

Appendix E: Select Completed, Current and Planned Deployment Health Studies in Humans

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Agency	Study Name and Brief Summary	Study Population	Study Design	Information Collected	Status
VA OPH	<p>National Health Study for a New Generation of U.S Veterans (NewGen)</p> <p><u>Research Aims</u></p> <p>1. Do veterans of OIF/OEF have an increased prevalence of health problems and behavioral risk factors following deployment in combat theaters relative to non-deployed veterans?</p> <p>2. Are some health problems among deployed veterans associated with a specific exposure or experience in combat theaters?</p>	<p>-30,000 OIF/OEF Veterans and 30,000 Veterans who served elsewhere during same period (October 2001-June 2008)</p> <p>-representative of each branch</p> <p>-representative for component</p> <p>-oversample women for 20%</p>	<p>-Prospective Cohort</p> <p>-Three follow up surveys over ten years.</p> <p>-Self Report Survey</p> <p>-Medical records review of 1,000 subjects</p>	<p>-Health Risk Behaviors (ETOH, HIV, sexual behavior, helmet use, seatbelt use, smoking, speeding)</p> <p>-Health Conditions (anxiety, asthma, cancer, depression, chronic disease, CVD, IBS, PTSD, TBI, pain, migraines)</p> <p>-General Health (functional status, general health perception, pregnancy outcomes, reproductive health)</p> <p>-Health Care Utilization (doctor visits, hospitalizations, prescription drug use, CAM, VA facility use)</p> <p>-Potential Exposures (accidents, blasts, burn pits, chemicals, dust/sand, falls, head injury, MST, smoke, vaccinations)</p>	<p>-Active</p> <p>-22,000 participated in first wave.</p> <p>Barth, SK, Dursa, EK, Peterson, MR, Schneiderman A. Prevalence of Respiratory Diseases Among Veterans of Operation Enduring Freedom and Operation Iraqi Freedom: Results From the National Health Study for a New Generation of U.S. Veterans. <i>Mil Med</i> 2014; 179: 241-245.</p> <p>Yoon, FB, Jang D, Sukasih A, Kress AM, Barth SK, Mahan CM, Coughlin SS, Dursa EK, Schneiderman AI. 2013. Adjustments for misclassification of deployment status in a population based health study of Operation Enduring Freedom and Operation Iraqi Freedom Veterans. In <i>JSM Proceedings, Mental Health Statistics Section. Alexandria, VA: American Statistical Association. 1996-2008.</i></p> <p>Barth SK, Dursa EK, Bossarte R, Schneiderman A. <u>Lifetime Prevalence of Respiratory Diseases and Exposures Among Veterans of Operation Enduring Freedom and Operation Iraqi Freedom Veterans: Results From the National Health Study for a New Generation of U.S. Veterans.</u> <i>J Occup Environ Med.</i> 2016 Dec;58(12):1175-1180.</p> <p>Cypel YS, Hamlett-Berry K, Barth SK, Christofferson DE, Davey VJ, Eber S, Schneiderman AI, Bossarte RM. <u>Cigarette Smoking and Sociodemographic, Military, and Health Characteristics of Operation Enduring Freedom and Operation Iraqi Freedom Veterans: 2009-2011 National Health Study for a New Generation of US Veterans.</u> <i>Public Health Rep.</i> 2016 Sep;131(5):714-727.</p>

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VA ORD	Million Veteran Program (MVP)	1,000,000 Veterans (ideally) -Volunteer -Active duty military recruitment starting in 2017 with invitations to 202,000 individuals enrolled in DoD Millennium Cohort Study	-Prospective cohort -Retrospective cohort (assuming access to past medical records)	-Demographics (race, ethnicity, ancestry, education, marital status, income) -Family information (structure, vital status of biological family members, family medical history) -Medical history (CV, ID, MH, GI, neurological, and musculoskeletal) -Functional health status (SF-12) -Frequency of physical activity -ETOH and tobacco consumption -History of military service (period of service, location, exposure to selected deployment related agents) -Physical features -Healthcare utilization (hospitalizations, prescription use, VA usage) -Biological specimen (blood) -Past medical records -Access to future medical records	Currently enrolling. Over 555,000 enrolled as of April 2017.
VA ORD	CSP #595: Respiratory Health and Deployment to Iraq and Afghanistan Objective: Assess association of deployment and airborne exposures during deployment with current measures of respiratory health	Population based sample of VA and non-VA users Six sites will enroll a cohort of 4500.	Cross-sectional study of deployed and non-deployed Veterans	Estimate individual-level particulate-matter (PM) exposure while deployed using validated spatial-temporal mapping of air quality Assess relationships between PM exposure and respiratory health assessed by spirometry and respiratory symptoms	Planning stage for pilot was funded Project is funded for 5/2016 – 9/2022

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VA ORD	Project Numbers DHI 09-237) and HSR5-329-10W Identifying and Validating Complex Comorbidity Clusters in OEF-OIF Veterans	OBJECTIVES: Objective 1. Identify comorbidity clusters among OEF-OIF veterans at baseline and describe patterns of comorbidity trajectories (stable vs. deterioration) over 3 years. Objective 2. Identify risk factors for trajectories of deterioration vs. stability. Objective 3. Compare VA health care utilization for individuals with stable comorbidity trajectories vs. those who exhibit patterns of deterioration. trajectories within each initial comorbidity cluster.	METHODS: This is a cohort study that will combine data from VA national data repositories Approximately 2,000 OEF-OIF VA patients	Examines the prevalence of respiratory diagnoses in OEF/OIF/OND Veterans between FY02-FY11.	<ul style="list-style-type: none"> • Recently completed (10/2010 - 9/2015) • Findings of increasing healthcare utilization for respiratory conditions over time in light of concern for the impact of environmental exposures in OEF/OIF/OND suggests that there may be chronic effects of exposures. • Smoking was significantly associated with all forms of respiratory conditions. • Findings also suggest pulmonary screening in those with symptoms may help to identify and treat chronic pulmonary disease early, and may alter the disease trajectory. • Publication: Mary Jo Pugh, et. Al. "Increasing Prevalence of Chronic Lung Disease in Veterans of the Wars in Iraq and Afghanistan." MILITARY MEDICINE, 181, 5:476, 2016
VA ORD	1I21RX001079-01 Effects of Deployment Exposures on Cardiopulmonary and Autonomic Function (PI: Falvo MJ)	OEF/OIF/OND Veterans	Case-control	Physiological Assessments: 1 – Exercise Challenge 2 – Spirometry 3 – Autonomic battery	Data Acquisition Completed 9/2015 ClinicalTrials.Gov Updated (link) Manuscripts in final draft.

