





# Deployment Pulmonary Health

February 11, 2015





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#### **OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE HEALTH AFFAIRS** 7700 ARLINGTON BOULEVARD, SUITE 5101 FALLS CHURCH, VA 22042-5101

February 11, 2015

# MEMORANDUM FOR UNDER SECRETARY OF DEFENSE FOR PERSONNEL AND READINESS

#### SUBJECT: Deployment Pulmonary Health Report

The Defense Health Board (DHB) is pleased to submit its report summarizing the findings and recommendations from our independent review on Deployment Pulmonary Health.

On January 20, 2012, the Acting Under Secretary of Defense for Personnel and Readiness requested that the Defense Health Board (DHB) review evidence relevant to deployment-related pulmonary disease and recommend a comprehensive approach for assessment and prevention, in addition to providing direction for future research and surveillance in this area. Following the approval and swearing in of the Public Health Subcommittee members in June 2013, the DHB assigned the Subcommittee to conduct a review of the major issues in deployment pulmonary health.

The Subcommittee received information and engaged in discussions with multiple subject matter experts in this area from the Department of Defense (DoD), the Department of Veterans Affairs (VA), and civilian and academic institutions. In addition, they held an open session to receive feedback from members of the public, advocacy groups, and other stakeholders. The Subcommittee also reviewed relevant DoD and VA policies and regulations, as well as peer-reviewed publications and lay media reports.

The DHB was impressed that many talented individuals in DoD have been working diligently to collaborate with Federal and civilian stakeholders to design and conduct high quality research to advance the science in protecting and caring for our Service members. We sincerely hope the findings and recommendations provided in this report will assist in that endeavor. On behalf of the DHB, I appreciate the opportunity to provide DoD with this independent review of deployment pulmonary health.

Hanny W. Duckey mo

Nancy W. Dickey, M.D. President, Defense Health Board

Attachments: As stated

cc: ASD(HA)



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# **EXECUTIVE SUMMARY**

Significant attention has been given to examining the association between exposure to potential inhalational hazards during deployment to Southwest Asia and possible adverse health outcomes. In 2006, a U.S. Air Force bioenvironmental engineer expressed concern in a memorandum that "there is an acute health hazard for individuals" and possible "chronic health hazards" associated with burn pit smoke at Joint Base Balad.<sup>1</sup> A similar memorandum from a U.S. Army environmental science engineering officer summarized air quality over an eight-year period regarding particulate matter (PM) for Bagram Air Field in Afghanistan. The results documented elevated levels of PM10 (diameter less than 10 microns) and PM2.5 (diameter less than 2.5 microns) and reported an air quality index considered "unhealthy" by U.S. Environmental Protection Agency (EPA) standards.<sup>2</sup> The results of the Department of Defense (DoD) Enhanced Particulate Matter Surveillance Program (EPMSP) indicated that PM10 and PM2.5 levels exceeded the annual Military Exposure Guideline values of the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) and World Health Organization guidelines at all sites tested.<sup>3</sup> The results also showed that PM2.5 levels exceeded the U.S. EPA's annual and 24-hour standards at all locations sampled.<sup>3</sup> Media coverage has also heightened concerns of Service members about hazardous exposures during deployment and possible development of pulmonary disease.<sup>4-6</sup>

A number of Service members have developed chronic pulmonary symptoms or have been diagnosed with chronic pulmonary diseases following deployment to Southwest Asia. In some Service members diagnosed with constrictive bronchiolitis, a plausible exposure to a recognized pulmonary hazard occurred (sulfur dioxide). In other cases, potential exposures, which may have precipitated pulmonary symptoms or disease, have been hypothesized (e.g., burn pit emissions, diesel exhaust, PM) or are unknown. However, most of the data analyzed to date indicate that the rate at which Service members deployed to Southwest Asia have been affected by chronic pulmonary symptoms or disease is not greater than the expected background rate on a population level. This does not preclude the possibility that subgroups may have experienced unique exposures or have unique individual susceptibilities that contributed to development of chronic pulmonary symptoms or disease. In addition, there is suggestive evidence of an increase in asthma diagnoses or exacerbations in relation to deployment to Southwest Asia.<sup>7,8,9</sup> One of these studies showed an association between increased diagnoses of asthma and deployment to Southwest Asia as well as assignment to South Korea, raising the question of whether potential causal exposure(s) may not be unique to Southwest Asia.<sup>9</sup> Moreover, the majority of Operation IRAQI FREEDOM (OIF) and Operation ENDURING FREEDOM (OEF) epidemiologic studies conducted to date give the impression that chronic pulmonary symptoms observed in Service members are solely limited to Southwest Asia deployment. Most of these studies have not included necessary control groups, such as non-deployed individuals, individuals deployed to other theaters of operation, or civilian cohorts. Coupled with the lack of accurate individual tracking data and military occupational specialty-related exposures, it is not possible to determine the scope of the problem or establish a clear causal link between any specific



environmental exposure, such as PM or burn pits, and a specific pulmonary condition at this time.

On January 20, 2012, the Acting Under Secretary of Defense for Personnel and Readiness (USD (P&R)) requested that the Defense Health Board (DHB) address deployment-related pulmonary health issues and recommend a comprehensive approach for health assessment and disease prevention, in addition to providing direction for future research and surveillance in this area. In response to this request, the DHB assigned the Public Health Subcommittee to review the issues and evidence related to deployment pulmonary health and develop findings and recommendations. The Subcommittee received briefings from and consulted with a variety of subject matter experts from both government and civilian institutions. Additionally, the Subcommittee held a public session in which interested stakeholders were invited to present information and positions regarding deployment pulmonary health.

The resulting report focuses on: 1) establishing pre-deployment clinical baselines and post-deployment screening for chronic pulmonary symptoms and disease; 2) diagnosis of pulmonary disease; 3) surveillance for deployment-related pulmonary disease; 4) deployment pulmonary health registries; 5) deployment pulmonary health research activities; and 6) prevention of deployment-related pulmonary disease.

The term "chronic" is defined as symptoms lasting three months or more. In addition, since there are multiple published guidelines for the evaluation and management of chronic obstructive pulmonary disease, asthma, and other pulmonary diseases, this report focuses on unexplained chronic dyspnea as a key symptom of interest.

The Subcommittee also provided a grade for each of its recommendations based on the strength of the data. Recommendations were made using the following criteria:

I - Based on data from randomized clinical trials with clinical endpoints; II - Based on data from observational cohort studies or randomized trials with surrogate endpoints; or

III - Based on expert opinion, case-control, cross sectional or ecological studies, or case series.

With the exception of a level II recommendation related to smoking, all of the remaining recommendations are at level III.

The topic of pulmonary health in deploying Service members is an important one. The recommendations listed below reflect our current understanding of the situation based on the information available.

# 2.0 ESTABLISHING PRE-DEPLOYMENT CLINICAL BASELINES AND POST-DEPLOYMENT SCREENING FOR CHRONIC PULMONARY DISEASE

Service members are required to maintain a high level of medical readiness at all times; however, a number of factors, including chronic pulmonary diseases, may inhibit a



Service member's ability to perform their duties. Capturing appropriate baseline clinical information can help determine whether there are

changes in pulmonary health potentially related to deployment. Post-deployment screening may identify adverse trends or unexpected findings, which may lead to the identification and reduction or elimination of potential causal factors and subsequent cases of pulmonary disease.

#### Findings and Recommendations

**Finding 1:** The current DoD pre-deployment screening questionnaire (Defense Department Form (DD) 2795) does not contain any pulmonary-specific questions, and it does not contain the same questions as the two post-deployment questionnaires (DD Form 2796, DD Form 2900). The forms also do not sufficiently capture smoking history, such as number of pack-years smoked or the use of electronic cigarettes (e-cigarettes).

Implementing a pre-deployment health assessment with as many identical questions to the post-deployment health assessments, as logical, will allow a direct comparison of baseline responses to post-deployment responses on both an individual and population level. This will provide both a surveillance and research tool in detecting adverse trends.

**Recommendation 1: DoD should alter pre- and post-deployment** questionnaires as follows:

- a) Add the same symptom questions to the pre-deployment questionnaire as are found on the post-deployment questionnaires (Question 11 in DD Form 2796 and Question 8 in DD Form 2900).
- b) Add "wheezing" to the symptom questions on all deployment questionnaires.
- c) Add quantitative and qualitative questions about smoking behaviors, including e-cigarettes and like products, on all deployment questionnaires.

**Evidence Level: III** 

**Finding 2:** With the exception of the broader Airborne Hazards and Open Burn Pit Registry questionnaire, a single, standardized pulmonary questionnaire is not used across both DoD and the Department of Veterans Affairs (VA) in evaluating individuals with chronic post-deployment pulmonary symptoms.

It would be helpful to use a single, standardized pulmonary questionnaire for clinical evaluations to allow for collection of a consistent set of data for epidemiologic analyses. If completion of this questionnaire was triggered by positive responses on the pre/post deployment health assessments, completed electronically, and included in the pre/post deployment assessment database, this would provide access for both surveillance purposes and evaluation of symptomatic individuals.





Recommendation 2: DoD should work with the VA and other stakeholders to harmonize practices through the use of a single, standardized pulmonary questionnaire in evaluating patients who present with chronic post-deployment pulmonary symptoms. The questionnaire should not be cumbersome and should have clinical use.

#### **Evidence Level: III**

#### Finding 3:

- a) There have been no studies conducted on Service members who already have baseline occupational spirometry as a consequence of their specific duty assignment, such as firefighters, to determine if an objective post-deployment decline in pulmonary function has occurred in association with deployment.
- b) It is unclear whether quality assurance reviews are consistently conducted across the Services for occupational spirometry programs in accordance with American Thoracic Society (ATS) and American College of Occupational and Environmental Medicine guidelines.
- c) Spirometry data are not currently captured in a centralized electronic database to allow for efficient individual or population-level longitudinal analysis.
- d) While it is clear that baseline spirometry is of value in certain occupational settings, it is unclear whether conducting baseline spirometry on all deploying military personnel is justified. Baseline spirometry is generally obtained based on a risk assessment for potential exposure to pulmonary hazards. A similar risk-based approach may be appropriate for deploying military personnel.
- e) If DoD were to consider implementing a large-scale pre-deployment baseline spirometry program, a feasibility study would first be necessary to determine the resources needed to implement such a program at multiple sites with sufficient quality assurance.

An assessment of the quality of spirometry being performed as a component of existing medical surveillance programs would provide a baseline indication of the overall effectiveness of these programs. It would also be prudent to confirm the quality of existing spirometry programs prior to considering a larger scale pre-deployment effort. Identifying an accelerated decrease in spirometry values over time on a case-by-case basis can be a clinically relevant screening tool. In addition, longitudinal analysis of changes in pulmonary function by occupational group or location is impractical without a centralized database of spirometry test results. Although a study by Morris et al of pre-and post-deployment spirometry is currently in progress on deploying soldiers and likely to provide useful data, it will not provide sufficient information on the challenges of maintaining a high level of quality assurance when multiple technicians at multiple locations are conducting large numbers of spirometry tests. A decision to accomplish pre-deployment baseline spirometry should be based on a risk assessment for potential exposure to pulmonary hazards as is done in occupational medical surveillance.



**Recommendation 3: DoD should:** 

- a) Conduct an independent assessment of the quality of baseline and follow-on spirometry currently performed as part of occupational medical surveillance programs in each of the Services using the 2014 Official ATS Technical Standards: Spirometry in the Occupational Setting<sup>10</sup> and the American College of Occupational and Environmental Medicine Guidance Statement: Spirometry in the Occupational Health Setting--2011 Update<sup>11</sup> as guides. This should include an analysis of key spirometric parameters previously obtained over at least a five-year period using a statistical sample from several representative locations from each Service and an assessment of the presence and effectiveness of quality assurance reviews.
- b) Implement a mechanism to routinely enter all occupational spirometry results into a centralized electronic database to allow for monitoring and analysis of trends in pulmonary function among occupational groups.
- c) Provide the capability for providers and population health officials to view a graphical presentation of key spirometric parameters for individual and group data superimposed on expected results over time for visual detection of adverse trends.
- d) Based on the results from Recommendation a) above, conduct a feasibility study assessing pre-deployment spirometry in selected groups using random selection quality assurance reviews as specified in the American College of Occupational and Environmental Medicine Guidance Statement: Spirometry in the Occupational Health Setting--2011 Update.<sup>11</sup> This will help inform the feasibility of obtaining high-quality pre-deployment baseline spirometry on a wider scale.
- e) Conduct pre-deployment baseline spirometry if there is a significant risk of exposure to a pulmonary hazard based on the deployed location or anticipated duties.

#### **Evidence Level: III**

#### **3.0 DIAGNOSIS OF PULMONARY DISEASE**

As clinicians investigate the potential associations between deployment and adverse pulmonary health outcomes of Service members, a systematic approach is necessary to evaluate and accurately diagnose pulmonary disease both pre- and post-deployment. Having clear guidance and a consistent approach is a key component of this.



#### **Findings and Recommendations**

#### Finding 4:

- a) A consistent approach to evaluation of patients with unexplained post-deployment dyspnea on exertion across DoD, the VA, and civilian institutions would facilitate accurate characterization of the diagnoses associated with this clinical presentation.
- b) Diseases of the small airways may occur in the absence of objective findings on noninvasive testing.
- c) While surgical lung biopsy may provide a histopathological diagnosis, it may or may not inform treatment or prognosis.

The results of the King et al<sup>12</sup> study initiated further dialogue on the necessary components of a clinical evaluation and diagnostic criteria for Service members returning from deployment with chronic pulmonary symptoms, of which dyspnea on exertion is of specific interest. The Denver Working Group<sup>13</sup> and other investigators<sup>14-16</sup> have provided recommendations for the evaluation of patients with chronic post-deployment dyspnea on exertion and there are many similarities in these approaches. A more consistent approach to evaluation of these patients across DoD, the VA, and civilian institutions would facilitate accurate characterization of the diagnoses associated with this clinical presentation.

The use of surgical biopsy as an early diagnostic tool in evaluating chronic unexplained dyspnea in the absence of significant, progressive symptoms or objective clinical findings based on non-invasive evaluation is not appropriate. However, diseases of the small airways may occur in the absence of objective findings on non-invasive testing. While surgical lung biopsy may provide useful histopathological information, particularly when correlated with the available clinical data, the histopathological findings in themselves may or may not inform treatment or prognosis. Although the risks associated with video-assisted thoracoscopic surgery (VATS) lung biopsy are low in a healthy, young population, it is an invasive procedure with some inherent significant risk.<sup>17-21</sup> A summary of key principles for clinical evaluation of chronic post-deployment dyspnea follows:

1) A stepwise evaluation should be conducted until a diagnosis is established or further testing would not be of clinical benefit to the patient;

2) A comprehensive clinical evaluation of all potential causes of significant and progressive dyspnea should be completed prior to considering surgical lung biopsy;

3) If surgical lung biopsy is being conducted to study the prevalence and characteristics of disease without clear prognostic benefit to the patient, it should be conducted under an Institutional Review Board (IRB) approved research protocol; and

4) There are clear medical indications for surgical lung biopsy. Qualification for disability compensation is not an appropriate indication for surgical lung biopsy.



**Recommendation 4:** 

Clinicians should use a consistent approach when evaluating Service members or veterans for chronic post-deployment pulmonary symptoms. A diagnostic approach for unexplained dyspnea greater than three months duration using a summary of approaches reviewed is included below as a reasonable starting point (see Section 3.1).

Tier 1)

- Medical and occupational history including pulmonary questionnaire
- Physical exam with focus on cardiovascular and pulmonary findings
- Height, weight, and waist circumference
- Spirometry including flow volume loops
- Chest radiograph
- Comparison of results with any previous available records, such as spirometry

#### Tier 2)

- Spirometry with bronchodilators or methacholine challenge
- Studies of lung volumes and diffusion
- Consideration of laryngoscopy (rest or exercise)
- Consideration of echocardiography

Tier 3)

- High-resolution computed tomography (HRCT) scan (depending on potential diagnosis, may want prone and supine positions with full inspiratory and expiratory views)
- Six-minute walk, resting and exercise/post-exercise pulse oximetry
- Consider specific blood tests depending on differential diagnosis

#### Tier 4)

• Maximum cardiopulmonary exercise tolerance testing with arterial blood gases pre-exercise and at maximum exercise

#### Tier 5)

• Depending on results, follow with periodic repeat testing to determine potential adverse long-term trends. Consider lung biopsy on a case-by-case basis if disease process is unknown and severe or progressive, and/or potentially amenable to therapy. Physician judgment and patient preference will continue to be key considerations

#### **Evidence Level: III**

#### Finding 5:



- a) Currently, a combined VA/DoD clinical practice guideline for evaluation of chronic post-deployment pulmonary symptoms, and specifically unexplained dyspnea, has not been published.
- b) Inaccurate and inconsistent International Classification of Disease (ICD) coding has impeded efforts to conduct accurate surveillance and epidemiologic analysis.

The Veterans Health Administration has published a fairly comprehensive interim guideline as an information letter (IL-10-2014-13), but not as a formal guideline. The Army Public Health Command has also published an information letter for health care providers (TA 223-0614) that provides several clinical evaluation references, including a basic initial evaluation flowchart. For consistency, a common baseline approach codified as a joint DoD/VA clinical practice guideline would improve consistency in post-deployment evaluation of patients. This guideline could include recommendations for primary care providers as well as specialists.

Recommendation 5: DoD should publish a clinical practice guideline for evaluation of chronic post-deployment pulmonary symptoms on the VA/DoD Clinical Practice Guidelines website and the PDHealth.mil website. To facilitate use of these guidelines, templates should be created within the electronic health record including health and occupational/exposure history and clinical evaluation elements. Guidance should also be provided for proper ICD coding.

### Evidence Level: III

# 4.0 SURVEILLANCE FOR DEPLOYMENT-RELATED PULMONARY DISEASE

DoD employs surveillance to inform health and exposure concerns to improve military readiness. The Department has a range of established surveillance systems, including DoD-wide and Service-specific efforts, to monitor and enhance force health protection.

#### **Findings and Recommendations**

#### Finding 6:

- a) Deployment-related epidemiologic studies are compromised by a lack of individual exposure data.
- b) At present, the best available surrogates for individual exposure are location data, but classification barriers have impeded the ability of researchers to obtain these data.

#### **Recommendation 6: DoD should:**

- a) Continue efforts to improve techniques for collecting and maintaining individual and area exposure data, such as with the Individual Longitudinal Exposure Record initiative and the Periodic Occupational and Environmental Monitoring Summary, to facilitate more effective analysis of exposure/outcome associations.
- b) Develop a mechanism to allow investigators expedited access to demographic information by specific deployment location, time period, and military occupational specialty in the conduct of approved research and surveillance.



The Board supports the Assistant Secretary of Defense for Health Affairs' 2014 request to expedite access to individual location data to support epidemiologic research and surveillance. This may include declassification or work in a classified environment.

#### **Evidence Level: III**

**Finding 7:** DoD is not currently monitoring and analyzing pulmonary symptom response data from post-deployment health questionnaires on a population level.

As outlined in the <u>Baselines and Screening</u> chapter, DoD currently captures all the data entered on deployment health assessment forms electronically. The 2012 revision of the post-deployment health assessment and reassessment forms includes specific questions related to pulmonary symptoms. The Armed Forces Health Surveillance Center (AFHSC) prepares periodic deployment health reports, including summaries of deployment health assessment data. However, it does not appear that the data from the pulmonary related questions are routinely analyzed by the AFHSC or the Services to assess baseline population responses to these questions or to monitor for adverse trends. AFHSC indicated it is ready to support DoD and the Services with analyses of these data if requested. There may be value in conducting this type of surveillance if careful thought is given to what would constitute an adverse trend sufficient to warrant follow up investigation and who would conduct those investigations.

Recommendation 7: DoD should conduct routine analyses of aggregate symptom response data from pre-deployment health assessment, postdeployment health assessment, and post-deployment health re-assessment forms by deployed location, unit, and/or other levels, to identify normal background response rates and adverse trends.

**Evidence Level: III** 

**Finding 8:** Clinical and epidemiologic researchers have reported that inaccuracy and inconsistency in ICD coding of medical encounters has impeded efforts to conduct deployment-related pulmonary health surveillance and research.

Inaccurate ICD coding may result in disease misclassification with falsely increased and/or decreased numbers of specific diagnoses. This may lead to overestimating or underestimating the significance of an observed trend, making it difficult to determine if additional scrutiny is warranted.

**Recommendation 8:** DoD should investigate and implement mechanisms to improve ICD coding in the electronic health record (EHR). Including an appropriate decision support system in the next generation EHR may be one mechanism to consider.

#### **Evidence Level: III**



# **5.0 DEPLOYMENT PULMONARY HEALTH REGISTRIES**

There are several registry efforts in the public and private sectors relevant to deployment pulmonary health, including the DoD and VA Airborne Hazards and Open Burn Pit Registry, the Burnpits 360 registry, the Study of Active Duty Military for Pulmonary Disease Related to Environmental Dust Exposure (STAMPEDE) registry, and the Millennium Cohort Study. These registries can be used to help medical providers identify and connect with patients who require care.

#### Findings and Recommendations

**Finding 9:** There are a series of registries currently in operation that are capturing data in an effort to better characterize the nature and scope of potential deployment-related pulmonary disease. However, there is no enterprise-wide clinical registry for chronic deployment-related pulmonary symptoms or disease.

Establishing a registry of this nature would allow DoD to better assess the magnitude of the problem and provide a more effective tool to assess the best diagnostic and treatment modalities. Providing a mechanism for DoD, VA, and civilian institutions to participate in this registry would be the only way to allow all relevant cases to be included. The Defense and Veterans Eye Injury and Vision Registry (DVEIVR) was identified as an existing registry that is serving this purpose for ocular conditions. An EHR with structured data elements would facilitate automated data flow into registries, reducing expensive and time-consuming manual data abstraction.

Recommendation 9: DoD should implement an enterprise-wide clinical registry of deployment-related chronic pulmonary symptoms or disease. This registry should incorporate the STAMPEDE registry, reach out to other registries, and provide a mechanism for including cases evaluated at the VA and civilian institutions. The DVEIVR might be used as a starting point in determining an appropriate model.

**Evidence Level: III** 

#### 6.0 DEPLOYMENT PULMONARY HEALTH RESEARCH ACTIVITIES

A number of studies have shown variable associations between deployment and adverse pulmonary health outcomes. The Denver Working Group, the VA/DoD Deployment Health Working Group, and the Institute of Medicine (IOM) have provided recommendations on research gaps and priorities. There are opportunities to improve deployment-related pulmonary health research activities.

#### **Findings and Recommendations**

#### Finding 10:

a) There are opportunities to conduct additional observational studies to identify or test hypotheses regarding potential associations between deployment exposures of interest and pulmonary outcomes of interest.



- b) Currently, there is no comprehensive effort to track Service members and veterans with persistent post-deployment pulmonary symptoms or disease.
- c) The STAMPEDE series of studies may provide valuable objective information regarding some of the key clinical and policy questions related to deployment pulmonary health. There are concerns that losses to follow up may degrade the results.
- d) The Millennium Health Cohort may be used to conduct additional assessments of potential associations between deployment exposures and pulmonary outcomes of interest. Losses to follow up are also a concern with this study.

DoD has the capability to design and conduct effective observational studies to examine potential causal associations between specific exposures and outcomes. Additional effort in this area would also help to illustrate the true magnitude of the problem. However, challenges related to accurately characterizing individual exposure are recognized. Welldesigned prospective cohort studies or case-control studies of Service members and veterans may help determine the presence or absence of associations between exposures of concern and pulmonary outcomes of interest. An approach similar to that outlined by the IOM for burn pit exposures would be appropriate in assessing other exposures of interest.<sup>22(pp117)</sup> Conducting additional sub-studies within the Millennium Health Cohort may provide insight on potential causal factors and on the prognoses for individuals with deployment-related chronic pulmonary symptoms or disease. To study the long-term pulmonary consequences of deployment, it is necessary to have high quality, long-term follow up. A prospective cohort study of Service members and veterans who develop chronic post-deployment pulmonary symptoms or disease would characterize the nature and proportions of specific diagnoses established over time, provide prognostic information, and may yield insight as to the best practices for evaluating and treating these individuals. Expansion of the STAMPEDE III study taking place at San Antonio Military Medical Center to include all individuals, whether or not deployed, with unexplained dyspnea, as well as all Services and the VA, would be one approach.

The STAMPEDE series of studies in general are focused on practical questions related to the establishment of clinical baseline information, feasibility and utility of spirometric surveillance, and clinical evaluation of chronic post-deployment pulmonary symptoms with longitudinal follow up in a military population. These studies provide a unique opportunity to obtain information that may provide some of the best evidence available in addressing the specific questions posed to the Subcommittee. Continued and expanded support of these efforts in the form of resources and staff, including incentives to reduce losses to follow up, is advised and may assist in fulfilling other recommendations.

#### **Recommendation 10: DoD should:**

a) Conduct additional observational studies in Service members and veterans to identify or test hypotheses regarding potential associations between deployment exposures of interest and pulmonary outcomes of interest and quantify the incidence of those outcomes.



- b) Conduct a prospective cohort study of Service members and veterans with unexplained chronic dyspnea to better characterize pulmonary outcomes over time. Approaches might include expansion of the STAMPEDE III study and STAMPEDE registry.
- c) Provide resources necessary to ensure the STAMPEDE series of studies are able to accomplish their aims in a manner that maximizes internal validity and allows sufficient long-term follow up of registry patients.
- d) Provide resources necessary to conduct further studies of deploymentrelated chronic pulmonary symptoms and/or disease within the Millennium Health Cohort.

# **Evidence Level: III**

**Finding 11:** A number of individuals have received surgical lung biopsies as part of their evaluation for post-deployment pulmonary symptoms. It is not evident that systematic follow up of these individuals has been conducted to determine prognosis associated with specific pathological findings, responses to treatment, or long-term morbidity associated with the biopsy, such as chronic pain.

Although the Board does not support continued use of surgical lung biopsies for diagnostic purposes in the absence of other supporting clinical indications, a comprehensive follow up of those individuals who did undergo biopsy would provide valuable prognostic data on this group. This could be a substudy of the cohort study in Recommendation 10 and may benefit from comparing them to those with similar symptoms of similar severity who did not receive lung biopsy to determine differences in prognosis or morbidity as well as level of disability rating.

Recommendation 11: DoD should conduct a prospective study of all Service members who have undergone surgical lung biopsies for post-deployment pulmonary symptoms to assess long-term outcomes associated with specific diagnoses and morbidity associated with the procedure itself.

# **Evidence Level: III**

#### Finding 12:

- a) Research activity within the area of deployment-related chronic pulmonary symptoms or disease would benefit from improved coordination and direction.
- b) Information on ongoing, recently awarded, and proposed DoD research is divided between multiple websites or is not posted at all.
- c) The DoD electronic Institutional Review Board (IRB) system does not allow investigators to review descriptions of ongoing research from outside of their own location.

DoD has made progress in coordinating tri-Service research efforts with the establishment of the Joint Program Committees to provide oversight for the selection and funding of priority research projects. Additionally, the VA/DoD Health Executive





Council Deployment Health Working Group, the Military Operational Medicine Research Area Directorate Pulmonary Working Group, and the Denver Working Group have provided direction for research gaps and priorities. However, oversight by a single official/office with authority to determine research priorities and allocate or re-allocate funding for the DoD deployment pulmonary health research portfolio would foster coherent, complementary, and collaborative efforts in accomplishing priority research. Additionally, it is difficult, or in some cases impossible, to efficiently locate information related to ongoing or proposed DoD sponsored or initiated research. Having easy access to this information would provide investigators with a tool to reduce duplication, locate collaborators, and design research to complement studies already in progress. A single DoD research web portal and an electronic IRB system with access across the Military Health System (MHS) would provide visibility on submitted and approved clinical research protocols across DoD.

# Recommendation 12: DoD should:

- a) Designate a single office with the authority to determine priorities and allocate or re-allocate funding for the DoD deployment-related pulmonary health research portfolio.
- b) Hold, at a minimum, annual meetings with investigators and other subject matter experts to discuss deployment pulmonary health research.
- c) Create one web portal from which information on all historical, ongoing, and recently awarded deployment-related (or all) DoD health research projects may be accessed.
- d) Link DoD's electronic IRB system so that any authorized investigator at any site can review, at a minimum, titles and brief descriptions of all submitted and approved research projects.

#### Evidence Level: III

**Finding 13:** Lung tissue specimens are available from both deployed and non-deployed military personnel and provide an opportunity to assess if there are any histopathological differences between these groups.

The Joint Pathology Center estimates it has approximately 1,000 (non-neoplastic) surgical lung biopsy specimens from OIF/OEF era patients, of which about half are from patients who deployed to Iraq or Afghanistan. The Armed Forces Medical Examiner System has conducted more than 5,000 autopsies since 2001. Lung tissue specimens may be available from a large proportion of these autopsies. Conducting a histopathological comparison of a representative number of biopsy and autopsy samples may provide insight to the question of whether exposure to PM or other inhalational exposures in Southwest Asia was associated with objective findings of lung damage compared to those who had not deployed. Multiple civilian and military researchers have commented on the potential value of this information. In particular, a study of this nature may provide insight on issues related to constrictive bronchiolitis. Recent funding to resume the study of "Histopathological and chemical analytical evaluation of pulmonary specimens from



deployed and non-deployed U.S. military Service members" is a positive development in this area.

Recommendation 13: DoD should conduct a histopathological study of already available lung tissues from Service members who deployed to Southwest Asia compared to those who did not deploy as well as to those deployed to other theaters of operation in order to determine if there are characteristic histopathological changes associated with deployment to areas with high levels of airborne PM such as Southwest Asia.

**Evidence Level: III** 

**Finding 14:** Despite the substantial number of publications describing the elevated levels of PM in Southwest Asia, there is limited research on respiratory personal protective equipment (PPE) specifically for reducing PM exposures in a military field environment for military field use.

**Recommendation 14: DoD should continue research to develop respiratory PPE appropriate for field or combat use to reduce PM exposures.** 

#### **Evidence Level: III**

#### 7.0 DEPLOYMENT-RELATED PULMONARY DISEASE PREVENTION

At present, there are opportunities to prevent deployment-related pulmonary disease, including smoking cessation efforts and limiting exposure to high levels of ambient PM. Furthermore, there are opportunities to improve awareness of potential deployment-related pulmonary diseases.

#### **Findings and Recommendations**

#### Finding 15:

- a) Smoking is a known risk factor for cardiovascular and pulmonary diseases, including chronic obstructive pulmonary disease (COPD) and cancer. Secondhand smoke exposure has been causally linked to cancer, respiratory disease, and cardiovascular disease.<sup>23</sup>
- b) The percentage of Service members who smoke is higher than in the general population,<sup>24</sup> thereby increasing their risk for development of these diseases.<sup>23</sup>
- c) The MHS has a number of initiatives in this area and has prioritized supporting smoking cessation and prevention of initiation.<sup>25-28</sup> Effective, evidence-based tobacco cessation efforts would help reduce preventable morbidities in Service members.

Recommendation 15: DoD should provide evidence-based tobacco cessation programs, periodically review the effectiveness of those programs, and continue to reduce acceptance of tobacco use, e-cigarettes, and like products (e.g., discouraging sales, smoke-free bases, educational campaigns). DoD



should identify the most vulnerable groups and aggressively target tobacco cessation efforts toward these groups.

#### **Evidence Level: II**

#### Finding 16:

- a) Currently, there are insufficient individual exposure data on military members, particularly in the deployed environment.
- b) Military members operate in many parts of the world where PM levels and other air pollutants are higher than in the United States.<sup>29</sup> PM has been shown to have adverse acute and chronic health effects depending on level and duration of exposure, dose to the target organ, and susceptibility factors. Current PM respiratory protection options are suboptimal for continuous use in military field operations.
- c) Recent inspection reports indicate regulations governing operation of open burn pits have not been adequately enforced and waste management practices could be improved.<sup>30</sup>

Better characterization of individual exposures to environmental and occupational inhalation hazards may help identify potential risks to long-term health. Continued analyses and monitoring of PM and associated air quality measures would allow commanders to determine when additional preventive measures, such as respiratory PPE, may be appropriate. Current challenges in providing respiratory protection for PM are outlined in the U.S. Army Public Health Command Fact Sheet on PM Air Pollution Exposures during Military Deployments.<sup>29</sup> Improved enforcement of current regulations on open burn pit use and improved overall waste management would reduce inhalational hazards.

#### **Recommendation 16: DoD should:**

- a) Continue efforts to better characterize (quantitatively and qualitatively) and minimize potentially harmful environmental and occupational exposures.
- b) Continue efforts to develop better and more effective PPE to reduce hazardous exposures to things such as high PM levels.
- c) Improve enforcement of existing regulations on the operation of open burn pits and improve overall waste management.

#### **Evidence Level: III**

#### Finding 17:

- a) Impairment from pulmonary disease can have financial, occupational, social, and psychological effects on both patients and their families.
- b) Patients and families have indicated difficulty in navigating the medical evaluation and treatment systems. This is especially true for Reserve component members and the disability evaluation process.

In situations where medical professionals are unable to provide a specific diagnosis, there may be additional stress related to the uncertainty of



whether they may qualify for medical discharge or disability benefits in conjunction with not being able to adequately carry out their civilian or military occupation. Providers have indicated that military members with potentially disabling pulmonary symptoms of unknown cause may receive appropriate medical evaluation board processing and qualification for disability benefits without a histopathological diagnosis if a comprehensive evaluation is completed and the specialty consultant provides an appropriate narrative.

Recommendation 17: DoD should review the range of current resources available to support patients, families, and providers dealing with chronic pulmonary symptoms and disease, including those available through the VA, and, with stakeholder input, identify gaps and make improvements. This review should include issues ranging from access to care, the disability evaluation process, and other available resources such as support groups, to improve patient-centered outcomes.

# Evidence Level: III

# CHARGE TO THE DEFENSE HEALTH BOARD

#### **Guiding Principles**

On January 20, 2012, the Acting Under Secretary of Defense for Personnel and Readiness (USD (P&R)) requested that the Defense Health Board (DHB) address deployment-related pulmonary health issues and recommend a comprehensive approach for health assessment and disease prevention, in addition to providing direction for future research and surveillance in this area (see <u>Appendix A</u>).

In response to USD (P&R)'s request, the DHB assigned its Public Health Subcommittee to address the major concerns of deployment pulmonary health. The Subcommittee developed Terms of Reference (Appendix B) to define the scope of the investigation, the Subcommittee's criteria for grading the recommendations, and a set of Guiding Principles (see Box 1A). The Subcommittee met in person and by telephone conference to receive briefings and consultations from subject matter experts from a variety of organizations both within and outside DoD. In addition, it conducted a session to which members of the public were invited to present information and positions regarding deployment pulmonary health. Appendix D contains a complete list of meetings and briefings received.



#### **Box 1A: Guiding Principles**

The following Guiding Principles were adopted as a foundation for review of the questions posed to the Public Health Subcommittee regarding assessment of deployment pulmonary health.

#### **Overarching Principle:**

DoD has an obligation to develop, implement, and enforce policies to monitor and protect the health of Service members; to promptly identify and mitigate health threats; and to assess, diagnose, and treat health issues according to best available practices.

#### **Guiding Principles:**

These principles anticipate the recommendations of the Board will:

1) make the Service member's health of primary concern;

2) be based on the best available, highest quality evidence;

3) be measurable and outcomes-based to the extent possible;

4) consider the relative risks, benefits, and mission impact associated with implementing specific recommendations;

5) take into consideration current DoD and other Federal Agency initiatives, undertakings, and recommendations regarding assessment of deployment pulmonary health; and

6) consider prevention to the greatest extent possible in formulating recommendations.

# Summary of Objectives

This report addresses current and proposed policies, best practices, and the best available evidence to provide recommendations regarding:

- 1. Establishing pre-deployment baseline pulmonary status including pulmonary function;
- 2. Screening for potential deployment-related chronic pulmonary symptoms and disease;
- 3. Clinical protocols to diagnose individuals with persistent post-deployment change in pulmonary status;
- 4. Appropriate surveillance for post-deployment chronic pulmonary symptoms and disease;
- 5. The sufficiency of current and planned registries of individuals with chronic postdeployment change in pulmonary status or disease;
- 6. Guidance for future deployment pulmonary health research with respect to priority and direction; and
- 7. Prevention of deployment-related chronic pulmonary disease.

# Establishing Pre-Deployment Clinical Baselines and Post-Deployment Screening for Chronic Pulmonary Disease

Capturing appropriate baseline clinical information is important in determining if there are quantitative or qualitative temporal and longitudinal changes in pulmonary health



potentially related to deployment. It is also important to document if baseline risk factors are present, such as smoking, which may act as

confounders in assessing the relative contribution of other exposures to the outcomes of interest. As stated by the Occupational Safety and Health Administration, "the fundamental purpose of screening is early diagnosis and treatment of the individual," and is a component of medical surveillance programs.<sup>31</sup> Screening is implicit in the predeployment process of acquiring baseline clinical information, as this information is used to determine if someone is qualified for deployment or continued service. If a pulmonary condition is identified or other abnormal test results are discovered, this may lead to additional evaluation and possibly a medical evaluation board, with potential adverse career implications. Consideration of the relative risks and benefits are imperative in selecting appropriate items to include in establishing clinical baselines. The risks may manifest in the potential harm that may result from inaccurate or misleading test results, lost productivity due to medical appointments and testing, iatrogenic complications of follow up testing, or adverse career actions.

