repository: Opportunities for seroepidemiologic research utilizing the world's largest serum repository. Presentation to the Johns Hopkins Bloomberg School of Public Health Department of Epidemiology; October 31, 2005; Baltimore, MD.

Acknowledgements

- 2016 Avilés-Santa ML, Hsu LL, Arredondo M, Menke A, Werner E, Thyagarajan B, Heiss G, Teng Y, Schneiderman N, Giachello AL, Gallo LC, Talavera GA, Cowie CC. Differences in Hemoglobin A1c Between Hispanics/Latinos and Non-Hispanic Whites: An Analysis of the Hispanic Community Health Study/Study of Latinos and the 2007-2012 National Health and Nutrition Examination Survey. *Diabetes Care.* 2016;39(6):1010-1017.
- 2012 Wang Z, Chen F, Ward M, Bhattacharyya T. Compliance with Surgical Care Improvement Project Measures and Hospital-Associated Infections Following Hip Arthroplasty. *J Bone Joint Surg Am.* 2012;94(15):1359-1366.
- 2011 Hutfless S, Matos P, Talor MV, Caturegli P, Rose NR. Significance of Prediagnostic Thyroid Antibodies in Women with Autoimmune Disease. *J Clin Endocrin Metab.* 2011;96(9):e1466-71.
- 2009 Ollivier L, Romand O, Marimoutou C, Michel R, Pognant C, Todesco A, Migliani R, Baudon D, Boutin J. Use of short message service (SMS) to improve malaria chemoprophylaxis compliance after returning from a malaria endemic area. *Malar J.* 2009;8:236.
- 2007 Army Medical Surveillance Activity. Concordance of measles and rubella immunity with immunity to mumps; enlisted accessions, U.S. armed forces, 2000-2004. *MSMR.* 2007;13(2):10-12.
- 2006 Munger KL, Levin LI, Hollis BW, Howard NS, Ascherio A. Serum 25-hydroxyvitamin D levels and risk of multiple sclerosis. *JAMA.* 2006;296(23):2832-8.
- Army Medical Surveillance Activity. Hepatitis A immunity among enlisted accessions to the U.S. Army, Fort Benning, GA, April-August 2006. *MSMR.* 2006;12(7):18-20.

Army Medical Surveillance Activity. Incidence of mumps in relation to universal MMR vaccination versus vaccination after serological screening of U.S. military recruits, 2000-2004. MSMR. 2006;12(7):21-23.

Army Medical Surveillance Activity. Hepatitis B immunity among U.S. Army basic trainees, Fort Leonard Wood, MO, July 2005-December 2005. MSMR. 2006;12(5):7-8.

EXHIBIT B

Classification: UNCLASSIFIED//FOR OFFICIAL USE ONLY

***** UNCLASSIFIED / *****

Subject: CEASING USE OF MEFLOQUINE IN US ARMY SPECIAL OPERATIONS COMMAND UNITS

Originator: MESSAGE CENTER(MC)

DTG: 132013Z Sep 13

Precedence: ROUTINE

DAC: General

To: USASFC MSG CENTER(MC), USAJFKSWCS MSG CTR(MC), ARSOAC MSG CENTER(MC), MISOC
MSG CENTER(MC), CDR75RGRRT(SC), 95TH CA BDE MSG CTR(MC), 528 SUST BDE MSG
CTR(MC), JTF SWORD MSG CENTER(MC)

UNCLASSIFIED/

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PASSING INSTRUCTION: MESSAGE CENTER, PASS TO DIR ACE

13XXXXSEP2013

FM CDR USASOC

TO CDR USASFC

CDR USAJFKSWCS

CDR USASOAC

CDR MISOC

CDR 75TH RANGER REGIMENT

CDR 95TH CA BDE

CDR 528TH SBSO(A)

CDR TF SWORD

DIR ACE

BT

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MSGID/GENADMIN/USASOC G33 OPNS//