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	<p>Research Aims:</p> <p>1 – Evaluate cardiopulmonary function (i.e. exercise gas exchange and spirometry) in deployed OEF/OIF Veterans versus those deployed elsewhere.</p> <p>2- Determine whether deployment-related exposures alter cardiovascular autonomic control.</p>			<p>Questionnaires:</p> <p>1 – Health history</p> <p>2 – Deployment history</p> <p>3 – Exposure history (DARE)</p> <p>4 – Symptoms</p>	<p>Conference Abstracts:</p> <p>2014: Experimental Biology</p> <p>2015: Experimental Biology</p> <p>2015: ACSM Annual Meeting</p> <p>2016: ACSM Annual Meeting</p>
<p>VA PDHS; NJ WRIISC</p>	<p>Airborne Hazards Exposure and Cardiorespiratory Health of Veterans.</p> <p>(PI: Falvo MJ)</p> <p>Research Aims</p> <p>To describe and compare cardiorespiratory health of deployed Veterans, and determine the relationship between airborne hazards exposure and</p>	<p>OEF/OIF/OND Veterans referred to the NJ WRIISC</p>	<p>Retrospective Cohort Study</p>	<p>Physiological Assessments:</p> <p>1 – Pulmonary Function Testing</p> <p>2 – Cardiopulmonary Exercise</p> <p>3 – Forced Oscillometry</p> <p>4 – Methacholine Challenge</p> <p>Questionnaires:</p> <p>1 – Health history</p> <p>2 – Deployment history</p>	<p>Active accrual, data analysis</p> <p>Publications:</p> <p>Falvo MJ, Abraham JH, Osinubi OY, Klein JC, Sotolongo AM, Ndirangu D, Patrick-DeLuca LA, Helmer DA. Bronchodilator Responsiveness and Airflow Limitation Are Associated With Deployment Length in Iraq and Afghanistan Veterans. J Occup Environ Med. 2016 Apr;58(4):325-8.</p> <p>Falvo MJ, Helmer DA, Klein JC, Osinubi OY, Ndirangu D, Patrick-DeLuca LA, Sotolongo AM. Isolated diffusing capacity reduction is a common clinical presentation in deployed Iraq and Afghanistan veterans with deployment-related environmental exposures. Clin</p>

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	symptoms with cardiorespiratory health.			3 – Exposure history 4 – Symptoms	Respir J. 2016 Sep 10. Conference Abstracts: 2013: ATS Annual Meeting 2014: ATS Annual Meeting #1 2014: ATS Annual Meeting #2 2015: ATS Annual Meeting #1 2015: ATS Annual Meeting #2 2016: ATS Annual Meeting
VA ORD	1I01CX001515-01 Pulmonary vascular dysfunction after deployment-related exposures. (PI: Falvo MJ)	OEF/OIF/OND Veterans	Case-control with longitudinal follow-up	Physiological Assessments: 1 – Pulmonary Function Testing 2 – Cardiopulmonary Exercise 3 – Forced Oscillometry 4 – Exercise Echocardiography 5 – Vascular Reactivity 6 – Vascular Injury Biomarkers Questionnaires: 1 – Health history 2 – Deployment history 3 – Exposure history 4 – Symptoms	New; Pending IRB Review