Post-deployment screening has secondary and tertiary prevention objectives with primary prevention implications. As with any screening program, the goal is to use screening tests that have sensitivity, specificity, predictive value, and reliability for diseases in which early intervention may provide the greatest benefit. Identification of adverse trends or sentinel events (unexpected findings) may lead to primary prevention activities to identify and reduce or eliminate potential causal factors and subsequent disease cases. A key question before the Board in its consideration of appropriate clinical baseline and screening is whether obtaining baseline pulmonary function (spirometry) on all Service members prior to deployment is indicated to allow objective post-deployment assessment of changes over time. Furthermore, if baseline spirometry is indicated, sufficient quality control measures must be implemented to ensure reliability and validity of spirometry data.

#### Diagnosis of Pulmonary Disease

A focus area of the tasking is the evaluation of data regarding Service members and veterans who may have one or more persistent post-deployment pulmonary symptoms including unexplained shortness of breath/dyspnea, cough, wheezing, and/or chest tightness.<sup>13,32</sup> Once an individual is identified as having persistent pulmonary symptoms following deployment, there is a lack of consensus on which systematic processes or approaches should be used in pursuing a diagnosis. For example, a specific item of controversy involves the use of surgical lung biopsy in an individual with unexplained shortness of breath and relatively normal noninvasive test results.<sup>33,34</sup> In a study by King et al<sup>12</sup> the sentinel impairment of multiple Service members was the inability to pass a physical fitness test following deployment, suggesting this could be one possible indicator of underlying pulmonary disease. A related area of controversy and uncertainty addressed in this report is the clinical significance of the histopathological presence of constrictive bronchiolitis and to what extent it may occur at higher rates in veterans of OEF/OIF than in the general or non-deployed population. This report assesses and comments on appropriate strategies to evaluate post-deployment chronic pulmonary



symptoms, such as chronic unexplained dyspnea, and chronic pulmonary disease in Service members and veterans.

#### Pulmonary Health Surveillance

The World Health Organization defines public health surveillance as "the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice."<sup>35</sup> It further states the purposes may include serving "as an early warning system for impending public health emergencies," documenting "the impact of an intervention," tracking "progress towards specified goals," and monitoring and clarifying "the epidemiology of health problems, to allow priorities to be set and to inform public health policy and strategies."<sup>35</sup> Public health surveillance may also be specific to occupational health or chronic disease.

Occupational health surveillance is, "the ongoing systematic collection, analysis, and dissemination of exposure and health data on groups of workers for the purpose of preventing illness and injury."<sup>36</sup> Medical surveillance is a component of occupational health surveillance and includes the initial and periodic health evaluation of those potentially exposed to work-related hazards.<sup>37</sup> The National Institute for Occupational Safety and Health (NIOSH) defines occupational respiratory disease surveillance as "the ongoing, systematic collection, analysis, and dissemination of health and hazard data to monitor the extent and severity of occupationally-related lung disease and related workplace exposures for use in public health education and in disease prevention."<sup>38</sup> This report assesses current surveillance activities for sufficiency in achieving the above goals in the area of deployment pulmonary health.

#### Pulmonary Health Registries

The Board was asked to assess the types of registries that are being used or could be used to track individuals with pulmonary symptoms or disease. Because of concerns regarding exposure to PM and burn pits and other potential environmental and occupational hazards during deployment, a number of health registries have been established, including the Department of Veterans Affairs (VA) Airborne Hazards and Open Burn Pit Registry and the non-profit Burnpits 360 registry, both self-report registries.<sup>39,40</sup> In addition, San Antonio Military Medical Center in San Antonio, Texas has been maintaining a patient registry of Service members and veterans evaluated for chronic post-deployment pulmonary symptoms as part of the STAMPEDE study.<sup>41</sup> Finally, the Millennium Cohort Study, a prospective cohort study, tracks Service member health data through questionnaire responses and complementary data sources from DoD and VA, among others.<sup>42</sup> Existing registries are assessed to determine if they are sufficient to support the objectives of the Department related to deployment pulmonary health.

#### Pulmonary Health Research Activities

Ongoing and planned research in deployment pulmonary health includes prevention, clinical, pathologic, epidemiologic, and toxicologic studies. Significant challenges exist in identification and follow up of patients and control groups, accuracy and completeness of electronic health and other records, and ascertainment of individual-level exposure



data. This report addresses completed, ongoing, and planned research; identifies gaps; and provides recommendations.

#### Prevention of Deployment-Associated Chronic Pulmonary Disease

The levels of prevention include primary, secondary, and tertiary.<sup>43(p5-6)</sup> Primary prevention involves taking action to prevent the initial development of disease, such as immunization or limiting hazardous exposures.<sup>43(p5)</sup> The hierarchy of controls for limiting exposure include elimination/substitution, engineering controls, administrative controls, and personal protective equipment.<sup>44</sup> Secondary prevention, such as screening, allows for early detection of disease, and tertiary prevention reduces the impact of existing disease.<sup>43(p6)</sup> Current post-deployment screening processes should identify individuals with exposures of concern or symptoms associated with development of chronic pulmonary disease or exacerbation of a pre-existing disease, such as asthma. Appropriate screening may provide an opportunity for prevention of chronic pulmonary disease through interventions such as smoking cessation, obesity prevention,<sup>45-47</sup> and exclusion of individuals diagnosed with specific pulmonary conditions from certain military occupational specialties. In the absence of clear causal factors, significant effort may be directed at tertiary prevention in an attempt to improve symptoms, slow progression, prevent or delay complications of a disease, and improve overall function. Additionally, if patterns emerge in which specific exposures are identified as likely causal factors, primary prevention may be directed toward reducing or eliminating these exposures. This report examines potential areas for improvement in prevention of deployment-related pulmonary disease.

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# **1.0 INTRODUCTION**

# 1.1 BACKGROUND: HISTORY OF DEPLOYMENT PULMONARY HEALTH CONCERNS

This report examines issues related to improving the ability to identify, prevent, and treat chronic pulmonary disease potentially related to deployment exposures. With the exception of asthma, there has historically been little evidence of a clear epidemiologic association between deployment and chronic pulmonary disease. Exacerbations of asthma were noted to be associated with overseas deployment, exertion, and dust during World War II.<sup>48</sup> Studies have also reported an association between deployment to the Persian Gulf War and respiratory symptoms or illness. Respiratory complaints were frequent among a group of troops deployed to Saudi Arabia and were variously associated with environmental exposures, living conditions, history of respiratory disease prior to deployment, and smoking; with troops deployed a longer period of time more likely to report respiratory problems.<sup>49</sup> Veterans deployed to the Persian Gulf area were found to have a higher prevalence of pulmonary symptoms in comparison to veterans who deployed only to Germany, and self-reported exposure to smoke from tent heaters was significantly associated with self-reported exposure-symptom scores.<sup>50</sup> Another study found that Gulf War era veterans who had deployed had a higher rate of hospitalization in the Department of Veteran Affairs (VA) system for diseases of the respiratory system compared to non-deployed veterans, with a proportionate morbidity ratio of 1.19 (confidence interval (CI) 1.10-1.29).<sup>51</sup> However, the authors highlighted potential sources of bias as a possible explanation for this finding, and a similar comparison in two other hospital systems showed no association. A case-control study looking at the association between exposure to oil fire smoke and diagnoses of asthma among U.S. Army Gulf War veterans found a significant association, with an adjusted odds ratio of 1.4 (CI 1.1-1.8).<sup>52</sup> An Institute of Medicine (IOM) report concluded, however, there was insufficient evidence to determine an association between deployment to the Gulf War and pulmonary disease, and there was limited evidence of an association between deployment to the Gulf War and decreased lung function in the first 10 years after the war.<sup>53</sup>

Following the Gulf War, the sustained operational pace of the U.S. military increased dramatically. Meanwhile, the number of Service members was significantly reduced and the deployment rate increased.<sup>54</sup> In the past decade, military operations in Iraq and Afghanistan have required longer, repeated, and higher intensity deployments.<sup>55</sup> As a result, Service members may have been vulnerable to potential exposures over the course of multiple deployments.

Significant attention has been given to examining a potential link between exposure to various inhalation hazards associated with deployment to Southwest Asia, such as particulate material, burn pits, industrial pollution, diesel exhaust, and others, and adverse health outcomes. To better characterize the possible environmental hazards in the deployed environment, the Department of Defense (DoD) Central Command Area of Operations implemented air, water, and soil sampling at the outset of Operation



#### ENDURING FREEDOM (OEF) and Operation IRAQI FREEDOM

(OIF).<sup>56</sup> Sampling revealed that particulate matter (PM) was the most ubiquitous exposure, prompting the charter of the Particulate Matter Joint Working Group in 2005 by the Assistant Secretary of Defense for Health Affairs to investigate potential health issues associated with PM exposures in OEF/OIF.<sup>57,58</sup> A symposium was held at the National Institute for Occupational Safety and Health (NIOSH) to identify gaps in knowledge about PM and its toxicity.<sup>59</sup> As a result, the U.S. Army Center for Health Promotion and Preventive Medicine, now the U.S. Army Public Health Command, implemented the Enhanced Particulate Matter Surveillance Program,<sup>57</sup> which collected and analyzed PM samples between 2005 and 2007 from 15 sites where U.S. military forces were located.<sup>3,60</sup>

In 2006, a U.S. Air Force bioenvironmental engineer expressed concern in a memorandum regarding potential hazards associated with the burn pit at Joint Base Balad, stating "there is an acute health hazard for individuals."<sup>1</sup> Furthermore, media coverage heightened concerns of Service members about exposure to open air burn pits at Joint Base Balad and the potential risk of adverse health outcomes, including pulmonary disease.<sup>4,5,61</sup> A similar memorandum from a U.S. Army environmental science engineering officer summarized air quality over an eight-year period regarding PM for Bagram Air Field in Afghanistan. The results documented elevated levels of PM10 (diameter less than 10 microns) and PM2.5 (diameter less than 2.5 microns) and reported an air quality index considered "unhealthy" by U.S. Environmental Protection Agency (EPA) standards.<sup>2</sup> The results of the DoD Enhanced Particulate Matter Surveillance Program (EPMSP) indicated that PM10 and PM2.5 levels exceeded the annual Military Exposure Guideline values of the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) and World Health Organization guidelines at all sites tested.<sup>3</sup> The results also showed that PM2.5 levels exceeded the U.S. EPA's annual and 24-hour standards at all locations sampled.<sup>3</sup> Public and congressional concerns about deployed U.S. military personnel exposure to open burn pits in Iraq and Afghanistan prompted an investigation of the potential long-term health consequences by the IOM.<sup>22</sup> The subsequent IOM report found only limited, suggestive evidence of an association between exposure to combustion products from burn pits and decreased pulmonary function. The report concluded that deployment may be associated with long-term health effects, particularly in highly exposed populations or susceptible populations, but that there was insufficient evidence of association between exposure to combustion products from burn pits and cancer, respiratory disease, circulatory disease, neurologic disease, or adverse reproductive or developmental outcomes.

# 1.2 EPIDEMIOLOGY OF DEPLOYMENT PULMONARY HEALTH

#### Summary of Studies to Date

The potential association between deployment in OEF/OIF and pulmonary health has been examined in multiple studies. A review of health events documented in the Joint Medical Workstation theater medical surveillance system was conducted for Service members deployed during 2003. This review found the second-most reported number of diagnoses to be in the category of respiratory conditions, affecting 21 percent of first-time deployers.<sup>62</sup> Other studies have shown results varying from no significant associations



observed to increased respiratory symptoms<sup>63-66</sup> to an increase in pulmonary diseases such as asthma or chronic obstructive pulmonary

disease (COPD).<sup>7,9,66,67</sup> Summaries of relevant OEF/OIF deployment-related pulmonary health studies follow. Unfortunately, the findings of some of these studies are limited by small sample size, exposure or outcome misclassification, inadequate methodology, use of inappropriate statistics, and potential conflicts of interest on the part of the investigators.

#### Respiratory Symptoms

Some studies have found no association between deployment and increased respiratory symptoms. For instance, Abraham and Baird conducted a case crossover study comparing in-theater electronic medical records with short term exposure to PM and found no statistically significant association between PM and acute cardiorespiratory outcomes.<sup>68</sup> However, this study had only limited statistical power and no non-deployed individuals or individuals deployed to other theaters of operation were included.<sup>68</sup> In other reports, increased respiratory symptoms have been documented in relation to deployment.

Sanders et al examined the prevalence of common ailments and the impact on combat operations among U.S. military personnel deployed to Iraq or Afghanistan using a self-reported survey of 15,459 veterans.<sup>69</sup> They reported that 69 percent of military personnel deployed to OEF/OIF experienced acute respiratory illness, 17 percent of which required medical care. This study sampled OIF/OEF deployers only and no non-deployed individuals or individuals deployed to other theaters of operation were included.

Abraham et al conducted a retrospective cohort study of military deployment and postdeployment medical encounters for respiratory conditions and determined that OIF deployment was associated with a 25 percent increase in the rate of respiratory symptoms relative to non-deployers stationed in the United States, but no significant increases relative to personnel stationed in South Korea.<sup>9</sup> This study suggests that the increasing incidence of respiratory symptoms may be associated with some other factor or deployment in general, and may not be specific to deployment to Southwest Asia.

Roop and colleagues conducted a retrospective observational cohort study that included military occupational specialty and smoking history and also found higher rates of newly reported respiratory symptoms in asthmatic and non-asthmatic deployers during deployment compared to pre-deployment.<sup>66</sup> The same study noted that an increase in respiratory symptoms was accompanied by a small but significant increase in difficulty performing assigned duties in asthmatics.<sup>66</sup> Additionally, elevated odds of respiratory symptoms (cough, shortness of breath) were associated with land-based deployment, and symptoms increased with longer deployment periods.<sup>65</sup> No associations were observed with asthma, chronic bronchitis, or emphysema. Inconsistent risk with cumulative exposure time suggested that specific exposures rather than deployment in general are determinants of post-deployment respiratory illness.



Finally, Barth et al examined the prevalence of respiratory diseases among veterans of OIF/OEF and reported that deployed veterans were more likely to be diagnosed with sinusitis during and after 2001 compared to nondeployed veterans. No significant differences in asthma or bronchitis risk between deployed and non-deployed veterans were reported.<sup>64</sup>

#### Unexplained Dyspnea

In 2002, Morris and colleagues conducted a study of active duty personnel complaining of exertional dyspnea (breathlessness).<sup>70</sup> Obstructive pulmonary disease was found in 52 percent of the patients, including 35 percent with exercise-induced asthma and 12 percent with asthma. Importantly, because most of these patients had been on active duty for a short time, their disease likely predated their entry into the military, was not detected on the entry examination, and was not associated with deployment. A subsequent investigation, the Study of Active Duty Military Personnel with Environmental Dust Exposure (STAMPEDE I), evaluated 50 Service members that had deployed to OEF/OIF and had returned complaining of dyspnea and reduced exercise tolerance.<sup>41</sup> For this study, returning military personnel underwent standardized evaluation within 6 months of return. Twenty-one individuals (42 percent) remained undiagnosed. However, 18 individuals (36 percent) had evidence of airway hyperreactivity, with 8 (16 percent) meeting the criteria for an asthma diagnosis, and 10 (20 percent) with nonspecific airway hyperreactivity.<sup>41</sup> A follow-on clinical evaluation study titled STAMPEDE III is currently in progress.<sup>71</sup>

#### **Obstructive Lung Diseases**

While acute respiratory symptoms have been found to be common among deployed personnel, concerns have arisen regarding a possible association between chronic lung diseases and deployment. A 2010 retrospective review of 6,233 medical records of veterans serving between March 2004 and April 2007 showed that, among those veterans seeking health care through the Northport Veterans Affairs Medical Center, individuals who served in Iraq or Afghanistan had a higher proportion of asthma diagnoses when compared to those serving stateside during the same study period (6.6 percent versus 4.3 percent; with a crude odds ratio of 1.58; 95 percent CI, 1.18-2.11). Since many veterans obtain their health care through employer-provided or other sources of insurance, extrapolation of these findings to the overall population of veterans is not possible.<sup>7</sup>

A nested case-control study that linked deployment history with post-deployment inpatient and out-patient medical records found the post-deployment rate of medical encounters for obstructive pulmonary disease was significantly higher than the predeployment rate for those with a single deployment to Iraq or Afghanistan (predeployment rate, 20.4 encounters per 1,000 person-years, 95 percent CI, 18.5-22.3; postdeployment rate, 30.1 encounters per 1,000 person-years, 95 percent CI, 27.8-32.5).<sup>67</sup> This study lacked a specific exposure assessment and no non-deployed individuals or individuals deployed to other theaters of operation were included.

An ongoing retrospective chart review of active duty members who underwent a medical evaluation board (MEB) for a diagnosis of asthma is examining the proportion who



deployed, and of those who deployed, what proportion were diagnosed prior to deployment.<sup>8,15</sup> Of 1,445 active duty Army personnel with a

diagnosis of asthma in the MEB database from 2005-2009, 50 records were reviewed. Of those fifty, twenty (40 percent) had been deployed. Ten of those who had deployed (50 percent) were diagnosed with asthma post-deployment. A similar chart review looked at the proportion of active duty military with a diagnosis of COPD in the electronic medical record system who had deployed to OEF/OIF, and what proportion of those were diagnosed prior to deployment.<sup>72</sup> A total of 1,033 patients were identified as having a diagnosis of COPD between 2005 and 2009. Of these, only 154 had spirometry as part of their evaluation, the average age was 45 years old, and the mean pack-year tobacco history was 20. Forty-two patients (27 percent) had deployed and only two had a pre-existing diagnosis of COPD. The remaining 40 patients (95 percent) were diagnosed after deployment on the basis of increased symptoms. In both studies, limitations in the data and sample size analyzed thus far make it difficult to determine the strength of any associations.

A recent study by Abraham et al cites a higher rate of medical encounters for asthma for those deployed to OIF compared to U.S. stationed personnel (incidence rate ratio = 1.54; 95 percent CI, 1.33-1.78).<sup>9</sup> However, no association was noted with deployment to a burn pit location compared to a non-burn pit location. As with respiratory symptoms overall, there was no significant increase noted in encounters for asthma in those deployed to OIF relative to personnel deployed to Korea.

#### **Constrictive Bronchiolitis**

In 2011, King et al published an article in the *New England Journal of Medicine* reporting that a significant proportion of Service members referred with unexplained dyspnea on exertion after deployment were diagnosed with constrictive bronchiolitis (CB) following surgical lung biopsy. In this study, 80 Service members with relatively normal standard pulmonary evaluations were referred from Fort Campbell for further evaluation. Of those, 49 underwent surgical lung biopsy and 38 were diagnosed with CB.<sup>12</sup> CB is a condition that has been associated with certain inhalational exposures, including diacetyl<sup>73</sup> and sulfur mustard.<sup>74</sup> There is no specific treatment for this condition other than attempting removal from the potentially associated exposure. Of note, of the 38 soldiers in the King et al study diagnosed with CB, 28 had been exposed to sulfur fires.<sup>12</sup> Associations between inhalational exposure to sulfur dioxide and development of CB are reported in the literature.<sup>75,76</sup>

However, the study failed to examine appropriate control groups (e.g., non-deployers or civilians with dyspnea on exertion) and only clinical data from the 38 who had been diagnosed with CB were presented, so causality can only be inferred. Furthermore, CB is a rare disease that had not been previously characterized in Service members, and the prevalence of lung tissue findings consistent with CB in the normal background population is unknown; thus, there is no useful comparison group. The conclusion of the study that there is a strong association between CB and exercise limitation in a cohort of soldiers who served in the Middle East remains an untested hypothesis.<sup>77</sup>



There is also clinical and pathologic imprecision in the diagnosis of CB. CB sometimes has been used interchangeably with obliterative

bronchiolitis or bronchiolitis obliterans,<sup>78</sup> though the use of these terms in the literature is inconsistent.<sup>75</sup> One definition of CB includes a range of bronchiolar changes including submucosal scarring, narrowing of the bronchial lumen, and chronic inflammation.<sup>79</sup> Another definition states that "clinically significant disease is associated with the fibrotic obliteration of the bronchiolar airways. This fibrotic constrictive lesion develops externally to the airway lumen, constricting the airway in a concentric manner with eventual obliteration of the lumen."<sup>78</sup> When CB results in complete obliteration of the bronchiolar lumen.<sup>79</sup>

Shortness of breath (dyspnea) has been reported as a common presenting symptom of CB, followed by cough.<sup>75,78,80</sup> Key diagnostic findings may include a fixed obstructive airflow pattern on spirometry and mosaic attenuation on high resolution computed tomography (CT) scan, although these are not always present, particularly early in the disease process, and normal, restrictive, or mixed patterns on spirometry have been reported.<sup>75,78,80-83</sup> CB is primarily associated with lung transplants, but may also result from autoimmune disorders, post-infection, toxic fume inhalation, and other exposures.<sup>75,78,81,83</sup> In a case series of 29 patients with non-transplant related CB, all patients reported dyspnea as a symptom with five (17 percent) reporting cough as a symptom. All 29 patients had abnormal pulmonary function tests, with an obstructive defect in 25 (86 percent), and all had mosaic perfusion and air trapping on CT. The most common diagnoses were rheumatoid arthritis in 10 patients (34 percent) and cryptogenic CB in nine patients (31 percent).<sup>80</sup> Classical non-transplant CB was reported as having three stages: an acute respiratory stage, a remission stage, followed by progressive respiratory decline.<sup>82,83</sup> In the past decade, cases described as indolent CB have been reported which developed insidiously following exposures without an initial exposureacute illness event.<sup>82</sup> Primary examples of this include CB in workers exposed to diacetyl and other flavorings.<sup>82,84</sup> As a result, it has been suggested that since noninvasive tests may be insensitive and the clinical course may initially be insidious, that a high index of suspicion for this disease is warranted, particularly in young workers with new-onset exertional dyspnea.<sup>82</sup>

Despite the challenges in diagnosing CB with non-invasive testing, the Defense Health Board does not support the use of surgical lung biopsy as an early diagnostic tool in evaluating chronic unexplained dyspnea in the absence of significant, progressive symptoms or objective clinical findings based on non-invasive evaluation, as was done in the *New England Journal of Medicine* study,<sup>33</sup> unless as part of an Institutional Review Board (IRB) approved research protocol. While surgical lung biopsy may provide useful histopathological information, particularly when correlated with the available clinical data, the histopathological findings in themselves may or may not inform treatment or prognosis. In addition, it does not support the use of non-clinically indicated surgical lung biopsy as a way to make a determination of disability.

#### Acute Eosinophilic Pneumonia



Acute Eosinophilic Pneumonia (AEP) is a rare disease with unclear etiology, characterized by febrile illness, acute respiratory symptoms



(e.g., dyspnea), infiltrates on radiographs and eosinophilia.<sup>85</sup> In 2004, 18 cases of AEP were reported from a group of 183,000 soldiers deployed in or near Iraq.<sup>86</sup> All patients reported smoking while a majority had just begun smoking and all but one of the patients reported exposure to fine sand or dust.<sup>86</sup> Two patients died, but the rest recovered and subsequently returned to near normal lung function.<sup>86</sup> A chart review of diagnosed idiopathic AEP in deployed active duty soldiers from March 2003 to March 2010 identified 44 cases, in which a history of smoking was common.<sup>87</sup>

# **1.3 ANIMAL STUDIES**

Animal studies, or toxicological studies, have been used to investigate the effects of PM exposure. However, the physiologic relevance of these animal models for chronic exposure is uncertain. Several studies have examined the effects of dust from Kuwait,<sup>88</sup> Iraq,<sup>89,90</sup> Afghanistan,<sup>90</sup> and as well as Fort Irwin, California<sup>90</sup> and Northeastern Arizona<sup>91</sup> on the rat. For example, Wilfong et al reported low toxicity of PM10 (less than 10 microns) after examination of bronchoalveolar fluid and histopathological changes in the lungs of rats following a single intratracheal instillation of high doses of Kuwait PM10.<sup>88</sup> In another study, adult rats underwent a six-week exposure of air or mainstream cigarette smoke that included Iraqi sand or crystalline silica or air during the last two weeks.<sup>92</sup> Overall, the authors demonstrated that exposure to Iraqi sand did not result in alterations in body weight gain or motor activity, impaired pulmonary function, or airway pathology, and only minimal toxicological responses, similar to or less than seen following as a confounder.

Ghio et al examined the biological effects of Northeastern Arizona desert dust in cultured respiratory epithelial cells and in an acute animal toxicity model. The authors also reported the biological effects were similar to those seen with silica, though statistical comparisons between sand and silica exposed groups were not reported and no individual effect could be reliably linked to any specific exposure.<sup>91</sup> Szema et al performed a single intratracheal instillation in mice of high doses of dust from Camp Victory, Iraq, which caused lung inflammation in this model.<sup>89</sup> However, there is concern that the design of this study does not reflect a realistic exposure, the conclusions are not supported by the data, and the methodology and analysis are not scientifically sound. Taylor et al also performed in vitro and in vivo studies on dust samples from various sites and found the dust from Taji and Talil, Iraq to be the most cytotoxic, followed by Afghanistan; Camp Victory, Iraq; and Fort Irwin dusts.<sup>90</sup> Unfortunately, this study was based entirely on soluble extracts of sand and lacked any normalization between samples, so it is difficult to justify any of the comparisons between groups. Overall, the authors concluded the lung pathology was similar in all dust-exposed rats.<sup>89,90</sup>

# **1.4 EXPOSURE CONCERNS**

Service members may be exposed to various occupational and environmental hazards whether in garrison, in training or field exercises, or deployed in support of ongoing

military operations. Some of these exposures may be visible, have distinctive odors or acute effects, while others may go unnoticed. As



mentioned above, there has been concern raised about potential hazards associated with inhalational exposures among Service members and veterans who were deployed to Southwest Asia.<sup>56,93-96</sup> Specific exposures of concern include PM, combustion sources, industrial pollution, as well as personal health behaviors such as smoking.

#### Particulate Matter (PM)

PM is defined as air pollutants that are a mixture of small, solid particles and liquid droplets.<sup>29</sup> PM can be composed of acids, organic chemicals, metals and soil or dust particles.<sup>97</sup> Another source of PM is smoking. In general, PM levels are higher in Southwest Asia than in the United States.<sup>29</sup> Southwest Asia sources include dust storms, emissions from local industries, burn pits, and vehicle emissions near base camps and military operations.<sup>29</sup>

PM10 is small enough to get into the lungs.<sup>98</sup> The incremental particulate sizes of most concern include particles with a diameter less than 2.5 microns (PM2.5), and particles with a diameter of less than 0.1 microns (PM0.1), or ultrafine PM, as all these particle sizes may reach deep into the lungs.<sup>99,100</sup> A number of time-series studies in various locations have shown associations between small, short-term PM exposure and increases in daily mortality and symptoms of certain illnesses, including exacerbation of asthma and increase in deaths due to respiratory and cardiovascular diseases in the general population.<sup>101-103</sup> Cohort studies have also indicated associations between long-term PM exposure and higher death rates due to cardiovascular disease and increased incidence of respiratory disease.<sup>104,105</sup> The impact on a younger, healthier military population is unknown.

#### **Combustion Sources**

To manage military waste, open air burn pits have been the primary method of waste management in combat operations, including in Iraq and Afghanistan.<sup>22</sup> Comprehensive guidance on the use of open burn pits in OIF/OEF was published in U.S. Central Command Regulation 200-2<sup>95</sup> and DoD Instruction 4715.19<sup>106</sup> in an effort to reduce potential exposures. Burn pit emissions contain PM and numerous combustion products with known toxicities, some of which are associated with pulmonary disease. Other exposures of concern that have been identified include vehicle exhaust, industrial emissions, munitions, and sulfur fires (in Iraq).<sup>65</sup>

#### Smoking

According to results of a 2011 survey, the percentage of current smokers in the U.S. military was 24 percent, in comparison to 21.2 percent of the U.S. civilian population.<sup>24</sup> The percentage of current smokers varies by Service, with the U.S. Marine Corps having the highest percentage of smokers (30.8 percent), followed by the U.S. Army (26.7 percent), U.S. Navy (24.4 percent), and the U.S. Air Force (16.7 percent). "Across all services, personnel exposed to high combat were more often heavy cigarette smokers than personnel exposed to low or no combat, with Army personnel exposed to moderate or high combat more often heavy smokers than those not combat deployed. On the other



hand, personnel who did not experience combat were more often smoking abstainers than personnel exposed to combat; in particular, Navy and Air Force personnel with no combat exposure were more often smoking abstainers than personnel exposed to combat."<sup>24</sup>

A number of researchers have also examined the association between smoking and deployment. Forgas et al surveyed predominantly ship-based active duty U.S. Naval personnel deployed to Operation DESERT STORM regarding their smoking and smokeless tobacco habits.<sup>107</sup> Of those with reported smoking histories, 69.1 percent smoked at the time of their deployment and 73.8 percent indicated they smoked during their deployment. While 3.2 percent indicated quitting while deployed and 3.0 percent smoked less, 29.2 percent reported smoking more and 7.0 percent reported initiation of smoking while in the Persian Gulf. The top reasons cited for changes in smoking habits were stress (35.1 percent) and boredom (21.4 percent). The authors noted the ready availability of tobacco products and low prices (or gifts of cigarettes) were considered possible contributing factors. Although 22.8 percent of respondents indicated that military or DoD efforts had been successful in influencing them to quit, 31 percent of respondents had indicated beginning their habit after entering the Navy.<sup>107</sup>

Boos and Croft conducted a survey to assess smoking rates in British Armed Forces personnel assigned to a military field hospital before and during a wartime deployment to Iraq in 2003.<sup>108</sup> Smoking prior to deployment was reported in 29 percent of respondents (160 of 556 surveyed). Six weeks into the deployment, the prevalence of smoking rose to 38 percent (an additional 52 smokers). For the additional smokers, 33 of the respondents had resumed smoking and 19 initiated smoking. Prevalence of smoking was higher in regular Army personnel (42 percent) compared to Reservists (32 percent, *P*=0.017); and higher in non-officers (47 percent) than in officers (38 percent, *P*=0.048). The median age of current regular smokers (31.9; 95 percent CI, 30.8-33.0) was less than non-smokers (34.4; 95 percent CI, 33.5-35; *P*<0.0001). The most reported reasons for starting or increasing smoking were boredom (54 percent), perceived social benefits (24 percent), and stress (13 percent).<sup>108</sup>

Toward the end of a 6- to 7-month deployment in a combat theater, DiNicola and colleagues randomly interviewed 150 male enlisted military personnel, predominantly from the U.S. Marine Corps, regarding their cigarette smoking habits.<sup>109</sup> They found that 36 percent smoked prior to deployment and 56 percent smoked during deployment. Of the 56 percent who smoked during deployment, 59 percent indicated they increased their amount of smoking during the deployment, and 81 percent indicated they intended to stop smoking upon returning home. Factors attributed to increased smoking habits included emotional stress, boredom, peer pressure, a perceived pleasurable way to socialize, and nicotine addiction. Only one Marine smoked before but not during deployment.<sup>109</sup>

An analysis of Millennium Health Cohort data was conducted to describe new smoking among baseline never smokers, smoking recidivism among past smokers, and changes in daily smoking among smokers in relation to military deployment.<sup>110</sup> Initiation of smoking among never smokers was nominally higher among single-time deployers (2.3



percent) and multiple-time deployers (2.2 percent) compared to nondeployers (1.3 percent). However, the odds of initiation of smoking

among never smokers was only significant for deployments with combat exposures (adjusted odds ratio (AOR) of 1.6; 95 percent CI, 1.15-2.32). Resumption of smoking was also higher among single-time deployers (39.4 percent) and multiple-time deployers (40.3 percent) compared to non-deployers (28.7 percent). Deployment with combat exposures was associated with a 1.3 times greater odds of resuming smoking among baseline past smokers (95 percent CI, 1.07-1.51). Deploying for more than 9 months (AOR 1.28; 95 percent CI 1.03-1.59), single deployments (AOR 1.23; 95 percent CI, 1.06-1.41), and multiple deployments (AOR 1.55; 95 percent CI, 1.24-1.93) were all independently associated with increased odds for smoking recidivism among past smokers as well. However, deployment was not associated with a significant change in daily amount smoked among baseline smokers, regardless of deployment length or combat exposure.<sup>111</sup>

Barton et al conducted an analysis on the prevalence of smoking in a sample of Australian Defence Force personnel deployed to the Solomon Islands between July 2003 and December 2005, compared to a non-deployed group.<sup>112</sup> The authors also examined whether smoking patterns changed during deployment and which factors may be associated with smoking. Although more than 40 percent of the sample for whom smoking status could be determined had reported current or past smoking habits, there was no significant difference between those who had deployed to the Solomon Islands (23 percent) and those who had not (18 percent). However, 63 percent of current or former smokers who had been on any overseas deployment indicated smoking more while on overseas deployment, citing boredom, stress, and the lower cost of cigarettes as reasons for changing smoking behaviors.

A study of 278 Air Force security forces personnel who completed a one-year deployment to a high threat combat environment in Iraq was conducted to examine tobacco use patterns cross-sectionally and longitudinally.<sup>113</sup> Patterns of tobacco use (including smoking or smokeless tobacco) were assessed pre-deployment, during deployment, and, in a subset of 142 Airmen, post-deployment. The nominal prevalence of any level of smoking found by summation of the proportion of daily smokers, dual users, and occasional smokers was noted as follows: pre-deployment 47.1 percent; during deployment 52.1 percent; and post-deployment 38 percent. The number of personnel who reported daily smoking nominally rose from 21.2 percent pre-deployment to 26.6 percent during deployment, falling back to 22.5 percent in the subset assessed post-deployment. However, the overall prevalence patterns reflecting different types of tobacco use did not vary significantly across the deployment cycle (pre-deployment to deployment chi-square (4)=5.70, P=.22; pre-deployment to deployment to postdeployment chi-square (8)=8.06, P=.43). A sub-analysis of individual trajectories of the Airmen who completed all three assessments indicated 1 in 6 (16.9 percent) initiated tobacco use (smoking or smokeless tobacco) or engaged in harm escalation (occasional to daily or dual use; daily to dual use; or daily smokeless tobacco use to daily cigarette use) in transitioning from the pre-deployment to deployment phase. Only 4.9 percent of those already using tobacco stopped or engaged in harm reduction during deployment. These



trajectories differed significantly from the deployment to post-deployment trajectories in which only 5.6 percent showed patterns of initiation or

harm escalation and 26.1 percent reported either cessation or harm reduction. Overall, the study showed a non-significant trend toward increased prevalence of tobacco use during deployment, with a significant net increase in individual trajectories of tobacco use initiation or harm escalation from pre-deployment to deployment followed by net increase in cessation or harm reduction from deployment to the post-deployment period (Chi-square (3)=29.93, P<.001).<sup>113</sup>

A review of studies of smoking in military personnel clearly indicates a higher prevalence of smoking in the military compared to the general population, with multiple factors including stress, boredom, social pressures, military culture, and others noted as potentially contributory. Former smokers who deployed appeared to be the group at greatest risk of adversely changing their smoking status during deployment, particularly with exposure to combat. Other trends indicate there may be a slight increase in the number of never smokers who initiate smoking on deployment compared to nondeployers who initiate smoking, and current smokers may increase the amount smoked during deployment; however, these findings are less consistent.

#### Other Variables

Military trainees and newly mobilized troops may be at increased risk of respiratory disease epidemics due to living in close quarters, stressful working environments, and exposure to respiratory pathogens.<sup>114-117</sup> Due to the use of improvised explosive devices and mines in OEF/OIF, Service members are also at risk for blast exposures and their sequelae, including blast lung injury.<sup>118</sup> Furthermore, research studies have suggested possible correlations between posttraumatic stress disorder and increased health care provider-diagnosed physiological disorders or diseases, or self-reported current health problems including respiratory symptoms.<sup>119-121</sup>

#### **1.5 About This Report**

This report addresses the objectives posed in the Terms of Reference (<u>Appendix B</u>). <u>Section 2.0</u> focuses on assessing best practices for establishing pre-deployment baseline pulmonary status and pulmonary function and conducting post-deployment screening for chronic pulmonary disease. <u>Section 3.0</u> assesses best practices for clinical diagnosis of post-deployment chronic pulmonary symptoms and disease. <u>Section 4.0</u> discusses the use of surveillance for the purpose of screening for and detecting pulmonary disease. <u>Section 5.0</u> provides an assessment of the sufficiency of deployment pulmonary health registries under DoD and VA. <u>Section 6.0</u> addresses current deployment pulmonary health research activities and provides suggestions for future efforts. <u>Section 7.0</u> discusses the role of prevention in addressing deployment pulmonary health concerns.

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#### 2.0 PRE-DEPLOYMENT CLINICAL BASELINES AND POST-**DEPLOYMENT SCREENING**

#### 2.1 CURRENT PRE-DEPLOYMENT CLINICAL BASELINES AND SCREENING

Service members are required to maintain a high level of medical readiness at all times as specified in Department of Defense Instruction (DoDI) 6025.19 Individual Medical *Readiness (IMR).*<sup>122</sup> Medical readiness standards require completing periodic dental and preventive health assessments, immunizations, laboratory testing, and issuance of medical equipment such as gas mask inserts (corrective lenses). Chronic pulmonary diseases, which are identified and may limit a Service member's ability to perform their duties, such as asthma, may require a medical evaluation board to determine if the Service member remains qualified for continued service and/or deployment.<sup>123-125</sup> Prior to a deployment. Service members are required to undergo additional health screening and other preparatory activities. Minimum pre-deployment health requirements are specified in DoDI 6490.03 *Deployment Health* and may include some variation based on deployment type, location, and specific Department of Defense (DoD), Service-level, or Commander policies.<sup>126</sup> A matrix highlighting these pre-deployment health activities is presented in Table E4.T1 of DoDI 6490.03 (Table 1).