REF/A/MEMORANDUM/OSD-HA/15APR2013//

REF/B/MEMORANDUM/OSD-HA/4FEB2009//

REF/C/DRUG SAFETY COMMUNICATION/FDA/29JUL2013// REF/D/DODI/DOD/20MAR2009//

REF/E/DOCUMENT/NCMI/23AUG2011

REF/F/ARTICLE/J AM ACAD PSYCHIATRY LAW/41:2013// NARR/REF A IS OSD-HA MEMORANDUM
"GUIDANCE ON MEDICATIONS FOR PROPHYLAXIS OF MALARIA". REF B IS HA POLICY 09-017
"POLICY MEMORANDUM ON THE USE OF MEFLOQUINE (LARIUM) IN MALARIA PROPHYLAXIS". REF
C IS FDA DRUG SAFETY COMMUNICATION "FDA APPROVES LABEL CHANGES FOR ANTIMALARIAL
DRUG MEFLOQUINE HYDROCHLORIDE DUE TO RISK OF SERIOUS PSYCHIATRIC AND NERVE SIDE
EFFECTS". REF D IS DODI 6420.01 NATIONAL CENTER FOR MEDICAL INTELLIGENCE. REF E
IS DEFENSE INTELLIGENCE REFERENCE DOCUMENT DIA-16-1108-093 "USING NCMI MALARIA
RISK ASSESSMENTS TO SUPPORT CHEMOPROPHYLAXIS CHOICES". REF F IS A PEER REVIEWED
ARTICLE "PSYCHIATRIC SIDE EFFECTS OF MEFLOQUINE: APPLICATIONS TO FORENSIC
PSYCHIATRY".// 1. (U) SITUATION. ON 29 JUL 2013 THE FDA ANNOUNCED A BLACK BOX
WARNING FOR MEFLOQUINE IN A SIGNIFICANT CHANGE TO THE DRUG'S APPROVED LABELING.
UPDATED FDA GUIDANCE NOW EXPANDS ON PRIOR GUIDANCE TO EMPHASIZE THE NEED TO
DISCONTINUE MEFLOQUINE SHOULD ANY NEUROLOGICAL OR PSYCHIATRIC SYMPTOMS DEVELOP
WHILE TAKING THE DRUG AND HIGHLIGHTS THAT CERTAIN NEUROLOGIC SYMPTOMS HAVE BEEN
REPORTED TO BE PERMANENT. FURTHER, MILITARY AUTHORS WRITING FOR THE CDC HAVE
NOTED THAT THE SYMPTOMS CAUSED BY MEFLOQUINE MAY "CONFOUND THE DIAGNOSIS" OF PTSD
AND TBI. THE UPDATED PRODUCT DOCUMENTATION NOTES THAT PSYCHIATRIC SYMPTOMS
RANGING FROM ANXIETY, FEELING RESTLESS OR CONFUSED, PARANOIA AND DEPRESSION TO

HALLUCINATIONS AND PSYCHOTIC BEHAVIOR CAN OCCUR AND CONTINUE FOR MONTHS OR YEARS AFTER MEFLUQUINE USE; CASES OF SUICIDAL IDEATION AND SUICIDE HAVE BEEN REPORTED.// 2. (U) MISSION. USASOC COMMANDERS AND MEDICAL PERSONNEL WILL DECREASE THE RISK OF NEGATIVE DRUG RELATED SIDE EFFECTS BY CEASING USE OF MEFLUQUINE AS A MEANS OF CHEMOPROPYLAXIS FOR THE PREVENTION OF MALARIA; CONCURRENTLY ADDRESS AND ASSESS THE POSSIBILITY AND IMPACT OF MEFLUQUINE TOXICITY IN THEIR POPULATIONS.// 3. (U) EXECUTION.

3.A. CONCEPT OF THE OPERATION.

3.A.1. USASOC MEDICAL PERSONNEL WILL IMMEDIATELY CEASE THE PRESCRIBING AND USE OF MEFLUQUINE FOR MALARIA PROPHYLAXIS.

3.A.2. PERSONNEL CURRENTLY TAKING MEFLUQUINE FOR PREVENTION OF MALARIA WILL TRANSITION TO ONE OF THREE ALTERNATIVE OPTIONS FOR PROPHYLAXIS DEPENDING ON THEIR LOCATION, DRUG RESISTANCE, AND THE MALARIA RISK.

3.A.3. PERSONNEL CONDUCTING MEDICAL INTELLIGENCE PREP OF THE ENVIRONMENT (MPOE) WILL REVIEW REF E TO IDENTIFY PREVALENCE AND TYPE OF MALARIA AS WELL AS DRUG RESISTANCE TO ENSURE THE APPROPRIATE USE OF EFFECTIVE MEDICATIONS.