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DoD NHRC	<p>Millennium Cohort Study (MilCo)</p> <p>Largest prospective study in US military history, designed to assess the long-term health effects of military service both during and after service time.</p>	<p>-Active Duty, Reserve, and National Guard (deployed and non-deployed)</p> <p>-To date approximately 202,000 have been enrolled (2001-2013, Panels 1-4)</p> <p>-Oversampled for specific subgroups including females, Marines, prior deployers (SWA, Bosnia/Kosovo after 8/97), National Guard/Reserves, and married</p> <p>-58% of sample has deployed in support of Iraq/Afghanistan since 2001</p> <p>-45,381 were in service during the 1991 GW, with 9,249 deployed to this conflict</p> <p>-70% of all participants have separated</p>	<p>-Prospective Cohort Study</p> <p>-Follow-up planned through 2068, thus spanning lifetime of service members</p> <p>-Questionnaires approximately every three years</p> <p>New enrollments approximately every six years</p> <p>-DoD military and medical record data linkages for objective deployment and medical data</p>	<p>Questionnaire includes:</p> <ul style="list-style-type: none"> -Demographics -General health information (functional status, well-being, general health perception) -Health behaviors (smoking, alcohol use, physical activity) -Health conditions and symptoms (asthma, chronic bronchitis, emphysema, cough, and shortness of breath, and others) (depression, PTSD, anxiety, cancer, pain) (pregnancy outcomes and reproductive health) -Health care utilization (physical or mental health, CAM) -Potential exposures (combat, injuries, burn-pit/smoke, chemicals, pesticides) (physical and sexual assault) -Military life (deployments, rank, occupation, perception of military) -Other (employment, income, self-mastery, life stress) <p>-Linkage to medical and military records with data on demographics, occupation, deployment, separation, vaccinations, health care utilization, pharmacy prescriptions, lost work days, employability, and mortality</p>	<p>Analysis complete:</p> <ul style="list-style-type: none"> • Deployment and asthma analysis complete. Findings presented at 2016 American Public Health Association Annual Meeting (abstract link). Manuscript in preparation. <p>Analyses in progress:</p> <ul style="list-style-type: none"> • Long-term respiratory health with a focus on cardiovascular and mental health comorbidities • Post-deployment exertional dyspnea • Deployment and risk of chronic obstructive pulmonary disorder <p>Other activities:</p> <ul style="list-style-type: none"> • Study in development to identify molecular biomarkers in serum associated with proximity to open-air burn pit sites • VA OPH and ORD contributing resources to link VA medical records with MilCo survey data • Next survey cycle planned for 2017-2019 with concurrent enrollment of Panel 5 <p>Completed works:</p> <p>Smith B, Wong CA, Boyko EJ, Phillips CJ, Gackstetter GD, Ryan MAK, Smith TC, for the Millennium Cohort Study Team. The effects of exposure to documented open-air burn pits on respiratory health among deployers of the Millennium Cohort Study. <i>Journal of Occupational and Environmental Medicine</i>. 2012 June;54(6):708-16.</p> <p>Smith B, Wong CA, Smith TC, Boyko EJ, Gackstetter GD, Ryan MAK, for the Millennium Cohort Study Team. Newly reported respiratory symptoms and conditions among military personnel deployed to Iraq and Afghanistan: a prospective population-based study. <i>American Journal of Epidemiology</i>. 2009 Dec;170(11):1433-42.</p>

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DoD NHRC	Birth Outcomes Among Military Personnel After Exposure to Documented Open-Air Burn Pits Before and During Pregnancy	Active duty women and men within a 3-mile radius of select open-air burn pits	Retrospective cohort	Live births and infant health outcomes	Complete J Occ Envir Med, Vol 54;6:689-697
DoD/ USA/USN	Identification of molecular indicators associated with open-air burn pit smoke exposure	US military: Millennium Cohort Study	Epidemiology, cohort, analysis of DoDSR samples	Deployment, DoDSR combustion product biomarkers, self-report health data, miRNA biomarkers	FY17 new start. Follow-up to Smith 2012 J Occup Environ Med 54(6):708-16 with objective measures of combustion product exposure based on "Deployment exposures, metabolomics and inflammatory biomarkers and health outcomes" study at USUHS

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DOD, USAPHC	<p>Mishraq Sulfur Fire Cohort</p> <p><u>Research Aim</u> To assess whether or not exposure to chemicals released during the 2003 Mishraq Sulfur Fire may have caused or exacerbated any adverse health conditions among exposed personnel during or after OIF deployment</p>	<p>-6,532 Exposed Active Duty composed of 191 Army firefighters who extinguished the fire and 6,341 Soldiers assigned, attached to, or co-located with units that were located within 50km of Mishraq Sulfur plant during active burning-1 Jun 2003-21 Aug 2004. Majority were members of 101 DIV, either 1st Brigade Combat Unit of 326th Engineering Unit</p>	<p>Historical cohort</p> <p>-4,153 Unexposed Active Duty</p> <p>Time based: 1,869 OIF/OEF Soldiers who were deployed during the year prior to or following the exposure period according to DMDC)</p> <p>Location based: 2,284 Soldiers who were deployed for at least 1 day to Q-West area (largest established camp in that area) 14 to 24 months after burn period ended, and were not in either of the other two groups</p> <p>10,685 total</p>	<p>-Self reported health status before and after deployment (DD 2795 and 2796)</p> <p>-Medical encounter data</p>	<p>Completed.</p> <p>Baird CP, DeBakey S, Reid L, Hauschild VD, Petrucci B, Abraham JH. <u>Respiratory health status of US Army personnel potentially exposed to smoke from 2003 Al-Mishraq Sulfur Plant fire.</u> J Occup Environ Med. 2012 Jun;54(6):717-23</p> <p>Findings:</p> <ul style="list-style-type: none"> -The two exposed groups had significantly more frequent self reports of fair or poor health -Exposed groups significantly more often referred for further care, significantly more reports of health concerns and exposure concerns -Exposed groups had significantly more frequent reports of runny nose, difficulty breathing, rash, tearing, and coughing during deployment. -Both exposed and unexposed had a significant increase in the percent reporting poorer health post deployment compared to pre-deployment -Incidence of respiratory diagnoses encounters decreased from pre to post deployment, but not significant. -Incidence of encounters for acute respiratory infections decreased from pre to post deployment period-and was significant in each of the groups
DoD Brooke Army Medical Center	A Database Registry of Military Personnel	Asthma = 400	Retrospective database	Diagnoses included in this	Delvecchio SP, Collen JF, Zacher LL, Morris MJ. The impact of combat deployment on asthma diagnosis and severity.