**Table 1** Deployment Health Required Pre-Deployment Health Activities
 X = Required; C = Commander's decision; P = Based on potential high-risk exposure or per combat commands or Service component policy. \* = Highly recommended for deployments with health threats that have an extremely high or high-risk estimate, but may depend on whether the appropriate supporting medical assets are deployed. For Special Operations Forces and very short deployments, it may not be feasible to fulfill required activities. OCONUS = Outside of the Continental United States; MTF = Military Treatment Facility; CONUS = Continental United States.

Pre-Deployment Health Activity	All OCONUS Deployments > 30 Days, OCONUS Deployments with Fixed U.S. MTFs, and CONUS Deployments	All OCONUS Deployments < 30 Days, OCONUS Deployments with Fixed U.S. MTFs, and CONUS Deployments
Complete or confirm as Defense Department (DD) Forms 2795 within 60 days of expected deployment date.	Х	C*
Administer deployment-specific or occupational-related immunizations, prophylaxis, and any medical countermeasures or protective measures, as indicated.	Х	Х



Pre-Deployment Health Activity	All OCONUS Deployments > 30 Days, OCONUS Deployments with Fixed U.S. MTFs, and CONUS Deployments	All OCONUS Deployments < 30 Days, OCONUS Deployments with Fixed U.S. MTFs, and CONUS Deployments
Prescribe Force Health Protection Prescription Products (FHPPPs), as indicated.	Х	Х
Perform pre-deployment tuberculosis screening.	Р	Р
Issue occupational personal protective equipment (e.g., hearing or industrial respiratory protection) and monitoring devices (e.g., thermo luminescent dosimeter) as required by occupational specialty of personnel.	Х	Х
Draw pre-deployment serum specimens.	Х	С
Conduct Human Immunodeficiency Virus (HIV) testing (or as required for HIV threat or country requirements).	Х	С
Establish biomonitoring baselines as required for potentially at-risk personnel.	Х	С
Prescribe minimum 90-day supply of prescription medications other than FHPPPs.	Х	С
Update medical records and deployment health records (DD Forms 2766).	Х	С
Conduct pre-deployment occupational and environmental health site assessments including health risk assessments.	Х	С



Pre-Deployment Health Activity	All OCONUS Deployments > 30 Days, OCONUS Deployments with Fixed U.S. MTFs, and CONUS Deployments	All OCONUS Deployments < 30 Days, OCONUS Deployments with Fixed U.S. MTFs, and CONUS Deployments
Conduct health threat briefings whenever health threats are identified and/or countermeasures are required.	Х	Х
Develop and implement health risk communication plan.	Х	C*
Develop deployment health surveillance plan.	Х	C*

For most deployments, a Defense Department (DD) Form 2795 *Pre-Deployment Health Assessment* must be completed within 60 days prior to the expected deployment date and must be immediately reviewed by a health care provider with further evaluation and disposition as appropriate.<sup>126</sup> Additionally, deployment specific immunizations, tuberculosis screening, chemical prophylaxis, other medical countermeasures or protective measures and corresponding training are provided, along with a supply of prescription medications if needed.<sup>126</sup> Occupational personal protective equipment, respiratory protection, or monitoring devices may be issued and fit tested as needed. Training is conducted on their proper use and anticipated job-specific hazard information is provided. A pre-deployment serum specimen is collected and human immunodeficiency virus (HIV) testing is conducted within two years of deployment or less based on country entry requirements.<sup>126</sup> Of note, there are no pulmonary health questions on the pre-deployment health assessment.

Each Service also requires at least an annual physical fitness test including both aerobic and strength components.<sup>127-130</sup> An individual's ability to pass this test and their overall performance may be an indirect indicator of pulmonary health and function. However, a decline in performance on a physical fitness test is not a specific indicator of a decline in pulmonary function, and performing well on a physical fitness test would not necessarily indicate an absence of pulmonary disease. Deconditioning associated with deployment itself may be a factor associated with a decline in aerobic performance/capacity following deployment.<sup>131,132</sup>

Any deficiencies identified in individual medical readiness must be corrected and documented in Service-specific tracking systems. If disqualifying conditions are discovered, medical evaluation board processing may be required as well. Once an individual has been cleared for deployment, an abbreviated deployment health record



(DD Form 2766 or equivalent) is assembled that includes documentation of blood type and Rhesus factor, prescription medications and/or allergies,

corrective lens prescription, immunizations, completed DD Form 2795, and a medical summary sheet identifying past and current medical conditions and screening tests.

Overall, a fairly comprehensive pre-deployment health screening and preparation process is currently in place. Thus, an existing diagnosis or symptoms consistent with a chronic pulmonary disease should be identified during the annual preventive health assessment or during the pre-deployment screening process.

#### 2.2 Should Pre-Deployment Baseline Spirometry be Obtained?

It has been proposed that conducting baseline spirometry on Service members prior to deployment would be of value as a component of medical surveillance in this population.<sup>13</sup> Conducting serial spirometry on populations with potentially hazardous exposures provides an opportunity to identify adverse trends, both at an individual and population level. Identification of adverse trends may also trigger an investigation to identify a potentially hazardous exposure that may not have been previously recognized. A recent American Thoracic Society publication on spirometry in the occupational setting notes, "The purpose of such periodic testing is to detect progressive lung disease at an earlier stage, which might otherwise be missed, especially when lung function values are above LLN" (LLN=lower limit of normal).<sup>10</sup> Without baseline spirometry, a post-exposure result may be within the normal range while also representing a significant and unrecognized decline from pre-exposure function. If unmeasured baseline function was in the supra-normal range, an even more physiologically significant decline may occur before it is recognized as "abnormal." Thus, to objectively document a specific decline in pulmonary function in an individual, accurate baseline spirometry is required. In a study examining soldiers with spirometry pre- and post-deployment, preliminary analysis of pre-deployment data showed a significant number of abnormalities, with 13 percent demonstrating a baseline obstruction to expiratory airflow.<sup>133</sup> A prior study of baseline spirometry on combat medic trainees found asymptomatic airway obstruction in 14 percent of those who participated.<sup>134</sup>

In follow up of Fire Department of New York City workers who were present at the World Trade Center between September 11, 2001 and September 24, 2001, a decrease in the mean forced expiratory volume in one second (FEV1) was noted for all workers in the first year, which was beyond expected age-related declines.<sup>135</sup> This decline in mean FEV1 was reported as being persistent and without recovery over the next six years. By having baseline spirometry as part of their medical surveillance program, the Fire Department was able to recognize and document these post-exposure declines, both at an individual and population level. The analysis also noted that the proportion of workers who never smoked and had an FEV1 value below the lower limit of normal increased during the first year of follow up from 3 percent to 18 percent in firefighters and from 12 percent to 22 percent in emergency medical services workers.<sup>135</sup> These data also imply that the majority of nonsmoking workers who had a decline in FEV1 still had post-exposure spirometry values within the normal range. The baseline spirometry data



facilitated the ability to recognize and document an objective and persistent decline in lung function beyond what was expected due to age. The primary concerns associated with requiring pre-deployment spirometry include cost, the challenge of ensuring quality control in testing, the potential impact of false positive findings in asymptomatic individuals, and the extent with which testing should be conducted. With respect to cost, estimates for spirometry testing range from \$15 to \$50 for each test,<sup>136,137</sup> not including interpretation of results or follow up evaluation of those with abnormal findings. The total cost would be based on the size of the population targeted for inclusion for pre-deployment baseline spirometry as part of a medical surveillance program.

Ensuring proper quality control in conducting spirometry is a critical factor, particularly when conducting periodic testing over time.<sup>138</sup> The Occupational Safety and Health Administration notes that "technically flawed tests too often lead to inaccurate interpretations of worker respiratory health, falsely labeling normal subjects as "impaired" or impaired subjects as "normal."<sup>138</sup> Thus, conducting a high-quality baseline measurement is especially important, since it is the result all subsequent tests are compared to. When high-quality spirometry is performed, false-positive rates in the single digit percentages may be anticipated in a young healthy population.<sup>139,140</sup> False positive results may trigger further medical evaluation, time away from duty or training, and psychological stress on an individual who may fear having a more serious condition or face potential discharge from the military pending completion of the evaluation. The "Screening Spirometry for Assessment of Pulmonary Disease in Active Duty Military Personnel" study being conducted at Fort Sam Houston, Texas is attempting to determine the prevalence of abnormal baseline spirometry results in a young active duty soldier population. The results of this study should provide an estimate of the proportion of those tested in an asymptomatic screening program that may require additional evaluation.

The frequency of spirometry testing in medical surveillance is ideally based on the characteristics of the disease related to the specific exposure(s).<sup>138</sup> In groups that anticipate routine risk for some type of hazardous exposure, such as firefighters, annual testing has been adopted.<sup>141</sup> However, in populations for which the risk of a specific hazardous exposure is unpredictable, the difficulty in determining whether spirometry is warranted as part of an on-going pulmonary surveillance program or the frequency with which testing should occur is apparent.

For one disease entity of interest, constrictive bronchiolitis, many Service members who were diagnosed with this at civilian institutions did not initially demonstrate significant abnormalities on spirometry.<sup>12,13</sup> It has been suggested that having baseline spirometry may have allowed identification of an objective decline in pulmonary function when post-deployment results were still in the normal range. A patient presenting with nonspecific symptoms and an objective decline in pulmonary function, even if still in the normal range, may prompt an earlier specialty referral and more extensive evaluation than someone with no change in pulmonary function or other abnormality on testing. The primary question is whether conducting pre-deployment spirometry on Service



members would provide substantial benefit relative to the risks and expense. The value of baseline spirometry lies primarily in allowing objective documentation of the presence or absence of a temporal change in pulmonary function, and this is of value if the knowledge has a tangible effect on treatment or prevention.

There are currently more than 1.3 million military personnel on active duty in DoD<sup>142</sup> and 1.1 million in the National Guard and Reserve forces.<sup>143</sup> The peak number of personnel deployed at one time in support of Operation ENDURING FREEDOM (OEF) and Operation IRAQI FREEDOM (OIF) in the past decade was approximately 300,000.144 DoD recruited 276,210 new enlisted members in Fiscal Year 2013.<sup>145</sup> Thus, if one were to implement a program requiring either pre-deployment spirometry or baseline spirometry following enlistment, as many as 300,000 tests would be needed per year. An occupational medicine approach would dictate that either a specific pulmonary hazard would be identified or duties requiring participation in activities that pose tangible risk of exposure to a variety of pulmonary hazards, such as firefighting, would be present prior to establishing a medical surveillance program including spirometry. Conducting baseline spirometry prior to deployment or following enlistment would imply a nonspecific pulmonary hazard is associated with any deployment or military service itself. A more pragmatic approach may entail a risk assessment regarding pulmonary hazards associated with a specific deployment and/or identification of specific military specialties, not already required to have spirometry as part of a medical surveillance program, for which the potential for exposure to pulmonary hazards may warrant at least baseline spirometry.

A significant challenge in conducting spirometry, especially on a large scale with multiple testing locations, is ensuring sufficient quality control. As outlined above, this also has a tremendous impact on the utility of testing. The American Thoracic Society (ATS) provides minimum criteria for satisfactory spirometry results; however, these criteria may not ensure the level of accuracy needed to detect smaller objective declines.<sup>146(p321)</sup> There would also be additional overhead in training and periodic quality assurance reviews to ensure consistent, high-quality data were obtained. In addition, acquisition of software to longitudinally track a large, highly mobile population would be required to efficiently monitor and analyze the data collected.

If a decision was made to conduct baseline spirometry, the fundamental question would be what targeted risk groups should be included. In addition, at what point in time would testing be conducted? Members might be tested during basic training, advanced training, when assigned to their first permanent duty station, when assigned to a deployable position, or as part of pre-deployment processing. Within each Service, subgroups of personnel with occupations more likely to be exposed to pulmonary hazards or more likely to deploy to high-risk environments may be identified to have baseline spirometry included in their readiness requirements. In general, obtaining baseline spirometry on healthy, asymptomatic personnel with no clinical indication may result in unnecessary evaluations of a certain percentage of false positives and would take significant resources and time to implement and maintain with a high level of quality control. Conversely,



routine screening could identify some individuals who have clinically significant pre-existing pulmonary disorders and who would be at higher

risk for exacerbation under certain adverse environmental conditions. The existence of pre-deployment spirometry values would also provide objective data to compare with post-deployment spirometry obtained for evaluation of new onset symptoms.

The U.S. Preventive Services Task Force has concluded that "there is at least moderate certainty that screening for chronic obstructive pulmonary disease using spirometry has no net benefit" in "healthy adults who do not recognize or report respiratory symptoms to a clinician."<sup>147</sup> In the American College of Physicians, American College of Chest Physicians, ATS, and European Respiratory Society 2011 Clinical Practice Guideline on the Diagnosis and Management of Stable Chronic Obstructive Pulmonary Disease, they recommend that "spirometry should not be used to screen for airflow obstruction in individuals without respiratory symptoms."<sup>148</sup> Although Service members may have opportunities for unique hazardous airborne exposures during deployments, many deployments may not have predictable *a priori* exposure risks. Thus, the usual occupational indication for baseline and periodic spirometry testing of a clearly identifiable exposure risk may not be present for all Service members or all deployments.<sup>138,149</sup>

Currently, only specific occupational groups in DoD, such as firefighters, are required to have periodic spirometry as part of occupational medical surveillance programs. The level of quality assurance reviews in the conduct of routine spirometry in these programs is uncertain. In addition, DoD does not appear to require that medical surveillance spirometry results be captured in a central electronic database for population-level monitoring and assessment. Longitudinal analysis of changes in spirometry results by individual, occupational group, or location is impractical without this capability. It does not appear a study has been conducted on the effect of deployment to Southwest Asia on the pulmonary function of those already enrolled in medical surveillance programs that require spirometry, such as firefighters, for which pre- and post-deployment spirometry records should be available. Since the majority of these records are in paper format, this may be a challenging study to undertake.

Other devices for assessing pulmonary function have been reviewed for their potential utility in comparison to spirometry in diagnosing pulmonary disease. Impulse Oscillometry (IOS) is one technique being used in conjunction with spirometry to diagnose and manage diseases of the airways. Advantages include being a noninvasive and rapid technique requiring only passive cooperation of the patient.<sup>150,151</sup> Some of the limitations of IOS include airway leak and poor holding of the cheeks, as well as tongue effect, cough, swallowing, shallow breaths, and vocalization.<sup>152,153</sup> IOS alone has not been reported to be of significant value in initial diagnosis of post-deployment pulmonary diseases.

An Airflow Perturbation Device (APD) has been developed and is being compared to traditional pulmonary function testing to assess the correlation of specific measurements and the possible utility of this device.<sup>154</sup> Initial testing indicated the device may be most



useful for serial measurements to monitor lung function in those already diagnosed with lung disease. Multi-center studies are being conducted to

better characterize the potential role of this device in the diagnosis and management of pulmonary disease.<sup>155</sup> However, as noted above, there is no indication the APD will provide a significant initial diagnostic advantage for post-deployment pulmonary disease.

#### 2.3 Post-Deployment Screening

DoD policy requires a number of post-deployment screening activities to ensure military members document their health status on return from deployment, address exposure concerns, and identify injuries or illnesses for prompt evaluation and treatment. Included in this screening is the DD Form 2796, Post-Deployment Health Assessment (PDHA), which must be completed within 30 days of redeployment.<sup>a</sup> The individual must meet face-to-face with a trained health care provider to review their responses and concerns.<sup>126</sup> Individuals with positive responses or health concerns will be evaluated with the tools and protocols of the Post-Deployment Health Clinical Practice Guideline.<sup>156</sup> Additionally, post-deployment tuberculosis screening, serum specimens, biomonitoring, and post-deployment health and risk communication debriefings occur as appropriate to the specific deployment.

The DD Form 2900, Post-Deployment Health Reassessment (PDHRA), is administered to each redeployed individual within 90 to 180 days after return to home station from a deployment that required completion of a post-deployment health assessment. A trained health care provider will discuss health concerns indicated on the form and determine if referrals are required, in addition to providing education on post-deployment health readjustment issues and providing information on resources available for assistance.<sup>157</sup>

Although beyond the scope of this report, it was noted that health assessment questionnaires have expanded over the years to a length and level of detail collected that appears to be beyond what may be needed for a screening tool. The DD Form 2795 has increased from 2 to 7 pages since 1999, and the DD Forms 2796 and 2900 have both increased from 4 to 10 pages from 2003 and 2005 to 2012 respectively. It may be of value to identify opportunities to reduce the length of the screening tool and develop more specific surveys to be completed when triggered by positive responses to the screening questions. In other words, a more detailed pulmonary health questionnaire would be triggered whenever there was a positive response to a pulmonary health screening question.

A single pre-deployment and three post-deployment mental health assessments are also required for those who are required to complete deployment health assessments.<sup>158</sup> Baseline, periodic, and incident-related occupational and environmental health reports and data are also to be submitted to the Military Exposure Surveillance Library within

<sup>&</sup>lt;sup>a</sup> Redeployment is defined as returning from deployment.

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specified time periods. In addition, "Appropriate medical surveillance should be conducted to detect emerging (latent) health conditions on redeployed personnel."<sup>126</sup>

The pre-deployment health assessment asks the Service member how often he or she smokes (cigarettes, cigars, pipe or hookah) with three possible choices: just about every day, some days, or not at all. The PDHA asks the same question regarding smoking during deployment. The PDHRA does not include this question. Additionally, there is no quantification of smoking, such as number of packs smoked per day or number of years smoked, and no questions on other nicotine delivery devices such as electronic (e-) cigarettes. Furthermore, the assessments do not contain qualitative questions, such as the type of tobacco product used or when or why smoking was initiated.

In addition to the screening activities listed above, all military members are required to receive annual preventive health assessments (PHAs). The PHAs typically include a health history along with a review of any current health concerns, provision of recommended preventive services, and an assessment of the military members' fitness for continued duty as well as their ability to deploy. Thus, there are multiple opportunities to identify individuals with persistent post-deployment symptoms and provide appropriate evaluation, treatment, and referrals if indicated.

Based on a review of current requirements, it appears there should be ample opportunity to identify anyone with persistent post-deployment pulmonary symptoms. Those with symptoms would be referred for additional evaluation that most likely would include spirometry that then could be compared to pre-deployment baseline spirometry. A remaining question would be whether additional screening is warranted for asymptomatic individuals. If baseline spirometry were accomplished prior to deployment, would post-deployment spirometry be indicated to identify objective declines in those who may not have symptoms? The primary advantages and disadvantages of conducting spirometry in asymptomatic individuals have been discussed above. One consideration in post-deployment screening is that a subclinical adverse trend in decline of pulmonary function in a population may be identified and trigger further investigation. However, screening for this purpose would only be warranted if a specific exposure concern were identified for a specific deployment location.

#### 2.4 Summary of Evidence Reviewed

The current pre- and post-deployment screening process is fairly robust and should provide adequate opportunity to identify individuals with significant pulmonary symptoms or disease. Updating the pre-deployment health assessment questionnaire to include the same symptom questions as are included on the post-deployment health assessment questionnaires will allow more specific documentation of baseline pulmonary symptoms and allow pre- to post-deployment comparison of responses at an individual and population level. Adding wheezing to the reported symptoms will provide additional granularity to the type of symptom captured. The accuracy of this data is subject to the



limitations of self-reporting, but may still provide valuable information if only in identifying trends.

There is evidence that having baseline spirometry may allow identification of objective declines in pulmonary function following an adverse exposure, particularly if the post-exposure spirometry results remain in the normal range. However, it is generally accepted that obtaining baseline spirometry is only warranted in the context of an anticipated exposure risk. There is no clear evidence at present that deployment to Southwest Asia or deployment in general is associated with an *a priori* risk of exposure to a pulmonary hazard. Current research efforts may provide data that will elucidate risks related to particulate matter or other exposures associated with deployment. At present, there is insufficient evidence to recommend for or against accomplishing baseline spirometry on all deploying military members in the absence of identification of a specific exposure risk associated with a specific deployment or occupational duties of the individual Service member. However, obtaining baseline spirometry prior to deployment to locations identified as having specific pulmonary hazards in excess of military exposure guidelines or environmental protection agency guidelines would be recommended.

#### 2.5 FINDINGS AND RECOMMENDATIONS

**Finding 1:** The current DoD pre-deployment screening questionnaire (DD Form 2795) does not contain any pulmonary-specific questions, and it does not contain the same questions as the two post-deployment questionnaires (DD Form 2796, DD Form 2900). The forms also do not sufficiently capture smoking history, such as number of pack-years smoked or the use of electronic cigarettes (e-cigarettes).

Implementing a pre-deployment health assessment with as many identical questions to the post-deployment health assessments, as logical, will allow a direct comparison of baseline responses to post-deployment responses on both an individual and population level. This will provide both a surveillance and research tool in detecting adverse trends.

## **Recommendation 1: DoD should alter pre- and post-deployment** questionnaires as follows:

- a) Add the same symptom questions to the pre-deployment questionnaire as are found on the post-deployment questionnaires (Question 11 in DD Form 2796 and Question 8 in DD Form 2900).
- b) Add "wheezing" to the symptom questions on all deployment questionnaires.
- c) Add quantitative and qualitative questions about smoking behaviors, including e-cigarettes and like products, on all deployment questionnaires.

**Evidence Level: III** 



**Finding 2:** With the exception of the broader Airborne Hazards and Open Burn Pit Registry questionnaire, a single, standardized pulmonary questionnaire is not used across both DoD and the Department of Veterans Affairs (VA) in evaluating individuals with chronic post-deployment pulmonary symptoms.

It would be helpful to use a single, standardized pulmonary questionnaire for clinical evaluations to allow for collection of a consistent set of data for epidemiologic analyses. If completion of this questionnaire was triggered by positive responses on the pre/post deployment health assessments, completed electronically, and included in the pre/post deployment assessment database, this would provide access for both surveillance purposes and evaluation of symptomatic individuals.

Recommendation 2: DoD should work with the VA and other stakeholders to harmonize practices through the use of a single, standardized pulmonary questionnaire in evaluating patients who present with chronic postdeployment pulmonary symptoms. The questionnaire should not be cumbersome and should have clinical use.

#### **Evidence Level: III**

#### Finding 3:

- a) There have been no studies conducted on Service members who already have baseline occupational spirometry as a consequence of their specific duty assignment, such as firefighters, to determine if an objective post-deployment decline in pulmonary function has occurred in association with deployment.
- b) It is unclear whether quality assurance reviews are consistently conducted across the Services for occupational spirometry programs in accordance with ATS and American College of Occupational and Environmental Medicine guidelines.
- c) Spirometry data are not currently captured in a centralized electronic database to allow for efficient individual or population-level longitudinal analysis.
- d) While it is clear that baseline spirometry is of value in certain occupational settings, it is unclear whether conducting baseline spirometry on all deploying military personnel is justified. Baseline spirometry is generally obtained based on a risk assessment for potential exposure to pulmonary hazards. A similar risk-based approach may be appropriate for deploying military personnel.
- e) If DoD were to consider implementing a large-scale pre-deployment baseline spirometry program, a feasibility study would first be necessary to determine the resources needed to implement such a program at multiple sites with sufficient quality assurance.

An assessment of the quality of spirometry being performed as a component of existing medical surveillance programs would provide a baseline indication of the overall effectiveness of these programs. It would also be prudent to confirm the quality of existing spirometry programs prior to considering a larger scale pre-deployment effort. Identifying an accelerated decrease in spirometry values over time on a case-by-case

basis can be a clinically relevant screening tool. In addition, longitudinal analysis of changes in pulmonary function by occupational group or



location is impractical without a centralized database of spirometry test results. Although a study by Morris et al of pre- and post-deployment spirometry is currently in progress on deploying soldiers and likely to provide useful data, it will not provide sufficient information on the challenges of maintaining a high level of quality assurance when multiple technicians at multiple locations are conducting large numbers of spirometry tests. A decision to accomplish pre-deployment baseline spirometry should be based on a risk assessment for potential exposure to pulmonary hazards as is done in occupational medical surveillance.

#### **Recommendation 3: DoD should:**

- a) Conduct an independent assessment of the quality of baseline and followon spirometry currently performed as part of occupational medical surveillance programs in each of the Services using the 2014 Official ATS Technical Standards: Spirometry in the Occupational Setting<sup>10</sup> and the American College of Occupational and Environmental Medicine Guidance Statement: Spirometry in the Occupational Health Setting--2011 Update<sup>11</sup> as guides. This should include an analysis of key spirometric parameters previously obtained over at least a five-year period using a statistical sample from several representative locations from each Service and an assessment of the presence and effectiveness of quality assurance reviews.
- b) Implement a mechanism to routinely enter all occupational spirometry results into a centralized electronic database to allow for monitoring and analysis of trends in pulmonary function among occupational groups.
- c) Provide the capability for providers and population health officials to view a graphical presentation of key spirometric parameters for individual and group data superimposed on expected results over time for visual detection of adverse trends.
- d) Based on the results from Recommendation a) above, conduct a feasibility study assessing pre-deployment spirometry in selected groups using random selection quality assurance reviews as specified in the American College of Occupational and Environmental Medicine Guidance Statement: Spirometry in the Occupational Health Setting--2011 Update.<sup>11</sup> This will help inform the feasibility of obtaining high-quality pre-deployment baseline spirometry on a wider scale.
- e) Conduct pre-deployment baseline spirometry if there is a significant risk of exposure to a pulmonary hazard based on the deployed location or anticipated duties.

#### **Evidence Level: III**



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### 3.0 DIAGNOSIS OF POST-DEPLOYMENT PULMONARY DISEASE

As clinicians examine the possible association between deployment and the pulmonary health of military personnel, a systematic approach to evaluate and accurately diagnose pulmonary disease (pre- and post-deployment) is needed, both as a clinical best practice and to facilitate epidemiologic analysis. In addition, it is important to have a surveillance system to recognize adverse trends in illness among personnel presenting with a similar constellation of signs and symptoms that may trigger an investigation of potential causes and clinical outcomes. International Classification of Disease (ICD) codes may lack specificity for certain pulmonary diseases, and improper use of these codes may contribute to outcome misclassification. Thus, it is imperative that clinicians code conditions as accurately and consistently as possible to facilitate accurate surveillance and epidemiologic analysis. Annual preventive health assessments, pre-deployment health assessments, post-deployment health assessments, post-deployment health reassessments, and physical fitness tests provide ample opportunities to assess individual medical readiness and identify potential health issues. In one study, exertional dyspnea was found to be the most common pulmonary complaint among military personnel, regardless of deployment history, and often manifested during physical training and/or physical fitness testing.<sup>14</sup> There are multiple published guidelines for the evaluation and management of chronic obstructive pulmonary disease (COPD), asthma, and other pulmonary diseases. Thus, this section reviews diagnostic approaches to evaluating Service members with persistent post-deployment pulmonary symptoms, focusing on chronic dyspnea on exertion as a key symptom of interest.

#### 3.1 CLINICAL PROTOCOLS FOR DIAGNOSIS OF DYSPNEA ON EXERTION

Dyspnea is defined by the American Thoracic Society (ATS) as "a subjective experience of breathing discomfort that consists of qualitatively distinct sensations that vary in intensity."<sup>159</sup> However, the etiology of dyspnea cannot be determined by its duration or severity and the differential diagnosis is extensive.

In a case series of 72 patients with chronic dyspnea unexplained by history, physical examination, chest roentgenogram, and spirometry, a definite cause was found in 58 patients (80 percent). The most frequent diagnoses were hyperventilation syndrome, asthma, coronary artery disease, pulmonary thromboembolic disease, and gastroesophageal reflux.<sup>160</sup> One review article found that asthma, congestive heart failure, COPD, cardiac ischemia, interstitial lung disease, and psychogenic causes accounted for 85 percent of the diagnoses.<sup>161</sup>

The ATS 2011 Update on the Mechanisms, Assessment, and Management of Dyspnea<sup>162</sup> refers to a chapter on Dyspnea by Schwartzstein and Adams in a recent respiratory medicine text for the general approach to the evaluation of patients with dyspnea.<sup>163</sup> The same reference also provides an extensive table categorizing mechanisms and clinical conditions associated with dyspnea.<sup>163</sup> A January 2014 update of a clinical decision support resource by Schwartzstein lists the top five causes of chronic dyspnea of unclear etiology as asthma, COPD, interstitial lung disease, myocardial dysfunction, and



obesity/deconditioning.<sup>164,165</sup> Therefore, the symptom of chronic dyspnea on exertion among Service members may be the result of various

underlying medical conditions, including pulmonary diseases. Additionally, the distribution of diseases eventually diagnosed in a younger, more physically fit military population may be different from the distribution in other demographic groups.

In response to concerns that chronic pulmonary symptoms that developed in Service members following deployment to Iraq or Afghanistan may be deployment-related, the Denver Working Group proposed recommendations for clinical evaluation and medical surveillance.<sup>13</sup> The Working Group suggested any Service member deployed to these areas for more than 30 days complete standardized pre- and post-deployment questionnaires (documenting demographic information, current respiratory symptoms, smoking history, body mass index, previous lung disease, and job duties); spirometry (pre- and post-bronchodilator); and a Physical Readiness/Fitness Test (including run times), adding that a lower threshold for diagnostic referral should be used until further information is obtained.<sup>13</sup> The referral criteria outlined include persistent pulmonary symptoms (unexplained cough, shortness of breath, or wheezing/chest tightness) lasting more than three months, abnormalities or concerning changes in pre/post deployment spirometry results, and excessive declines in Physical Readiness Test results.

The Working Group approach to diagnostic testing in evaluating possible deploymentrelated lung disease is outlined in <u>Table 2</u>.<sup>13</sup> The authors suggest that complete pulmonary function tests (PFTs) including pre- and post-bronchodilator spirometry can ascertain whether there is fixed or reversible airflow obstruction, suggestive of constrictive bronchiolitis (CB) or asthma. Despite specific findings that often are seen in association with bronchiolitis, the authors note the sensitivity of high-resolution computed tomography for early disease detection is unclear. Additionally, they suggest other tests to consider include methacholine challenge and metabolic exercise testing to evaluate for cardiac, ventilatory, and gas exchange abnormalities.<sup>13</sup>



**Table 2** Denver Working Group Approach to Diagnostic Testing of Patients

 Referred for Possible Deployment-Related Lung Disease<sup>13</sup>

Comprehensive medical questionnaire, including full occupational exposure history

Physical examination, with attention to cardiopulmonary findings as well as body mass index

Full pulmonary function tests (including lung volumes, diffuse capacity for carbon monoxide, and pre-and post bronchodilator spirometry)

Methacholine challenge

High-resolution computed tomography (prone and supine, expiratory views)

Maximum exercise tolerance testing with arterial blood gases and full metabolic exercise

Consider referral for surgical lung biopsy to assess constrictive bronchiolitis on a case-by-case basis

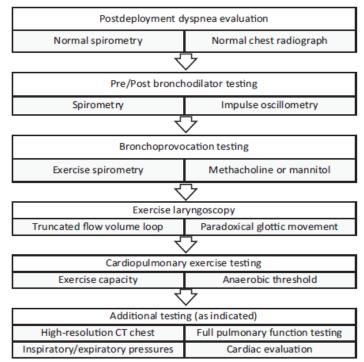
From Rose C., 2012.

In 2013, Morris et al suggested a diagnostic approach for persistent exertional dyspnea and associated pulmonary symptoms (unexplained cough, shortness of breath, wheezing, or chest tightness for more than three months duration) in military personnel.<sup>14</sup> They proposed the initial evaluation should document details of the deployment including relationship to development of symptoms and any specific exposures. Minimum testing should include spirometry and a chest radiograph. For those individuals with persistent unexplained symptoms unresponsive to treatment, they recommend a stepwise approach to evaluation as outlined in Figure 1.<sup>14</sup> In a 2014 publication, Hamilton and Morris provide similar evaluation recommendations with additional elaboration on specialty referral indications, goals of individual test modalities, and addition of pulse oximetry and fiberoptic bronchoscopy to the menu of possible studies.<sup>15</sup>





**Figure 1** Morris et al 2013 Proposed Algorithm for Evaluation of Chronic Postdeployment Dyspnea<sup>14</sup>



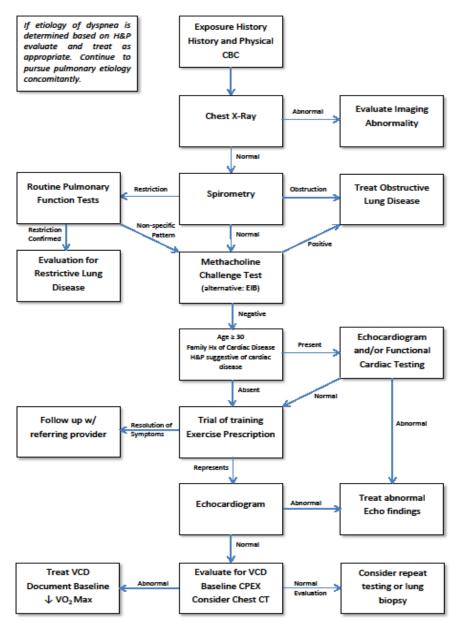
From Morris M. et al, 2013.

The Naval Medical Center San Diego (NMCSD) pulmonology clinic also developed an approach for evaluation of chronic dyspnea in active duty patients similar to Morris et al, beginning with exposure history, patient history, physical, and complete blood cell count. If etiology of dyspnea is still undetermined, a chest radiograph and spirometry would be completed.<sup>16</sup> Additional testing may be conducted as indicated in the flow chart in Figure 2.

In anticipation of evaluating participants in the Department of Veterans Affairs (VA)/Department of Defense (DoD) Airborne Hazards and Open Burn Pit Registry, DoD developed an algorithm to guide military providers in conducting clinical evaluations of Service members with symptoms or concerns related to deployment exposures (Figure 3). Specialty consultation may be considered for significant symptoms when the diagnosis is not clear. In addition, the Veterans Health Administration (VHA), the U.S. Army Public Health Command (USAPHC), and other stakeholders worked together to develop more detailed discretionary clinical guidance for their providers.<sup>166</sup> DoD has also indicated it is working to develop a mechanism to transfer the registry questionnaire responses from the VA to the DoD electronic health record, and it is currently engaged in an outreach campaign to educate providers, including development of an online training module.<sup>166</sup>



**Figure 2** Naval Medical Center San Diego Algorithm for Evaluation of Chronic Dyspnea in Active Duty Patients<sup>16</sup>



From Naval Medical Center San Diego Pulmonary Department, 2014.

The VHA published its guidance for clinicians to use in evaluating participants in the Airborne Hazards and Open Burn Pit Registry in an information letter on June 26, 2014.<sup>167</sup> The guidance suggests assessing veterans for conditions of interest related to Iraq and Afghanistan deployments and reviewing post-deployment health screening questionnaires through the DoD/VA Bidirectional Health Information Exchange, in

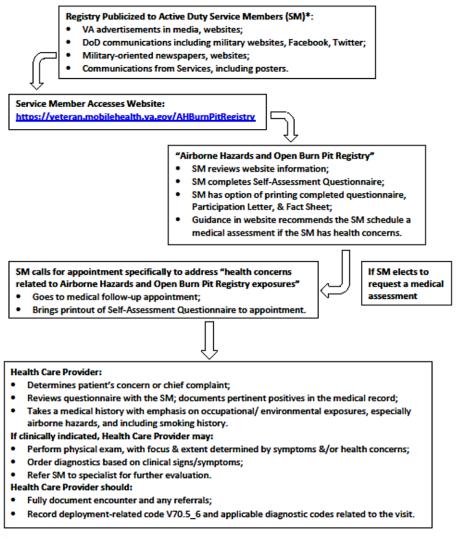
Diagnosis of Post-Deployment Pulmonary Disease



addition to reviewing the Airborne Hazards and Open Burn Pit Registry questionnaire. The VHA is creating standardized clinical templates and processes to facilitate these evaluations. The guidance provides detailed recommendations for an initial basic evaluation and subsequent pulmonary and other specialty evaluations.

**Figure 3** DoD Algorithm for Conducting Clinical Evaluation of Service Members with Symptoms or Concerns Related to Deployment Exposures.<sup>166</sup>

#### Schematic of DoD Medical Follow-up Program for VA Airborne Hazards and Open Burn Pit Registry



\*Retirees and Reserve Component personnel who are not activated will be managed by VA

From ASD(HA), 2014



The VHA, in collaboration with DoD and other leading professional organizations, has developed and published evidence-based clinical

practice guidelines for a number of conditions on the VA/DoD Clinical Practice Guidelines website.<sup>168</sup> DoD also publishes a subset of specific post-deployment health clinical practice guidelines on its PDHealth.mil website, a product of the Deployment Health Clinical Center (DHCC), to assist clinicians in the evaluation and management of deployment-related health concerns.<sup>156</sup> The DHCC works to improve deployment-related health care, including deployment-related health education and outreach.<sup>169</sup> Both these websites would be appropriate locations for a single VA/DoD guideline to facilitate a consistent approach for evaluating chronic post-deployment pulmonary symptoms in Service members and veterans. As indicated above, the VHA has published initial guidance for clinicians in an information letter to assist in evaluation of chronic postdeployment pulmonary symptoms in beneficiaries who present subsequent to enrolling in the Airborne Hazards and Open Burn Pit Registry. However, this guidance has not been published as a formal guideline on the VA/DoD Clinical Practice Guidelines website at the time of this report. The VA/DoD Clinical Practice Guidelines website does currently contain diagnostic and management guidelines for asthma and COPD under the Chronic Disease in Primary Care category, and these guidelines overlap with some of the approaches outlined above.