3.A.3.A. MEDICAL PERSONNEL WILL ENSURE THAT THE SELECTION OF ATOVAQUONE-PROGUANIL (MALARONE), DOXYCYCLINE OR CHLOROQUINE IS DRIVEN BY COMMAND POLICY, PREVALENCE AND TYPE OF MALARIA, INDIVIDUAL CONTRAINDICATIONS, AND REGIONALLY UNIQUE DRUG RESISTANCE.

3.A.3. PERSONNEL REDEPLOYING FROM P. VIVAX ENDEMIC AREAS (IAW REF E) WILL CONTINUE TO TAKE FOURTEEN DAYS OF APPROVED POST-EXPOSURE CHEMOPROPHYLAXIS (PRIMAQUINE).

3.A.4. MEDICAL PERSONNEL WILL ADDRESS AND, IF APPROPRIATE, REFER REPORTS OF SUSPECTED CASES OF "MEFLUQUINE TOXICITY" IAW COORDINATING INSTRUCTIONS.

3.B. COORDINATING INSTRUCTIONS.

3.B.1. COMMANDERS AND SUPERVISORS AT ALL LEVELS WILL:

3.B.1.A. ENSURE THAT DEPLOYED PERSONNEL CONTINUE TO BE PROTECTED FROM MALARIA THROUGH THE USE OF ATOVAQUONE-PROGUANIL, DOXYCYCLINE AND CHLOROQUINE (PRE-EXPOSURE) AND PRIMAQUINE (POST-EXPOSURE FOR P. VIVAX AND P. OVALE ENDEMIC AREAS) IAW COMMAND POLICY.

3.B.1.B. APPROVED MEDICATIONS FOR MALARIA CHEMOPROPHYLAXIS IN USASOC.

3.B.1.B.1. ATOVAQUONE-PROGUANIL IS THE FIRST LINE CHEMOPROPHYLAXIS FOR USASOC PERSONNEL BASED ON THE RESIDUAL PROTECTION AND MINIMAL SIDE-EFFECT PROFILE. DOXYCYCLINE IS AN EQUALLY EFFECTIVE MEDICATION FOR THE PREVENTION OF MALARIA AND NO KNOWN RESISTANCE EXISTS. IF EVIDENCE OF ATOVAQUONE-PROGUANIL RESISTANCE EXISTS OR EMERGES, DOXYCYCLINE IS THE DRUG OF CHOICE. PRE-DEPLOYMENT RESEARCH IS CRITICAL TO DETERMINING THE MOST APPROPRIATE AND EFFECTIVE CHEMOPROPHYLAXIS FOR ANY DEPLOYMENT.

3.B.1.B.2. THE EFFECTIVENESS OF CHLOROQUINE VARIES BY TYPE OF MALARIA AND BY REGION.

3.B.1.B.2.A. P. FALCIPARUM: HIGH LEVELS OF RESISTANCE RESULTING FROM YEARS OF HEAVY USE HAVE RENDERED CHLOROQUINE INEFFECTIVE IN THE PREVENTION OF P. FALCIPARUM MALARIA IN AFRICOM, CENTCOM, PACOM, AND A FEW AREAS OF SOUTHCOM. CHLOROQUINE REMAINS AN EFFECTIVE CHEMOPROPHYLAXIS AGAINST P. FALCIPARUM ONLY IN PARTS OF SOUTHCOM, INCLUDING BELIZE, COSTA RICA, THE DOMINICAN REPUBLIC, EL SALVADOR, HAITI, HONDURAS, NICARAGUA, AND PARAGUAY.

3.B.1.B.2.B. P. VIVAX: HIGH LEVELS OF CHLOROQUINE-RESISTANT P. VIVAX HAVE BEEN REPORTED IN TURKEY AND INDONESIA, AND RESISTANCE IS INCREASINGLY BEING DOCUMENTED THROUGHOUT MUCH OF ASIA. INCREASING RESISTANCE HAS BEEN NOTED IN PARTS OF SOUTHCOM, PARTICULARLY IN BRAZIL AND COLOMBIA. DESPITE MANY YEARS OF CHLOROQUINE

USE, EVEN AS SINGLE-DRUG THERAPY, CHLOROQUINE REMAINS LARGELY EFFECTIVE AGAINST P. VIVAX IN MUCH OF CENTCOM.