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(BAMC)	<p>Diagnosed with Post-“A Database Registry of Military Personnel Diagnosed with Post-Deployment Chronic Pulmonary Disease”</p> <p><u>Research Aim</u></p> <p>To examine the relationship between onset of chronic pulmonary disease and deployment history</p> <p>2005-2009- Active duty with any disease anyone seen in pulmonary clinics at any MTF</p>	<p>COPD = 371</p> <p>Sarcoidosis = 505</p>		<p>database:</p> <ul style="list-style-type: none"> -Asthma (those undergoing a Medical Evaluation Board (MEB) and new onset) -COPD (COPD, emphysema, chronic bronchitis) -Sarcoidosis (including MEB) - Other pulmonary interstitial or infiltrative disorders (pulmonary fibrosis, constrictive bronchiolitis) 	<p>J Asthma. 2015 May; 52(4):363-9. (PMID: 25290816).</p> <p>Matthews T, Abraham J, Zacher LL, Morris MJ, The impact of deployment on COPD in active duty military personnel Mil Med. 2014 Nov; 179(11):1273-8 (PMID: 25373054)</p> <p>Forbes DA, Hamilton JA, Rawlins FA, Tinkelpaugh C, Abraham JH, Morris MJ. The effect of deployment on sarcoidosis staging and severity in military personnel. (In submission)</p>

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DOD (BAMC)	<p><i>STAMPEDE</i></p> <p><i>Study of Active Duty Military for Pulmonary Disease related to Environmental Dust Exposure</i></p> <p><u>Research Aim</u></p> <p>To evaluate military personnel who have recently returned from OIF/OEF for evidence of lung disease related to prolonged environmental dust exposure in the current theaters of operation</p>	<p>N=50</p> <p>Subjects recruited from units returning from deployment to Fort Hood (Army) within past six months with primary complaints of dyspnea.</p>	Prospective Study	<p>Detailed history</p> <p>Physical exam</p> <p>Risk factor assessment</p> <p>Complete pulmonary evaluation:</p> <ul style="list-style-type: none"> -chest radiograph -high resolution CT of chest -full pulmonary function testing -impulse oscillometry -methacholine challenge testing -bronchoscopy with BAL <p>Location of unit during deployment.</p>	<p>Morris MJ, Dodson DW, Lucero PF, Haislip GD, Gallup RA, Nicholson KL, Zacher LL. Study of active duty military for pulmonary disease related to environmental dust exposure (STAMPEDE). American Journal of Respiratory and Critical Care Medicine 1 July 2014; 190 (1):77-84. (PMID: 24922562)</p> <p>Brown JN, Brewer HM, Nicora CD, Weitz KK, Morris MJ, Skabelund AJ, Adkins JN, Smith RD, Cho JH, Gelin R. Protein and microRNA biomarkers from lavage, urine, and serum in military personnel evaluated for dyspnea BMC Medical Genomics 5 Oct 2014; 7(1): 58 (PMID: 25282157)</p>
DOE/Pacific Northwest Labs Institute for Systems Biology DoD/USA	Biomarkers for Pulmonary Injury Following Deployment (microRNA and protein biomarkers in lung lavage fluid and serum from Military personnel)	USA Military Personnel (STAMPEDE 1)	Toxicology/Case Series	microRNA and protein biomarkers in lung lavage fluid and serum and urine	<p>Completed: Analysis of STAMPEDE 1 project BALF, urine, and serum for miRNA and protein biomarkers was examined. A clear miRNA signature was observed in the BAL from a subset of dyspneic patients with obstructive respiratory symptoms.</p> <p>Brown JN, Brewer HM, Nicora CD, Weitz KK, Morris MJ, Skabelund AJ, Adkins JN, Smith RD, Cho JH, Gelin R. Protein and microRNA biomarkers from lavage, urine, and serum in military personnel evaluated for dyspnea. BMC Med Genomics. 2014 Oct 5;7:58.</p>
DoD/USA/ Johns Hopkins University	Clinical Evaluation of Post-Deployment Dyspnea: Identification	USA Military personnel	Toxicology/Case Series: technical validation and	miRNA and protein biomarkers in BAL and serum	Ongoing. Technical validation studies under way.

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Applied Physics Lab	of miRNA Biomarkers in Bronchoalveolar Lavage Fluid		assessment of reproducibility of findings in “Biomarkers for Pulmonary Injury Following Deployment” (above) in a separate study cohort		
DoD (BAMC)	<p><i>STAMPEDE Registry of Deployment Related Lung Disease</i></p> <p><u>Research Aim</u></p> <p>Establish a centralized database registry of patients diagnosed with lung disease related to deployment to OIF/OEF/OND from DoD medical treatment facilities.</p>	<p>Projected N=3,000</p> <p>Likely members of this cohort are also members of the other STAMPEDE cohorts and other BAMC studies</p>	<p>Prospective registry (with ten year follow-up).</p>	<p>Enrolls all patients seen at a pulmonary clinic in DoD with diagnosed chronic lung disease related to deployment, including:</p> <ul style="list-style-type: none"> -asthma -COPD -bronchiectasis -sarcoidosis -interstitial lung disease <p>-Will collect clinical data for 10 years post-diagnosis</p>	Ongoing data collection
DoD BAMC and Darnell Army Medical Center (CRDAMC)	<p><i>(STAMPEDE-II)</i></p> <p><i>Pre- and Post-Deployment Evaluation of Military Personnel for Pulmonary Disease</i></p>	<p>Deploying Soldiers from Ft. Hood</p> <p>(Predominately Army)</p> <p>N=1700</p>	Prospective	<p>Chest radiography, standard spirometry and impulse oscillometry, pre and post deployment;</p> <p>Respiratory questionnaire</p>	Skabelund AJ, Rawlins FA, McCann ET, Lospinoso JA, Burroughs L, Gallup RA, Morris MJ, Pulmonary Evaluation of Military Personnel Prior to Southwest Asia Deployment. Accepted to Respiratory Care (Pre-deployment data only)