There are many similarities in the diagnostic approaches outlined by the Denver Working Group, Morris and colleagues, the NMCSD pulmonology department, and the DoD and VHA guidelines for evaluating unexplained dyspnea. They all overlap with ATS recommendations and other referenced publications. Two key areas of difference are the need to obtain baseline spirometry on all military personnel prior to deployment and the clinical indication for surgical lung biospy. An extensive review of the issues and recommendations related to baseline spirometry testing are outlined in the previous section.

With respect to surgical lung biopsy, a number of DoD clinicians have indicated that an appropriate clinical presentation and abnormal findings based on a comprehensive clinical evaluation should be present prior to consideration of surgical lung biopsy.<sup>170</sup> Other clinicians indicate that criteria for conducting surgical lung biopsies to obtain histopathological evidence of constrictive bronchiolitis in undiagnosed post-deployment dyspnea should include: 1) completion of an evaluation for dyspnea on exertion; 2) defining the prevalence of disease; 3) identifying a cohort to follow; 4) avoidance of ineffective or harmful treatment; 5) avoidance of future deployment/exposure; 6) providing a basis for a medical board rating; 7) obtaining compensation through the VA or social security.<sup>171</sup>

Diagnosing diseases of the small airways in the absence of objective findings on noninvasive testing may be challenging. It is also acknowledged that pulmonary function testing may be an inadequate screening test for small airway disease, particularly when pre-exposure baseline data are not available. However, in the absence of effective treatment modalities, a biopsy in search of CB, especially in a patient with no objective evidence of pulmonary abnormalities, does not appear to yield a prognostic benefit to the



patient while exposing them to the potential complications of the procedure. If the purpose of performing surgical lung biopsy is to collect epidemiologic data regarding a population of interest, it should be done in the context of an Institutional Review Board (IRB) approved research protocol. If the purpose is to facilitate disability compensation, this may be more appropriately accomplished through thorough documentation of clinical findings and level of impairment based on objective physiologic parameters.

#### 3.2 SUMMARY OF EVIDENCE REVIEWED

Currently, DoD has not disseminated a standard guideline for evaluation of postdeployment chronic dyspnea. Therefore, clinical diagnostic approaches are at the discretion of the examining physician. In King et al's 2011 study, 49 soldiers with chronic dyspnea on exertion underwent thoracoscopic lung biopsy and 38 of those received a histopathological diagnosis of CB, despite a majority having normal pulmonary function and normal radiographic studies.<sup>2</sup> The approach taken by King et al in the absence of objective pulmonary findings on noninvasive testing has been controversial.<sup>3,4</sup> DoD clinicians do not recommend the use of surgical lung biopsies without a clinical presentation, abnormal PFTs, and/or high-resolution computed tomography (HRCT) findings suggestive of CB or other parenchymal lung disease.<sup>170</sup> This has raised the question of when a lung biopsy is appropriate in evaluating whether chronic post-deployment pulmonary symptoms are associated with histopathological findings of constrictive bronchiolitis. Because there is currently no effective treatment for CB,<sup>172</sup> there are potential complications from video-assisted thoracoscopic surgery (VATS) procedures,<sup>18-20</sup> and because occupationally induced CB appears to stabilize after removal from exposure, biopsy solely to establish a histopathological diagnosis to determine prevalence or characterize the disease should be conducted under an IRBapproved research protocol.

There are significant risks to surgical lung biopsy. In a 22-year retrospective review of surgical lung biopsies (open minithoracotomy or VATS), the authors reported an overall complication rate of 16 percent.<sup>18</sup> The most common complication is prolonged air leakage, reported in about 5 to 12 percent of patients.<sup>17-20</sup> In another study on the effectiveness and complications of VATS for the treatment of spontaneous pneumothorax, the overall complication rate was 13.7 percent for a study population with a mean age of 28.3 years.<sup>173</sup> Potential complications of VATS include pneumonia, pneumothorax, pleural effusions, hemothorax, empyema, and the need for mechanical ventilatory support.<sup>18-20</sup> Solaini et al reported a complication rate of 13.6 percent for 98 patients who underwent VATS lung biopsy, with no postoperative mortality.<sup>21</sup> One study of patients with idiopathic interstitial pneumonia who underwent VATS reported 30-day operative mortality of 4 percent and 90-day operative mortality of 8 percent; however, the mean age of patients in this study was 57.4 years and the increased mortality was attributed to acute exacerbation of the underlying disease at the time of biopsy.<sup>19</sup> In the King study, the median age of the patients that received surgical biopsies was 33 years.





The recommendations of the Denver Working Group include comprehensive evaluations of patients with unexplained chronic post

deployment pulmonary symptoms in order to better characterize the nature and extent of a potential pulmonary disorder. The approaches outlined by Morris et al and NMCSD's pulmonology clinic (Figure 1 and 2) also support a stepwise clinical evaluation for a potential pulmonary disorder. The Denver Working Group recommends surgical lung biopsy on a case-by-case basis, where unexplained pulmonary function or radiographic abnormalities are present and CB is considered within the differential diagnosis. The NMCSD pulmonologists may consider surgical lung biopsy on a case-by-case basis for patients with undiagnosed potential pulmonary disorders, or follow the patient over time for potential changes in pulmonary status. Morris et al do not advocate surgical lung biopsy in the absence of abnormal imaging or other typical indications, partly due to the fact that there is no clear treatment or prognostic advantage associated with biopsy at this time.

# 3.3 FINDINGS AND RECOMMENDATIONS REGARDING DIAGNOSIS OF PULMONARY DISEASE

#### Finding 4:

- a) A consistent approach to evaluation of patients with unexplained post-deployment dyspnea on exertion across DoD, the VA, and civilian institutions would facilitate accurate characterization of the diagnoses associated with this clinical presentation.
- b) Diseases of the small airways may occur in the absence of objective findings on noninvasive testing.
- c) While surgical lung biopsy may provide a histopathological diagnosis, it may or may not inform treatment or prognosis.

The results of the King et al<sup>12</sup> study initiated further dialogue on the necessary components of a clinical evaluation and diagnostic criteria for Service members returning from deployment with chronic pulmonary symptoms, of which dyspnea on exertion is of specific interest. The Denver Working Group<sup>13</sup> and other investigators<sup>14-16</sup> have provided recommendations for the evaluation of patients with chronic post-deployment dyspnea on exertion and there are many similarities in these approaches. A more consistent approach to evaluation of these patients across DoD, the VA, and civilian institutions would facilitate accurate characterization of the diagnoses associated with this clinical presentation.

The use of surgical biopsy as an early diagnostic tool in evaluating chronic unexplained dyspnea in the absence of significant, progressive symptoms or objective clinical findings based on non-invasive evaluation is not appropriate. However, diseases of the small airways may occur in the absence of objective findings on non-invasive testing. While surgical lung biopsy may provide useful histopathological information, particularly when correlated with the available clinical data, the histopathological findings in themselves may or may not inform treatment or prognosis. Although the risks associated with VATS lung biopsy are low in a healthy, young population, it is an invasive procedure with some



inherent significant risk.<sup>17-21</sup> A summary of key principles for clinical evaluation of chronic post-deployment dyspnea follows:

1) A stepwise evaluation should be conducted until a diagnosis is established or further testing would not be of clinical benefit to the patient;

2) A comprehensive clinical evaluation of all potential causes of significant and progressive dyspnea should be completed prior to considering surgical lung biopsy;

3) If surgical lung biopsy is being conducted to study the prevalence and characteristics of disease without clear prognostic benefit to the patient, it should be conducted under an IRB approved research protocol; and

4) There are clear medical indications for surgical lung biopsy. Qualification for disability compensation is not an appropriate indication for surgical lung biopsy.

#### **Recommendation 4:**

Clinicians should use a consistent approach when evaluating Service members or veterans for chronic post-deployment pulmonary symptoms. A diagnostic approach for unexplained dyspnea greater than three months duration using a summary of approaches reviewed is included below as a reasonable starting point (see Section 3.1).

Tier 1)

- Medical and occupational history including pulmonary questionnaire
- Physical exam with focus on cardiovascular and pulmonary findings
- Height, weight, and waist circumference
- Spirometry including flow volume loops
- Chest radiograph
- Comparison of results with any previous available records, such as spirometry

#### Tier 2)

- Spirometry with bronchodilators or methacholine challenge
- Studies of lung volumes and diffusion
- Consideration of laryngoscopy (rest or exercise)
- Consideration of echocardiography

#### Tier 3)

- HRCT scan (depending on potential diagnosis, may want prone and supine positions with full inspiratory and expiratory views)
- Six-minute walk, resting and exercise/post-exercise pulse oximetry
- Consider specific blood tests depending on differential diagnosis

Tier 4)



• Maximum cardiopulmonary exercise tolerance testing with arterial blood gases pre-exercise and at maximum exercise

Tier 5)

• Depending on results, follow with periodic repeat testing to determine potential adverse long-term trends. Consider lung biopsy on a case-by-case basis if disease process is unknown and severe or progressive, and/or potentially amenable to therapy. Physician judgment and patient preference will continue to be key considerations

#### **Evidence Level: III**

#### Finding 5:

- a) Currently, a combined VA/DoD clinical practice guideline for evaluation of chronic post-deployment pulmonary symptoms, and specifically unexplained dyspnea, has not been published.
- b) Inaccurate and inconsistent International Classification of Disease (ICD) coding has impeded efforts to conduct accurate surveillance and epidemiologic analysis.

The Veterans Health Administration has published a fairly comprehensive interim guideline as an information letter (IL-10-2014-13), but not as a formal guideline. The Army Public Health Command has also published an information letter for health care providers (TA 223-0614) that provides several clinical evaluation references, including a basic initial evaluation flowchart. For consistency, a common baseline approach codified as a joint DoD/VA clinical practice guideline would improve consistency in post-deployment evaluation of patients. This guideline could include recommendations for primary care providers as well as specialists.

Recommendation 5: DoD should publish a clinical practice guideline for evaluation of chronic post-deployment pulmonary symptoms on the VA/DoD Clinical Practice Guidelines website and the PDHealth.mil website. To facilitate use of these guidelines, templates should be created within the electronic health record including health and occupational/exposure history and clinical evaluation elements. Guidance should also be provided for proper ICD coding.

**Evidence Level: III** 

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## 4.0 SURVEILLANCE FOR DEPLOYMENT RELATED PULMONARY DISEASE

The term "surveillance" has several semantic connotations in health care and medicine. Public health surveillance is "the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice."<sup>35</sup> Public health surveillance data can be used for planning, implementing, and evaluating public health interventions and programs, as well as determining the need for public health action, and assessing program effectiveness.<sup>174</sup>

Occupational surveillance is, "the ongoing systematic collection, analysis, and dissemination of exposure and health data on groups of workers for the purpose of preventing illness and injury."<sup>36</sup> Occupational health surveillance includes medical surveillance, which involves the initial and periodic health evaluation of those potentially exposed to work-related hazards.<sup>37</sup> Occupational respiratory disease surveillance may be defined as "the ongoing, systematic collection, analysis, and dissemination of health and hazard data to monitor the extent and severity of occupationally-related lung disease and related workplace exposures for use in public health education and in disease prevention."<sup>38</sup>

Department of Defense (DoD) Directive 6490.02E states that "comprehensive health surveillance is an important element of force health protection (FHP) programs to promote, protect, and restore the physical and mental health of DoD personnel throughout their military service and employment, both in garrison and during deployment. <sup>"175</sup> It further directs that "Comprehensive, continuous, and consistent health surveillance shall be conducted by the Military Services to implement early intervention and control strategies."<sup>175</sup> Surveillance systems shall capture individual and population health data, and link it with occupational and environmental exposure data to identify potential health risks and enable "timely interventions to prevent, treat, or control disease and injury."<sup>175</sup> The data shall also be shared with the Department of Veterans Affairs. This section reviews DoD and Service-specific surveillance activities and provides recommendations applicable to deployment pulmonary health surveillance.

#### 4.1 CURRENT DEPARTMENT OF DEFENSE POLICIES AND PRACTICES

DoD maintains surveillance activities through DoD-wide efforts, such as the Armed Forces Health Surveillance Center and the Millennium Cohort Study, as well as Servicespecific efforts under the U.S. Army, Navy, and Air Force.

#### **DoD-Wide** Efforts

#### Armed Forces Health Surveillance Center

The Armed Forces Health Surveillance Center (AFHSC) was established in February 2008 by the Deputy Secretary of Defense with the mission to "promote, maintain, or enhance the health of military and military-associated populations,"<sup>176</sup> and acts as the primary source for DoD-level health surveillance information.<sup>175</sup> AFHSC has four divisions, including data management and technical support; epidemiology and analysis;



Global Emerging Infections Surveillance and Response; and Integrated Biosurveillance.<sup>177</sup> AFHSC maintains the Defense Medical Surveillance System (DMSS) database and analyzes and interprets data for reports, including the Medical Surveillance Monthly Report. Furthermore, the AFHSC oversees the DoD Serum Repository.<sup>177</sup> The DMSS is a database that documents military and medical experiences of Service members throughout their careers, including current and historical data on diseases and medical events as well as longitudinal data on personnel and deployments.<sup>178</sup> The DMSS is the primary link between the DoD Serum Repository and other databases.<sup>178</sup> The data tables integrated with the DMSS are shown in Table 3.

Table 3. Data Tables Integrated with the DMSS $^{178}$				
Table	Source	Frequency	Services	Variables to Capture Pulmonary Health Issues
Person	Defense Manpower Data Center (DMDC)	Monthly	All	
Demographics	DMDC	Monthly	All	
Military Entrance Processing Station	Military Entrance Processing Command	Monthly	All	Yes
Deployment	DMDC	Monthly	All	Yes
Inpatient (medical encounters)	Defense Health Services System (DHSS)	Monthly	All	Yes
Pre/Post- Deployment Health assessment questionnaires	Service feeds	Daily	All	Yes
Outpatient (medical encounters)	DHSS	Daily	All	Yes
Immunizations	Defense Enrollment Eligibility System (DEERS)	Daily	All	
Serum	Testing Labs	Weekly	All	Yes
Casualty	Armed Forces Medical Examiner System (AFMES)	Monthly	All	Yes
<b>Reportable Events</b>	Service feeds	Daily	All	Yes
Chem and Micro	DHSS	Daily	All	Yes
Adapted from AFHSC.				

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Surveillance for Deployment-Related Pulmonary Disease



The Defense Medical Epidemiology Database (DMED) is derived from the DMSS and provides select, de-identified data through the AFHSC website to civilians.<sup>177</sup> Through DMED, authorized military and civilian medical providers, epidemiologists, and researchers can access de-identified data on active duty Service members. Through data acquired by the DMSS and DoD Serum Repository, AFHSC's epidemiology and analysis division prepares ad hoc and periodic reports. Periodic reports include deployment, disease, injury, mental health, and special reports, while ad hoc reports originate from congressional inquiries, comparative studies, or serum studies, among others. Periodic deployment reports include pre-deployment health assessment summaries, as well as post-deployment health assessment (PDHA) and postdeployment health reassessment (PDHRA) summaries. AFHSC also publishes periodic respiratory illness reports.<sup>177</sup> The 2012 revision of the post-deployment health assessment and reassessment forms includes specific questions related to pulmonary symptoms. However, it does not appear that data from the pulmonary related questions are routinely analyzed by AFHSC or the Services to assess baseline population responses to these questions or to monitor adverse trends.

Within DoD, AFHSC collects surveillance data from the tri-Service surveillance hubs, unified commands, and the Defense Health Agency, formerly the Tricare Management Agency.<sup>179</sup> AFHSC also acquires data from the Department of Veterans Affairs (VA), academia, and the U.S. Department of Health and Human Services (DHHS). AFHSC surveillance data inform the operations of the Joint Chiefs of Staff, combatant commands, and the readiness needs of the Services. Furthermore, AFHSC surveillance efforts help to advise policy of the Assistant Secretary of Defense for Health Affairs and research of the Under Secretary of Defense for Acquisition, Technology, and Logistics. Finally, AFHSC activities support national and international health strategies through interactions with DHHS, the Department of Homeland Security, and the World Health Organization.<sup>179</sup>

AFHSC is projected to begin operation under the Public Health Division in the Healthcare Operations Directorate of the Defense Health Agency, whose mission is to streamline health care among the Armed Forces. AFHSC will also join selected assets from the U.S. Army Public Health Command, U.S. Air Force School of Aerospace Medicine, and the Navy and Marine Corps Public Health Command. Finally, these Service-specific surveillance hubs will become satellites of AFHSC.

#### Millennium Cohort Study

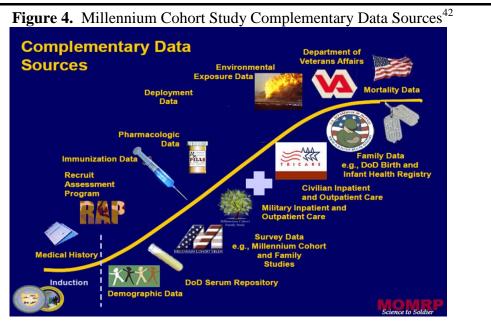
The Millennium Cohort Study was established as a result of recommendations published in reports regarding the need for systematic collection of population data to evaluate U.S. military personnel<sup>180</sup> and the association of deployment-related exposures with health outcomes. The study is a prospective cohort study encompassing all branches of the U.S. military, and its primary objective is to determine whether certain risk factors related to military service, such as occupational specialty or deployment history, are associated with chronic diseases.<sup>181</sup> Furthermore, it examines whether characteristics of military service are associated with common physician-diagnosed diseases and with scores on

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self-report health questionnaires.<sup>181</sup> It is the first comprehensive effort to prospectively evaluate health outcomes associated with military

service.<sup>182</sup> The study uses numerous data sources, such as data from the Department of Veterans Affairs and DoD Serum Repository (Figure 4).<sup>42</sup> The Millennium Cohort Study has a 21-year follow up from its study's initiation in 2001, with preliminary plans for 75-year follow up.<sup>42</sup>



From Frasco M., 2014

Past pulmonary health studies performed by the Millennium Cohort Study include an evaluation of smoking and military deployment,<sup>110</sup> the effects of exposure to open air burn pits,<sup>183</sup> and newly reported respiratory symptoms and conditions among U.S. military personnel deployed to Iraq and Afghanistan.<sup>65</sup> It will also investigate particulate matter and health outcomes, as well as respiratory symptoms and conditions among Service members and veterans.<sup>42</sup> Although the study continues to support assessment of health risks in U.S. military personnel, there is concern that additional effort is needed to improve response rates.





#### Service-Specific Efforts

#### Army

The USAPHC, a subordinate of the U.S. Army Medical Command, consists of the U.S. Army Institute of Public Health and five Public Health Command Regions.<sup>184</sup> In turn, the Public Health Command Regions are supported by 14 Public Health Command Districts (Figure 5).<sup>184</sup> Within the purview of the USAPHC is epidemiological and disease surveillance, conducted to identify disease trends or potential conditions that require intervention.<sup>184</sup> For example, the USAPHC has conducted epidemiologic studies on deployment pulmonary health, examining the potential association between deployment to Southwest Asia and respiratory outcomes.<sup>9,67,68,185</sup> The USAPHC coordinates with the AFHSC for its surveillance data for such studies.

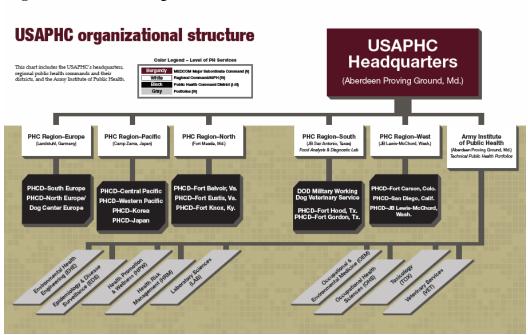


Figure 5. USAPHC Organizational Structure<sup>184</sup>

#### From USAPHC, 2013.

In collaboration with other DoD partners, the USAPHC environmental medicine and health risk management portfolios assess, report, and document characteristics and possible risks of exposure due to particles and dust from industry, sulfur fires, and burn pits within U.S. Central Command.<sup>184</sup> Furthermore, USAPHC provides air, water, and soil sampling in garrison and deployed environments in order to identify, evaluate, and manage risk.<sup>184</sup>

#### Navy and Marine Corps

The Navy and Marine Corps Public Health Center (NMCPHC), previously the Navy Environmental Health Center, provides "worldwide Force Health Protection services to Naval and Joint forces in support of the National Military Strategy."<sup>186,187</sup> The NMCPHC



encompasses a variety of programs, including environmental, population health, and preventive medicine.

Within the occupational and environmental medicine division of the environmental program, NMCPHC serves as the Service-level advisor for the Defense Occupational and Environmental Health Readiness System, which captures the longitudinal exposure record for DoD personnel.<sup>188</sup> Additionally, the occupational and environmental medicine division encompasses the necessary training and certification examinations for health care professionals to perform surveillance on workplace and environmental exposure hazards. The population health program houses the Epidemiology Data center (EpiData), which executes communicable disease surveillance and prepares reports using the Disease Reporting System-internet, as well as analyses of health outcomes related to environmental or occupational exposures. EpiData also supports epidemiological surveillance and analyses of deployment-related conditions in Service members, including analyses of deployment health assessments. The preventive medicine program maintains several electronic surveillance systems, including Disease and Injury surveillance, the aforementioned Disease Reporting System-internet, and the Electronic Surveillance System for the Early Notification of Community-Based Epidemics.<sup>189</sup> Finally, the NMCPHC has laboratory operations and field activities, such as Navy Environmental Preventive Medicine Unit-5, which support force health protection and surveillance of Naval personnel.<sup>188</sup>

#### U.S. Air Force

The U.S. Air Force Medical Operations Agency (AFMOA) executes programs and policies on surveillance, reporting, and prevention, treatment, and control of conditions or diseases of public health or military significance. <sup>190</sup> AFMOA also reviews periodic reports related to disease surveillance, prevention, and control in order to form recommendations for the Air Force Surgeon General's Office. The agency also utilizes evidence-based information and population health data to inform military treatment facilities and Major Commands on how to optimize population health.<sup>190</sup> The U.S. Air Force School of Aerospace Medicine Public Health and Preventive Medicine Department (USAFSAM/PH) provides surveillance, as well as develops and provides training on prevention, investigation, control, reporting requirements, and applied epidemiology on diseases affecting USAF personnel. USAFSAM/PH consults worldwide to USAF and DoD on public health surveillance, epidemiology, preventive medicine, and outbreak response. Furthermore, USAFSAM/PH oversees the management, monitoring, and analysis of surveillance data and reports to the appropriate USAF or DoD authorities. The department also manages the DoD influenza surveillance program and coordinates with Service representatives and the AFHSC's Global Emerging Infections Surveillance and Response System.<sup>190</sup>

Air Education and Training Command and Air Force Training Centers also have the capability to provide surveillance on recruits and training populations in order to reduce morbidity and mortality.<sup>190</sup>

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#### 4.2 Summary of Evidence Reviewed

With regard to DoD-wide efforts, AFHSC has the capability to monitor International Classification of Disease (ICD) codes from electronic health records fairly reliably through DMSS. Obtaining individual exposure information has been more challenging, though. In the absence of accurate individual exposure data, location may be used as a surrogate, and if environmental exposure data is available for a particular location, an estimate of individual exposure may be extrapolated from these data. However, classification barriers have impeded the ability to access specific location data for personnel. In addition, individuals may be administratively assigned to a particular location, but may spend the majority of their time at an alternate location. Even within a specific location, exposures may vary based on occupation, wind direction, season, or other factors, making it an imprecise estimate at best. Exposure data for specific locations may also be incomplete or non-existent. Thus, even having location data may not provide an accurate representation of exposure. These limitations make it difficult to link specific exposures to specific health outcomes. In addition, inaccurate coding<sup>191</sup> by providers, along with the inherent ambiguity of some ICD codes for pulmonary disease, creates another barrier. As mentioned above, the 2012 revision of the post-deployment health assessment and reassessment forms includes specific questions related to pulmonary symptoms. However, the data from the pulmonary related questions are not routinely analyzed by AFHSC or the Services to assess baseline population responses to these questions or to monitor adverse trends. There may be value in conducting this type of surveillance if careful thought is given to what would constitute an adverse trend sufficient to warrant follow up investigation and who would conduct those investigations. A graphical plot of response rates over time would provide a clear visual depiction of any specific trends.

The Millennium Cohort Study uses various complementary data sources, but also relies on self-report survey data in determining deployment-associated exposures and health outcomes. Thus, there are opportunities for exposure or outcome misclassification. There are also concerns regarding low survey response rates, which could potentially lead to bias related to losses to follow up.

At present, there are no mechanisms in place for accurate, long-term follow up of individuals who have served. Moreover, this population accesses care in complex patterns.<sup>191</sup> Therefore, there may be underreporting of pulmonary conditions diagnosed in the long-term DoD-wide and Service-specific surveillance efforts. Successfully conducting a long-term cohort study of at-risk individuals would be of great value in identifying health outcomes related to military service.

## 4.3 Findings and Recommendations Regarding Deployment Health Surveillance

#### Finding 6:

a) Deployment-related epidemiologic studies are compromised by a lack of individual exposure data.



b) At present, the best available surrogates for individual exposure are location data, but classification barriers have impeded the ability of researchers to obtain these data.

#### **Recommendation 6: DoD should:**

- a) Continue efforts to improve techniques for collecting and maintaining individual and area exposure data, such as with the Individual Longitudinal Exposure Record initiative and the Periodic Occupational and Environmental Monitoring Summary, to facilitate more effective analysis of exposure/outcome associations.
- b) Develop a mechanism to allow investigators expedited access to demographic information by specific deployment location, time period, and military occupational specialty in the conduct of approved research and surveillance. The Board supports the Assistant Secretary of Defense for Health Affairs' 2014 request to expedite access to individual location data to support epidemiologic research and surveillance. This may include declassification or work in a classified environment.

#### **Evidence Level: III**

**Finding 7:** DoD is not currently monitoring and analyzing pulmonary symptom response data from post-deployment health questionnaires on a population level.

As outlined in the <u>Baselines and Screening</u> chapter, DoD currently captures all the data entered on deployment health assessment forms electronically. The 2012 revision of the post-deployment health assessment and reassessment forms includes specific questions related to pulmonary symptoms. The AFHSC prepares periodic deployment health reports, including summaries of deployment health assessment data. However, it does not appear that the data from the pulmonary related questions are routinely analyzed by the AFHSC or the Services to assess baseline population responses to these questions or to monitor for adverse trends. AFHSC indicated it is ready to support DoD and the Services with analyses of these data if requested. There may be value in conducting this type of surveillance if careful thought is given to what would constitute an adverse trend sufficient to warrant follow up investigation and who would conduct those investigations.

Recommendation 7: DoD should conduct routine analyses of aggregate symptom response data from pre-deployment health assessment, postdeployment health assessment, and post-deployment health re-assessment forms by deployed location, unit, and/or other levels, to identify normal background response rates and adverse trends.

**Evidence Level: III** 

**Finding 8:** Clinical and epidemiologic researchers have reported that inaccuracy and inconsistency in ICD coding of medical encounters has impeded efforts to conduct deployment-related pulmonary health surveillance and research.



Inaccurate ICD coding may result in disease misclassification with falsely increased and/or decreased numbers of specific diagnoses. This may lead to overestimating or underestimating the significance of an observed trend, making it difficult to determine if additional scrutiny is warranted.

**Recommendation 8:** DoD should investigate and implement mechanisms to improve ICD coding in the electronic health record (EHR). Including an appropriate decision support system in the next generation EHR may be one mechanism to consider.

#### **Evidence Level: III**

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#### 5.0 DEPLOYMENT PULMONARY HEALTH REGISTRIES

As defined by the National Committee on Vital and Health Statistics, a registry is "an organized system for the collection, storage, retrieval, analysis, and dissemination of information on individual persons who have either a particular disease, a condition that predisposes to the occurrence of a health-related event, or prior exposure to substances (or circumstances) known or suspected to cause adverse health effects."<sup>192</sup> A registry has also been defined as a "prospective observational study of subjects, with certain shared characteristics, that collects ongoing and supporting data over time on well-defined outcomes of interest for analysis and reporting."<sup>193</sup> Registries may be used to estimate the extent of a condition or disease within a population, as well as determine incidence of disease, trends, or conduct research.<sup>192</sup> Furthermore, disease registries help medical providers identify and connect with patients who require care.<sup>194</sup>

There are several registry efforts in the public and private sectors relevant to deployment pulmonary health, including the Department of Defense (DoD) and Department of Veterans Affairs (VA) Airborne Hazards and Open Burn Pit Registry, the Burnpits 360 registry, the Study of Active Duty Military for Pulmonary Disease related to Environmental Exposure (STAMPEDE) registry, and the Millennium Cohort Study.

#### 5.1 CURRENT AND PLANNED REGISTRIES

#### Millennium Cohort Study

The Millennium Cohort Study is a prospective cohort study that obtains data primarily through questionnaire responses, and also links with other complementary objective data sources (Section 4.0, Figure 4).<sup>42</sup> The study has enrolled more than 200,000 Service members and around 10,000 military spouses since it launched in 2001, and has a 21-year follow up period with enrollees.<sup>42</sup> Through 2011, the first panel recruited has a follow up response rate of 67 percent, while the second (2004) and third panels (2007) have follow up response rates of 49 and 51 percent, respectively.<sup>42</sup> The Millennium Cohort Study is discussed more fully in the <u>Surveillance</u> section.

#### STAMPEDE

The San Antonio Military Medical Center in San Antonio, Texas maintains a patient registry of individuals evaluated for chronic post-deployment pulmonary symptoms as part of STAMPEDE.<sup>71</sup> The registry is a prospective database that includes referrals from U.S. Army Military Treatment Facility (MTF) specialty clinics and patients evaluated under the STAMPEDE III protocol at the Brooke Army Medical Center, Walter Reed National Military Medical Center, and Blanchfield Army Community Hospital. The investigators plan to collect clinical data on patients for 10 years post-diagnosis, and the database is centralized to examine for short- and long-term pulmonary effects.<sup>71</sup>

#### Burnpits 360

Burnpits 360 is a non-profit organization with a mission to "promote awareness of disease and illness of our Military, Veterans, and Contractors due to environmental toxic chemical exposures from burn pits in war zones."<sup>195</sup> It has a self-report national registry,



and its goals include identifying the need for a longitudinal study and demonstrating correlations of health outcomes from exposures.<sup>195</sup> In a

press release, the organization states that it is conducting a cohort study in coordination with Dr. Anthony Szema of the State University of New York at Stony Brook.<sup>196</sup> At the time of this report, no summary data from this registry have been reported. However, during a public statement to the Defense Health Board (DHB) Public Health Subcommittee, the President and Chief Executive Officer of Burnpits 360 stated the registry had more than 3,500 registered members.<sup>197</sup>

#### DoD/VA Airborne Hazards and Open Burn Pit Registry

On January 10, 2013, a bill was enacted directing the Secretary of the VA, in coordination with the Secretary of Defense, to establish an open burn pit registry for individuals deployed in support of a contingency operation while serving in the Armed Forces on or after September 11, 2001 to a location where an open burn pit was used.<sup>198</sup> In fulfillment of this law, the VA created a self-report registry entitled the Airborne Hazards and Open Burn Pit Registry and expanded eligibility to include veterans from other operations in Southwest Asia on or after August 2, 1990.<sup>40</sup> The registry is open to all veterans, reserve component, and active duty military personnel who meet this criteria. The VA is required to maintain this registry for members of the Armed Forces who may have been exposed to airborne hazards caused by open burn pits and notify them of significant advancements in the "study and treatment of conditions associated with exposure" to these hazards.<sup>4</sup> The questionnaire used in the registry was developed by the Exposure Assessment Subcommittee of the VA/DoD Deployment Health Working Group.<sup>199<sup>1</sup></sup> The questionnaire asks for deployment information, exposure concerns, diagnosed conditions and symptoms, activity limitations, and additional risk factors such as smoking.<sup>199</sup> The registry was initially planned to be implemented in January 2014, but was launched in late June 2014.<sup>40</sup> In the first seven weeks after the June 19 national release, more than 13,000 individuals completed the questionnaire. Approximately 11,000 more eligible individuals have signed up and begun the questionnaire.<sup>200</sup>

#### 5.2 OTHER DOD REGISTRIES

The Vision Center of Excellence (VCE), a collaborative effort between DoD and the VA, established the Defense and Veterans Eye Injury and Vision Registry (DVEIVR), began data collection in 2011.<sup>201,202</sup> The DVEIVR is the first joint eye registry to be developed and shared between the agencies. The registry collects ocular-related data as well as diagnoses, surgical procedures, treatments, and follow up of significant eye injuries incurred by active duty Service members. Additionally, this registry allows for longitudinal analysis of outcomes, assessing interventions, as well as enhancing performance improvement.<sup>201</sup> The registry aims to provide data to support evidence-based care, research, education, and policy.<sup>202</sup> Furthermore, the VCE is leading DoD registry efforts and is coordinating to assist with registry efforts by both the Hearing, Extremities and Amputation Center of Excellence and the Psychological Health and Traumatic Brain Injury Center of Excellence.<sup>202</sup>

The Joint Theater Trauma Registry (JTTR), a component of the Joint Theater Trauma System, was created by DoD to improve battlefield



care.<sup>203</sup> JTTR collects, maintains, and reports all combat injury demographics, care, and outcomes for both military and civilian casualties into a single database. The registry allows for the evolution of combat medical doctrine, process improvement, materiel development, training, and research.<sup>203</sup>

DoD's experience with these registries should provide both the functional design expertise as well as the information technology requirements to effectively develop a clinical registry of deployment-related pulmonary disease. Representatives from the DVEIVR indicated that an explicit effort was made to develop database constructs that may be reused in subsequent registries.

#### 5.3 Summary of Evidence Reviewed

There are a variety of registry types that serve different purposes, whether to estimate the extent of a disease or condition or to help examine the health effects of certain exposures.<sup>192</sup> Self-report registries, such as the Burnpits 360 and Airborne Hazards registries, provide those who have exposure-related health concerns an opportunity to report these concerns and contribute to advocacy and visibility for these issues. These registries may also help identify high risk groups, provide insight to the potential magnitude of deployment-related pulmonary health issues and disease trends, and possibly help assess service delivery.<sup>192</sup> Additionally, these registries may provide data that could be used to develop future deployment pulmonary health studies.<sup>93</sup>

Although the Airborne Hazards registry uses some complementary data sources, the Burnpits 360 registry data appears to be entirely self-reported. In general, self-report registries have limitations related to information/reporting bias as well as self-selection bias.<sup>204(p228)</sup> Self report of exposures and disease may lead to health outcome misclassification and measurement error as well as exposure misclassification due to the lack of objective, individual-level exposure data.<sup>191</sup> If individual-level exposure data cannot be verified, conclusions regarding any associations noted between reported exposures and health outcomes also cannot be verified. The STAMPEDE registry relies on physician evaluation and referral to link individuals to the registry; thus, the enrolled cases have a more objective clinical assessment for inclusion. However, this process may also contribute to selection bias as it relies on physician judgment and compliance for enrollment.

The STAMPEDE registry is currently only linked to Army MTFs, but there are preliminary plans to possibly coordinate with other military or VA facilities. Effectively ascertaining the true magnitude of the problem would require a coordinated effort across the Services, the VA, and civilian institutions that evaluate and treat veterans. Individuals with chronic post-deployment pulmonary symptoms should be evaluated in a consistent manner to allow consistent data elements to be captured for accurate surveillance and epidemiologic analysis. Although resources are being expended in

Deployment Pulmonary Health Registries

multiple areas, there is currently no enterprise-wide clinical registry for deployment-related pulmonary symptoms or disease. An effectively

implemented registry of this nature would provide more accurate and useful information to complement self-report registries. The ideal solution would be to create a streamlined registry template process that would facilitate creation of other enterprise-wide (or DoD/VA) clinical registries for diseases or conditions of interest. The VCE is currently attempting to create processes to facilitate this.

#### 5.4 FINDINGS AND RECOMMENDATIONS REGARDING DEPLOYMENT PULMONARY HEALTH REGISTRIES

**Finding 9:** There are a series of registries currently in operation that are capturing data in an effort to better characterize the nature and scope of potential deployment-related pulmonary disease. However, there is no enterprise-wide clinical registry for chronic deployment-related pulmonary symptoms or disease.

Establishing a registry of this nature would allow DoD to better assess the magnitude of the problem and provide a more effective tool to assess the best diagnostic and treatment modalities. Providing a mechanism for DoD, VA, and civilian institutions to participate in this registry would be the only way to allow all relevant cases to be included. The DVEIVR was identified as an existing registry that is serving this purpose for ocular conditions. An EHR with structured data elements would facilitate automated data flow into registries, reducing expensive and time-consuming manual data abstraction.