3.B.1.B.3. POST-EXPOSURE CHEMOPROPHYLAXIS WITH PRIMAQUINE IS NECESSARY TO KILL THE LIVER STAGE OF THE P. VIVAX AND P. OVALE MALARIA PARASITES. IF NOT TREATED WITH PRIMAQUINE THESE TYPES OF MALARIA WILL RELAPSE UNTIL THE LIVER STAGE OF THE PARASITE IS TREATED.

3.B.1.B.3.A. PRIMAQUINE IS NOT BE USED IN PERSONNEL WITH G6PD DEFICIENCY WITHOUT THE CONSULTATION OF AN INFECTIOUS DISEASE SPECIALIST.

3.C. MEFLOQUINE TOXICITY.

3.C.1. SEE ENCLOSURE 1 FOR DETAILS REGARDING THE SYMPTOMS OF MEFLOQUINE TOXICITY BASED ON ITS POSSIBLE EFFECTS ON THE LIMBIC SYSTEM AND BRAINSTEM.

3.C.2. CLINICAL EXPERTISE ON MEFLOQUINE TOXICITY IS CURRENTLY LIMITED; HOWEVER THERE ARE INDIVIDUAL CLINICIANS AVAILABLE FOR CONSULTATION.

3.C.2.A. CLINICAL QUERIES REGARDING MEFLOQUINE-RELATED VESTIBULAR DISORDERS MAY BE DIRECTED TO CAPT MICHAEL E. HOFFER, MC, NAVAL MEDICAL CENTER SAN DIEGO, MICHAEL.HOFFER@MED.NAVY.MIL, (619) 532-6964.

3.C.2.B. GENERAL CLINICAL INQUIRIES REGARDING SUSPECTED CASES OF MEFLOQUINE TOXICITY MAY BE SUBMITTED THROUGH THE WAR RELATED ILLNESS AND INJURY STUDY CENTER (WRIISC) WEBSITE: WWW.WARRELATEDILLNESS.VA.GOV.

3.C.3. PERSONNEL CURRENTLY IN OR TRANSITIONING TO THE VETERANS HEALTHCARE ADMINISTRATION (VHA) CAN BE REFERRED TO THE WRIISC BY A PROVIDER IN THE VHA. POC AT THE WRIISC IS DR. DREW HELMER, DREW.HELMER@VA.GOV, (908) 202-4382.

4. (U) SUSTAINMENT. N/A.//

5. (U) USASOC POCS.

5.A.1. SURGEON CHOPS IS LTC CURTIS DOUGLASS 910-432-3038
CURTIS.W.DOUGLASS@AHQB.SOC.MIL.

5.A.2. USASOC SURGEON POC IS COL JENNIFER CACI 910-432-9884
JENNIFER.CACI@AHQB.SOC.MIL.

AUTHENTICATION/BROWER, COL, COFS, OFFICIAL: DODGE, COL, G3//

AKNLDG/YES/INST: ALL CSC/U ACKNLDG UPON RECEIPT, TO DSN 236-0371, COMM (910) 396-0371.// ENCLOSURE 1. (U) INFORMATION PAPER: SIDE EFFECTS OF MEFLOQUINE.// BT UUUU