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	<p><i>Related to Environmental Dust Exposure</i></p> <p><u>Research Aims</u></p> <p>Evaluate active duty military pre and post deployment for the development of lung disease measured by chest imaging and PFTs.</p>			Smoking history	Manuscript comparing pre and post deployment data in progress.
DoD BAMC and Walter Reed National Military Medical Center (WRNMMC)	<p><i>Study of Active Military Personnel for Pulmonary Disease Related to Environmental Dust Exposure – Comprehensive Dyspnea Evaluation (STAMPEDE-CDE)</i></p> <p><u>Research Aims</u></p> <p>The objective of this study is to evaluate military personnel with symptoms of post-deployment dyspnea from the current theaters of operation in SWA for evidence of lung disease with a standardized and comprehensive testing</p>	<p>US Military Personnel with new onset pulmonary symptoms related to deployment</p> <p>Anticipated enrollment of 400</p>	Prospective cohort	<p>Study procedures include:</p> <ul style="list-style-type: none"> - Chest radiography - Spirometry with pre/post BD - Full PFTs with LV, DLCO - High resolution CT chest - Respiratory questionnaire - Burn Pit questionnaire - Sleep Study questionnaires - Impulse oscillometry - Exercise laryngoscopy - Fiberoptic bronchoscopy 	<p>Abstract Presentations</p> <ul style="list-style-type: none"> - Morris M, Comprehensive evaluation of military personnel with post-deployment respiratory symptoms. World CHEST Congress, Mar 2014, Madrid, Spain - Morris MJ, Cardiopulmonary exercise testing in the evaluation of post-deployment dyspnea., ATS, May 2015, Denver, CO - Weinstein DJ, Exercise associated excessive dynamic airway collapse. ATS, May 2015, Denver, CO - McLaughlin C, Segmental airway collapse associated with dyspnea and localized wheezing, ATS, May 2016. San Francisco, CA - Huprikar N, Impulse oscillometry in the evaluation of

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	strategy.			<ul style="list-style-type: none"> - Echocardiography - Cardiopulmonary exercise testing - Exhaled nitric oxide 	<p>post-deployment dyspnea: preliminary data from STAMPEDE III, CHEST 2016, Montreal, Canada</p> <p>- Chaudry GH, A multiplex quantitative analysis of secreted proteins in bronchoalveolar lavage samples from war veterans with chronic respiratory symptoms, ASCB, Dec 2016</p> <p>- McMahon M, Post-traumatic stress disorder is associated with an increased ventilatory response to exercise. ATS, May 2017, Washington, DC</p> <p>- Zusin D, Correlation of lung function measurements to assess small airway disease, ATS, May 2017, Washington, DC</p> <p>- Mabe D, Identification of isolated small airway disease and correlation with respiratory workload during exercise, ATS, May 2017, Washington, DC</p> <p>Publication:</p> <p>-Weinstein D, Hull JE, Ritchie B, Hayes JA, Morris MJ. Exercise-induced excessive dynamic airway collapse. Annals ATS. Sept 2016 (PMID: 27332956)</p>

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DoD Joint Pathology Center (JPC) and BAMC	<p><i>Pathological Diagnoses of Deployed Military Personnel with Pulmonary Disease</i></p> <p><u>Research Aims</u></p> <p>Compare differences in pathological findings between deployed and non-deployed military personnel</p>	<p>US Military personnel</p> <p>N = 375</p>	Retrospective	Comparison of lung pathological specimens reviewed at JPC between deployed and non-deployed military	Madar CS, Lewin-Smith MR, Franks TJ, Harley RA, Morris MJ. Histological diagnoses of deployed military personnel undergoing lung biopsy. Submitted to Lung
DoD (BAMC)	<p><i>The Effect of Deployment on Cardiopulmonary Exercise (CPEX) Testing in Military Personnel</i></p> <p><u>Research Aims</u></p> <p>Compare differences in exercise studies between deployed and non-deployed military personnel</p>	<p>US Military Personnel</p> <p>N = 268</p>	Retrospective	<p>Comparison of cardiopulmonary exercise testing studies between deployed and non-deployed military personnel</p> <p>CPEX parameters including cardiac and respiratory parameters</p>	Hiles PA, Porr WH, Hannah WN, Morris MJ. Deployment-related pulmonary symptoms and cardiopulmonary exercise testing in military personnel. <i>Pulmonary and Critical Care Medicine</i> 2016;1(3):72-77.

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DoD BAMC and Landstuhl Regional Medical Center (LRMC)	<i>Vocal Cord Dysfunction Related to Combat Deployment</i> <u>Research Aims</u> Identify causes for vocal cord dysfunction (VCD) in patients evaluated at LRMC after SWA deployment	US Military Personnel N = 48	Retrospective	Review of PFT, imaging and etiologies for VCD (psych, exercise, stress) in patients at LRMC after evacuation from SWA theater	Morris MJ, Oleszewski R, Sterner JB, Allan PF. Vocal cord dysfunction related to combat deployment. <i>Military Medicine</i> . 2013; 178(11):1208-1212. (PMID: 24183767)
DoD (BAMC)	<i>Screening Spirometry for Assessment of Pulmonary Disease in Active Duty Military Personnel</i> <u>Research Aims</u> To determine feasibility of performing screening PFTs in the population	US Military personnel in Advanced Individual Training at AMEDD Center and School N = 900	Prospective	Demographics with smoking, symptoms, asthma and Armed Forces Physical Test history. Perform a single spirometric exam within American Thoracic Society standards.	Morris MJ, Anderson DM, Ondrasik NR, Zanders TB, Rawlins FA, Lospinioso JA. Screening spirometry in military personnel correlates poorly with exercise tolerance and asthma history. (In submission)
DoD (LRMC)	<i>Acute Eosinophilic Pneumonia in the Deployed Setting</i> <u>Research Aims</u> Review the treatment course of military personnel with AEP	US Military Personnel with AEP N = 43	Retrospective	Review of imaging, lab findings, BAL and treatment course for AD personnel evacuated to LRMC with a diagnosis of AEP.	Sine CR, Shuping EE, Scoville SL, Haynes RL, Hultman A, Allan PF, Osborn EC, Franks TJ, Hiles PD, Morris MJ. Acute eosinophilic pneumonia in the deployed military setting. Submitted to <i>Chest</i>