Recommendation 9: DoD should implement an enterprise-wide clinical registry of deployment-related chronic pulmonary symptoms or disease. This registry should incorporate the STAMPEDE registry, reach out to other registries, and provide a mechanism for including cases evaluated at the VA and civilian institutions. The DVEIVR might be used as a starting point in determining an appropriate model.

#### **Evidence Level: III**

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### 6.0 DEPLOYMENT PULMONARY HEALTH RESEARCH ACTIVITIES

In response to concerns about potential adverse health effects associated with Operation ENDURING FREEDOM and Operation IRAQI FREEDOM (OEF/OIF) deployment exposures, a number of working groups were convened to provide recommendations for future deployment pulmonary health research activities.

In February 2010, a Denver Working Group comprised of Department of Defense (DoD), Department of Veterans Affairs (VA), and public/private physician and scientist representatives reviewed the risks of inhalational exposures and pulmonary diseases in U.S. military members deployed to OEF/OIF.<sup>205</sup> In the 2012 publication by Rose et al discussing the Denver Working Group's recommendations, the authors acknowledge the need for additional epidemiologic and toxicological research.<sup>13</sup> They also recognized a need for "future clinical and translational research" on the pathogenesis and treatment of lung diseases in military personnel.<sup>13</sup>

The Military Operational Medicine Research Area Directorate convened a Pulmonary Working Group in June 2010 to provide direction for research to address pulmonary health threats for deployed Service members.<sup>206</sup> The Working Group proposed a variety of recommendations for clinical, animal, and epidemiological studies.<sup>206</sup> Furthermore, a VA/DoD Health Executive Council Deployment Health Working Group prepared a joint action plan in response to the 2011 recommendations from the Institute of Medicine (IOM) report on Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan.<sup>22,207</sup> The Deployment Health Working Group also recommended research on markers of early disease or injury, validated exposure assessment tools, toxicology studies, and exposure modeling.

The array of current and proposed deployment pulmonary health research activities under DoD and VA include epidemiologic, clinical, anatomic, pathophysiologic, and toxicologic studies. This section includes highlights of various deployment pulmonary health research activities for which information was available or provided to the Defense Health Board (DHB) (see Figures 6-9).

#### 6.1 DEPARTMENT OF DEFENSE DEPLOYMENT PULMONARY HEALTH RESEARCH

#### Human Studies

<u>Epidemiologic Studies of Health Outcomes among Troops Deployed to Kabul/Bagram</u> This is a surveillance report assessing outcome rates in active component Service members that deployed to one of two bases located near Kabul and Bagram compared with selected control location groups.<sup>208</sup> The study has been completed.

#### Screening Spirometry for Assessment of Pulmonary Disease in Active Duty Military Personnel

The study, screening spirometry for assessment of pulmonary disease in active duty military personnel, is ongoing at the U.S. Army Medical Department Center and School.

Deployment Pulmonary Health Research Activities





The investigation will establish baseline normal values and spirometric abnormalities and plans to include 2,000 soldiers during initial combat medic training.<sup>71,209</sup> The investigation will establish baseline normal values and prevalence of spirometric abnormalities for this population, and determine the feasibility of conducting baseline spirometry studies for new active duty military personnel.<sup>209</sup>

#### **STAMPEDE**

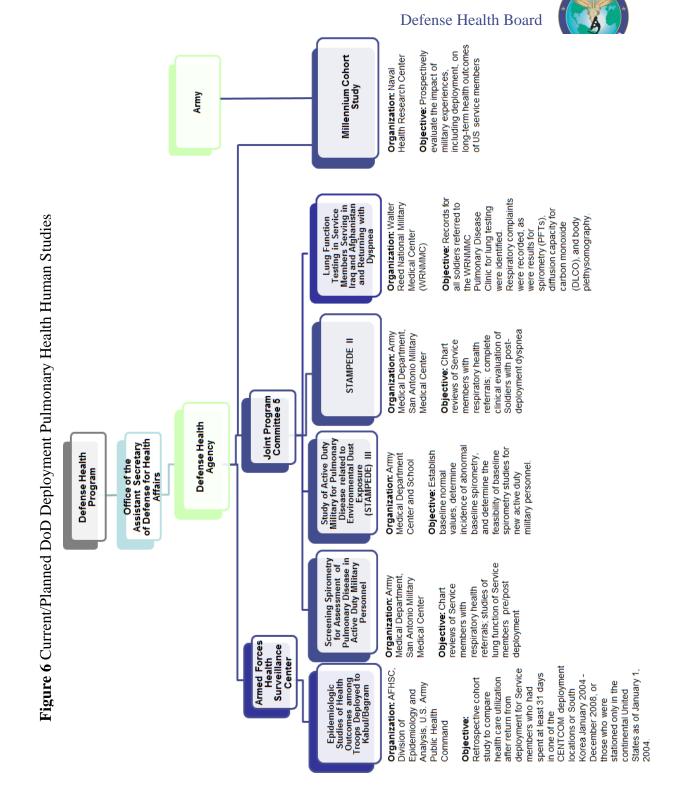
The Study of Active Duty Military for Pulmonary Disease Related to Environmental Dust Exposure (STAMPEDE) is a series of three studies and a registry related to deployment pulmonary health in Service members. STAMPEDE I<sup>41</sup> was a clinical evaluation study of Service members with exertional dyspnea during or within six months following deployment and was previously described in the Introduction. This study was followed by two additional studies, STAMPEDE II and III. STAMPEDE II is conducting pre- and post-deployment pulmonary evaluations on soldiers with a symptom survey, spirometry, impulse oscillometry, and chest radiograph.<sup>15,71</sup> STAMPEDE III, similar to STAMPEDE I, includes an even more comprehensive clinical evaluation of military personnel with post-deployment exertional dyspnea.<sup>71</sup> The registry was discussed in <u>Section 5.0</u>.

#### Lung Function Testing in Service Members Serving in Iraq and Afghanistan and Returning with Dyspnea

The Pulmonary Disease Clinic at Walter Reed National Military Medical Center (WRNMMC) is evaluating lung function testing results in Service members who have had respiratory complaints after having served in OEF/OIF.<sup>210</sup> The study is recording these complaints, as well as results for spirometry (pulmonary function tests), diffusion capacity for carbon monoxide (DLCO), and body plethysmography.

#### Millennium Cohort Study

Planning for the Millennium Cohort Study was initiated in 1999 and it opened in 2001 after the IOM recommended a coordinated prospective cohort study of Service members.<sup>42</sup> The Millennium Cohort Study relies primarily on questionnaire responses, but it also links with other sources such as environmental exposure and deployment data or VA records.<sup>42</sup> Currently, the Millennium Cohort Study is examining particulate matter (PM) and newly reported respiratory symptoms as well as the relationships among PM levels, time deployed, and respiratory symptoms.<sup>42</sup> Additionally, follow up surveys (every three years) are being implemented in order to evaluate the risk of new-onset respiratory symptoms and pulmonary conditions associated with military experiences among Service members and veterans.<sup>42</sup> (See also Section 4.0, Surveillance.)





#### <u>Airflow Perturbation Device (APD) for the Evaluation of Pulmonary and</u> <u>Sleep Disorders</u>

The objectives of this study are to 1) determine whether the Airflow Perturbation Device (APD) accurately assesses inspiratory and expiratory resistances by correlating APDderived values with the current gold standard: flow and resistance measured via spirometry, plethysmography, and impulse oscillometry (performed by a trained respiratory technician); 2) explore whether the APD accurately reflects changes in airway resistance with exercise, bronchodilators, and bronchoprovocation in individual patients; and 3) determine whether APD-derived values accurately predict flow, pressure, and resistance changes seen in the upper airway during polysomnography.<sup>211</sup> It is currently being conducted at Walter Reed National Military Medical Center (WRNMMC) and may be expanded to include Brooke Army Medical Center.<sup>212</sup>

#### Morphometric Approach to Quantification of Small Airways Disease and Particulate Matter Exposure of Deployed U.S. Military Personnel

National Jewish Health (NJH), in conjunction with Vanderbilt University, examined a morphometric approach to quantification of small airways disease and PM exposure in previously collected lung biopsies of deployed U.S. military personnel.<sup>213</sup> The study aimed to characterize histopathological abnormalities in lung tissue samples from deployed personnel compared to normal lungs and non-deployment bronchiolitis samples. Furthermore, it created a scoring system for lung biopsy interpretation; characterized minerals, fiber, and PM components in lung tissue from individuals who have deployed; and acquired deployment exposure data to help inform histopathological and PM findings.<sup>214</sup> The results are pending publication.

#### <u>Histopathological and Chemical Analytical Evaluation of Pulmonary Specimens from</u> Deployed and Non-Deployed U.S. Military Service Members

This study was initiated at the Armed Forces Institute of Pathology (AFIP) and transferred to the Joint Pathology Center (JPC) in April 2011. The study protocol specifies a histopathological examination of all non-neoplastic surgical lung biopsies from Service members obtained between 2002 and 2013 from U.S. military personnel. Additionally, a subset of specimens will be subjected to *in situ* Scanning Electron Microscopy/Energy Dispersive X-ray Analysis (SEM/EDXA) to determine the composition of retained particles. There is no civilian comparison group. This study recently received funding to resume work.

#### Pilot Metabolomics Study

The pilot metabolomics study is an investigation of polycyclic aromatic hydrocarbons, metabolomics, and inflammatory biomarkers present in serum samples.<sup>191</sup> Serum samples of deployed Service members will be compared to samples of non-deployed Service members. The study is an attempt to demonstrate the value of using biomarkers of exposure measured by high-resolution mass spectrometry.<sup>191</sup>

#### Pathological Diagnosis of Deployed Military Personnel with Pulmonary Disease



The study will evaluate lung biopsy cases that were reviewed at AFIP and JPC between January 1, 2005 and December 31, 2012.<sup>215</sup> The study will

include deployed and non-deployed active duty military personnel and will take into consideration the time interval between deployment(s).<sup>215</sup> The study will only review pathological reports; no histopathological or chemical analyses are to be performed.<sup>215</sup>

#### U.S. Navy Seabee Study

Between 2007 and 2008, the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) collaborated with NJH to initiate a research study examining the implications of high PM levels on the pulmonary health of deployed military personnel. USACHPPM had developed a protocol to assess the effect of deployment on pulmonary function with pre-, during, and post-deployment spirometry and had received U.S. Army Medical Research and Materiel Command (MRMC) Institutional Review Board (IRB) indication it would qualify for expedited approval due to minimal risk, but would require additional information and approvals.<sup>216</sup> The protocol was modified to include U.S. Navy Seabees as study subjects and received expedited approval by the NJH IRB.<sup>216</sup> However, the protocol was not resubmitted to the MRMC IRB. Baseline predeployment and during deployment spirometry was performed on a number of Seabees with their informed consent; however, investigators received notice while deployed that Multi-National Corps-Iraq (MNC-I) IRB approval was required.<sup>216</sup> The protocol was submitted to the MNC-I IRB and research activity stopped pending approval. Subsequently, the U.S. Navy became aware of the study and ordered it terminated and the data sequestered due to failure to obtain a DoD IRB approval prior to initiation. Subsequent attempts to obtain DoD approvals to complete the study have been denied.<sup>216</sup>

#### Other Studies

<u>High-Flow, Extended-Wear Respirators for Ambient Particulate Matter Protection</u> The Small Business Innovation Research study, "High-Flow, Extended-Wear Respirators for Ambient Particulate Matter Protection," consists of three phases. The objective of the first phase is to develop and demonstrate a filtration device that significantly reduces inhalation of PM10 and PM 2.5 and can be incorporated into a wearable device.<sup>217</sup> The second phase is to develop and demonstrate a respirator or mask using the technology from phase one, and the goal of phase three is to develop a National Institute for Occupational Safety and Health N95 compliant respirator resistant to clogging that can perform in extreme PM conditions.<sup>217</sup>

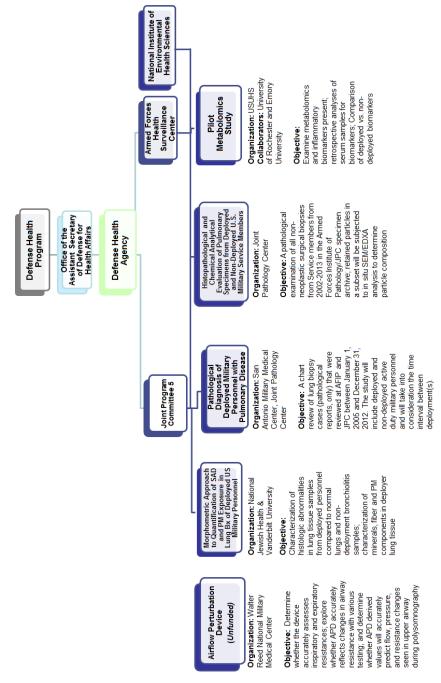
#### Toxicity Evaluation and Biomarker Identification in Rats

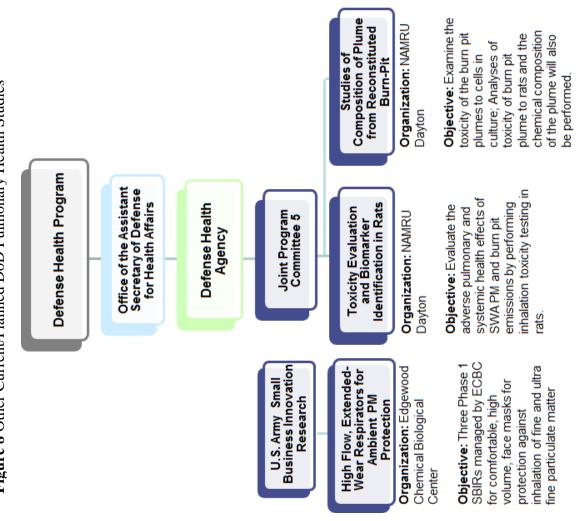
The study aims to evaluate the adverse pulmonary and systemic health effects of Southwest Asia PM2.5 and burn pit emissions through inhalation toxicity testing of rats.<sup>218</sup> The study will also attempt to identify potential biomarker candidates for pre-validation studies, and perform pre-validation studies on up to five candidates identified.<sup>218</sup>

#### Studies of Composition of Plume from Reconstituted Burn Pit



This study is currently examining the toxicity of the burn pit plumes to cells in culture.<sup>219</sup> Additional analyses include determining the chemical composition of the burn pit plume and its toxicity in rats.<sup>219</sup>



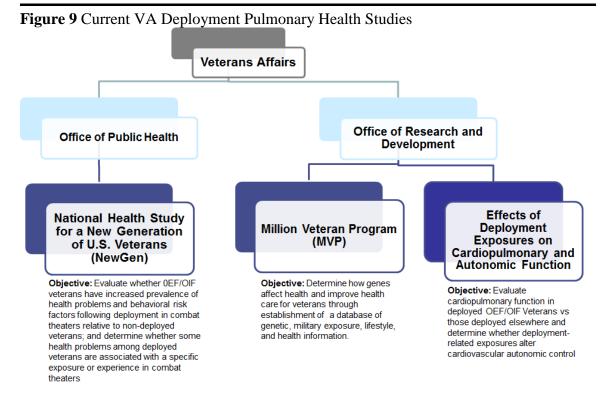








#### 6.2 DEPARTMENT OF VETERANS AFFAIRS RESEARCH



#### National Health Study for a New Generation of U.S. Veterans

The National Health Study is a 10-year longitudinal study of veterans that served in the military between October 2001 and June 2008, including OEF/OIF and those who served at other locations during the same period.<sup>220</sup> The survey topics range from health risk behaviors to health care utilization, in order to provide insight into the current health needs of veterans.<sup>220</sup> It is based on self-reporting.

#### Million Veteran Program

The Million Veteran Program (MVP) is attempting to understand the link between genes and veterans' health, including why certain veterans may be at greater risk for developing a disease than others.<sup>221</sup> The MVP is not directly studying the potential association between deployment and pulmonary health; the primary objective is to provide knowledge that may better inform prevention and treatment of certain conditions such as heart disease, diabetes, and cancer.<sup>221</sup>

#### Effects of Deployment Exposures on Cardiopulmonary and Autonomic Function

The effects of deployment exposures on cardiopulmonary and autonomic function will be investigated in veterans who deployed to OEF/OIF and Operation NEW DAWN in comparison to veterans who never deployed to this region.<sup>222</sup> Study participants will be given a standardized exercise challenge and bronchodilator spirometry, and investigators



will assess heart rate variability and cardiovascular reflex regulation during various tasks.<sup>222</sup>

### 6.3 CHALLENGES IN CONDUCTING DEPLOYMENT PULMONARY HEALTH RESEARCH

The deployment pulmonary health research portfolio seeks to identify and characterize specific pulmonary health threats and diseases and determine appropriate strategies to mitigate them. Additionally, it is attempting to advance the science in evaluating and treating patients with exposure-related chronic pulmonary disease. Although DoD and the VA have attempted to improve coordination and oversight through the establishment of working groups and the Joint Program Committees, there are still opportunities to improve the establishment of priority research objectives and direction. Some important research activities have yet to be accomplished. The long-term follow up and prognosis of Service members or veterans who have received surgical lung biopsies and were diagnosed with constrictive bronchiolitis is one example. The histopathological comparison of biopsy and autopsy lung tissue of those who deployed to Southwest Asia with those who did not deploy or deployed elsewhere is another. Although a number of investigators have indicated that a histopathological comparison of autopsy lung tissue would be of value, since these specimens are obtained under statutory authority, additional administrative and legal requirements would apply in using these for research purposes.

A number of challenges posed by unique aspects of military Service are associated with deployment pulmonary health research. First, there are higher rates of smoking among active duty personnel in comparison to the general U.S. population.<sup>24</sup> Smoking is the primary risk factor for the development of chronic obstructive pulmonary disease (COPD),<sup>23</sup> and also adversely affects physical fitness.<sup>223-225</sup>

Second, other confounders include the possible effects of deconditioning and obesity in Service members. Service members with higher levels of body fat may have impaired cardiorespiratory function,<sup>226</sup> and deconditioning post-deployment.<sup>131,132</sup> It is also possible that some of the pulmonary difficulties observed are related to preexisting conditions that were exacerbated by exposures during deployment.

Third, Service members may suffer from co-morbidities, such as gastroesophageal reflux disease, obstructive sleep apnea, cardiac disease, or pre-existing conditions such as asthma or allergies that may be exacerbated by deployment.<sup>214</sup> Additionally, Service members may be afflicted with mental health issues, such as posttraumatic stress disorder (PTSD), anxiety, or depression. A few research studies have suggested PTSD may be correlated with increased physician-diagnosed physiological disorders or diseases, or self-reported current health problems.<sup>119-121</sup> Therefore, it is possible that Service members with mental health afflictions may be over-reporting physiological symptoms. Furthermore, Service members may suffer from residual effects of blast lung injury from improvised explosive devices.<sup>118</sup>



Finally, International Classification of Disease (ICD) codes may lack specificity for pulmonary disease, which may result in under-reporting of certain pulmonary diseases or misclassification. Improper use of these codes also contributes to this outcome misclassification. The role of disability compensation may affect the collection of accurate data, especially if military personnel and veterans are encouraged to undergo unnecessary invasive surgical procedures, in the absence of clear clinical indications, in anticipation of future disability ratings.

A continually challenging factor in determining possible associations between environmental exposures and adverse deployment-related pulmonary health outcomes is the lack of accurate, individual-level exposure data. Without these data, it is difficult to determine whether true associations exist between specific environmental exposures and development of pulmonary diseases. In the absence of individual exposure data, location data, in conjunction with environmental monitoring data when available, may be used as a less accurate surrogate. However, location data may be classified below the country level, complicating any attempt to determine associations between specific deployment locations and outcomes. Even when location data are available, they may not represent the actual location an individual spent the majority of their time and the microenvironments at a particular location may vary considerably. Furthermore, periodic sampling may over or underestimate exposures depending on the sampling frequency. All of these factors contribute to the potential for exposure misclassification in using location data as a surrogate. DoD recognizes this and is attempting to address the issue with the individual longitudinal exposure record initiative.<sup>227</sup> In the interim, Periodic Occupational and Environmental Monitoring Summary (POEMS) documents are being created to summarize the DoD medical interpretation of occupational and environmental health exposure information for deployment sites.<sup>228</sup> An additional challenge in pulmonary health research is losses to follow up. Service members are a highly mobile population; thus, studies such as STAMPEDE or the Millennium Cohort Study have difficulty retaining study participants, resulting in possible selection bias and perhaps incomplete study results.

The ability to locate and share information is a key asset in the conduct of research and a tool for collaboration. A search of the Defense Medical Research and Development Program DeployMED website<sup>229</sup> in an attempt to locate current and proposed research in the area of deployment pulmonary health was challenging and unproductive. Various ongoing and recently awarded studies known to be funded by DoD were not discoverable. In addition, the current DoD electronic IRB system does not allow investigators from one MTF or site to view submitted or approved protocols or titles from another site. Thus, opportunities to reduce duplication, encourage collaboration, or identify complementary research in deployment pulmonary health are impeded by the structure of this system.



#### 6.4 Research Gaps and Priorities

A DoD panel identified existing gaps in deployment pulmonary health to include the prevalence and severity of deployment-related pulmonary disease, toxicity of PM, screening and diagnosis, and prevention and treatment.<sup>230</sup> Proposed focus areas for research included clinical studies, animal studies, exposure assessments, and biomarker studies.<sup>230</sup> The VA/DoD Deployment Health Working Group supports these focus areas, proposing markers of early disease or injury, exposure assessment tools, animal studies, and exposure modeling as research priorities.<sup>207</sup>

Rose et al stated that the existence of collaborative clinical research centers with shared data coordination and case review<sup>13,214</sup> would support future studies of deployment pulmonary health. Furthermore, the Denver Working Group recognized additional research is needed on the health effects of complex inhalational exposures faced by military personnel during deployment. The Working Group also noted animal studies of PM exposure are needed to understand its effects on the airways. Finally, additional epidemiologic studies in combination with exposure assessments were indicated as a priority.<sup>13</sup>

A number of studies have shown an association between deployment and increased respiratory symptoms, but there remains a great deal of uncertainty regarding an association between any specific pulmonary disease (e.g., asthma, bronchitis, COPD) and a single environmental factor (e.g., "Iraqi dust," PM, burn pits, oil-well fires).<sup>9,65,66,69</sup> A few studies have shown an association between deployment to Southwest Asia and exacerbation of existing asthma<sup>66,67</sup> or new diagnoses of asthma.<sup>7</sup> A recent retrospective cohort study compared deployment and post-deployment medical encounters for respiratory conditions in Army and Air Force personnel assigned to four OIF bases with a reference group from personnel assigned to the US and a reference group assigned to Korea. The incidence rate ratio for asthma diagnoses was 1.54 (95 percent confidence interval 1.33-1.78) for any of the four OIF bases compared to the U.S. assigned reference group.<sup>9</sup> There were no significant differences between asthma diagnoses at all four OIF bases and the Korea reference group. Questions have also been raised regarding an association between deployment and constrictive bronchiolitis based on a single case series report.<sup>12</sup>

It is important to note that many of the published studies lack the necessary controls to prove causality and can be considered anecdotal or hypothesis generating, at best. Specifically, only a few studies include comparisons to non-deployed or individuals deployed to other theaters of operation. Moreover, a number of studies have drawn conclusions based on small sample sizes and insufficient statistics. Given the potential impact on the health of Service members and veterans, rigorous attention to experimental detail is critical.

Concern surrounding burn pit exposures led an Institute of Medicine (IOM) committee to provide a number of recommendations in 2011, including that a prospective cohort study of veterans and active duty military be conducted to assess potential long-term health



effects related to burn pit emissions, preceded by a pilot study for feasibility.<sup>22</sup> The committee also suggested an assessment of the potential exposures at Joint Base Balad before beginning epidemiologic studies.<sup>22</sup> A review was conducted of Millennium Cohort Study and Defense Manpower Data Center data to investigate the possible association between respiratory illnesses and potential open-air burn pit exposures among a cohort deployed to Iraq or Afghanistan.<sup>183</sup> The study did not demonstrate an elevated risk for respiratory outcomes among personnel deployed in proximity to documented open burn pits in Iraq.<sup>183</sup> However, administrative assignment in proximity to a burn pit may not provide an accurate correlate for individual exposure. To sufficiently address these questions, additional focused research effort is needed.

One priority is to conduct additional observational studies as needed to establish whether there is a clear association between specific deployment exposures of concern and pulmonary outcomes of interest, comparing incidence rates in those deemed to be "exposed" relative to those "not-exposed." Even if no association is evident on a population level comparing those who deployed to those who have not deployed, associations might be identified for specific subgroups with unique exposure profiles, such as significant exposures to the sulfur fires near Mosul, burn pit smoke and fumes, or other exposures. Identifying and accurately classifying these exposure groups will require significant effort and cooperation between DoD, the Department of Veterans Affairs (VA), and advocacy groups. DoD has the expertise to design and conduct these studies, but will need continued leadership support and the necessary resources to complete them.

Another priority is to identify and accomplish long-term follow up of personnel who develop pulmonary outcomes of interest to determine the natural history of disease and assess effectiveness of interventions. This should include all personnel who develop the pulmonary outcomes of interest regardless of deployment status, as highlighted in the discussion of registries. It would also be of value to systematically review medical evaluation board submissions for pulmonary outcomes of interest to compare characteristics, including demographics, exposures, clinical findings, and disability ratings to identify any trends or associations. An additional priority is to ensure successful completion of the STAMPEDE series of studies that are attempting to answer key questions regarding deployment pulmonary health issues. Another important focus is ensuring oversight and transparency of research efforts in deployment pulmonary health. Ensuring that information on DoD-sponsored and/or funded research activities is posted on web portals for public access in addition to making IRB research protocols visible to all researchers within DoD should foster greater awareness and collaboration among researchers. Posting information on sponsored/funded research is something that should be accomplished immediately. Conducting a comparison of pulmonary tissue histology from deployed and non-deployed personnel to determine if there are significant differences is also something that would be of value. This is something multiple researchers have advocated and should provide information to augment similar research currently being performed in the collaboration between National Jewish Health and Vanderbilt University. Recent funding has been made available to accomplish this effort.



Finally, it is important to develop effective respiratory protection suitable for field use to minimize inhalational exposure to particulate matter of concern.

#### 6.5 FINDINGS AND RECOMMENDATIONS REGARDING DEPLOYMENT PULMONARY HEALTH RESEARCH ACTIVITIES

#### Finding 10:

- a) There are opportunities to conduct additional observational studies to identify or test hypotheses regarding potential associations between deployment exposures of interest and pulmonary outcomes of interest.
- b) Currently, there is no comprehensive effort to track Service members and veterans with persistent post-deployment pulmonary symptoms or disease.
- c) The STAMPEDE series of studies may provide valuable objective information regarding some of the key clinical and policy questions related to deployment pulmonary health. There are concerns that losses to follow up may degrade the results.
- d) The Millennium Health Cohort may be used to conduct additional assessments of potential associations between deployment exposures and pulmonary outcomes of interest. Losses to follow up are also a concern with this study.

DoD has the capability to design and conduct effective observational studies to examine potential causal associations between specific exposures and outcomes. Additional effort in this area would also help to illustrate the true magnitude of the problem. However, challenges related to accurately characterizing individual exposure are recognized. Welldesigned prospective cohort studies or case-control studies of Service members and veterans may help determine the presence or absence of associations between exposures of concern and pulmonary outcomes of interest. An approach similar to that outlined by the IOM for burn pit exposures would be appropriate in assessing other exposures of interest.<sup>22(pp117)</sup> Conducting additional sub-studies within the Millennium Health Cohort may provide insight on potential causal factors and on the prognoses for individuals with deployment-related chronic pulmonary symptoms or disease. To study the long-term pulmonary consequences of deployment, it is necessary to have high quality, long-term follow up. A prospective cohort study of Service members and veterans who develop chronic post-deployment pulmonary symptoms or disease would characterize the nature and proportions of specific diagnoses established over time, provide prognostic information, and may yield insight as to the best practices for evaluating and treating these individuals. Expansion of the STAMPEDE III study taking place at San Antonio Military Medical Center to include all individuals, whether or not deployed, with unexplained dyspnea, as well as all Services and the VA, would be one approach.

The STAMPEDE series of studies in general are focused on practical questions related to the establishment of clinical baseline information, feasibility and utility of spirometric surveillance, and clinical evaluation of chronic post-deployment pulmonary symptoms with longitudinal follow up in a military population. These studies provide a unique opportunity to obtain information that may provide some of the best evidence available in

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addressing the specific questions posed to the Subcommittee. Continued and expanded support of these efforts in the form of resources and staff,

including incentives to reduce losses to follow up, is advised and may assist in fulfilling other recommendations.

#### **Recommendation 10: DoD should:**

- a) Conduct additional observational studies in Service members and veterans to identify or test hypotheses regarding potential associations between deployment exposures of interest and pulmonary outcomes of interest and quantify the incidence of those outcomes.
- b) Conduct a prospective cohort study of Service members and veterans with unexplained chronic dyspnea to better characterize pulmonary outcomes over time. Approaches might include expansion of the STAMPEDE III study and STAMPEDE registry.
- c) Provide resources necessary to ensure the STAMPEDE series of studies are able to accomplish their aims in a manner that maximizes internal validity and allows sufficient long-term follow up of registry patients.
- d) Provide resources necessary to conduct further studies of deploymentrelated chronic pulmonary symptoms and/or disease within the Millennium Health Cohort.

#### **Evidence Level: III**

**Finding 11:** A number of individuals have received surgical lung biopsies as part of their evaluation for post-deployment pulmonary symptoms. It is not evident that systematic follow up of these individuals has been conducted to determine prognosis associated with specific pathological findings, responses to treatment, or long-term morbidity associated with the biopsy, such as chronic pain.

Although the Board does not support continued use of surgical lung biopsies for diagnostic purposes in the absence of other supporting clinical indications, a comprehensive follow up of those individuals who did undergo biopsy would provide valuable prognostic data on this group. This could be a substudy of the cohort study in Recommendation 10 and may benefit from comparing them to those with similar symptoms of similar severity who did not receive lung biopsy to determine differences in prognosis or morbidity as well as level of disability rating.

Recommendation 11: DoD should conduct a prospective study of all Service members who have undergone surgical lung biopsies for post-deployment pulmonary symptoms to assess long-term outcomes associated with specific diagnoses and morbidity associated with the procedure itself.

**Evidence Level: III** 

#### Finding 12:

- Research activity within the area of deployment-related chronic pulmonary symptoms or disease would benefit from improved coordination and direction.
- b) Information on ongoing, recently awarded, and proposed DoD research is divided between multiple websites or is not posted at all.
- c) The DoD electronic IRB system does not allow investigators to review descriptions of ongoing research from outside of their own location.

DoD has made progress in coordinating tri-Service research efforts with the establishment of the Joint Program Committees to provide oversight for the selection and funding of priority research projects. Additionally, the VA/DoD Health Executive Council Deployment Health Working Group, the Military Operational Medicine Research Area Directorate Pulmonary Working Group, and the Denver Working Group have provided direction for research gaps and priorities. However, oversight by a single official/office with authority to determine research priorities and allocate or re-allocate funding for the DoD deployment pulmonary health research portfolio would foster coherent, complementary, and collaborative efforts in accomplishing priority research. Additionally, it is difficult, or in some cases impossible, to efficiently locate information related to ongoing or proposed DoD sponsored or initiated research. Having easy access to this information would provide investigators with a tool to reduce duplication, locate collaborators, and design research to complement studies already in progress. A single DoD research web portal and an electronic IRB system with access across the Military Health System (MHS) would provide visibility on submitted and approved clinical research protocols across DoD.

#### **Recommendation 12: DoD should:**

- a) Designate a single office with the authority to determine priorities and allocate or re-allocate funding for the DoD deployment-related pulmonary health research portfolio.
- b) Hold, at a minimum, annual meetings with investigators to discuss deployment pulmonary health research.
- c) Create one web portal from which information on all historical, ongoing, and recently awarded deployment-related (or all) DoD health research projects may be accessed.
- d) Link DoD's electronic IRB system so that any authorized investigator at any site can review, at a minimum, titles and brief descriptions of all submitted and approved research projects.

#### **Evidence Level: III**

**Finding 13:** Lung tissue specimens are available from both deployed and non-deployed military personnel and provide an opportunity to assess if there are any histopathological differences between these groups.



The Joint Pathology Center estimates it has approximately 1,000 (nonneoplastic) surgical lung biopsy specimens from OIF/OEF era patients, of which about half are from patients who deployed to Iraq or Afghanistan. The Armed Forces Medical Examiner System has conducted more than 5,000 autopsies since 2001. Lung tissue specimens may be available from a large proportion of these autopsies. Conducting a histopathological comparison of a representative number of biopsy and autopsy samples may provide insight to the question of whether exposure to PM or other inhalational exposures in Southwest Asia was associated with objective findings of lung damage compared to those who had not deployed. Multiple civilian and military researchers have commented on the potential value of this information. In particular, a study of this nature may provide insight on issues related to constrictive bronchiolitis. Recent funding to resume the study of "Histopathological and chemical analytical evaluation of pulmonary specimens from deployed and non-deployed U.S. military Service members" is a positive development in this area.

Recommendation 13: DoD should conduct a histopathological study of already available lung tissues from Service members who deployed to Southwest Asia compared to those who did not deploy as well as to those deployed to other theaters of operation in order to determine if there are characteristic histopathological changes associated with deployment to areas with high levels of airborne PM such as Southwest Asia.

#### Evidence Level: III

**Finding 14:** Despite the substantial number of publications describing the elevated levels of PM in Southwest Asia, there is limited research on respiratory personal protective equipment (PPE) specifically for reducing PM exposures in a military field environment for military field use.

#### **Recommendation 14: DoD should continue research to develop respiratory PPE appropriate for field or combat use to reduce PM exposures.**

#### **Evidence Level: III**

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## 7.0 PREVENTION OF DEPLOYMENT-RELATED PULMONARY DISEASE

An important use of epidemiologic data is the identification of populations at high risk for disease.<sup>43(p5)</sup> Identification of such populations may help direct disease prevention efforts as well as identify the factors or characteristics that put those populations at higher risk.

Prevention may be classified as primary, secondary, or tertiary. Primary prevention involves taking action to prevent the initial development of disease, such as immunization or limiting hazardous exposures. Secondary prevention denotes early detection of disease before development of clinical signs and symptoms, the purpose of which is to facilitate early intervention that may cure or improve the natural course of the disease. Tertiary prevention intervenes after the diagnosis of clinical disease (or onset of symptoms) to reduce its impact.<sup>43(p5-6)</sup>

Ideally, prevention of deployment-related pulmonary disease would involve all levels of prevention. Primary prevention may include smoking cessation and the use of personal protective equipment (PPE), while secondary prevention would involve screening for asymptomatic disease, and tertiary prevention would include any interventions to improve symptoms, delay progression of disease, and improve quality of life and access to care, respectively. There is some ambiguity in the distinctions between the various levels of prevention. The discussion below attempts to categorize prevention recommendations according to the above definitions, but some may overlap levels or may be considered to fall in one category or another based on what is considered a disease or a risk factor.<sup>231</sup> It is recognized that security and mission requirements may often limit the extent to which some prevention recommendations can be pursued. However, opportunities to limit exposures to airborne hazards should be sought and implemented when operationally feasible.

#### 7.1 PRIMARY PREVENTION

Two key areas for primary prevention of deployment-related pulmonary disease are related to infectious diseases and environmental exposures, of which the primary focus of this report is the latter. The hierarchies of controls for limiting exposure include elimination/substitution, engineering controls, administrative controls, and PPE.<sup>44</sup> In the area of elimination/substitution, the most apparent example is smoking cessation, which is discussed further below. Another widely publicized example is the operation of openair burn pits. Department of Defense (DoD) regulations prescribe that incinerators should be used whenever feasible,<sup>106</sup> and U.S. Central Command 200-2 indicates that if any base exceeds 100 U.S. personnel for 90 days, it must construct a plan for installing waste disposal technologies, such as incinerators, to discontinue use of open-air burn pits.<sup>232</sup> Multiple inspections indicated that even following the update of this DoD Instruction (DODI) in 2011, open-air burn pit use continued as incinerators sat idle or were underutilized due to faulty construction or lack of operating funds.<sup>30,233,234</sup> Other

considerations include reducing the quantity of waste generated and alternate disposal methods.<sup>235-237</sup> Including air quality as one



consideration in base camp site selection is another example. Substitution of non-internal combustion engine vehicles and machinery when operationally feasible may also assist in improving air quality.

Engineering controls related to ambient air quality could range from efforts to reduce emissions from local industry or military specific activities to effective air filtration for buildings or vehicles. Commanders could attempt to have engineers work with local industries to improve equipment or practices to decrease air pollution or coordinate with other government agencies or host nation officials to assist with these goals. Improvements in the level of emissions from internal combustion engine vehicles and machinery used would also fall in this category.

Administrative controls may include limiting the number of personnel assigned to poor air quality areas and limiting the level of outdoor exertion on poor air quality days.<sup>238</sup> For example, Kabul, Afghanistan has been shown to have high levels of particulate matter (PM), polycyclic aromatic hydrocarbons (PAHs), and oxygenated PAHs,<sup>239</sup> some of which are classified as probable carcinogens in humans.<sup>240</sup> However, there may be limited opportunities to implement either of these recommendations in the context of military operations. Limiting the use of internal combustion engine vehicles and machinery when operationally feasible would be another potential administrative control.

PPE is another example of primary prevention and refers to equipment worn by an individual to prevent or minimize exposure to hazards, such as chemical, radiological, microbiological, or physical.<sup>241</sup> PPE may include items such as vests, full body suits, gloves, safety glasses, and respirators for pulmonary specific protection.<sup>241</sup> U.S. Army, Navy, and Air Force regulations or instructions refer to the Occupational Safety and Health Administration 29 Code of Federal Regulations (CFR) 1910 Subpart I for PPE requirements.<sup>242-244</sup> However, implementation and specific requirements vary by Service branch.<sup>242-244</sup>

Under DoDI 6490.03 *Deployment Health*, "Deployment-Specific or Occupationally Related Protective Measures" must be available and Service members must be trained on their use.<sup>126</sup> Occupational PPE, respiratory protection, or monitoring devices may be issued and fit tested as needed. Thus, if ambient PM levels were deemed a potential health hazard, there is regulatory guidance to support provision of PPE and training in proper use to mitigate the hazard.

The U.S. Army Public Health Command's (USAPHC) PM fact sheet provides military exposure guidelines for acute and chronic PM levels and their health effects; however, it acknowledges there are limited strategies to mitigate PM exposure.<sup>29</sup> For example, military personnel could limit outdoor activity during periods of high PM levels or use cravats or handkerchiefs to minimize exposure. USAPHC also proposes the use of N95 filtering face pieces when PM levels are very high, acknowledging that they may not be feasible for long-term use.<sup>29</sup> No specific threshold of PM exposure is specified to trigger

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a requirement for PPE, although recommendations could be made based on the military exposure guidelines (MEGs) outlined by USAPHC and/or U.S. Environmental Protection Agency (EPA) standards.<sup>245</sup>

Currently, respiratory protection specifically designed for PM reduction and continual use in combat is not available. A current research project is underway to develop a field usable filtration device that will significantly reduce inhalation of PM and can be incorporated into a wearable, clog-resistant NIOSH N95 compliant respirator.<sup>217</sup> Expediting completion of this research and development of appropriate policy for use may have a positive impact in reducing exposure to PM in future military operations.

In summary, addressing the sources of potentially hazardous airborne exposures will require a holistic approach in assessing and attempting to reduce or mitigate those exposures. A key aspect of this will include being able to effectively monitor the level of airborne hazards to determine when additional actions may be warranted.

## 7.2 Secondary Prevention

Secondary prevention would involve screening military members to identify pulmonary disease prior to the manifestation of symptoms, with the idea that early intervention may improve prognosis. However, there may be few pulmonary conditions that fall into this category. Some military occupational specialties , such as firefighters, may be at higher risk for exposures to pulmonary hazards due to the nature of their occupational duties.<sup>246</sup> In theory, periodic spirometry in this group may identify early declines in pulmonary function, which may trigger early evaluation, treatment, and possibly increased efforts to avoid subsequent hazardous exposures prior to the development of symptoms.

The utility of screening high-risk populations for asymptomatic pulmonary disease is not universally endorsed and is discussed in <u>Section 2.0</u>, Pre-Deployment Clinical Baselines and Post-Deployment Screening. The U.S. Preventive Services Task Force (USPSTF) does not recommend screening chest radiographs or spirometry to identify asthma or chronic obstructive pulmonary disease in asymptomatic populations.<sup>247</sup> Current screening efforts in DoD include the required pre- and post-deployment health assessments, as well as post-deployment health reassessments. Service members also have annual preventive health assessments to include physical examinations and laboratory testing. Screening through these mechanisms may identify those with pre-existing pulmonary conditions, such as asthma, which may be exacerbated by deployment exposures.<sup>66</sup> This provides an opportunity for education, optimal medication management to prevent or minimize exacerbations, and other preventive measures.



# 7.3 TERTIARY PREVENTION

Tertiary prevention of deployment-related pulmonary disease involves ensuring the best available treatment is provided in a timely manner and that affected individuals are provided the greatest opportunity to maintain or recover function. Educating patients, families, and providers to recognize signs and symptoms that may warrant early evaluation would support these goals. Early treatment of lung diseases such as Acute Eosinophilic Pneumonia<sup>85,86</sup> and chronic obstructive pulmonary disease<sup>248</sup> (COPD) may improve outcome measures. In addition, making patients aware of opportunities to participate in various registries and clinical research evaluations would be beneficial. A major focus in this area should be patient-centered outcomes. Debilitating pulmonary disease may have significant financial, occupational, social and psychological impacts on patients and their families. Ensuring applicable websites or hotlines provide sufficient information on available resources may assist them in overcoming obstacles to accessing these resources.

## 7.4 Smoking

Individual behavior, such as physical activity and cigarette use, affects a variety of health outcomes<sup>249</sup> and may affect an individual's pulmonary health in particular.<sup>23</sup> The social and cultural environment of Service members, including attitudes and social support, may also impact a wide range of health outcomes.<sup>249</sup> According to the 2011 DoD Health Related Behaviors Survey of Active Duty Military, 24 percent of Service members were smokers in comparison to 21.2 percent of the U.S. civilian population.<sup>24</sup> However, the percentage of current smokers varies between the Services. The highest percentage of smokers was reported in the U.S. Marine Corps (30.8 percent), followed by the U.S. Army (26.7 percent), the U.S. Navy (24.4 percent), and the U.S. Air Force (16.7 percent).<sup>24</sup> "Across all services, personnel exposed to high combat were more often heavy cigarette smokers than personnel exposed to low or no combat, with Army personnel exposed to moderate or high combat more often heavy smokers than those not combat deployed. On the other hand, personnel who did not experience combat were more often smoking abstainers than personnel exposed to combat; in particular, Navy and Air Force personnel with no combat exposure were more often smoking abstainers than personnel exposed to combat."<sup>24</sup> Given these rates of smoking, the military population may be at even greater risk of adverse health outcomes such as reduced physical fitness,<sup>223-225</sup> development of COPD, or even cancer.<sup>23</sup> Furthermore, exposure to secondhand smoke has also been linked to cancer, cardiovascular, and respiratory disease.<sup>23</sup> Thus, if deployment results in an increase in the prevalence of smoking and/or exposure to secondhand smoke, this may accelerate the onset of adverse health outcomes or exacerbate existing conditions.

A 2009 Institute of Medicine report estimated that DoD spends more than \$1.6 billion each year on tobacco-related medical care, increased hospitalization, and lost productivity.<sup>250</sup> Given the potential risks to Service members' health and related costs, DoD is targeting smoking as a priority threat to public health and readiness and aims to

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have to bacco-free installations by 2020.<sup>251</sup> DoD has also executed several to bacco cessation efforts such as the Quit Tobacco – Make Everyone

Proud campaign,<sup>26</sup> which provides online smoking cessation resources, and services through TRICARE including "quitlines," counseling, and nicotine replacement therapy.<sup>25</sup> Dr. Jonathan Woodson, the Assistant Secretary of Defense for Health Affairs, has also encouraged all military medical leaders to urge their local installations and units to reduce tobacco use.<sup>28</sup> In 2012, the U.S. Navy ended discounts on tobacco products sold on Navy and Marine Corps bases.<sup>252</sup> Currently, tobacco products sold at commissaries for the other Services are taxed at a discounted rate, sometimes up to 20 percent;<sup>253</sup> however, this may be discontinued, pending passage of a DoD bill through Congress.<sup>27</sup>

There is evidence that suggests the use of electronic cigarettes, also known as ecigarettes, may help individuals reduce or cease smoking. In one study of e-cigarettes among smokers with no desire to quit, there was a smoking cessation rate of 22.5 percent after six months.<sup>254</sup> Furthermore, at least a 50-percent reduction in cigarette smoking was observed in 32.5 percent of participants. Another survey of e-cigarette users reported a six-month point prevalence smoking abstinence rate of 31 percent, and those who had used e-cigarettes over 20 times a day had a cessation rate of 70 percent.<sup>255</sup> However, caution should be used in assessing the potential role for e-cigarettes to facilitate smoking cessation until there is more robust research on e-cigarette safety,<sup>256</sup> as this may result in the substitution of one expensive and potentially hazardous addiction for another. Due to the potential hazards associated with e-cigarette or other nicotine delivery device use,<sup>257</sup> every effort should be made to discourage use of these devices in those who are not current smokers.

## 7.5 SUMMARY OF EVIDENCE REVIEWED

There are studies that indicate that high levels of PM may exacerbate some existing medical conditions and may lead to a decline in pulmonary function with prolonged exposure.<sup>258</sup> In addition, the EPA has established air pollution standards for PM based on a review of the literature in this area.<sup>259,260</sup> Some studies have also indicated an increase in asthma diagnoses or exacerbations associated with deployment to Southwest Asia.<sup>7,9</sup> One of these studies showed an increase in asthma diagnoses associated with deployment to Southwest Asia.<sup>23,261</sup> In addition, there is strong evidence that exposure to products of combustion, including and especially tobacco smoke, have adverse health effects.<sup>23,261</sup>

PM levels have been documented to be elevated at some deployment locations in Southwest Asia.<sup>29</sup> Published guidance provides for Service members to be equipped with respiratory PPE when deemed necessary by their operational tasks and/or Commander.<sup>242-244</sup> However, there appears to be ambiguity regarding when it may be appropriate to issue respiratory PPE in the context of elevated levels of ambient PM at deployed locations and limited options for issuance of effective, sustainable, operationally acceptable respiratory PPE.

Screening high-risk asymptomatic populations, such as smokers, with spirometry is not recommended in current guidelines.<sup>148,247</sup> The USPSTF guidance indicated that smoking



cessation interventions and influenza vaccination may be of more value than screening spirometry.<sup>247</sup> However, the results of a recent study

indicate that screening asymptomatic smokers with spirometry may potentially provide them an opportunity to benefit from early treatment.<sup>262</sup> Similar questions have been raised regarding the value of screening spirometry in Service members and are discussed further in <u>Section 2.0</u>, Pre-Deployment Clinical Baselines and Post-Deployment Screening.

There may be opportunities to improve awareness among patients, families, and providers on the importance of recognizing early signs and symptoms of pulmonary disease and seeking appropriate evaluation and treatment. Ensuring patients are aware of opportunities to participate in registries or clinical research evaluations may enhance understanding of the disease processes involved, the magnitude of the problem, and provide more effective diagnostic and treatment tools. Patients and families have indicated that impairment from pulmonary symptoms and disease has caused financial, occupational, social, and psychological hardships. Additional focus on supporting patients and families in coping with chronic debilitating disease processes may be beneficial as well.

Smoking among Service members affects their overall physical fitness and military readiness, including increasing their risk for development or exacerbation of pulmonary diseases.<sup>23</sup> Validated tobacco cessation programs have been shown to be effective in reducing smoking.<sup>263</sup> There are significant efforts underway throughout DoD to promote smoking cessation, prevent initiation, and transform the environment and culture of the military to make smoking less appealing,<sup>25,26,251</sup> including the possible elimination of the discounted tax on tobacco products at commissaries.<sup>27</sup>

# 7.6 FINDINGS AND RECOMMENDATIONS REGARDING PREVENTION OF DEPLOYMENT-RELATED PULMONARY DISEASE

## Finding 15:

- a) Smoking is a known risk factor for cardiovascular and pulmonary diseases, including COPD and cancer. Secondhand smoke exposure has been causally linked to cancer, respiratory disease, and cardiovascular disease.<sup>23</sup>
- b) The percentage of Service members who smoke is higher than in the general population,<sup>24</sup> thereby increasing their risk for development of these diseases.<sup>23</sup>
- c) The Military Health System (MHS) has a number of initiatives in this area and has prioritized supporting smoking cessation and prevention of initiation.<sup>25-28</sup> Effective, evidence-based tobacco cessation efforts would help reduce preventable morbidities in Service members.

Recommendation 15: DoD should provide evidence-based tobacco cessation programs, periodically review the effectiveness of those programs, and continue to reduce acceptance of tobacco use, e-cigarettes, and like products (e.g., discouraging sales, smoke-free bases, educational campaigns). DoD



should identify the most vulnerable groups and aggressively target tobacco cessation efforts toward these groups.

#### **Evidence Level: II**

#### Finding 16:

- a) Currently, there are insufficient individual exposure data on military members, particularly in the deployed environment.
- b) Military members operate in many parts of the world where PM levels and other air pollutants are higher than in the United States.<sup>29</sup> PM has been shown to have adverse acute and chronic health effects depending on level and duration of exposure, dose to the target organ, and susceptibility factors. Current PM respiratory protection options are suboptimal for continuous use in military field operations.
- c) Recent inspection reports indicate regulations governing operation of open burn pits have not been adequately enforced and waste management practices could be improved.<sup>30</sup>

Better characterization of individual exposures to environmental and occupational inhalation hazards may help identify potential risks to long-term health. Continued analyses and monitoring of PM and associated air quality measures would allow commanders to determine when additional preventive measures, such as respiratory PPE, may be appropriate. Current challenges in providing respiratory protection for PM are outlined in the USAPHC Fact Sheet on PM Air Pollution Exposures during Military Deployments.<sup>29</sup> Improved enforcement of current regulations on open burn pit use and improved overall waste management would reduce inhalational hazards.

#### **Recommendation 16: DoD should:**

- a) Continue efforts to better characterize (quantitatively and qualitatively) and minimize potentially harmful environmental and occupational exposures.
- b) Continue efforts to develop better and more effective PPE to reduce hazardous exposures, such as high PM levels.
- c) Improve enforcement of existing regulations on the operation of open burn pits and improve overall waste management.

#### **Evidence Level: III**

#### Finding 17:

- a) Impairment from pulmonary disease can have financial, occupational, social, and psychological effects on both patients and their families.
- b) Patients and families have indicated difficulty in navigating the medical evaluation and treatment systems, especially as a Reserve component member, and the disability evaluation process.

In situations where medical professionals are unable to provide a specific diagnosis, there may be additional stress related to the uncertainty of whether they may qualify for



medical discharge or disability benefits in conjunction with not being able to adequately carry out their civilian or military occupation. Providers

have indicated that military members with potentially disabling pulmonary symptoms of unknown cause may receive appropriate medical evaluation board processing and qualification for disability benefits without a histopathological diagnosis if a comprehensive evaluation is completed and an appropriate narrative is provided by the specialty consultant.

Recommendation 17: DoD should review the range of current resources available to support patients, families, and providers dealing with chronic pulmonary symptoms and disease, including those available through the Department of Veterans Affairs, and, with stakeholder input, identify gaps and make improvements. This review should include issues ranging from access to care, the disability evaluation process, and other available resources such as support groups, to improve patient-centered outcomes.

#### **Evidence Level: III**

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#### UNDER SECRETARY OF DEFENSE 4000 DEFENSE PENTAGON WASHINGTON, DC 20301-4000

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READINESS

#### MEMORANDUM FOR PRESIDENT, DEFENSE HEALTH BOARD

#### SUBJECT: Request to the Defense Health Board to Recommend a Comprehensive Approach to the Assessment of Deployment Pulmonary Health

Concern is growing in the military community, media, and Congress that inhalational exposures in Southwest Asia may be associated with pulmonary disease in Service members and veterans. There is some evidence of acute respiratory symptoms possibly associated with in-theater inhalational exposures, but assessment of possible long-term pulmonary disease is inconclusive. Detection of disease in symptomatic individuals following deployment has been difficult using standard methodology. Moreover, studies on indigenous populations have been fraught with uncontrolled variables confounding research methodology.

To address this issue, we request that the Defense Health Board (DHB) review evidence relevant to deployment-related pulmonary disease and recommend: 1) a comprehensive approach to its assessment and prevention, including the identification of preferred screening and clinical diagnostic tools, and 2) a direction for future research and surveillance. The DHB's evaluation may include the interaction of physical, roxic, infectious, and immunologic factors and their influence on pulmonary health, and should address the following questions as they relate to the deployed environment:

- What clinical protocols should be used for diagnosing symptomatic individuals in the future?
- 2) How should clinical baselines be established in deploying personnel, and what types of registries are recommended to track individuals with pulmonary symptoms or disease?
- 3) What future research studies are recommended, and how should these, as well as those already planned, be prioritized?

The point of contact for this action is Dr. Craig Postlewaite, Force Health Protection and Readiness. Dr. Postlewaite may be reached at (703) 578-8513, or Craig.Postlewaite@tma.osd.mil.

Já Ann Roáney /Acting



# APPENDIX B. TERMS OF REFERENCE

These terms of reference establish the objectives for the Defense Health Board's (DHB) review of deployment-related pulmonary health issues, including prevention, surveillance, screening, clinical assessment, and future research priorities. The terms outline the scope of the Board's examination as well as the Board's methodology for responding to the Department's request.

<u>Mission Statement:</u> The Board will conduct a comprehensive review of deployment-related pulmonary health issues and offer recommendations regarding best practices pertaining to prevention, surveillance, screening, and clinical assessment. Additionally, the Board will identify gaps in research and provide guidance for future research priorities.

**Issue Statement:** There is concern that inhalational exposures experienced by Service members and veterans who were deployed to Southwest Asia may be associated with development of pulmonary disease. Specific exposures of concern include particulate matter, emissions from burning waste, other fires, munitions, vehicles, and local industry, as well as personal habits such as smoking. Research to date evaluating associations between deployment exposures and chronic pulmonary disease has been inconclusive, although some studies have shown a possible association with acute respiratory symptoms. There is continuing debate about whether additional measures are needed to better establish baseline pulmonary status and pulmonary function prior to deployment, how to effectively screen and diagnose symptomatic Service members and veterans for chronic deployment-related pulmonary symptoms and disease, and what future research efforts are most needed. On January 20, 2012, the Acting Under Secretary of Defense for Personnel and Readiness requested the DHB review deployment-related pulmonary health issues and recommend a comprehensive approach for assessment and prevention, in addition to providing direction for future research and surveillance.

**Objectives and Scope:** This report addresses current and proposed policies, best practices, and the best available evidence to provide recommendations regarding:

- 1. Establishing pre-deployment baseline pulmonary status including pulmonary function;
- 2. Screening for potential deployment-related chronic pulmonary symptoms and disease;
- 3. Clinical protocols to diagnose individuals with chronic post-deployment change in pulmonary status;
- 4. Appropriate surveillance for post-deployment chronic pulmonary symptoms and disease;
- 5. The sufficiency of current and planned registries of individuals with chronic post-deployment change in pulmonary status or disease;
- 6. Guidance for future deployment pulmonary health research with respect to priority and direction; and
- 7. Prevention of deployment-related chronic pulmonary disease.

<u>Methodology:</u> The Public Health Subcommittee will review current and proposed policy, research literature, and clinical best practices regarding establishment of pre-deployment

baseline pulmonary status and pulmonary function, surveillance for deployment-related chronic pulmonary symptoms and disease, postdeployment screening and clinical evaluation, and opportunities for prevention. As needed,



members will receive briefings from subject matter experts in pulmonary disease, occupational/environmental exposures, pre/post deployment screening and evaluation, and other areas as deemed appropriate. This evaluation may include the interaction of physical, toxic, infectious, and immunologic factors and their influence on pulmonary health. The members will review the literature and information received from briefings, conduct site visits as needed, and present their preliminary findings and proposed recommendations to the DHB for consideration and deliberation.

A. The Subcommittee will provide a grade for each of its recommendations based upon the strength of the data upon which those recommendations were made using the following criteria:

I - Based upon data from randomized clinical trials with clinical endpoints; II - Based upon data from observational cohort studies or randomized trials with surrogate endpoints; or

III - Based upon expert opinion, case-control, cross sectional or ecological studies, or case series.

B. The Subcommittee has heard a number of presentations and reviewed a substantial body of information on the issue of pulmonary health. At times, we have received contradictory information. In an effort to provide our perspectives on the quality of these datasets, we have provided a brief commentary at the end of each section regarding our views as to the strengths and weaknesses of the information contained in that section.

The DHB will deliberate the findings and consider the recommendations proposed by the Subcommittee, making revisions as deemed necessary, and vote on those recommendations in an open public session.

**Deliverable:** The Board will deliberate the final findings and recommendations presented by the Public Health Subcommittee in 2014 and produce the final report immediately following acceptance by the DHB for presentation to the Department. The Subcommittee will provide progress updates to the Board at each DHB meeting before then.

<u>Membership</u>: The Public Health Subcommittee members will conduct the primary investigation and will consult subject matter experts as needed.

## Support:

- 1. The DHB office will provide any necessary administrative, analytical/research and logistical support for the Subcommittee and Board.
- 2. Funding for this review is included in the DHB operating budget.

# APPENDIX C. GUIDING PRINCIPLES

#### Context

There is concern that inhalational exposures experienced by Service members and veterans during deployment to Southwest Asia may be associated with development of chronic pulmonary disease. A number of media reports have focused on exposures to smoke and fumes from open burn pits used to dispose of waste and elevated levels of particulate matter as possible causes. Epidemiologic studies conducted by the Department of Defense (DoD) to determine whether any specific associations between deployment location or proximity to burn pits was associated with a significant increase in chronic pulmonary diagnoses have been inconclusive. These epidemiologic studies have been limited by inaccurate International Classification of Disease coding (outcome misclassification), the absence of accurate individual exposure data (exposure misclassification), and challenges in obtaining accurate location data as a surrogate for exposure. On January 20, 2012, the Acting Under Secretary of Defense for Personnel and Readiness requested the Defense Health Board review deployment-related pulmonary health issues and recommend a comprehensive approach for assessment and prevention, in addition to providing direction for future research and surveillance. The following Guiding Principles were adopted as a foundation for review of the questions posed to the Public Health Subcommittee regarding assessment of deployment pulmonary health.

#### **Overarching Principle:**

DoD has an obligation to develop, implement, and enforce policies to monitor and protect the health of Service members; to promptly identify and mitigate health threats; and to assess, diagnose, and treat health issues according to best available practices.

## Guiding Principles:

These principles anticipate the recommendations of the Board will:

- 1) make the Service member's health of primary concern;
- 2) be based on the best available, highest quality evidence;
- 3) be measurable and outcomes-based to the extent possible;
- 4) consider the relative risks, benefits, and mission impact associated with implementing specific recommendations;
- 5) take into consideration current DoD and other Federal Agency initiatives, undertakings, and recommendations regarding assessment of deployment pulmonary health; and
- 6) consider prevention to the greatest extent possible in formulating recommendations.



## APPENDIX D. MEETINGS AND PRESENTATIONS

August 28, 2013 Teleconference

The Public Health Subcommittee reviewed the tasking and its scope, the terms of reference, suggested site visits and briefers, as well as the way ahead. Subcommittee members Dr. H. Clifford Lane and Dr. Joseph Silva also commented on the Department of Defense (DoD)/Department of Veterans Affairs (VA) 2013 Airborne Hazards Symposium. There were no briefings at this meeting.

#### September 20, 2013

Defense Health Headquarters (DHHQ), Falls Church, VA

Members reviewed the tasking, draft terms of reference and guiding principles, and held a roundtable discussion with invited guests on various topics related to deployment pulmonary health. Members also heard the following briefings:

- Background of Pulmonary Health Issue Dr. Coleen Baird, Program Manager, Environmental Medicine, U.S. Army Public Health Command (USAPHC)
- *Exposure Characterization* Mr. Jeffrey Kirkpatrick, Portfolio Director, Health Risk Management Portfolio, USAPHC, Army Institute of Public Health
- Summary of Epidemiologic Studies Dr. Joseph Abraham, Epidemiologist, Environmental Medicine, USAPHC
- *Post-Deployment Dyspnea Evaluation: Current Approaches and Ongoing Research* Dr. Michael Morris, Associate Program Director, Internal Medicine Residency, San Antonio Uniformed Services Health Education Consortium, Brooke Army Medical Center
- VA/DoD Airborne Hazards/Burn Pit Registry Dr. Paul Ciminera, Director, Post 9/11 Era Environmental Health Program, Post-Deployment Health, Office of Public Health, VA

Additional subject matter experts in attendance that contributed to discussion included:

- Dr. Kelley Brix, Deputy Director, Defense Medical Research and Development Program
- Dr. Russell Harley, Senior Pathologist, Pulmonary and Mediastinal Pathology, The Joint Pathology Center (JPC)

## October 23, 2013

Teleconference

Members discussed the draft terms of reference, guiding principles, the takeaway messages from the previous meeting, as well as the report timeline and way ahead. There were no briefings at this meeting.



#### **December 5, 2013** DHHQ, Falls Church, VA

The Subcommittee received comments from various relevant subject matter experts, and heard the following briefings:

• Vanderbilt University's Experience and Research Evaluating Post-Deployment Dyspnea on Exertion

Dr. Robert Miller, Associate Professor of Medicine, Allergy, Pulmonary, and Critical Care Medicine, Hillsboro Medical Group, Vanderbilt University

- Occupational Constrictive Bronchiolitis
   Dr. Kathleen Kreiss, Field Studies Branch Chief, Division of Respiratory Disease Studies,
   National Institute of Occupational Safety and Health, Centers for Disease Control and
   Prevention
- National Jewish Health's Experience and Research Evaluating Post-Deployment Pulmonary Issues

Dr. Cecile Rose, Professor of Medicine, Division of Environmental/Occupational Health, National Jewish Health

- *Pathologic Characterization of Constrictive Bronchiolitis* Dr. Thomas Colby, Geraldine C. Zeiler Professor and Consultant, Department of Laboratory Medicine and Pathology, Mayo Clinic
- *DoD Deployment Pulmonary Health Research Agenda* Dr. David Jackson, Director, Pulmonary Health Program, U.S. Army Center for Environmental Health

Additional subject matter experts that contributed to discussion included:

- COL Thomas Baker, Director, The Joint Pathology Center (JPC), Defense Health Agency
- Dr. Teri Franks, Chairman, Department of Pulmonary and Mediastinal Pathology, JPC
- Dr. Jeffrey Galvin, Professor of Diagnostic Radiology, Professor of Internal Medicine, University of Maryland; Chief, Chest and Mediastinal Imaging, Armed Forces Institute of Pathology
- Dr. Elizabeth Higgs, Global Health Science Advisor, Division of Clinical Research, National Institute of Allergy and Infectious Disease (NIAID), National Institutes of Health (NIH)
- Dr. Michael Lewin-Smith, Senior Environmental Pathologist, JPC
- Dr. Craig Postlewaite, Acting Director, Public Health Division, Defense Health Agency (DHA)
- Dr. Mark Utell, Professor, Department of Medicine, Pulmonary Diseases and Critical Care, Professor, Department of Environmental Medicine, University of Rochester Medical Center



### January 16, 2014

Teleconference

Members reviewed the draft terms of reference and guiding principles and discussed the way ahead. Members also heard the following briefing:

• Seabee Spirometry Study Briefing Dr. Richard Meehan, Professor of Medicine, National Jewish Health Dr. Cecile Rose, Professor of Medicine, Division of Environmental/Occupational Health, National Jewish Health

## February 12, 2014

DHHQ, Falls Church, VA

Members discussed the way ahead and potential briefers. Members also heard the following briefings:

- FDNY Respiratory Evaluation and Management: 9/11 WTC Responders Dr. David Prezant, Chief Medical Officer, New York City Fire Department; Special Advisor to the Fire Commissioner for Health Policy; Co-Director, World Trade Center Health Program, New York City Fire Department
- Evaluation of Post-Deployment Pulmonary Health in Veterans Dr. Anthony Szema, Assistant Professor of Medicine and Surgery, Stony Brook School of Medicine; Managing Member, Three Village Allergy & Asthma, PLLC; Chief, Allergy Section, Veterans Affairs Medical Center
- Spirometry Surveillance and Screening Issues Dr. Roy McKay, Director, Occupational Pulmonary Services, University of Cincinnati
- WRNMMC Deployment Pulmonary Health Experience and Assessment of an Airflow Perturbation Device
   LTC Aaron Holley, Chief of Sleep Medicine, Pulmonary/Sleep and Critical Care Medicine Department; Assistant Program Director, Sleep Fellowship; Research Director, PSCCM
- Fellowships, WRNMMC
  Armed Forces Health Surveillance Center CAPT Kevin Russell, Director, Armed Forces Health Surveillance Center (AFHSC) MAJ Patricia Rohrbeck, Assistant Director; Chief, Preventive Medicine Resident Training, Division of Epidemiology & Analysis, AFHSC
- Deployment Pulmonary Health Update Dr. Joseph Abraham, Epidemiologist, Environmental Medicine, USAPHC Dr. Coleen Baird, Program Manager, Environmental Medicine, USAPHC

## March 21, 2014

Teleconference

Members discussed the draft terms of reference and guiding principles, the draft report outline, as well as the way ahead. There were no briefings at this meeting.



**April 7-8, 2014** DHHQ, Falls Church, VA

Members reviewed presentations on the pros and cons of various pulmonary health topics and drafted preliminary findings and recommendations. Members also heard the following briefings:

- VA Deployment Pulmonary Health Research Activities
   Dr. Robert Bossarte, Director, Epidemiology Program, Office of Public Health, Department of Veterans Affairs
   Dr. Aaron Schneiderman, Deputy Director, Epidemiology Program, Office of Public Health, Department of Veterans Affairs
   Ms. Shannon Barth, Health Science Specialist, Office of Public Health, Department of Veterans Affairs
   Dr. Debra Dougherty, Epidemiologist, Lockheed Martin

   *Toxicity of Iraq and Afghanistan Dust* CAPT Mark Lyles, Captain, Dental Corps, United States Navy Fellow, American Institute
- Toxicity of Iniq and Afghanistan Dust CAPT Mark Lyles, Captain, Dental Corps, United States Navy Fellow, American Institute for Medical and Biological Engineering, VADM Joel T. Boone Professor of Health and Security Studies, U.S. Naval War College Center for Naval Warfare Studies
- *Millennium Cohort Briefing* CDR Dennis Faix, Principal Investigator, Millennium Cohort Study, Deployment Health Research Department, Naval Health Research Center Dr. Melissa Frasco, Senior Epidemiologist, Deployment Health Research Department, Naval Health Research Center
- NMCSD Deployment Pulmonary Health Experience CDR Gilbert Seda, Pulmonary Department Head, Pulmonary, Naval Medical Center San Diego (NMCSD) CDR Greg Matwiyoff, Program Director Fellowship, NMCSD LCDR Michael Tripp, Pulmonary Clinic Director, NMCSD CAPT Scott Parrish, Assistant Program Director, NMCSD CDR Konrad Davis, Medical Director, NMCSD

Additional subject matter experts that contributed to discussion included:

• Dr. Elizabeth Higgs, Global Health Science Advisor, Division of Clinical Research, NIAID, NIH

## May 15, 2014

Teleconference

Members discussed the draft introduction chapter of the report and also heard the following briefing:

• *DoD Deployment-Related Research Prioritization, Funding, and Coordination* Dr. Terry Rauch, Director of Medical Research, Office of the Assistant Secretary of Defense (Health Affairs)



#### June 11, 2014 DHHQ, Falls Church, VA

Members received public comment from attendees, discussed the draft baselines and screening chapter, and heard the following briefings:

- STAMPEDE Update Dr. Michael Morris, Associate Program Director, Internal Medicine Residency, San Antonio Uniformed Services Health Education Consortium, Brooke Army Medical Center
- Disease Registries Dr. Richard Gliklich, Leffenfeld Professor of Otology and Laryngology, Harvard Medical School; Principal Investigator and Senior Editor, Registries for Evaluating Patient Outcomes: A User's Guide 3rd Edition (Agency for Healthcare Research and Quality)

Additional subject matter experts and stakeholders that contributed to discussion included:

- Ms. Coleen Bowman, Survivor of SGM Robert Bowman
- Ms. Rose Lopez-Torres, President & CEO, Burn Pits 360
- Ms. Patty Morris, Director of Technologies, Vision Center of Excellence
- Ms. Arlene Rich, Administrative Director, Severna Park Health and Wellness Center, Veterans and First Responders Projects
- Mr. Daniel Sullivan, President & CEO, The Sergeant Thomas Joseph Sullivan Center
- Mr. Peter Sullivan, Co-Founder, Assistant Treasurer & Chair of Science and Policy Advisory Committee, The Sergeant Thomas Joseph Sullivan Center
- Ms. Helen White, Director, Informatics and Information Management, Vision Center of Excellence

## July 1, 2014

Teleconference

Members discussed draft baselines and screening, diagnosis, and research chapters of the report. There were no briefings at this meeting.

July 10, 2014 Teleconference

Members discussed the draft report. There were no briefings at this meeting.

# July 25, 2014

Teleconference

Members discussed the revised draft report. There were no briefings at this meeting.

## July 31, 2014

Teleconference

Members discussed the revised draft report and voted to finalize the terms reference and guiding principles. There were no briefings at this meeting.



of

August 6, 2014 Teleconference

Members discussed and reviewed the report. There were no briefings at this meeting.

August 11, 2014 Defense Health Board Meeting Falls Church, VA

Dr. H. Clifford Lane, Subcommittee chair, presented the deliberative predecisional draft of the report. Defense Health Board members requested additional edits to the report.

September 30, 2014 Teleconference

Members discussed the revised report and feedback from the Defense Health Agency and the U.S. Army Public Health Command on the findings and recommendations. There were no briefings at this meeting.

October 10, 2014 Teleconference

Members discussed the revised report and feedback from Vanderbilt University and National Jewish Health on the findings and recommendations. There were no briefings at this meeting.

October 24, 2014 Teleconference

Members discussed and reviewed the draft report. There were no briefings at this meeting.

**November 6, 2014** Defense Health Board Meeting Dayton, OH

Dr. Lane presented the revised deliberative predecisional draft of the report. The Board unanimously approved the findings and recommendations with revisions.

**February 11, 2015** Defense Health Board Meeting Falls Church, VA

Dr. Dickey and Dr. Lane agree upon final revisions to the content of the report.



# APPENDIX E. DEPARTMENT OF DEFENSE PULMONARY HEALTH POLICIES AND EFFORTS

#### This form must be completed electronically. Handwritten forms will not be accepted.

	PRE-DEP	LOYMENT HEALTH AS	SSESSMENT					
		PRIVACY ACT STATEMENT						
This statemer	nt serves to inform you of the purpose for collection	ng personally identifiable information	through the DD Form 2795 (	Pre-Deployment Health Assessment).				
AUTHORITY:	IY: 10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness; 10 U.S.C. 1074f, Medical Tracking System for Members Deployed Overseas; DoDI 1404.10, DoD Civilian Expeditionary Workforce; DoDI 6490.02E, Comprehensive Health Surveillance, and E.O. 9397 (SSN), as amended.							
PURPOSE:	To obtain information from an individual in order to assess the state of the individual's health before possible deployment outside the United States, its territories and possessions as part of a contingency, combat, or other operation and to assist health care providers in identifying and providing present and future medical care to the individual. The information provided may result in a referral for additional health care that may include medical, dental, or behavioral health care or diverse community support services.							
ROUTINE USES:	Your records may be disclosed to other Federal and State agencies and civilian health care providers, as necessary, in order to provide medical care and treatment. Use and disclosure of you records outside of DoD may also occur in accordance with 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, which incorportates the DoD 'Blanket Routine Uses' published at <u>http://docl.odfense.gov/privacy/SOR.v5/blanket routine</u> uses.html. Any protected health information (PHI) in your records may be used and disclosed generally as permitted by the HIPAA Privacy Rule (45 CFR Parts 160 and 164), as implemented within DoD by DoD 6025.18-R. Permitted uses and discloses of PHI include, but are not limited to, treatment, payment, and healthcare operations.							
DISCLOSURE:	Voluntary. If you chose not to provide information, comprehensive healthcare services may not be possible or administrative delays may occur. HOWEVER, CARE WILL NOT BE DENIED.							
INSTRUCTIONS:	You are encouraged to answer all questions. You must at least complete the first portion on who you are and when you will deploy. If you do not understand a question, please discuss the question with a health care provider.							
DEMOGRAP	HICS			-				
Last Name		First Name		Middle Initial				
Social Secur	ity Number	Today's Dat	te (dd/mmm/yyyy)					
Date of Birth	(dd/mmm/yyyy)	Gender O	Male O Female					
O USPHS	Active Dut Diational George Reserves O Civilian Governme		Pay Grade           0         E1           0         E2           0         E4           0         E5           0         E6           0         E7           0         E8           0         E9	0       01       0       W1         0       02       0       W2         0       03       0       W3         0       04       0       W4         0       05       0       W5         0       06       0       004         0       07       0       0ther         0       08       09       0         0       010       0       0				
Current cont	act information:	Poir	nt of contact who	can always reach you:				
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	estion was answered as one or more return from your last deploymen							
DD FORM 279	5, SEP 2012 P	REVIOUS EDITION IS OBSO	LETE	Page 1 of 7 Pages				



This form must be completed electronically. Handwritten forms will not be accepted.

		Deployer's SSN (La	ast 4 digits):					
1.	Overall, how would you rate your health during the PAST MC O Excellent O Very Good O Good O Fair O Poor					1.8		
2.	Are you CURRENTLY on a profile, limited duty, waiting on a MOS/Medical Retention Board (MMRB) decision, or being referred to a medical evaluation board (MEB) or physical evaluation board (PEB)?	O Yes For O No O Don't kno	what reason? w					
3.	How often do you smoke tobacco (for example cigarettes, cigars, pipe or hookah)?	O Just abou O Some day O Not at all	ys					
4.	What problems, questions or concerns do you have about your medical, dental, or mental health?	O Please ex O None	plain:					
5.	FEMALES ONLY – Are you pregnant or is there a chance you could be pregnant?	O Don't kno O Yes O No	w					
6.	In the PAST YEAR did you receive care for a head injury?	O Yes Plea O No	ase explain:		A. 25	. <u> </u>		
7.	(including herbals/supplements) for sleep, pain, combat stress, or mental health conditions or		O Please list:					
8.	condition or concern such as, but not limited to post traumatic stress disorder (PTSD), depression, anxiev disorder, coho abuse or substance abuse							
9. During the PAST MONTH how much have the been botherer by any on the following prot/lems?								
	Symptom		Not bothered at all		and the state of the state of the state of the	ed a lot		
	<ul> <li>Noises in your head or ears (such as ringing, buzzing, crickets, Trouble hearing</li> </ul>	humming, tone, etc.)	0	0		о О		
<ul> <li>10. a. How often do you have a drink containing alcohol? O Never O Monthly or less O 2-4 times a month O 2-3 times per week O 4 or more times a week</li> <li>b. How many drinks containing alcohol do you have on a typical day when you are drinking? O 1 or 2 O 3 or 4 O 5 or 6 O 7 to 9 O 10 or more</li> <li>c. How often do you have six or more drinks on one occasion? O Never O Less than monthly O Monthly O Weekly O Daily or almost daily</li> <li>11. Have you ever had any experience that was so frightening, horrible, or upsetting that, in the PAST MONTH, you:</li> <li>a. Have had nightmares about it or thought about it when you did not want to?</li> <li>D Yes O No</li> <li>D. Tried hard not to think about it or wort out of your way to avoid situations that remind you of it?</li> </ul>								
	<ul> <li>c. Were constantly on guard, watchful or easily startled?</li> <li>d. Felt numb or detached from others, activities, or your surround</li> </ul>	dings?	Street van - 424000000		) Yes ) Yes	O No O No		

NOTE: If 2 or more items on 11a. through 11d. are marked yes, continue to answer items 11e. through 11v.

DD FORM 2795, SEP 2012

Page 2 of 7 Pages





#### This form must be completed electronically. Handwritten forms will not be accepted.

		C	eployer's S	SN (Last 4	aigits):			
	s a list of problems and complaints that people so y and check the box for how much you have beer		y that problem	in the PAST I	MONTH. I	Please ans	wer all i	tems.
			Not at all	A little bit	Modera	tely Q	uite a bi	t Extremely
	epeated, disturbing memories, thoughts, or image ressful experience from the past?	s of a	0	0	0		0	0
	epeated, disturbing dreams of a stressful experier e past?	nce from	0	0	0		0	0
	uddenly acting or feeling as if a stressful experien appening again (as if you were reliving it)?	ce were	0	0	0		0	0
	eeling very upset when something reminded you o ressful experience from the past?	ofa	0	0	0		0	0
bre	aving physical reactions (e.g., heart pounding, tro eathing, or sweating) when something reminded ressful experience from the past?		0	0	0		0	0
	void thinking about or talking about a stressful exp om the past or avoid having feelings related to it?	erience	0	0	0		0	0
	void activities or situations because they remind y ressful experience from the past?	ou of a	0	0	0		0	0
	ouble remembering important parts of a stressful perience from the past?		0	0	0		0	0
	ess of interest in things that you used to enjoy?		0	0	0		0	0
	eeling distant or cut off from other people?		0	0	0		0	0
fee	eeling emotionally numb or being unable to have I elings for those close to you?		0	0	0		0	0
1p. Fe	eling as if your future will somehow be cut short?		0	0	0		0	0
	ouble falling or staying asleep?		0	0	0		0	0
	eeling irritable or having angry outbursts?		0	0	0		0	0
	aving difficulty concentrating?		0	0	0		0	0
	eing "super alert" or watchful, on guard?		0	0	0		0	0
1u. Fe	eeling jumpy or easily startled?	Not difficu	0	0	0		0	emely difficult
	ngs at home, or get alone with other one ole? the LAST 2 WEEKS, how often have you been	bethered Not at all	y the foll win Few or seve	g problems	Moretha	half the	dave	Nearly every
	tle interest or pleasure in doing things eling down, depressed, or hopeless	0 0	0	<u>naruays</u>	wore that	0	uays	O O
TE: If	12a. or 12b. are marked "More than half the	days" or "	'Nearly every	day," cont	inue to a	nswer ite	ms 12c	. through 12i.
Over the LAST 2 WEEKS, how often have you been bothered by any of the following problems?		Not at all		Few or several days		n half vs	Nearly every da	
	ouble falling/staying asleep, sleep too much.		0	C		0	,-	0
	eeling tired or having little energy.		0	C		õ	-	0
	oor appetite or overeating.		0	c		ō		ō
2f. Fe	eeling bad about yourself – or that you are a failur yourself or your family down.	e or have	0	c		0		0
ne	ouble concentrating on things, such as reading the wspaper or watching television.		0	c	>	0		0
<ol> <li>Moving or speaking so slowly that other people could noticed. Or the opposite – being so fidgety that you been moving around a lot more than usual.</li> </ol>			0	c	0			0
			Not difficult at all	Som e diffi		Very diff	icult	Extremely difficult
for	ow difficult have these problems (12a.through12h r you to do your work, take care of things at home ong with other people?		0	c	0 0			0
you or thin ser	ver the PAST MONTH, what major life stressor u experienced that are a cause of significant of make it difficult for you to do your work, take ngs at home, or get along with other people (f rious conflicts with others, relationship proble jal, disciplinary or financial problem)?	concern care of or example	O Ple	one or ease list and	explain: _			
b. Are	e you currently in treatment or getting profess lo for this concern?	sional	O Ye	es O No				

## Deployer's SSN (Last 4 digits):

b. Are you currently in treatment or getting professional help for this concern?

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#### This form must be completed electronically. Handwritten forms will not be accepted.

. . . . . .

Deployer is de	ploying to		Has deployed	times before.	Last returned
I. Address o	oncerns identified on deploye	er questions	1 through 8.		
	Deployer question	Not answered	Deployer indicated concern or yes	Deployer's respon	nse Provider comments (if indicated)
Self health ra	ting	0	0		
MEB or PEB		0	0		
Medical, den	tal, or mental health concern	0	0		
Pregnancy		0	0		
Head injury		0	0		
Medications		0	0		
History of me	ental health care	0	0		
<ul> <li>b. If yes, r</li> <li>6. Alcohol us</li> <li>a. Deploy</li> </ul>	<sup>•</sup> or "trouble hearing"? eferral indicated? se as reported in deployer que er's AUDIT-C screening score w	/as	(If score between	) Yes (complete block ) No O Already und O Already has O No significa O Other reaso	ler care referral nt impairment
	en) or 0-3 (women) nothing requ	red, go to blo			
Numbe	r of drinks per week:	A Ma	ix num rumber of dra	ksper occasion:	— <b>—</b> —
Based	on the AUDIT-C score and asse	ssment of alc	onol se, ollow the	idance belov	
Sarah Markada	~ 1	Alo	cohol Use Intervention	Matrix	
	Assess Alcohol Use		M	F-C Score en 5-7 nen 4-7	AUDIT-C Score Men and Women ≥ 8
Men: ≤ 14 dr	WITHIN recommended limits: inks per week <u>OR</u> ≤ 4 drinks on drinks per week <u>OR</u> ≤ 3 drinks o		recomm	nt to stay below ended limits	Refer if indicated for further evalu
Alcohol use I	EXCEEDS recommended limits:		Conduct BR	IEF counseling*	AND conduct BRIEF counseling*

\* BRIEF counseling: Bring attention to elevated level of drinking; Recommend limiting use or abstaining; Inform about the effects of alcohol on health; Explore and help/support in choosing a drinking goal; Follow-up referral for specialty treatment, if indicated.

b. Referral indicated for evaluation?

O Yes (complete blocks 11 and 12) O No Provide education/awareness as needed. State reason if AUDIT-C score was 8+: O Already under care O Already has referral O No significant impairment O Other reason (explain): \_\_\_

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#### This form must be completed electronically. Handwritten forms will not be accepted.

#### Deployer's SSN (Last 4 digits):

#### 4. PTSD screening as reported in deployer question 11.

a. Did deployer mark yes on two or more of questions 11a. through 11d.? O Yes O No (go to block 5) O Not answered by deployer

O Not answered by deployer

b. If yes, deployer's responses to questions 11e. through 11u. resulted in a PCL-C score of \_\_\_\_\_\_ and the deployer's response to level of impairment with life events (11v.) is indicated in the table below.

O 11e. through 11v. were not answered or are incomplete.

Based on the PCL-C score, the deployer's level of functioning, and your exploration of responses, follow the guidance below:

	Post-Trauma	tic Stress Disorder Interve	ntion Matrix	
Self-Reported Level of Functioning	PCL-C Score <30 (Sub-threshold or no Symptoms)	PCL-C Score 30-39 (Mild Symptoms)	PCL-C Score 40-49 (Moderate Symptoms)	PCL-C Score ≥ 50 (Severe Symptoms)
Not Difficult at All O or Somewhat Difficult	No intervention	Provide PTS	D education*	Consider referral for further evaluation AND provide PTSD education*
Very Difficult O to Extremely Difficult	Assess need for further evaluation AND provide PTSD education*	Consider referral for further evaluation AND provide PTSD education*		Refer for further evaluation AND provide PTSD education*

\* PTSD Education = Reassurance/supportive counseling, provide literature on PTSD, encourage self-management activities, and counsel deployer to seek help for worsening symptoms.

c. Referral indicated?



O Not answered by deployer

No (ao to b

O Yes (complete blocks 11 and 12) O No O Already under care

O Already under care O Already has referral O No significant impair O Other reason (explai

b. If yes, deployer's responses to questions 12a. through 12h. resulted in a total PHQ-8 score of \_\_\_\_\_\_ and the deployer's response to level of impairment with life events (12i.) is indicated in the table below.

O 12c. through 12i. were not answered or incomplete.

Based on the PHQ-8 score, deployer's level of functioning, and exploration of responses, follow the guidance below:

Depression Intervention Matrix					
Self-Reported Level of Functioning	PHQ-8 Score 1-4 (No Symptoms)	PHQ-8 Score 5-9 (Sub-Threshold Symptoms)	PHQ-8 Score 10-14 (Mild Symptoms)	PHQ-8 Score 15-18 (Moderate Symptoms)	PHQ-8 Score 19-24 (Severe Symptoms)
Not Difficult at All O or Somewhat Difficult	No intervention	Depression education*		Consider referral for further evaluation AND provide depression education*	Consider referral for further evaluation AND provide depression education*
Very Difficult O to Extremely Difficult	/	r further evaluation AND ession education*	Consider referral for further evaluation AND provide depression education*	Consider referral for further evaluation AND provide depression education*	Refer for further evaluation AND provide depression education*

\* Depression Education = Reassurance/supportive counseling, provide literature on depression, encourage self-management activities, and counsel deployer to seek help for worsening symptoms.

c. Referral indicated?

O Yes (complete blocks 11 and 12) O No O Already under care O Already has referral O No significant impairment O Other reason (explain):

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	Deplo	yer's SSN (Last 4 digits):
6.	Major life stressor as reported on deployer question 13.	
	a. Did deployer mark they have a concern or a difficulty with a major life stressor?	O Yes Deployer's concern: O No ( <i>go to block 7</i> ) O Not answered by deployer
	b. If yes, ask additional questions to determine level of problem:	
	c. Consider need for referral. Referral indicated?	O Yes (complete blocks 11 and 12) O No O Already under care O Already has referral O No significant impairment O Other reason (explain):
	Suicide risk evaluation.	
	a. Ask "Over the PAST MONTH, have you been bothered by thoughts that you would be better off dead or of hurting yourself in some way?"	O Yes O No (go to block 8)
	b. If 7.a. was yes, ask: "How often have you been bothered by these thoughts?"	O Few or several days O More than half of the time O Nearly every day
	c. If 7.a. was yes, ask: "Have you had thoughts of actually hurting yourself?"	O Yes (If yes ask questions 7d. through 7g.) O No (If no thoughts of self-harm, go to block 8)
	d. Ask "Have you thought about how you might actually hurt yourself?"	O Yes How? O No
	e. Ask "There's a big difference between having a thought and acting on a thought. How likely do you think it is that you will act on these thoughts about hurting yourself or ending your life over the next month?"	O Not at all likely O Somewhat likely O Very likely
	f. Ask "Is there anything nat would preven or keep you from harming pursel?"	What H
	g. Ask "Have you ever at the determined to have you self in the past?"	O No
	h. Conduct further risk assessment (e.g., interpersonal conflicts, social isolation, alcohol/substance abuse, hopelessness, severe agilation/anxiety, diagnosis of depression or other psychiatric disorder, recent loss, financial stress, legal disciplinary problems, or serious physical illness).	Comments:
	i. Does deployer pose a current risk for harm to self?	O Yes (complete blocks 11 and 12) O No
	Violence/harm risk evaluation.	
	a. Ask, "Over the past month have you had thoughts or concerns that you might hurt or lose control with someone?"	O Yes O No (go to block 9)
	If yes, ask additional questions to determine extent of problem (target, plan, intent, past history) Comments:	
	b. Does member pose a current risk to others?	O Yes (complete blocks 11 and 12) O No (briefly state reason):
	Medical History Review – if available, hard copy and/or electronic health records (including DD2766 and SF-600 entries, and most recent past deployment health assessments).	O Completed O No health records available
	a. Significant findings related to ability to deploy:	
	b. Evidence of deployment limiting conditions or medications?	O Yes O No
D	FORM 2795, SEP 2012	Page 6 of 7 Pag



#### This form must be completed electronically. Handwritten forms will not be accepted.

#### Deployer's SSN (Last 4 digits):

10. Deployer issues with this assessment (mark as appropriate):

O Deployer declined to complete form

O Deployer declined to complete interview/assessment

Assessment and Referral: After review of deployer's responses and interview with the deployer, the assessment and need for further evaluation is indicated in blocks 11 through 14.

11. Summary of provider's identified concerns needing referral < Mark all that apply>	Yes	No
a. None Identified O		
b. Physical health	0	0
c. Dental health	0	0
d. Alcohol use	0	0
e. PTSD symptoms	0	0
f. Depression symptoms	0	0
g. Mental health symptoms	0	0
h. Risk of self-harm	0	0
i. Risk of violence	0	0
j. Other, list:	0	0

12. Recommended referral(s) < Mark all that apply even if deployer does not desire>	Within 24 hours	Within 7 days	Within 30 days
a. Primary Care, Family Practice, Internal Medicine	0	0	0
b. Behavioral Health in Primary Care	0	0	0
c. Mental Health Specialty Care	0	0	0
d. Dental	0	0	0
e. Other specialty care:	0	0	0
Audiology	0	0	0
Dermatology	0	0	0
OB/GYN	0	0	0
Physical Therapy	0	0	0
TBI/Rehab Med	0	0	0
Podiatry	0	0	0
Other, list	0	0	0
f. Case Manager / Care Manager	0	0	0
g. Substance Abuse Program	0	0	0
h. Immunization Clinic	0	0	0
i. Laboratory	0	0	0
j. Other, list:	0	0	0



#### 14. Medical assessment/disposition:

14. Medical assessment/disposition: O Deployable O Deployable at present, but requires medical readiness updates. May delay or make undeployable, e.g., pregnancy test, immunizations, overdue Pap test, dental exam, PHA, outdated eyeglass prescription, (add comments – block 15). O Not Deployable – potentially disqualifying condition requiring additional evaluation (add comments – block 15). O Not Deployable – other (add comments – block 15).

15. Comments (Mandatory for any type of Not Deployable disposition).

O Appointment Assistance O Contract Support:		O Family Support				
		O Military One Source	ce			
			O TRICARE Provider			
O Chaplain			O VA Medical Cente	r or Community	Clinic	
O Health Education and Information			O Vet Center			
O Health Care Benefits and Resources Information		O Other, list:				
O In Transition						
Provider's Name:			Date ( <i>dd/mm</i> r	m/yyyy)		
itle: O MD or DO	O PA	O Nurse Practitioner	O Adv Practice Nurse	O IDMT	O IDC	O IDHS
certify that this revi	ew process ha	s been completed.	This visit is o	oded by V70.5	_ D	

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## APPENDIX F. ACRONYMS AND GLOSSARY

Commonly Used A	Acronyms
AEP	Acute eosinophilic pneumonia
AFHSC	Armed Forces Health Surveillance Center
AFIOH	Air Force Institute of Operational Health
AFIP	Armed Forces Institute of Pathology
AFMES	Armed Forces Medical Examiner System
AFMOA	Air Force Medical Operations Agency
AOR	Adjusted odds ratio
APD	Airflow perturbation device
ASD(HA)	Assistant Secretary of Defense for Health Affairs
ATS	American Thoracic Society
BALF	Bronchoalveolar lavage fluid
СВ	Constrictive bronchiolitis
CBC	Complete blood count
CENTCOM	U.S. Central Command
CI	Confidence interval
CFR	Code of Federal Regulations
CONUS	Continental United States
COPD	Chronic obstructive pulmonary disease
CPEX	Cardiopulmonary exercise testing
СТ	Computed tomography
DD	Defense Department
DHCC	Deployment Health Clinical Center
DHHS	Department of Health and Human Service
DHSS	Defense Health Services System
DLCO	Diffusing capacity for carbon monoxide
DoD	Department of Defense
DoDI	Department of Defense Instruction
DEERS	Defense Enrollment Eligibility System
DMDC	Defense Manpower Data Center
DMED	Defenses Medical Epidemiology Database
DMSS	Defense Medical Surveillance System
DVEIVR	Defense and Veterans Eye Injury and Vision Registry
ECBC	Edgewood Chemical Biological Center
E-cigarettes	Electronic cigarettes
EHR	Electronic health record
EIB	Exercise induced bronchospasm
EpiData	Epidemiology Data
EPA	Environmental Protection Agency
EPMSP	Enhanced Particulate Matter Surveillance Program
ERS	European Respiratory Society
FEV1	Forced expiratory volume in one second
FHP	Force health protection



Commonly Used A	Acronyms
FHPPP	Force health protection prescription products
HIV	Human immunodeficiency virus
HRCT	High-resolution computed tomography
Hx	History
ICD	International Classifications of Disease
IMR	Individual medical readiness
IOM	Institute of Medicine
IOS	Impulse oscillometry
IS	Iraqi sand
IRB	Institutional Review Board
JPC	Joint Pathology Center
JTTR	Joint Theater Trauma Registry
LLN	Lower limit of normal
MEB	Medical evaluation board
MHS	Military Health System
MNC-I	Multi-National Corps-Iraq
MOS	Military occupational specialty
MRMC	Medical Research and Materiel Command
MSCS	Mainstream cigarette smoke
MTF	Military treatment facility
MVP	Million Veteran Program
NAMRU	Naval Medical Research Unit
NewGen	New Generation of U.S. Veterans
NIOSH	National Institute of Occupational Health and Safety
NJH	National Jewish Health
NMCPHC	Navy Marine Corps Public Health Center
NMCSD	Naval Medical Center San Diego
OCONUS	Outside of the continental United States
OEF	Operation ENDURING FREEDOM
OIF	Operation IRAQI FREEDOM
РАН	Polycyclic aromatic hydrocarbon
PDHA	Post-deployment health assessment
PDHRA	Post-deployment health re-assessment
РНА	Preventive health assessment
PM	Particulate matter
PM0.1	Particulate matter with a diameter less than 0.1 microns
PM2.5	Particulate matter with a diameter less than 2.5 microns
PM10	Particulate matter with a diameter less than 10 microns
PM20	Particulate matter with a diameter less than 20 microns
PFT	Pulmonary function test
PDHA	Post-deployment health assessment
PDHRA	Post-deployment health re-assessment
POEMS	Periodic Occupational and Environmental Monitoring Summary



Acronyms
Personal protective equipment
Posttraumatic stress disorder
Small Business Innovation Research
Scanning Electron Microscopy/Energy Dispersive X-ray Analysis
Service member
Study of Active Duty Military for Pulmonary Disease related to
Environmental Dust Exposure
Southwest Asia
Traumatic brain injury
U.S. Air Force
U.S. Air Force School of Aerospace Medicine
U.S. Air Force School of Aerospace Medicine Public Health and Preventive
Medicine Department
U.S. Army Public Health Command
U.S. Center for Health Promotion and Preventive Medicine
Under Secretary of Defense for Personnel & Readiness
U.S. Preventive Services Task Force
Uniformed Services University of the Health Sciences
Department of Veterans Affairs
Video-assisted thoracoscopic surgery
Vocal cord dysfunction
Veterans Health Administration
Maximal oxygen consumption
Walter Reed National Military Medical Center



Term	Definition
Acute eosinophilic	A rare disease with unclear etiology, characterized by febrile illness,
pneumonia	acute respiratory symptoms (e.g., dyspnea), infiltrates on radiographs
	and eosinophilia.
Constrictive	A range of bronchiolar changes including submucosal scarring,
bronchiolitis	narrowing of the bronchial lumen, and chronic inflammation.
Dyspnea	A subjective experience of breathing discomfort that consists of
	qualitatively distinct sensations that vary in intensity.
Occupational health	The ongoing systematic collection, analysis, and dissemination of
surveillance	exposure and health data on groups of workers for the purpose of
	preventing illness and injury.
Occupational	The ongoing, systematic collection, analysis, and dissemination of
respiratory disease	health and hazard data to monitor the extent and severity of
surveillance	occupationally related lung disease and related workplace exposures for
	use in public health education and in disease prevention.
Particulate matter	Air pollutants that are a mixture of small, solid particles and liquid
	droplets.
Primary prevention	Taking action to prevent the initial development of disease, such as
	immunization or limiting hazardous exposure.
Public health	The continuous, systematic collection, analysis and interpretation of
surveillance	health-related data needed for the planning, implementation, and
	evaluation of public health practice.
Redeployment	Returning from deployment.
Registry	An organized system for the collection, storage, retrieval, analysis, and
	dissemination of information on individual persons who have either a
	particular disease, a condition that predisposes to the occurrence of a
	health-related event, or prior exposure to substances (or circumstances)
	known or suspected to cause adverse health effects.
Secondary prevention	Early detection of before development of clinical signs and symptoms.
Tertiary prevention	Intervention after the diagnosis of clinical disease to reduce its impact.



2014

APPENDIX G. PUBLIC STATEMENTS RECEIVED FROM JUNE 11, PUBLIC COMMENT SESSION

Public Statement of Peter M. Sullivan of the Sergeant Thomas Joseph Sullivan Center



#### STATEMENT OF PETER M. SULLIVAN CO-FOUNDER, ASSISTANT TREASURER & CHAIR OF SCIENCE AND POLICY ADVISORY COMMITTEE THE SERGEANT THOMAS JOSEPH SULLIVAN CENTER TO THE PUBLIC HEALTH SUBCOMMITTEE OF THE DEFENSE HEALTH BOARD

## June 11, 2014

#### I. Introduction and Background

The Sergeant Thomas Joseph Sullivan Center is a tax-exempt, Sec. 501(c)(3) organization that seeks to confront and eradicate complex, deployment-related illnesses arising from toxic exposures and other causes that afflict hundreds of thousands of veterans of our Nation's recent wars. The Center promotes public awareness of such illnesses and funds research to improve diagnosis and treatment. The Center is named for my son, Marine Corps Sergeant Tom Sullivan, who was recognized for valor for his service in Iraq in 2004-05 and died from complications of such an illnesses.

Tom went to Iraq in top health, assigned to an elite Force Reconnaissance unit. He reported on his post-deployment health form that, among other things, he was exposed to ever-present dust, fumes from local chemical plants and burning feces and that, while deployed, he experienced rectal bleeding and congestion. After he returned, his medical problems multiplied in number and severity and included intestinal ulcerations and bleeding, hypertension, respiratory diseases (sleep apnea and asthma) and a liver disorder. He suffered from extreme and diffuse pain and swelling.

Tom had what the military medical system sometimes refers to as chronic multisymptom illness, and sometimes as medically unexplained symptoms (MUPS). His health declined despite several months of treatment. At this critical juncture, he asked for a fresh, multi-disciplinary re-assessment. He was sent to a clinic that specializes in MUPS and was offered only a program of exercise (that was precluded by his pain) and psychological counseling. Six months later he died. Tom's principal physician later told us he had believed Tom had a somatoform disorder (i.e., psychological illnesses).<sup>1</sup> The Virginia Medical Examiner's autopsy report found previously undetected heart damage that was designated as a contributing cause of his death. It also found that the combination of prescribed medications (including

<sup>&</sup>lt;sup>1</sup> After Tom died, his widow and I requested physician emails discussing the somatoform disorder which had been withheld from Tom's health records. Walter Reed Army Medical Hospital denied the request: No written record of the emails had been retained and they had been deleted from the computer system, and it would cost \$500,000 to search digital records to retrieve them.



large doses of immunosuppressant's and narcotic pain killers) contributed to the development of the pneumonia that was the immediate cause of death.

At the time Tom was deployed and upon his return the military medical system was aware of environmental health hazards in theater and the symptoms and illnesses they might produce. If warnings were issued to our troops before, during or after deployment, I have seen no record of them. The airborne hazards from dust and fumes could have been mitigated to a large extent by issuing simple N-95 dust masks that can be purchased in bulk for a couple of dollars. Indeed, recommendations had been made to the military to take such measures, but were ignored.

Despite Tom's failing health and his exposure history, his physicians did not tell him that many airborne troops at Fort Campbell who had served in Iraq and Afghanistan had been diagnosed with a rare lung disease; or that particulate matter to which he was exposed in Iraq far exceeded USG standards and was carrying toxic metals, bacteria, viruses and fungi, including toxins found naturally, plus those added by USG burn pits and local industrial pollution.<sup>2</sup> He was basically treated at though he never had left the United States, rather than as a person who might be suffering from a toxic wound received in a war zone.

The symptoms Tom exhibited, as did those by the Airborne soldiers at Ft. Campbell, and many thousands more who have served in Iraq and Afghanistan, are consistent with a toxic exposure of one or more kinds. Yet, Tom's health care was apparently <u>not</u> informed by the body of knowledge available to the military medicine at the time. Apparently baffled by his symptoms, medical judgment defaulted to the notion that they were psychosomatic. This is the same discredited explanation that had previously been ascribed to Gulf War Illnesses.

In the course of its work, The Sergeant Sullivan Center has encountered numerous post-9/11 war veterans who have complex respiratory and other symptoms similar to Tom's and whose military and/or veterans administration doctors have attributed their health problems to stress or other psychological factors.

<sup>&</sup>lt;sup>2</sup> In 2011, The SGT Sullivan Center made a FOIA request of the Navy and DOD Health Affairs for documents relating to findings and recommendations made by Captain Mark Lyles that had been the subject of a USA Today news article. The Navy stonewalled, insisting that The Center agree to pay unspecified search and copying fees before any search would be conducted and list of documents compiled and denied the Center's request for a fee waiver despite the Center's qualification based on public interest. DOD Health Affairs produced only one document (presumably withholding, without even acknowledging, there were many more), a Health Affairs letter to a Senator dismissing Captain Lyles's the concerns about toxic dust. We did not pursue litigation because it would be too costly and time consuming. I urge the Defense Health Board to obtain access to the complete documentation of DOD's handling of the toxic dust matter.





Commenting on Tom's case a Defense Health Agency spokesman (Craig Postlewaite) recently told the Washington Post,<sup>3</sup> that what caused Tom's conditions is unknown, but "very plausibly <u>could be related</u> to deployment." We agree that the specific physiological explanation remains uncertain, although there are obvious candidates. But the nexus with his service in Iraq is far stronger that "could be." When young military service members like Tom and others in pre-deployment peak health develop serious illnesses after deployment, it is at -- minimum -- <u>probable</u> that there is connection to deployment exposures. This spokesman's economical acknowledgement of the connection gives some insight into the thought process of a Department that can't seem to forthrightly acknowledge that the physical health of hundreds of thousands of troops has been severely diminished by service in Iraq and Afghanistan.

#### II. Discussion

#### **Deployment-Related Respiratory Diseases**

A recently published study, led by Dr. Joseph Abraham of the US Army Public Health Command, showed that military personnel deployed to Iraq are exposed to inhalational hazards that "may increase their risk of chronic lung conditions." Firsttime deployers to Iraq had significantly higher rates of medical encounters than personnel stationed in the U.S. (i.e., 54 percent for asthma and 25 percent for other respiratory symptoms).<sup>4</sup>

This study is consistent with VA health care utilization data for Iraq and Afghanistan veterans. The most recent VA report shows that about 58 percent of the 2.6 million who, thus far, have served in Iraq and Afghanistan have received VA healthcare. Of these, about over 150,000 patients (28 percent), have received a respiratory disease diagnosis.<sup>5</sup>

<sup>&</sup>lt;sup>3</sup> May 26, 2014, "On the Home Front, Battling A Mysterious Enemy," pp. A1, A6.

<sup>&</sup>lt;sup>4</sup> J.H. Abraham et al., A retrospective cohort study of military deployment and postdeployment medical encounters for respiratory conditions. <u>Military Medicine</u>, May 2014;179(5):540-6

<sup>&</sup>lt;sup>5</sup> Analysis of VA Health Care Utilization among Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) Veterans, *Cumulative from 1st Qtr FY 2002 through 1st Qtr FY 2014 (October 1, 2001 – December 31, 2013)*, Released March 2014. <u>http://www.publichealth.va.gov/docs/epidemiology/healthcare-utilization-report-fy2014-qtr1.pdf</u>



Another 58 percent, over 567,000, have "Symptoms, Signs and Ill Defined Conditions," of which one of the most common are Symptoms Involving Respiratory System and Other Chest Symptoms.<sup>6</sup> The number and percentage for this subcategory is not listed in the report, but it is likely to be significant and, thereby push the respiratory conditions total to well over 28 percent. Moreover, it is likely that a certain significant percentage of the approximate 40 percent of Iraq and Afghanistan veterans who have <u>not</u> received care at the VA have developed respiratory diseases as a result of their deployment.

The data relied on in the Abraham study and VA health care utilization data apparently was not detailed enough to address the severity of the conditions. This might explain the hedging language of the Abraham study -- that deployment to Iraq "<u>may</u> increase their risk of chronic lung conditions."

However, there is other data showing a likelihood that significant numbers of veterans suffer from chronic or otherwise severe conditions. For example, studies by Dr. Anthony Szema (of Stony Brook University and the Northport, NY VA) studies showed that deployers to Iraq and Afghanistan suffered from asthma (a chronic condition) at twice the rate of non-deployers.<sup>7</sup> National Jewish Health has encountered many deployers having serious chronic lung diseases.<sup>8</sup> The pioneering work of Dr. Robert Miller of Vanderbilt University found many Fort Campbell-based Airborne soldiers as well as many other service members and veterans who had served in Iraq and Afghanistan have a very rare lung disease, constrictive bronchiolitis, a condition that could be diagnosed only through biopsies.<sup>9</sup>

These respiratory conditions are almost certainly connected with deployment and demonstrate a <u>high risk</u> of chronic lung disease from deployment to Iraq and Afghanistan. I understand that VA analysis of clinical cases demonstrates a higher incidence of lung illnesses with longer deployment times. This strikes me as intuitively obvious. Greater doses of toxic elements will make more people sicker than smaller doses.

I am concerned that DOD personnel have attempted to discredit the work of Dr. Miller et al., including the findings published in August 2011 New England Journal of Medicine (NEJM) that many soldiers who served in Iraq and Afghanistan have

<sup>&</sup>lt;sup>6</sup> Id.

<sup>&</sup>lt;sup>7</sup> A.M. Szema et al., New-Onset Asthma Among Soldiers Serving in Iraq and Afghanistan, Allergy Asthma Proc., 31:67-71 (2010). See also, A.M. Szema, Respiratory Symptoms Necessitation Spirometry Among Solders with Iraq/Afghanistan War Lung Injury, Journal of Occupational and Environmental Medicine, 53:961-5 (2011).

<sup>&</sup>lt;sup>8</sup> C.S. Rose, Miltary Service and Lung Disease, Clinical Chest Meicine, 33:705-14 (2012).

<sup>&</sup>lt;sup>9</sup> M.S. King et al., Constrictive Bronchiolitis in Soldiers Returning from Iraq and Afghanistan, New England Journal of Medicine, 33:705-14 (August 2011).



constrictive bronchiolitis.<sup>10</sup> This effort has included a letter written by Department personnel to the NEJM alleging that these findings reflect "bias." <sup>11</sup>

I am also concerned that there is no longer any public visibility into how DOD is diagnosing and treating patients presenting symptoms similar to those exhibited by patients that Fort Campbell had referred to Vanderbilt. To our knowledge, the military medical system no longer refers such cases to Vanderbilt or any other medical institution outside the U.S. government.

I am also concerned about the conduct of DOD personnel with respect to a working group of experts hosted by National Jewish Health in Denver in February 2010. The proceedings of this meeting of Defense and private physicians, scientists and researchers on lung health matters produced what was thought to be consensus recommendations. They were published in the Journal of Occupational and Environmental Medicine June in 2012.<sup>12</sup>

Apparently without coordination with or even notice to the other members of the Denver working group, the DOD representatives published, in the same issue, an article, titled "Clarifications from Representatives of the Department of Defense," essentially dissenting from the key recommendations. For example, one of these called for developing pre-deployment, baseline pulmonary function testing for personnel as part more comprehensive health surveillance.<sup>13</sup> DOD reversed its supportive position, despite the fact that it is standard practice for fire fighters and mine workers to undergo baseline and follow-up pulmonary testing. The test is easily administered by use of a spirometer that measures lung capacity. In my opinion, failure to implement such a program constitutes dereliction of duty by those responsible in DOD for force protection and health.

In our course of The Sergeant Sullivan Center's work, we have found what appears to be a pattern of resistance in DOD to conducting the kind of research that might have helped assess toxic threats faced by our deployed troops. For example, failure to implement proposals for protective measures and for comprehensive air sample and testing, and correlating it with clinical data on lung function of deployed

<sup>11</sup> M. Morris and L. Zacher, Letter to Editor re Constrictive Bronchiolitis in Soldiers, New England Journal of Medicine, 365:1743-1745 (November 3, 2011).

<sup>12</sup> C. Rose et al., Overview of Recommendations for Medical Screening and Diagnostic Evaluation for Postdeployment Lung Disease in Returning Warfighters, JOEM, Vol. 54, Number 6, (June 2012).

<sup>13</sup> L. Zacher et al., Clarifications from the Department of Defense Representatives Regarding the Article "Recommendations for Medical Screening and Diagnostic Evaluation for Postdeployment Lung Disease in Returning Warfighters," JOEM, Vol, 54, Number 6 (June 2012).

<sup>&</sup>lt;sup>10</sup> M.S. King et al., Constrictive Bronchiolitis in Soldiers Returning from Iraq and Afghanistan, New England Journal of Medicine, 33:705-14 (August 2011).



personnel. As mentioned above, DOD and Navy declined to open its files to The Sergeant Sullivan Center on their decision making processes affecting respiratory health threats this subject.<sup>14</sup>

The Center also learned of a study done for the Army in 2002 by a prestigious respiratory research organization that found rats exposed to silica over 6 weeks developed autoimmune disease, as well as cellular immune responses. It also found that silica could compromise the blood-brain-barrier, allowing prophylactic drugs like pyridostigmine bromide to enter the nervous system and modulate neuroimmune communication.<sup>15</sup> To our knowledge, the Army did not act on the study recommendation for follow-up research. While I am not a scientist or a physician, it does appear that the respiratory and co-morbid conditions that many veterans exhibit have some of the characteristics of an immune system breakdown that could have been triggered by the dust in Iraq and Afghanistan.

Other animal studies have demonstrated toxic effects of exposure to Middle East dust For example, Naval Health Research Center scientists found acute pulmonary inflammations and lesions <u>after a single</u> intratracheal exposure of sand-derived particulate matter (PM10).<sup>16</sup>

Dr, Anthony Szema also recently published findings the demonstrated the toxix effects on mice of dust from Camp Victory, Iraq that contained very fine PM2.5 that included titanium, calcium and silicon.<sup>17</sup>

Captain Mark Lyles, has written and widely briefed on the health hazards presented by exposure to Iraq and Afghanistan dust based on a scientific analysis of the its characteristics. <sup>18</sup>

<sup>16</sup> E.W. Johnson et al., Naval Health Research Center, Wright-Patterson AFB, The Effects of Desert Sand (PM10) On Rat Airway, Poster (2007).

<sup>17</sup> A.M. Szema, Iraq Dust Is Respirable, Sharp, and Metal-Laden and Induces Lung Inflammation With Fibrosis in Mice via IL-2 Upregulation and Depletion of Regulatory T Cells, JOEM, 56:243-251 (March 2013).

<sup>18</sup> See, e.g., M.B. Lyles, M. B., Medical Geology: Dust Exposure and Potential Health Risks in the Middle East. In International Seminars on Nuclear War and Planetary Emergencies, 42th Session, Erice, Italy, August 19:24 (2009). Editor R. Ragaini, World Scientific Publishing Co. 497-502 (2010).

<sup>&</sup>lt;sup>14</sup> See footnote 2.

<sup>&</sup>lt;sup>15</sup> M.L. Sapori, Lovelace Respiratory Research Institute, Role of Respirable Arabian Sand and Pyridostigmine in the Gulf War Syndrome: An Autoimmune Adjuvant Disease? March 2002. I would add that this study also implies that other drugs, such as anthrax vaccinations, might also cross the blood brain barrier with similar effect.



I wish to take note of the registry principally compiled by Rosie Torres, wife of Army Captain Leroy Torres, who is now medically retired from military service, due to, among other things, constrictive bronchiolitis. Over 3000 military veterans of Iraq and Afghanistan who have responded to her call, through her website, www.burnpits360.org, for information on the adverse health consequences believed to be associated with exposures to burn pits and other toxic elements while they were deployed. Given the limited resources she had available for this undertaking, the number of respondents must be viewed not only as a significant, but also a likely the tip of an iceberg. This data also reveals that respondents who have respiratory illnesses commonly have a variety of other conditions, including, e.g., gastrointestinal symptoms, pain, and memory loss. Again, these conditions are consistent with toxic exposures.

It is also noteworthy, that this registry was compiled at a time when our government's executive branch was opposing establishment of an official government registry. Fortunately, legislation has rectified this, although VA implementation is painfully slow and now nearly 6 months late.

Veterans whom The SGT Sullivan Center has encountered also report chronic multisymptom illnesses that typically include a respiratory element. The pattern of clusters of symptoms is similar to the experience of veterans having Gulf War Illnesses.

#### Other Deployment-Related Illnesses and Co-Morbidities with Respiratory Diseases

While I appreciate that the Subcommittee on Public Health is currently focused on pulmonary matters, it should not ignore the co-morbidities associated with deployment-related respiratory illnesses. A more comprehensive review by the Defense Health Board could provide important clues to research approaches will more likely shed light on etiologies of the illnesses, possible treatments and preventive measures. The following information provides essential context for the consideration of pulmonary issues.

a. <u>The Data</u>

The VA utilization report shows high incidence of various categories of disease. They include, in addition to the respiratory ailments noted above, the following (numbers are rounded):

Disease	Percentage	No. Diagnosed	_
Digestive/gastro-intestina	l 37%	379,000	
Circulatory	23	237,000	
Skin	23	240,000	
Nervous System/Senses	48	496,000	



Endocrine/ Metabolic	36	367,000
Musculoskeletal System/	55	567,000
Connective Tissue		

All told, there the average patient has about 4.5 diagnoses, strongly implying hundreds of thousands of veterans having multiple-symptom illnesses.<sup>19</sup>

In January 2013, the Committee on Gulf War Health of the Institute of Medicine (IOM) reported that

Estimates of the numbers of 1991 Gulf War veterans who have CMI [Chronic Multisymptom Illnesses] range from 175,000 to 250,000 (about 25-35 percent of the 1991 Gulf War population). Preliminary data suggest that CMI is occurring in veterans of the Iraq and Afghanistan wars as well."<sup>20</sup>

The report cites, among other things, VA reports on health utilization by post-9/11 war veterans.  $^{\rm 21}$ 

Twenty-two years after the 1991 Gulf War, the understanding of the etiology of Gulf War Illnesses and how to treat them is far too limited. This lack of progress was explained, in part, by the Chair of the Research Advisory Committee on Gulf Veterans' Illnesses in his testimony in March 2014 before a subcommittee of the House Committee on Veterans' Affairs:

When Congress ordered VA to contract with the IOM for a review of best treatments for Gulf War Illnesses by a panel of doctors who treat Gulf War veterans, VA contracted for a literature review by a panel with no Gulf War expertise. The panel was overweighted with specialists in psychosomatic medicine, and the report largely reviewed psychiatric treatments.

When Congress ordered VA to contract with the IOM to review the health effects of toxic substances to which troops were exposed in the

<sup>21</sup> Id., p. 26.

<sup>&</sup>lt;sup>19</sup> The report shows 56% of diagnoses (573,000) were for mental disorders, a large portion of which are presumably for Post-Traumatic Stress Disorder. As noted above, about half of the diagnoses fall under "ill-defined conditions," but the distribution among the various medical categories is not disclosed in the report.

<sup>&</sup>lt;sup>20</sup> IOM Committee on Gulf War and Health, Gulf War and Health: Treatment for Chronic Multisymptom Illness, January 2013, pp. 2.



war, Congress specified multiple times that the reviews should consider animal as well as human studies. Yet the resulting IOM reviews have excluded animal studies from consideration in their conclusions. Since most studies of toxic substances are necessarily done in animals for ethical reasons, IOM reviews consistently find insufficient evidence that a substance causes health effects. This same standard is now being applied to mislead conclusions regarding the health effects of toxic exposures to veterans of the recent wars in Iraq and Afghanistan.<sup>22</sup>

A further indicator of a high incidence of post-9/11 war illnesses (and consistent with the foregoing data) is a recent Washington Post-Kaiser Family Foundation survey. The survey found a deterioration of physical health in 43 percent of veterans and worsened mental health in almost a third."  $^{23}$ 

The Department of Defense Health Surveillance System has detailed health data available like that contained in the VA's health care utilization data, but does not publish a report comparable to the VA's. Moreover, both VA and DOD presumably have more specific data on clinical details of their respective patients than is published in the VA utilization reports (e.g., more detailed data on diagnoses). Neither seems to make this data publicly available. For example, there should be data on, among other things, diagnoses over time, as well as disability determinations for personnel who served in the post-9/11 wars, as well as the 1991 Gulf War. Such information might shed would likely shed further light on trends and patterns. Moreover, I understand that the VA has data showing that medical problems are greater for those troops who are deployed longer. Such information could be used to improve diagnoses of veterans and to avoid treatments that exacerbate, rather than ameliorate, veterans' illnesses.<sup>24</sup> Private, VA and DoD clinical physicians, sick veterans, and the general public are being denied critical information that should inform the medical treatment of veterans.

b. The Psychological Explanation

<sup>&</sup>lt;sup>22</sup> James H. Binns, Hearing Before House Committee on Veteran's Affairs Subcommittee on Oversight and Investigations, March 25, 2014 (<u>http://veterans.house.gov/hearing/legislative-hearing-on-hr-3593-and-other-draft-legislation</u>).

 <sup>&</sup>lt;sup>23</sup> "The Other Wounds," The Washington Post, April 8, 2014.
 (http://www.washingtonpost.com/sf/national/2014/04/08/the-other-wounds/)

<sup>&</sup>lt;sup>24</sup> As noted above, the Virginia medical examiner stated that the medications prescribed by DoD physicians contributed to the pneumonia that caused my son's death. DOD had information available at the time of Tom's extended physical decline that may have helped Tom's physicians avoid damaging him -- had it been publicized. Many other veterans are suffering from this same failure to communicate important information that should inform diagnosis and treatment of veterans.



Craig Postlewaite, the aforementioned Defense Health Agency spokesman, told The Washington Post that the Pentagon had been worried it would see a repeat of the illnesses that were seen after the first Gulf War, but that "it didn't happen," because those now returning from deployment are being treated even if the cause is unknown. He suggested that treatment for Post-Traumatic Stress Disorder (PTSD) has resulted in a "reduction of these unexplained symptoms," noting that the "…mind control controls lots and lots of bodily processes…from anxiety and depression…to gastrointestinal symptoms to dermatologic conditions, respiratory conditions, cardiac."

The spokesman does not appear to be aware of the growing body of evidence that our post-9/11 war veterans are experiencing their own health crisis. While the Pentagon acknowledges that PTSD and traumatic brain injury are a serious problem, it continues to dismiss or minimize or simply ignore that large numbers of veterans are suffering from other, <u>physiological</u> illnesses that resulted from deployment.

If there is any evidence to support the spokesman's claim that PTSD treatment has reduced unexplained physical symptoms, I am not aware of it and doubt that it exists. His remarks reveal an apparent continuing bias toward treating physiological problems that are complex and difficult-to-diagnose as rooted in the psychological. Indeed, in our work at The SGT Sullivan Center, we have encountered many service members and veterans who have been told that they their health problems are "in their heads." My son's treatment was not an isolated case. This bias seems to be institutionalized in the VA as well as DOD. <sup>25</sup> Veterans of the post-9/11 wars served their country in an environment that is a toxic stew of heavy metals, burning trash, exploded munitions, and other known and unknown chemical and biological agents. To attribute their physical illnesses to psychological causes or to somatoform disorder without any scientific basis or

<sup>&</sup>lt;sup>25</sup> The House Committee on Veterans' Affairs Subcommittee on Oversight and Investigations found that the Research Advisory Committee on Gulf War Illnesses (RAC) had been marginalized by VA's efforts, among other things, to pack the RAC with members who had a bias toward seeing Gulf War as having a psychosomatic rather than biological basis. Subcommittee Press Release re Bipartisan Bill on Gulf War Health Research, March 14, 2014 (<a href="http://coffman.house.gov/media-center/press-releases/bipartisan-bill-on-gulf-war-health-research">http://coffman.house.gov/media-center/press-releases/bipartisan-bill-on-gulf-war-health-research</a>). On March 13, 2013, former VA epidemiologist, Dr. Steven Coughlin testified before this Subcommittee that the VA either doesn't release or manipulates data, particularly data relating to environmental exposures in deployment and the adverse health consequences of those exposures (<a href="http://veterans.house.gov/witness-testimony/dr-steven-s-coughlin">http://veterans.house.gov/witness-testimony/dr-steven-s-coughlin</a>).



support is both an insult and an injury. To fail to adequately investigate causes and potential treatments for our young veterans constitutes dereliction of duty.

We, the family of the young Marine who died through the misdiagnosis and misinformed medical treatment provided by his DoD physicians, believe in the core values of the Marine Corps: honor, courage and commitment. We formed an organization to promote the proper diagnosis and treatment of our servicemen and women through research, awareness and forging connections among the public and private sectors – and our public support is growing. It's time to face the problem with honor and honesty and to have the courage and commitment to solve it.

#### III. <u>Recommendations</u>

#### 1. Acknowledge the Problem

The time is well past due for the President and the Departments of Defense and Veterans Affairs to acknowledge officially that there is a growing health crisis affecting the veterans of our Nation's wars in Afghanistan and Iraq. Amputations of limbs, traumatic brain injury, PTSD (and to some extent suicide) are often referred to by DOD and VA spokesmen as "signature wounds" of these wars. By and large both departments have taken positive action to address them. This cannot be said of the hundreds of thousands of former and current service members who suffer from the other significant, albeit invisible wounds -- the diminution of their health due to likely toxic exposures while deployed.

It is difficult to marshal the resources essential to improve the diagnosis, treatment and prevention of these deployment-related respiratory, gastro-intestinal, neurological, skin and other diseases if our Nation's leaders continue to deny, deflect, minimize and/or finesse the deployment nexus and seriousness of these illnesses.

The current approach to post-9/11 toxic wounds will cause our post-9/11 veterans to suffer the fate of Vietnam war veterans exposed to Agent Orange and to 1991 Gulf War veterans suffering from their complex of illnesses – to wait 20 to 30 years for recognition of their war-related illnesses. This is insupportable, and, as an aside, not consistent with attracting a volunteer military.

Official acknowledgement of these apparent toxic wounds as additional "signature wounds" of our recent wars is an indispensable first step to treating the affected veterans with the dignity and professional care they deserve for their sacrifice.

#### 2. More and Better Research

There needs to be effective research to better understand the etiology of these illnesses, and how to diagnose, treat and prevent them. Long-term epidemiological studies are helpful to a point, but in the long-term, the patients we seek to benefit



will age, their health will worsen and many will die. Also, focus on population studies distracts from the unique needs of patients who were exposed to documented hazards and are now suffering from chronic lung and other diseases.

Spend more research money on connecting symptoms to likely causes like toxic exposures and interactions with medications that can trigger damage to autoimmune systems.

Greater emphasis should be given to studies that will produce objective and useful data that can help in diagnosis, treatment and prevention.

Examples of studies that are useful include—

--the case series study done at Vanderbilt reporting on the discover of constrictive bronchiolitis;  $^{\rm 26}$ 

--the Lovelace Laboratory Study done in 2002 that demonstrated that silica can cause damage to immune systems of rats and create opportunities for adverse reactions to prophylactic medications,<sup>27</sup> and the recent study by Szema et al. of Iraq dust and the impact of mice airways.<sup>28</sup>

--the ongoing Army-funded study by National Jewish Health (NJH) to provide independent, blinded pathology review of tissues from biopsies by Vanderbilt and NJH and identification of particles in those tissues;<sup>29</sup>

--a project by NJH, partly funded by The Sergeant Sullivan Center, to develop biomarkers that will help diagnose constrictive bronchiolitis without an invasive biopsy;

--a study by Dr. James Baraniuk et al. at Georgetown University that discovered abnormalities in Gulf War illness patients' brains, in the areas relate to the symptoms these patients have presented, such as pain and fatigue;<sup>30</sup>

<sup>27</sup> See footnote 15.

<sup>28</sup> See footnote 17.

<sup>29</sup> The Subcommittee Chair's terms of reference for its current work note pulmonary research work is being conducted at Brooke Army Medical Hospital. It would make sense for the Subcommittee to facilitate making the data and findings from this work available to the public so it can be subjected to independent peer review.

<sup>30</sup> R.U. Rayhan, Increased Brain White Matter Axial Diffusiivty Associated with Fatigue, Pain and Hyperalgesia in Gulf War Illness, PLOS One (8)3: 2013.

(http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0058493 )

<sup>&</sup>lt;sup>26</sup> See footnote 7.



-- a project by Georgetown University, which will be partly funded by The Sergeant Sullivan Center, to identify bio-markers that will help diagnose Gulf War illnesses;

--a study by Dr. Beatrice Golumb et al. of the University of California, San Diego (UCSD), that found mitochonrial dysfunction in veterans having Gulf War Illnesses. Gulf War Illness symptoms are consistent with such dysfunction, which can be triggered by the kinds of hazards the study subjects faced while deployed during that war. <sup>31</sup>

There seem to be continuing differences of opinion about the characteristics and hazards presented by the dust in Iraq and Afghanistan. While I think the preponderance of the evidence shows that exposure to it over several months has had toxic effects in many previously healthy military personnel, it might help understanding of the issues to conduct a comprehensive program of sampling and analyzing, including animal tests. This program would need to be designed and supervised by <u>independent experts</u> and must be transparent to the public. Before that is done, it would be helpful for DOD to release to the Subcommittee and the public the documentation on previous controversies over dust studies and proposals for additional sampling and testing that DOD refused to provide to The Sergeant Sullivan Center.

The Georgetown and UCSD studies were funded by the Congressionally Directed Medical Research Program (CDMRP). This program was established by Congress to to specifically fund innovative research that would have near-term treatment application. Congress designates the funds for specific research, and then allocates funds to deserving grant proposals. All grant proposals are peer reviewed, and grant recipients are required to collaborate with one another to avoid silos of information. An important feature of the CDMRP is that the unique voice and experiences of patients, survivors, family members and advocates play a pivotal role and they are involved in all aspects of the review process.<sup>32</sup>

I believe the CDMRP should be expanded to include research on post-9/11 deployment-related illnesses. Also, DOD should adopt this model, especially provision for participation by patients, survivors, family members and advocates, for all of its deployment-related research.

32 See http://cdmrp.army.mil/cwg/default.shtml

<sup>&</sup>lt;sup>31</sup> H.J. Koslik, G. Hamilton, B.A. Golomb, Mitochondrial Dysfunction in Gulf War Illness Revealed by 31Phosphorus Magnetic Resonance Spectroscopy: A Case-Control Study, PLoS ONE 9(3): 2014 (http://www.plosone.org/article/info:doi/10.1371/journal.pone.0092887)



DOD and VA know the patients in their health care system and the nature of their ailments and effects of various treatments. There is much clinical data to be mined, compiled, compared and analyzed for patterns, correlated to potential causes and relative benefits of therapies. This information needs to be shared within the DOD and VA medical systems and with independent researchers and the public at large.

DOD and the VA should post their websites or a joint website all ongoing and completed research relating to deployment-related illnesses.

#### 3. Improved, Multi-Disciplinary Medical Care

A comprehensive approach is necessary to tackle complex medical problems. Long waits for serial referrals and experts working in silos does not serve the patient who is at risk of falling through the cracks in the system, as my son did. The trend now is toward multi-disciplinary teams to deal with challenging cases. DOD needs to ensure that this concept is implemented. For example, DOD medical treatment facilities should be encourage to reach out and collaborate with centers of excellence when dealing with hard cases, as Fort Campbell reached out to Vanderbilt. The attitude that "We can take care of our own without outside help" does not help the patient.

DOD health care providers need to be educated about deployment health risks and how to diagnose, treat and prevent development-related illnesses. They need to be kept abreast of developments in the field through a program of Continuing Medical Education. There needs to be a program to ensure that they educate military personnel before deployment about health risks and carefully screen them and monitor them after their return, keeping in mind that the adverse effects may be, and frequently are, <u>latent</u>.

DOD should take steps to train military medical personnel to avoid treating unexplained physical symptoms as a psychosomatic problem. This dishonors the service of troops who are suffering from toxic wounds. DOD should encourage VA to do the same.

#### 4. Broader Collaboration

The DOD, in concert with the VA, should seek to enlist more centers of medical and scientific excellence in the USG (e.g., NIH, CDC, EPA, OSHA) and in private and public university medical centers to collaborate on a regular, sustained basis in research and clinical work. There is great expertise residing outside of these departments that should be called upon. And these experts can learn from DOD and VA physicians and researchers and apply it to their own work on behalf of the veteran population they treat. There is great potential for synergy of all these professionals play well for a good cause.



DOD, in concert with VA, should also encourage medical centers of excellence to develop programs like National Jewish Health's Center for Excellence for Deployment-Related Lung Disease and Massachusetts General Hospital's Operation Home Base (which is also supported by the Boston Red Sox). The Mass General program is focused on TBI and PTSD, but could be encouraged to cover other illnesses. The Home Base concept could be expanded to other sports team cities and serve as a vehicles to extend the DOD and VA's ability reach out to health care providers and veterans to educate them about deployment health risks and extend the network of research and clinical care.

The Department should consult with allied and coalition forces who served in Iraq and Afghanistan to obtain information on illnesses their personnel have encountered after deployment and make this information available to the public.. It would also be useful to obtain data from Iraq and Afghanistan on the health of their populations and trends during the last 13 years. Our country can learn from our partners and vice versa.

To educate the public about the deployment-related illnesses, it would be helpful if DOD and VA would ask the White House to sponsor a high level conference that would seek to enlist leading medical practitioners and scientists in government and the private sector in efforts to grapple with this problem.

#### 5. Better Data Sharing

More information needs to be made available and easily accessible to the public on data that is maintained in the Defense Medical Surveillance System (and its counterpart at the VA) and DOD (and VA) information on disability determinations and ratings for persons who have been deployed to Iraq and Afghanistan. If it is not already doing so, DOD should obtain and maintain data on the health of retired military personnel who obtain healthcare through TRIACE outside of the military medical system.

DOD, in conjunction with VA, should encourage medical centers of excellence outside of the DOD and VA health systems, to share relevant data relevant to the veterans population.

As noted above, over 40 percent of the 2.6 million post-9/11 veteran population has not enrolled in the VA health care system. This makes it difficult to monitor the health of this population or to provide them important research findings or other information affecting their health.



#### 6. Better Monitoring of Military Service Members' Pulmonary Functions

DOD should adopt and implement the recommendations made by the Denver working group, including but not limited to baseline and follow up pulmonary function testing via spirometry for personnel who are deployed abroad to high risk areas such as the Middle East, Africa and Asia. Deployment to these areas is analogous to the occupational risks faced by firefighters and coal miners who routinely receive regular pulmonary function testing. Failure to implement such a testing program is tantamount to malpractice and grounds for legislation to repeal the immunity that DOD now enjoys from claims under the Federal Tort Claims Act.

#### 7. Adopt Protective Measures

The Department should institute measures to equip personnel deployed to high-risk areas with masks or other devices to protect against toxic airborne exposures. This is like pulmonary testing – a low cost, non-brainer force protection measure.

#### 8. Make Effective Use of New Registry

Over two years ago, I attended a conference sponsored by the Jackson Foundation for the Advancement of Military Medicine. A military doctor said that a major challenge in treating military personnel and veterans with traumatic brain injuries is to "find the patients." Many sustained brain injuries without knowing it because diagnostic tools were limited or not applied effectively. So these patients slipped through the cracks. There is a lot of catch up to be done. But there at least appears to be a concerted DOD effort.

As noted above, there is not yet a concerned effort by DOD or VA to accurately identify and assess the number and variety of very serious respiratory and other deployment-related illnesses that are emerging from our post-9/11 wars. To make up for lost time, the VA plans to encourage all current and former military personnel who served in our post-9/11 wars and/or the 1991 Gulf War to enroll in the soon (we hope)-to-be-implemented Airborne Hazards and Burn Pit Registry—whether or not they are presently ill or experiencing possible symptoms of illness.

The VA's rationale appears to be that a major problem in conducting research and doing continuing health evaluation is finding and maintaining the ability to communicate with the relevant population. Enrollment in the registry will be the first to provide for registration via the internet. I believe the VA's objective for the registry is a good one and the VA's efforts should be supported by DOD.



#### 9. Treat Sick Veterans Fairly and Competently and with Respect

Data is never optimal for decision-making on deployment health matters any more than intelligence is ever adequate for making policy decisions affecting war and peace. Judgments have to be made. In deciding whether an illness that emerges after deployment is service connected, there sometimes needs to be a presumption to minimize unfair burdens on the patient. The benefit of the doubt should always go to the veteran. DOD's and the VA's handling of Agent Orange and Gulf War Illnesses and its uneven performance thus far in addressing post-9/11 war illnesses does not inspire confidence.

If the DOD and the VA continue on their current course, legislation may be the only effective course as it was to help the veterans of the previous two wars. This would take time and effort and the loser will be the sick veterans.

The dust in Iraq and Afghanistan is ubiquitous and abundant. The particulate matter is far in excess of standards set by DOD or EPA. It contains metals, bacteria, viruses, fungi and other toxic elements – those found in nature and aggravated by those added by man (including from pollutants from local industry and from USG burn pits). There have been animal studies and other research showing the illeffects of these elements.

The data supporting a high incidence of <u>deployment-related</u> respiratory diseases and other physiological illnesses suggest that the illnesses affecting our post-9/11 veterans "as likely as not" related to their deployment.<sup>33</sup> This is the standard for establishing service connection at the VA and it should be the standard for DOD as well. Based on the literature I have seen, this nexus is at least as compelling as that supporting the acknowledgement of the deployment nexus with TBI and PTSD. The key point that does not require a PhD or MD to understand is that troops who are deployed are medically cleared as "fit to be deployed;" when they develop illnesses after deployment that reasonably can be associated with the hazards and risks to which they have been subjected, they can be reasonably presumed to be connected with that service. Research is justified to seek a better understand the etiology of these illnesses to help diagnose and treat sick veterans and protect future deployers, but not to seek to disprove a nexus.

Recently, the VA denied a request to create a presumption that a veteran who develops constrictive bronchiolitis after service in Iraq or Afghanistan should be entitled to service connection determination and so he can receive appropriate compensation and health care. This action was taken even thought the Social Security Administration had previously established a compassionate allowance to enable expedited approval of post-9/11 war veterans' applications for disability.

 $<sup>^{33}</sup>$  The "as likely as not' standard is less than a preponderance of the evidence (more likely than not, i.e., 50%+).



DOD can and should take the lead in rectifying this error by establishing a presumption for this disease in its disability process.

DOD's opposition to biopsy creates a Catch 22-type problem for the patient. Resort to biopsy is appropriate when other tests cannot explain the symptoms, like shortness of breath presented by the Fort Campbell Airborne Soldiers. DOD is opposed to biopsy if other tests fail to produce sufficient data. Without one, DOD may deny the condition and the commensurate disability rating and related retirement and health benefits.

DOD should and must give active duty and retired service members patients the option to have a diagnostic biopsy and pay for it. It should also support research to find alternative/less invasive methods for diagnosing constrictive bronchiolitis and other lung diseases that me elude detection by standard testing.

In addition, an appropriate rating level needs to be assigned to such a determination. This disease is currently incurable and ultimately terminal. To our knowledge, DOD has not made available to the public data on how it has treated service members with a constrictive bronchiolitis biopsy finding versus those with similar symptoms. This information needs to be provided to the Subcommittee and the public. In my opinion, pending further study and patient followup, this condition warrants a minimum 60 percent disability rating; for some patients the condition may be 100 percent disability.

Iraq and Afghanistan war veterans also suffer form other serious pulmonary diseases resulting from deployment, such as pulmonary fibrosis, that are comparable in severity to constrictive bronchiolitis. A review needs to be done quickly in conjunction with the VA to establish presumptions and rating levels for deployment- related respiratory diseases that are equitable and ensure they receive continuing health care and compensation.

Treating patients presenting with respiratory symptoms competently means taking into account all aspects of the their health, including co-morbidities. For similar reasons, the Subcommittee should consider the illnesses and symptoms that tend to accompany the respiratory illnesses that are the focus of its review and analysis. As noted above, exclusive consideration of the lungs will likely lead to missing important clues that will shed light on the nature of this deployment-related pathology.

That patients should be treated with respect should go without saying, but it must be said. During the course of his treatment Tom said he was treated with more respect by Marine Corps generals for who he worked than by his military physicians. He felt they did not take him and the description of his symptoms seriously. Every Soldier, Sailor, Airman and Marine -- regardless of rank -- should be taken as seriously as a general officer.



#### 10. Open and Transparent Defense Health Board Process

I wish to commend the Defense Health Board and its Subcommittee on Public Health for providing an opportunity for veterans and their advocates to make a presentation in a public meeting. However, The Sergeant Sullivan Center has been handicapped in framing comments because it was denied access to most of the submissions that were made to the Subcommittee thus far. The Center was also denied admission to previous Subcommittee meetings.

This appears to be a violation of the spirit and the letter of the Federal Advisory Committee Act and guidance posted on the General Services Administration website. The gist of the requirement is that all submissions to an advisory committee and minutes of its meetings must be made available to the public for inspection and copying. The Board's own website says that news media may attend all Board and subcommittee meetings, which is consistent with the Act and posted GSA guidance.

I believe the deliberations of the Board and its Subcommittee on deploymentrelated illnesses are long-overdue and very important to the future treatment of hundreds of thousand of sick veterans. Denying the public visibility into the process will derogate from the quality of the Subcommittee's and full Board's analysis and findings and undermine public confidence in any recommendations it makes to DOD. In this connection, the Subcommittee membership does not appear to include experts who have made great strides in identifying and treating deployment-related lung disease. As a consequence, there is no meaningful opportunity for them to provide participate in the formulating the Subcommittee's findings and recommendations. Denying public access to submissions and minutes exacerbates this problem.

Accordingly, I urge the Board to make submissions to and minutes of the Subcommittee on Public Health and allow members of the public to attend future meetings of the Subcommittee and the Board. I also recommend either adding the aforementioned experts to the Subcommittee or, at least, ensuring that they are part of a "peer review" process for the Subcommittee's findings and recommendations.

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### Public Statement of Rosie Lopez-Torrez of Burnpits 360

### Rosie Lopez-Torres – Burnpits360 Statement

I am the wife of retired U.S. Army Captain Le Roy Torres and representative of Burnpits 360. I am here to speak on behalf of Captain Torres and the thousands of soldiers who have respiratory disease after deployment during operations OEF and OIF.

Until recently, my husband had excellent health, had no history of respiratory disease and had been a lifetime non smoker. He worked as a Texas State Trooper and served as a Captain in the U.S. Army Reserve. He was always physically fit and had excellent physical testing scores as a member of Reserves. He was able to complete his two mile run for the Army in less than 13 minutes at the time of his 2007 deployment.

He was deployed to Balad, Iraq in 2007 and began experiencing cough and chest congestion shortly after arrival. Many deployed personnel experienced such symptoms while serving their deployment; Le Roy assumed that his symptoms were part of a common pattern. He worked in logistics and had housing which was consistently downwind from the Balad burn pit. He also had exposure to dust and overwhelming dust storms.

Over time, Le Roy's symptoms took on a different character; he had more intense coughing, coughing fits and shortness of breath. His symptoms progressed after returning from deployment. He had difficulty walking without chest tightness and shortness of breath.

He was not able to perform his usual activities with his Texas State Trooper duties and was subsequently assigned to a desk job. His employers wanted to know why this longstanding State Trooper was no longer able to perform his day to day activities. Le



Roy went from having competitive Army two-mile run times to not being able to run two miles without stopping. My husband no longer met the physical fitness standards for the United States Army.

Le Roy was evaluated by the DOD facilities at Brooke Army Medical Center and Willford Hall Air Force Hospital in San Antonio, Texas during August timeframe in 2010. Numerous exams were conducted to include a bronchoscopy lavage which revealed inflammation of his upper respiratory regions. No follow up for care was recommended for Le Roy since he did not qualify for the "Stampede Study" as his return from deployment was too long, which was in November 2008.

Le Roy was later seen at the VA War Related Illness and Injury Center (WRIISC) in Washington D.C. in October 2010. His evaluation included x-rays, pulmonary function tests, MRIs, and swallow test in which all exams were normal. A sleep study did reveal that he had conditions of obstructive sleep apnea.

We felt as if our family and financial security were being severely threatened. It was at this point that we heard about a series of patients being evaluated at Vanderbilt University Medical Center by a team lead by Dr. Robert Miller. Dr. Miller first evaluated Leroy in 2010. His evaluation included pulmonary function tests, CT scans, and exercise tests, all of which returned normal. Dr. Miller indicated that Le Roy's presentation was in line with other soldiers who had been diagnosed with constrictive bronchiolitis and that a surgical lung biopsy was the only way to evaluate this possibility.

Le Roy underwent a lung biopsy in which his pathology showed the typical features of constrictive bronchiolitis. We learned that this was a condition without treatment. This was



very difficult to hear, but at least we were no longer being told that Le Roy was fine and that he just needed to exercise more. Le Roy's careers with the Texas State Troopers and the Army Reserve came to an end with this news of his medical conditions.

Shortly after Le Roy's diagnosis, we learned about other service members who were dealing with respiratory disease after deployment, many of whom who had been diagnosed with constrictive bronchiolitis

With help from others, I co-founded Burn Pits 360, an organization designed to advocate for service members suffering from respiratory disease and other illnesses post deployment. Our organization has over 3500 registered members who believe they have illnesses related to airborne exposures during OEF and OIF. 90% report respiratory symptoms. Many have stories similar to Leroy. They have significant limitations and illnesses and too often their medical issues have been dismissed. The members of Burn Pits 360 are similar to our family. They have experienced disabling diseases, financial loss, career loss and in many cases near homelessness.

I am here today to ask the U. S. Government, the Department of Defense and the Veteran's administration to address the issue of respiratory disease following deployment. There is no system or set of standards to deal with this issue. Several years ago, the DOD referred patients with respiratory disease to institutions such as Vanderbilt and NJH. Over time, such referrals were terminated. Some VA facilities will consider evaluations including surgical lung biopsy, but many will not. Some soldiers can get med-board ratings for this diagnosis, but most cannot. The VA will not rate for this even in situations that they admit that it is service connected.



My husband served his country honorably for over 23 years. He has no regrets about doing so and would do so again. He now knows the nature of his war related injuries and the cause for his disabling disease. He finally has a disability rating, but getting to this point has taken every minute of the last seven years. We have used all of our financial resources to get to this point. We believe that those who return with respiratory disabilities deserve the same consideration that other wounded service members receive. Thank you for your consideration.



Public Statement of Arlene Rich of the Severna Park Health and Wellness Center

Defense Health Board, Public Health Subcommittee Meeting of June 11, 2014

Statement of Arlene Rich, Director, Severna Park Health and Wellness Center, Annapolis Office

Thank you for this opportunity to make a brief statement.

My name is Arlene Rich and I am the Director of the Annapolis Office of the Severna Park Health and Wellness Center. I would like to share some experiences and information that relate to the subject of today's hearing.

Between the years 2003 and 2009, I worked in Manhattan, at a project that provided humanitarian services to police, military officers, firefighters, EMTs and others affected by exposures during the World Trade Center rescue and recovery operations.

The acute complaints of emergency responders were often pulmonary. Major concerns included persistent pulmonary syndromes such as reactive airways dysfunction syndrome and reactive upper airways dysfunction syndrome.

Over several years, we provided a specific rehabilitative therapy involving exercise, sauna, and nutritional supplements, developed by Hubbard, to more than 1,000 individuals. The program was delivered under medical supervision.

Although the attacks on the World Trade Center resulted in an exposure event with unique attributes, many of the substances released into the air could also be expected to be found in the vicinity of burn pits, fires, explosions and other events that could occur on the battlefield.

A survey of the cases of 484 of these men and women was published in 2006. Over half the clients required multiple pulmonary medications on entry to achieve near-normal pulmonary functions. On completion of detoxification, 72% of these individuals were free of pulmonary medication yet had improved pulmonary function tests.

I assisted in the administration of the program, but did not have a role in medical tests. I am not qualified to discuss details of pulmonary function testing. I can say that in case after case, I witnessed men and women arriving at our facility unable to walk more than a block or two without losing their breath and leaving the program within a few weeks able to run or jog for extended periods without difficulty.

We are currently providing this service at no cost to veterans at our facility in Annapolis. I would like to invite those present to visit us, or to refer individuals who might be potential candidates. Medical clearance is required.

We also have a Gulf War Illness Research Program currently underway in our facility. If you'd like more information about this study you are welcome to speak to me today, or to Dr Crystal Grant, the Study Coordinator, who is also present.

Thank you.

Contact information: Arlene Rich, Severna Park and Wellness Center, Annapolis Office 128 Lubrano Drive, Ste. L102 | Annapolis, MD 21401 (410) 224-9714 | arich@sphwc.com



Public Statement of Coleen Bowman

#### Testimony of Coleen Bowman to the Deployment Pulmonary Health Tasking June 11, 2014 Defense Health Headquarters Falls Church, Virginia

Thank you for giving me this opportunity to talk to you today about my late husband SGM Robert Bowman. Rob was a Soldier for 22 years and served 2 tours in Iraq. His first deployment was a 12-month tour in 2004-2005, assigned to the 1/24 Reconnaissance Platoon. His second was a 15-month deployment from 2007-2008, assigned to the 3/2 Stryker Cavalry Regiment. His first deployment was spent in the northern part of Iraq, in Mosul. His second deployment was spent in and around the Baghdad area. Both deployments had a very high OPTEMPO, which resulted in the loss of many men throughout the heated battles they confronted almost daily. Although Rob survived those battles, he ultimately lost his life fighting a different battle.

In June 2011, Rob was diagnosed with cholangiocarcinoma, stage 4 non-operable cancer. His cancer was very rare, 1 in 100,000, and totally unheard of in someone of his age. It is basically a cancer of the biliary tree. We never asked how much time they thought he had left to live...we didn't want to know. I have since scanned his medical records, and it looks like they expected him to live for only 6-11 months. He fought a good fight for 19 months and passed away on January 13, 2013. About 3-4 months after he was diagnosed, they ran a "BRAC" test on him at William Beaumont Army Medical center at Ft Bliss, Texas. This test can identify the gene that caused his cancer. The test results were basically negative, meaning he did not even have the gene that would cause this cancer. His doctors concluded that the cancer was environmental. We then went to MD Anderson cancer treatment center in Houston for a second opinion of his cancer. They did genetic counseling and came to the same conclusion, that the cancer was environmental.

Rob talked about a few incidents where he thought they were possibly exposed to something. He was in a Stryker brigade during both deployments and his vehicle was struck many times by IED's (improvised explosive device). On more than one occasion he would go back into the burning Stryker to retrieve equipment, or help Soldiers get out. I recall seeing him on the webcam when we would talk, and he was covered in dirt so thick, it turned him black. I could only see the white of his eyes, and his teeth. He spent a lot of time in the "hatch" of the Stryker so this put him in the environment most of each mission.

But it wasn't just Rob who experienced serious health issues following those deployments. Approximately 1/3 of the 1/24 Recon Platoon from his first deployment has some sort of serious health issue ranging from cancer, to Crohn's disease, liver issues, tumors, brain bleeds, miscarriages, births defects and other things. I believe they were exposed to something, and that there is a connection to the deployments to Iraq. My hope is that we can shed some light to this subject, and bring some attention to the illnesses. The more we learn, the more can help prevent other Soldiers from being exposed to whatever is causing these illnesses, and we can better treat those already affected.

Rob Bowman was a great Soldier, and a born leader who took care of his men. About 4 months before he died, Rob said to me, "maybe part of God's plan to allow me to continue leading men after I'm gone, is me being a "pioneer" in bringing awareness to the illnesses coming out of Iraq, and it will help Soldiers long after I'm gone." It was important to him that this be addressed and talked about. He asked me to "tell his story." I am honored to be the voice of SGM Robert Bowman.

Thank you.

## APPENDIX H. SUPPORT STAFF

Allen Middleton, S.E.S. Deputy Director, Defense Health Agency/ Designated Federal Officer

**Christine Bader, M.S., B.S.N., R.N.-B.C.** Executive Director, Defense Health Board and Independent Review Panel on Military Medical Construction Standards

## Camille Gaviola, M.B.A.

Deputy Director, Defense Health Board and Independent Review Panel on Military Medical Construction Standards

**Colonel Douglas Rouse, M.D., M.S., M.P.H.** Executive Secretary, Defense Health Board

**Katrina Badger, M.P.H., G.S.W.** Task Lead, Grant Thornton LLP (until October 2014)

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