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INFORMATION PAPER

SUBJECT: Side Effects of Mefloquine

1. **Purpose.** On 29 July 2013 the FDA announced a black box warning for mefloquine in a significant change to the drug's approved labeling. Updated FDA guidance now expands on prior guidance to emphasize the need to discontinue mefloquine should any neurological or psychiatric symptoms develop while taking the drug.
2. **Summary.** The development of any neurological or psychiatric symptoms may be an indication of a personal risk of mefloquine toxicity. These symptoms may occur at any time during use of mefloquine, even among individuals who have previously tolerated the drug. Recent changes in the product documentation warn of the potential for long lasting serious mental health problems and based on the widespread use of mefloquine within ARSOF consideration must be made for the impact of this medication on our population.
3. **Background and Discussion.**
 - a. Since 1989 mefloquine product labeling has warned that if symptoms of "anxiety, depression, restlessness or confusion" developed while taking the drug, the drug must be discontinued.
 - b. Some U.S. military personnel who were prescribed the drug despite a history of mental illness or TBI may have incorrectly attributed side-effects to their pre-existing condition, rather than to the drug. As a result, military personnel with persistent symptoms following use of mefloquine should be evaluated for the effects of possible drug toxicity.
 - d. The CDC now notes that the symptoms caused by mefloquine may "confound the diagnosis" of PTSD and TBI. Therefore lasting symptoms resembling those of PTSD or TBI without clear attribution to personal history need to be considered in the differential diagnosis.
 - e. Careful attention must also be paid to symptoms previously contributing to the diagnosis of malingering, conversion, somatoform, or personality disorders, as the subtle neurological and psychiatric effects of mefloquine toxicity may mimic or be mistaken for these disorders.
 - f. Neurologic symptoms such as dizziness or vertigo, tinnitus, and loss of balance have been reported. These adverse reactions may occur early in the course of mefloquine use and in some cases have been reported to continue for months or years after mefloquine has been stopped. Dizziness or vertigo, tinnitus and loss of balance have been reported to be permanent in some cases.

g. Psychiatric symptoms ranging from anxiety, paranoia and depression to hallucinations and psychotic behavior can occur with mefloquine use. Symptoms may occur early in the course of mefloquine use and in some cases these symptoms have been reported to continue for months or years after mefloquine has been stopped. Cases of suicidal ideation and suicide have been reported. The updated patient U.S. medication guide expands the list of psychiatric symptoms that can occur to include "feeling restless, unusual behavior or feeling confused".

h. Literature review suggests additional psychiatric symptoms may occur from the drug's toxicity, to include persistent sleep disorders and nightmares, cognitive problems, particularly deficits in short-term memory, panic attacks and agoraphobia, and changes in mood and personality, particularly irritability and decreased impulse control.

i. It is highly unlikely that individuals who have previously taken mefloquine without issue will suffer ill effects in the absence of future use.

j. There is limited support for clinical queries regarding mefloquine toxicity at this time. However, specific questions regarding mefloquine-related vestibular disorders may be directed to CAPT Michael E. Hoffer, MC, Naval Medical Center San Diego, michael.hoffer@med.navy.mil, office (619) 532-6964. General inquiries regarding suspected cases of mefloquine toxicity may be submitted through the War Related Illness and Injury Study Center (WRIISC) website: www.warrelatedillness.va.gov. The USASOC Surgeon's Office (910-432-9884) is also available to field queries and assist in finding clinical support.

EXHIBIT C

FDA Drug Safety Communication: FDA approves label changes for antimalarial drug mefloquine hydrochloride due to risk of serious psychiatric and nerve side effects

[7-29-2013] The U.S. Food and Drug Administration (FDA) is advising the public about strengthened and updated warnings regarding neurologic and psychiatric side effects associated with the antimalarial drug mefloquine hydrochloride. A boxed warning, the most serious kind of warning about these potential problems, has been added to the drug label. FDA has revised the patient Medication Guide dispensed with each prescription and wallet card to include this information and the possibility that the neurologic side effects may persist or become permanent. The neurologic side effects can include dizziness, loss of balance, or ringing in the ears. The psychiatric side effects can include feeling anxious, mistrustful, depressed, or having hallucinations (For a more complete list of potential side effects, see Additional Information for Patients).

Neurologic side effects can occur at any time during drug use, and can last for months to years after the drug is stopped or can be permanent. Patients, caregivers, and health care professionals should watch for these side effects. When using the drug to prevent malaria, if a patient develops neurologic or psychiatric symptoms, mefloquine should be stopped, and an alternate medicine should be used. If a patient develops neurologic or psychiatric symptoms while on mefloquine, the patient should contact the prescribing health care professional. The patient should not stop taking mefloquine before discussing symptoms with the health care professional.

Malaria is a serious disease caused by a parasite that commonly infects mosquitoes, which then bite humans. It is a major cause of death worldwide but is less common in the United States. The disease is a problem primarily in developing countries with warm climates. Persons who travel to these countries may be at risk of malaria infection and should take drugs to prevent or reduce that risk. People with malaria often experience fever, chills, and flu-like symptoms. Drugs must be taken to treat the disease if you have been infected, but may, themselves, have side effects.