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DoD (BAMC/LRMC)	<p><i>Long Term Complications of Acute Lung Injury Acquired in OIF/OEF/OND</i></p> <p><u>Research Aims</u></p> <p>Review the cases of evacuation from theater that are due to or associated with pulmonary exposures and identify the cause of respiratory failure in those requiring medical evacuation</p>	<p>US Military Personnel</p> <p>N = 1800</p>	Retrospective	Pulmonary data will be extrapolated from the TRACES data, CCATT transport data, and LRMC Essentris medical records after confirmation that patient was evacuated for a pulmonary disorder.	<p>Data collection ongoing</p> <p>Preliminary abstract submitted to MHSRS</p>
DoD (BAMC)	<p><i>Long Term Outcomes from Thoracic Trauma in OIF/OEF/OND</i></p> <p><u>Research Aims</u></p> <p>Retrospective chart review of active duty patients with thoracic trauma sustained during OIF/OEF</p>	<p>US Military Personnel</p> <p>N = 3845</p>	Retrospective	Review of DoD Trauma Registry for outcomes in patients with thoracic trauma; identified 480 with PFT values	Borders CA, Rawlins FA, Morris MJ. Long Term Pulmonary Outcomes from Thoracic Trauma During OIF/OEF Deployment; ATS 2016, San Francisco, CA

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DoD (BAMC)	<p><i>Longitudinal Evaluation of Spirometric Function in Military Firefighters as Related to Deployment</i></p> <p><u>Research Aims</u></p> <p>determine if firefighters who deployed in support of military operations in Southwest Asia have a decline in pulmonary function as measured by spirometry</p>	<p>USAF Military Personnel</p> <p>N =2000</p>	Retrospective	Recorded spirometry values in USAF firefighters on an annual basis	<p>George A, Pulmonary Function in Military Firefighters Pre and Post Southwest Asia Deployment</p> <p>ATS 2016; San Francisco, CA</p>
DoD (BAMC)	<p><i>Deployment-Related Chronic Pulmonary Disease in Military Personnel</i></p> <p><u>Research Aims</u></p> <p>Retrospective review of active duty military personnel from 2006 to 2015 evaluated in pulmonary clinics throughout the Department of Defense. This database will provide information on the evaluation of respiratory symptoms,</p>	<p>US Military Personnel</p> <p>N = 5000</p>	Retrospective	<p>Long term outcomes on patients from 2006 to 2015 with the following diagnoses:</p> <ul style="list-style-type: none"> - Constrictive bronchiolitis - Chronic bronchitis - Emphysema - Asthma - Bronchiectasis - Hypersensitivity pneumonitis - Chronic obstructive pulmonary disease (COPD) 	Data collection ongoing

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Agency	Study Name and Brief Summary	Study Population	Study Design	Information Collected	Status
	pulmonary function testing, and other information of procedures and diagnoses as related to chronic pulmonary disease and deployment.			<ul style="list-style-type: none"> - Post-inflammatory pulmonary fibrosis - Idiopathic pulmonary fibrosis - Bronchiolitis obliterans organizing pneumonia - Sarcoidosis - Eosinophilic pneumonia - Pulmonary interstitial/infiltrative disorders 	
DoD/Joint Pathology Center (JPC)	Histopathological and chemical analytical evaluation of pulmonary specimens from US military Operation Iraqi Freedom and Enduring Freedom veterans	US Military Personnel	Case Series	Histopathology physico-chemical characterization of inhaled PM	Ongoing. Over 20,000 biopsy samples screened for study inclusion. Approx. 500 non-neoplastic biopsy samples from deployed Service members identified. Pathological and exogenous particle analysis commencing.

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Agency	Study Name and Brief Summary	Study Population	Study Design	Information Collected	Status
DoD/USUHS	Deployment exposures, metabolomics and inflammatory biomarkers and health outcomes	50 Soldiers deployed to Iraq; 50 Soldiers deployed to Afghanistan from cohort of service members deployed to work adjacent to burn pits; 100 controls with no deployments.	Nested case control study	Area air monitoring data on PAHs, Dioxins adjacent to burn pits in Iraq, Breathing zone air samples in Afghanistan with PAHs. Serum GC/MS and LC analysis data for metabolomics, inflammatory biomarkers IL, IgE, cytokines, cotinine, micro-RNAs.	Complete: Candidate miRNAs for deployment-related exposures identified. Improved mass spectral analyses revealed differences in polyaromatic hydrocarbons associated with burn pit exposure in specimens from the DoD Serum Repository. No health effects were discerned in this limited study. J. Occup. Env. Med. 2016 58: Supplement 1 (entire issue)
DoD / Walter Reed National Military Medical Center (WRNMMC)	Lung Function Testing in Service Members Serving in Iraq and Afghanistan and Returning with Dyspnea	Active Duty/Retired Military with unexplained respiratory symptoms	Case control; longitudinal follow-up	Questionnaires; PFT	Baseline data collected; follow-up commencing. Holley AB, Sobieszczyk M, Sherner JH, Perkins MP. Respiratory symptoms in service members returning from Afghanistan and Iraq . Am J Respir Crit Care Med. 2014 Nov 1;190(9):1076-7. Holley AB, Sobieszczyk M, Perkins M, Cohee BM, Costantoth CB, Mabe DL, Liotta R, Abraham JH, Holley PR, Sherner J. Lung function abnormalities among service members returning from Iraq or Afghanistan with respiratory complaints . Respir Med. 2016 Sep;118:84-7.
DoD/ USA DOI/ USGS/ National Jewish Health	Development of a Morphometric Approach to Quantification of Small Airways Disease and a Particulate Matter Exposure Profile in Lung Biopsies of Deployed US Military Personnel	US Military Personnel and Veterans	Case-Control	Independent Pathological review of biopsy specimens and measurement of pathological features for objective diagnosis; characterization of PM in lungs. Most deployed participants previously received a histopathological diagnosis of constrictive bronchiolitis.	Completed. Subjective diagnostic evaluation of biopsy samples by pathology team completed. Morphometric evaluation completed. Methods development for visualization and analysis of PM in lung tissue.completed. Most biopsy specimens from the deployed cohort do not display constrictive bronchiolitis. Manuscripts in preparation. No clear association of particle composition with lesions.