FDA will continue to evaluate the safety of mefloquine and will communicate with the public again if additional information becomes available.

FACTS about mefloquine tablets

- Antimalarial drug indicated for the treatment of mild to moderate acute malaria caused by mefloquine-susceptible *P. falciparum* and *P. vivax*.
- Also indicated for the prevention of malaria infections by *P. falciparum* (including chloroquine-resistant *P. falciparum*) and *P. vivax*.

- Previously marketed under the brand name Lariam; however, the Lariam product is not currently marketed. Generic mefloquine products are available in the US.

Additional Information for Patients

- Mefloquine may cause dizziness, balance problems, and ringing in the ears. These symptoms can occur at any time during use and can last for months to years after the drug is stopped or can be permanent.
- Contact your health care professional right away if you take mefloquine and experience any of the following signs and symptoms; it may be necessary to stop mefloquine and take another medication to prevent malaria, but do not do so without first talking with your health care professional:
 - Dizziness
 - Balance problems such as a feeling that you or things around you are moving or spinning (vertigo)
 - Ringing in your ears (tinnitus)
 - Convulsions or seizures
 - Inability to sleep (insomnia)
- If you already have or develop any mental problems, you should contact your health care professional right away. These mental problems include:
 - Anxiety
 - Feelings of mistrust towards others (paranoia)
 - Seeing or hearing things that are not there (hallucinations)
 - Depression
 - Restlessness
 - Confusion
 - Behavior that is unusual
- Carefully read the Medication Guide and the wallet card that come with your mefloquine prescription.
- Discuss any questions or concerns about mefloquine with your health care professional.

- Report any side effects you experience to your health care professional and the FDA MedWatch program, using the information in the Contact FDA box at the bottom of the page.

Additional Information for Health Care Professionals

- Encourage your patients to contact you if they develop neurologic or psychiatric symptoms.
- Make sure your patients receive the Medication Guide with every prescription.
- Be alert to the potential for the development of neurologic and psychiatric adverse reactions in patients using the drug. If the patient develops psychiatric or neurologic symptoms during preventive use, mefloquine should be stopped and an alternate antimalarial medicine should be used.
- Neurologic and psychiatric symptoms can be difficult to identify in children.
- Report adverse reactions involving mefloquine to the FDA MedWatch program, using the information in the Contact FDA box at the bottom of the page.

Data Summary

The mefloquine drug label already states that mefloquine should not be prescribed to prevent malaria in patients with major psychiatric disorders or with a history of seizures. The changes to the mefloquine drug label better describe the possibility of persistent neurologic (vestibular) adverse effects after mefloquine is discontinued and the possibility of permanent vestibular damage.

In conducting its assessment of vestibular adverse reactions associated with mefloquine use, FDA reviewed adverse event reports from the FDA Adverse Event Reporting System (FAERS) and the published literature, identifying patients that reported one or more vestibular symptoms such as dizziness, loss of balance, tinnitus, and vertigo. Patients who reported vestibular adverse reactions were healthy with no known major medical problems prior to taking mefloquine for malaria prophylaxis. Some patients did not suspect their symptoms were due to mefloquine and continued to take the drug after the symptoms started.

In many cases, these symptoms developed early in the course of treatment, sometimes after one or two doses of mefloquine. Dizziness, loss of balance, tinnitus, or vertigo persisted for months to years after mefloquine was discontinued, and permanent vestibular damage was diagnosed in some cases. These symptoms interfered with patients' daily activities and ability to work. Some cases described abnormal vestibular function tests and a diagnosis of vestibular damage. In some cases, the vestibular damage was thought to be caused by mefloquine use. Some patients reported recurrence of psychiatric and vestibular symptoms when they took mefloquine for the second time. Patients who experienced vestibular symptoms usually had concomitant psychiatric symptoms such as anxiety, confusion, paranoia, and depression. Some of the psychiatric symptoms persisted for months to years after mefloquine was discontinued.

FDA will continue to evaluate the safety of mefloquine and will communicate again if additional information becomes available.