Appendix E: Select Completed, Current and Planned Deployment Health Studies in Humans

Agency	Study Name and Brief Summary	Study Population	Study Design	Information Collected	Status
National Jewish Health DoD/USN DOI/USGS	Mechanisms and Treatment of Deployment-Related Lung Injury: Repair of the Injured Epithelium	<p>>100 deployed veterans seen at National Jewish Health, including patients from “Development of a Morphometric Approach to Quantification of Small Airways Disease and a Particulate Matter Exposure Profile in Lung Biopsies of Deployed US Military Personnel” above.</p> <p>Cultured cells, mice</p>	<p>Case control for clinical studies. in vivo and on vitro toxicology.</p> <p>Project 1: Exposure Characterization and Identification of Noninvasive Methods (Lung Clearance Index) for Diagnosis of Deployment-Related Lung Disease, Project Leader: Dr. Cecile Rose, NJMRC</p> <p>Project 2: Acute Lung Injury in Deployed Military Personnel: Basic Mechanisms and Novel Therapeutic Approaches. Project Leader: Dr. Gregory Downey, NJMRC</p> <p>Project 3: Impact of Cigarette Smoke on PM-induced Airway Epithelial Injury</p>	<p>Chest CT images, surgical lung biopsies, and medical and deployment history questionnaires will be accessed by this project from participating patients. Bronchoscopy and BAL specimens, endobronchial brushings, nasal brushings for transcriptomic analysis, quantitative CT and Lung Clearance Index testing; exogenous particle testing in patient specimens by laser ablation mass spectrometry, field emission scanning electron microscopy molecular and cellular biology assays for epithelial growth and wound-healing in vitro.</p> <p>Toxicological and physiological assays for lung function in mice</p>	Commenced Fall 2016.

Appendix E: Select Completed, Current and Planned Deployment Health Studies in Humans

Agency	Study Name and Brief Summary	Study Population	Study Design	Information Collected	Status
			<p>and Exacerbation of Asthma and Bronchiolitis in Deployed Military Personnel, Project Leader: Dr. Brian Day, NJMRC</p> <p>Project 4: Omics' Analysis of Airway Epithelium in Deployment-Related Lung Diseases. Project Leader: Dr. Max Seibold, NJMRC</p>		
DoD AFHSC	Epidemiologic Studies of Health Outcomes among Troops Deployed to Burn Pit Sites	Active component service members of the US Army and US Air Force who were deployed to one of four locations in CENTCOM (two with a burn pit and two without), or Korea, compared to a never deployed CONUS based population	Retrospective cohort	Health care encounters during and following deployment (36 month follow-up); responses on post deployment health assessment forms (2796, 2900)	<p>Initial report with 36 month follow-up completed:</p> <p>Title of Report: "Epidemiologic Studies of Health Outcomes among Troops Deployed to Burn Pit Sites"</p> <p>Authors: AFHSC, Naval Health Research Center, and US Army Public Health Command; May 2010</p> <p>Link: http://www.dtic.mil/dtic/tr/fulltext/u2/a531001.pdf</p>

Appendix E: Select Completed, Current and Planned Deployment Health Studies in Humans

Agency	Study Name and Brief Summary	Study Population	Study Design	Information Collected	Status
DoD AFHSC	Epidemiologic Studies of Health Outcomes among Troops Deployed to Burn Pit Sites	Active component service members of the US Army and US Air Force who were deployed to one of four locations in CENTCOM (two with a burn pit and two without), compared to a never deployed CONUS based population	Retrospective cohort	Health care encounters during and following deployment (48 month follow-up)	Final report with 48 month follow-up completed: Link: Abraham JH, Eick-Cost A, Clark LL, Hu Z, Baird CP, DeFraités R, Tobler SK, Richards EE, Sharkey JM, Lipnick RJ, Ludwig SL. A retrospective cohort study of military deployment and postdeployment medical encounters for respiratory conditions . Mil Med. 2014 May;179(5):540-6.

Appendix E: Select Completed, Current and Planned Deployment Health Studies in Humans

Agency	Study Name and Brief Summary	Study Population	Study Design	Information Collected	Status
DoD AFHSC	Epidemiologic studies of Health Outcomes among Troops Deployed to Kabul and Bagram	Active component Service members deployed to one of two bases located near Kabul and Bagram, Afghanistan, or deployed to Korea, compared to a never deployed CONUS based population	Retrospective cohort	Location, electronic medical record data (respiratory symptoms and diagnoses)	Report complete: Link: Sharkey JM, Abraham JH, Clark LL, Rohrbeck P, Ludwig SL, Hu Z, Baird CP. Postdeployment Respiratory Health Care Encounters Following Deployment to Kabul, Afghanistan: A Retrospective Cohort Study . Mil Med. 2016 Mar;181(3):265-71

Appendix F: Select Non Human and Toxicological Studies

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Agency	Study Name and Brief Summary	Study Population	Study Design	Information Collected	Status
DOD/USA HHS/ NIOSH	Effects of Pulmonary Exposure of Rats to Airborne Particulate Matter from Iraq	Rats	Toxicology: Intratracheal instillation of fine PM from Camp Victory	histopathology, biochemical and immunological markers of injury in lung lavage	Completed. Limited toxicity of aerosol fine PM collected at Camp Victory and N. Kuwait in comparison with CONUS urban dust and silica. All dusts except silica are associated with low levels of emphysematous changes that are slightly greater than those in aging rats, but not constrictive bronchiolitis. J Toxicol Environ Health A 2015 78 (23-24):1385-1408
DoD/USN/ USA NC State	Biological Responses in Rats Exposed to Cigarette Smoke and Middle East Sand (Dust)	Rats	Toxicology: Inhalational exposure to Camp Victory soil	Biochemical and immunological markers of disease in lung lavage fluid, lung gene expression, serum and lung lavage proteomics, behavioral measures, PFTs	Completed. Limited toxicity of Camp Victory soil. Inhalation Toxicology, 2012; 24(2): 109–124
DoD/USN	The Acute and Long-Term Effects of Middle East Sand Particles on the Rat Airway Following a Single intratracheal Instillation	Rats	Toxicology	toxicity of Camp Buehring (Kuwait) dust	Completed. Limited toxicity of Camp Buehring (Kuwait) dust J Toxicol Environ Health A. 2011;74(20):1351-65
DoD/USN	Studies of composition of plume from reconstituted burn-pit	Cultured cells	Toxicology	toxicity of plume to cells in culture; toxicity of plume to rats pending, chemical composition of plume	Complete. Analysis and publication pending.
DoD/USN	In vitro toxicity of SWA soils, (toxicity of instilled extracts of soils)	Cultured cells, Rats	Toxicology	Cell viability, histology, biochemistry, cytology	Published. Inhalation Toxicology. 2013;25(7):405-416 Extracts of soils from different locations in Southwest Asia display different levels of toxicity

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DoD/ USUHS/ Emory/ Rochester	Validation of Exposure Biomarkers in Human Cell Lines	Cultured cells	Toxicology	miRNA expression; analysis of toxicant metabolites	Ongoing; Follow-on to “Deployment exposures, metabolomics and inflammatory biomarkers and health outcomes” at USUHS. Study to verify that miRNAs observed in DoDSR samples are associated with particular combustion product toxicants and that particular mass spectral peaks are associated with metabolized toxicants.
DOD/ USN/ USAF	Effects of exposure to burn pit smoke and Camp Victory Sand (45 day rat inhalational exposure study)	Rats	Toxicology	Pulmonary function, weight, histopathology, tissue metals content; in follow-on, BAL miRNAs, lung microbiome	Exposure, histology, lung function testing complete. Microbiome and miRNA follow-on, ongoing. Minimal effects of exposure on weight, lung function, and histology from either smoke or dust alone, or in combination. Soil elements present in lung; no unusual metal distribution in brain.

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Agency	Study Name and Brief Summary	Study Population	Study Design	Information Collected	Status
VA ORD	5I01BX002622-02 MECHANISMS OF CIGARETTE SMOKE-INDUCED ACUTE LUNG INJURY	Mice		Cigarette smoking contributes to the leading causes of death in the US, including lung and cardiovascular diseases. Cigarette smoking is common among Veterans. Among the lung disorders associated with cigarette smoking is acute lung injury that results from injury to cells lining the lung blood vessels. The goal of the proposed studies is to determine whether acrolein, a major component of cigarette smoking, is the cause of lung blood vessel injury and acute lung injury associated with smoking. Since acrolein is also a constituent of "burn pit" smoke, these studies are also relevant to occupational exposures among OEF/OIF Veterans.	Ongoing 1 July 2015 to 30 June 2019
VA ORD	5I01BX002221-04 CARBON BLACK INDUCED ACTIVATION OF LUNG APCS	Mice		Inhalation of smoke through tobacco smoking and other smoke exposures is known to cause lung disease, but why smoke causes such injury is not known. We have discovered that a common substance in smoke, termed carbon black, causes lung diseases such as emphysema. This application is important because it will reveal how carbon black causes harmful lung inflammation and suggest new ways to treat smoke-related lung disease.	Ongoing 1 July 2013 to 30 June 2017

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VA ORD	PULM-022-10F Nanoparticle Coupled Antioxidants for Respiratory Illness in Veterans	Mice and human sinonasal epithelial cells (HSNECs)	The hypothesis is that smoke and DEP exposure experienced by OEF/OIF Veterans impacts HSNEC-APC communication and that this inflammatory response can be ameliorated through the use of antioxidant nanoparticles targeted at the respiratory epithelium.	Inhibition of PM and DEP-induced inflammation after treatment with antioxidant-linked nanoparticles (NPs) made of polylactic acid. PM is particulate matter; DEP is diesel exhaust particulate	Recently Completed (4/1/2011 - 3/31/2015)

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Agency	Study Name and Brief Summary	Study Population	Study Design	Information Collected	Status
VA ORD	Project Number SPLD-002-12F Targeting HSC-derived Circulating Fibroblasts Precursors in Pulmonary Fibrosis	Mice	Using a silica model of PF that mimics particulate exposure in Veterans of the Gulf War, we have shown that CFPs increase in circulation with PF and traffic to the fibrotic lung. Together, our findings support the hypothesis that HSC-derived CFPs are critical to progression of PF and can be targeted to inhibit fibrotic progression.	Objective: Determine the extent to which silica in desert sand can induce the production of fibroblast precursors for pulmonary fibrosis. This will be tested using our novel clonal HSC cell transplantation method in conjunction with a silica instillation PF model in three disease and/or response to therapy.	Ongoing (10/2013 – 9/2017)