EXHIBIT D



THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

17 Jan 2012

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)
COMMANDER, JOINT TASK FORCE NATIONAL CAPITAL
REGION MEDICAL

SUBJECT: Service Review of Mefloquine Prescribing Practices

Some deploying Service members have been provided mefloquine for malaria prophylaxis without appropriate documentation in their medical records and without proper screening for contraindications. In addition, not all individuals have been provided the required mefloquine medication guide and wallet information card, as required by the Food and Drug Administration. Providing our Service members with the highest quality care is one of the most important things we do; thus, it is incumbent upon us to ensure our Service members are appropriately screened and informed about the medicines they are taking, and we must accurately record their prescriptions in their medical records.

The Department of Defense Instruction 6490.03, "Deployment Health," dated August 11, 2006, addresses the administration of Force Health Protection prescription products and remains in effect. It requires qualified personnel to dispense all Force Health Protection prescription products under a prescription, and that the prescription be recorded in individual medical records.

Please review your Service's quality assurance procedures for the use of mefloquine, with particular emphasis placed on screening for contraindications, documentation of patient education, and documentation of mefloquine prescriptions in medical records. The contraindications for mefloquine use are discussed in the attached Health Affairs Policy 09-017, "Policy Memorandum on the Use of Mefloquine (Lariam®) in Malaria Prophylaxis." Your review should include mefloquine dispensed at medical treatment facilities, pre-deployment processing locations, and in deployed locations. Your review also should confirm that your health care providers understand the important screening and documentation requirements associated with prescribing mefloquine.

Please provide me with the results of your review within 90 days of this memorandum, including deficiencies identified, and measures taken to correct them, along with a copy of any updated Service-wide policies addressing these issues. The point of contact for this matter is COL Scott Stanek. COL Stanek may be reached at (703) 575-2669, or Scott.Stanek@tma.osd.mil.

A handwritten signature in black ink, appearing to read "Jonathan Woodson". The signature is fluid and cursive, with the first name "Jonathan" and last name "Woodson" clearly distinguishable.

Jonathan Woodson, M.D.

Attachments:

As stated

Cc:

Surgeon General of the Army

Surgeon General of the Navy

Surgeon General of the Air Force

Medical Officer of the Marine Corps

Joint Staff Surgeon

EXHIBIT E



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8504150

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Y Country: USA Outcomes: OT (A)NDA/BLA: 019591 /

FDA Rcvd Date: 11-Apr-2012 Mfr Rcvd Date: 29-Mar-2012 Mfr Control #: US-ROCHE-1054403

Patient Information:

Age: Sex: Weight:

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	
1	LARIAM				PRODUCT USED FOR UNKNOWN INDICATION			
#	Product Name	Interval 1st Dose to Event	Dec	Rec	Lot#	Exp Date	NDC #	MFR/Labeler
1	LARIAM							

Event Information:

Preferred Term (MedDRA) Version #: 16.0)

HOMICIDE

Start Date End Date

Rec

Event/Problem Narrative:

Initial Information for this Spontaneous case, AER number 1054403, was received on 29/Mar/2012 from a Pharmacist and concerns a patient of unknown demographics who was treated with Mefloquine Hydrochloride (Lariam) for an unknown indication. Medical history included TBI (Traumatic brain injury). No concurrent illnesses were reported. No concomitant medications or past drugs were reported. On an unknown date, the patient started Mefloquine Hydrochloride (dose, form and frequency not reported). On an unknown date the patient who was a soldier in the US Army developed homicidal behavior and led to Homicide killing 17 Afghans. It was reported that this patient was administered Mefloquine in direct contradiction to US military rules that Mefloquine should not be given to soldiers who had suffered TBI (Traumatic brain injury) due to its propensity to cross blood brain barriers inciting psychotic, homicidal or suicidal behavior. The outcome of Homicide was not Reported. There was insufficient information regarding the therapy ongoing status of Mefloquine Hydrochloride. The reporter did not provide the seriousness criteria of the event of Homicide and its causal relationship with Mefloquine Hydrochloride. The company assessed the event of Homicide as medically significant. No further information was available.



FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 8504150

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	Events
Medical History Product(s)	Start Date	End Date	Indications	

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
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Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
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Reporter Source:

Study Report?: No Sender Organization: ROCHE

Literature Text: