

The seal of the Defense Health Board is a circular emblem. It features a central figure of a caduceus (a staff with two snakes and wings) superimposed on a globe. The globe is light blue and green. The caduceus is gold. The entire emblem is set within a purple circular border. The word "DEFENSE" is written in white capital letters along the top arc of the border, and "HEALTH BOARD" is written along the bottom arc. Two white stars are positioned on the left and right sides of the border.

# **Public Health Subcommittee**

## **Decision Brief: Deployment Pulmonary Health**

**RADM (Ret) H. Clifford Lane, MD**

Defense Health Board  
November 6, 2014



# Overview

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- Problem Statement
- Membership
- Timeline
- Briefings
- Structure of the Written Report
- Findings & Recommendations



# Problem Statement

(1 of 2)

- 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.



# Problem Statement

(2 of 2)

- 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.



# Common Environmental Exposures

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PREDECISIONAL



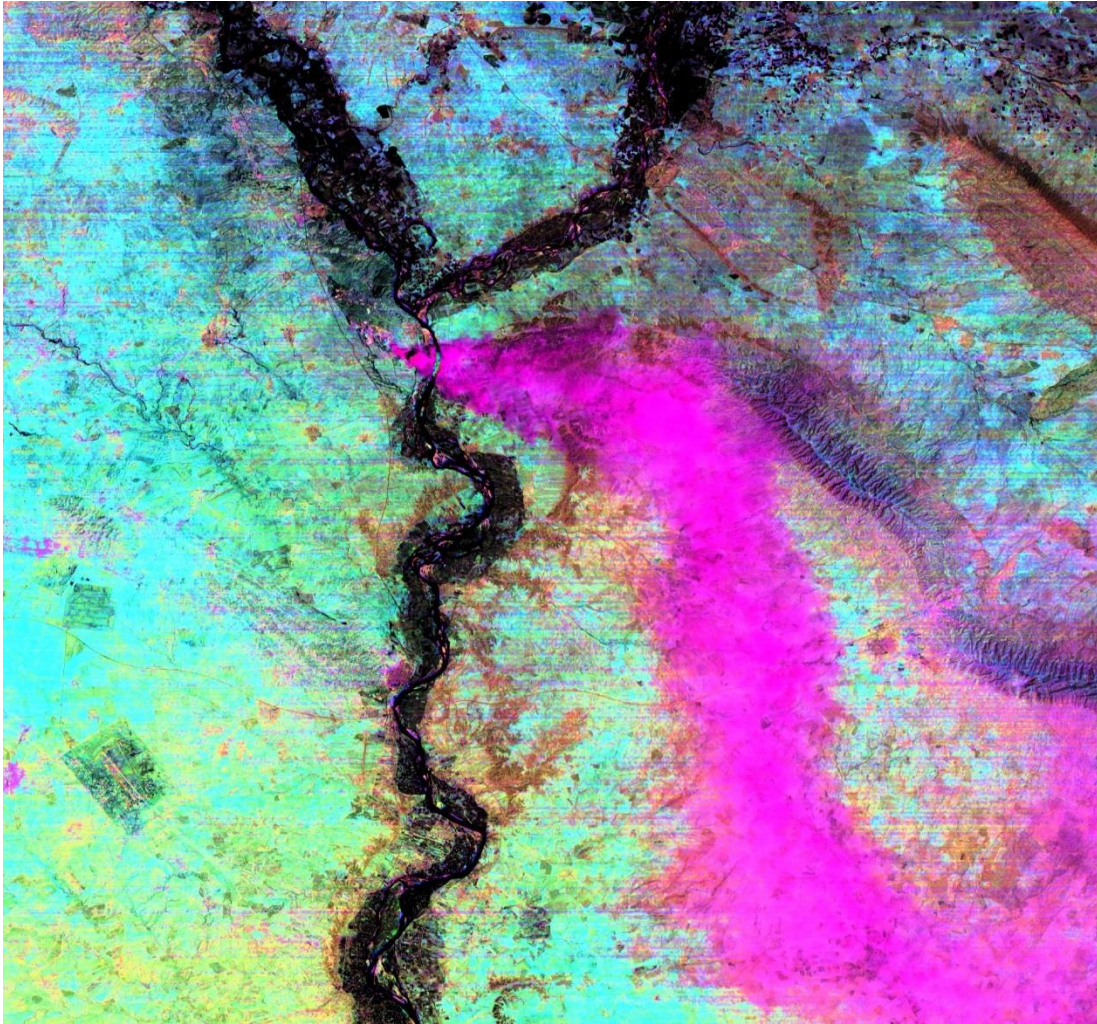
# Location-Specific Environmental Exposures



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# Event-Specific Environmental Exposures



2003  
Al Mishraq  
Sulfur Fire

(NASA photo)

ORIGINAL ARTICLE

# Constrictive Bronchiolitis in Soldiers Returning from Iraq and Afghanistan

Matthew S. King, M.D., Rosana Eisenberg, M.D., John H. Newman, M.D.,  
James J. Tolle, M.D., Frank E. Harrell, Jr., Ph.D., Hui Nian, Ph.D.,  
Mathew Ninan, M.D., Eric S. Lambright, M.D., James R. Sheller, M.D.,  
Joyce E. Johnson, M.D., and Robert F. Miller, M.D.

ABSTRACT





# Bottom Line

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- There is no doubt that deployed soldiers (whether to Southwest Asia or elsewhere) are exposed to situations that may lead to lung disease.
- There are inadequate data to provide any definitive cause and effect relationships with a specific exposure in Southwest Asia.
- Despite substantial effort there is still more that needs to be done.



# Membership

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## Public Health Subcommittee

- RADM (Ret) H. Clifford Lane, MD (Chair)
- Sonia A. Alemagno, PhD
- Gary P. Carlson, PhD
- John D. Clements, PhD
- Steven Gordon, MD
- John Groopman, PhD
- David Lakey, MD
- James E. Lockey, MD, MS
- Gregory A. Poland, MD
- Maj (Ret) Joseph Silva, Jr., MD



# Timeline

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**August 2013:** DHB subcommittee members begin investigation.

**September 2013 – June 2014:** Members receive briefings from **DoD and civilian** subject matter experts.

**May 2013 – July 2014:** Members develop draft report and refine findings and recommendations for the DHB consideration.

**August 2014:** Presented pre-decisional draft to DHB.

**September – October 2014:** Refined report for DHB's approval.



# Process

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- 12 Teleconferences
- 6 Face-to-face meetings
- 24 Briefings
- Discussion with 11 subject matter experts
- 1 Public session, with 4 public statements



# Briefings

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- **Department of Defense**
- Department of Veterans Affairs
- National Institute of Occupational Safety and Health
- Vanderbilt University
- National Jewish Health
- Fire Department of New York
- Other subject matter experts in occupational spirometry, epidemiology, toxicology, pulmonology, and pathology



# Structure of the Written Report

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- Executive Summary
- Introduction
- Pre-Deployment Clinical Baselines and Post-Deployment Screening
- Diagnosis of Post-Deployment Pulmonary Symptoms and Disease
- Surveillance for Deployment Related Pulmonary Symptoms and Disease
- Deployment Pulmonary Health Registries
- Deployment Pulmonary Health Research Activities
- Deployment Related Pulmonary Disease Prevention



# Findings & Recommendations

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## Grading System for Recommendations

**I = Based on data from randomized, controlled trials**

**II= Based on observational cohort studies**

**III=Based on expert opinion**

# INTRODUCTION





# Introduction

(1 of 2)

- The potential association between deployment in Operation ENDURING FREEDOM (OEF)/Operation IRAQI FREEDOM (OIF) and pulmonary health has been examined in many studies.
- There is a consistent report of increased respiratory symptoms/illness when deployed are compared to non-deployed.
- **Some studies have shown an increase in asthma diagnoses, but this is not specific to Southwest Asia deployment.**



# Introduction

( 2 of 2 )

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- Active duty military personnel have higher levels of smoking compared to the general population.
- Multiple studies indicate former smokers who deploy are more likely to resume smoking than those who do not deploy.
- Smoking is a significant risk factor for many forms of pulmonary disease.

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



# Pre-/Post-Deployment Screening

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- Service members are required to maintain a high level of readiness.
- This is assessed through a series of questionnaires and evaluations.
- The questions relating to pulmonary health are not consistent on all questionnaires.
- Routine spirometry **has been suggested** to periodically assess pulmonary function. This is not a trivial undertaking.



# Finding #1

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The current Department of Defense (DoD) pre-deployment screening questionnaire (DD2795) does not contain any pulmonary-specific questions and it does not contain the same questions as the two post-deployment questionnaires (DD2796, DD2900). The forms also do not sufficiently capture smoking history, such as number of pack-years smoked.



# Recommendation #1.1

**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 the Defense Department form 2796 and Question 8 in the Defense Department form 2900).
- b) Add “wheezing” to the symptom questions on all deployment questionnaires.
- c) Add quantitative and qualitative questions about smoking behaviors on all deployment questionnaires.

**Evidence Level: III**

**Added text in red**

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## Finding #2

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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.



# Recommendation #2.1

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**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

(1 of 3)

- a) There have been no studies conducted on Service members who already have baseline occupational spirometry data 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 and American College of Occupational and Environmental Medicine guidelines.



# Finding #3

(2 of 3)

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- 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 that 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 personnel.



# Finding #3

(3 of 3)

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- e) If DoD were to consider implementing a large-scale pre-deployment baseline spirometry program, a feasibility study would be necessary to determine the resources needed to implement such a program at multiple sites with sufficient quality assurance.



# Recommendation #3.1a

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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 American Thoracic Society Technical Standards: Spirometry in the Occupational Setting **and the American College of Occupational and Environmental Medicine Guidance Statement: Spirometry in the Occupational Health Setting—2011 Update** as guides. This should include an analysis of key spirometric parameters previously obtained over at least a 5-year period of time using a statistical sample from several representative locations from each Service and an assessment of the presence and effectiveness of quality assurance reviews.



# Recommendation #3.1b/c

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**DoD should:**

- 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.**



# Recommendation #3.1d/e

**DoD should:**

- 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. This will 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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# **DIAGNOSIS OF POST-DEPLOYMENT PULMONARY DISEASE**



# Diagnosis of Pulmonary Disease

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- A uniform, systematic approach to the diagnosis of pulmonary disease is desirable.
- Multiple algorithms are currently proposed including those by professional groups like the American Thoracic Society.
- Some have advocated for a more aggressive use of lung biopsy to provide a diagnosis that would facilitate a disability determination.
- A lung biopsy, like any invasive procedure, is associated with a degree of risk.





# Finding #4

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- 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) Diagnosing diseases of the small airways in the absence of objective findings on non-invasive testing may be challenging.
- c) While surgical lung biopsy may provide a histopathological diagnosis, it may or may not inform treatment or prognosis.



# Recommendation #4.1

(1 of 4)

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**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 3 months duration using a summary of approaches reviewed is included below as a reasonable starting point.**



# Recommendation #4.1

(2 of 4)

## 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
- Compare results with any previous available records, **such as spirometry**



# Recommendation #4.1

(3 of 4)

## Tier 2)

- **Spirometry with bronchodilators or methacholine challenge**
- **Lung volumes and diffusion studies**
- **Consider laryngoscopy (rest or exercise)**
- **Consider echocardiogram**

## 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 pulse oximetry**
- **Consider specific blood tests depending on differential diagnosis**



# Recommendation #4.1

(4 of 4)

## 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 or 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

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- 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.



# Recommendation #5.1

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**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 International Classification of Disease coding.****

**Evidence Level: III**

# **SURVEILLANCE FOR DEPLOYMENT-RELATED PULMONARY DISEASE**





# Enhanced Particulate Matter Surveillance Program: PM Exceeded Standards at All Sites

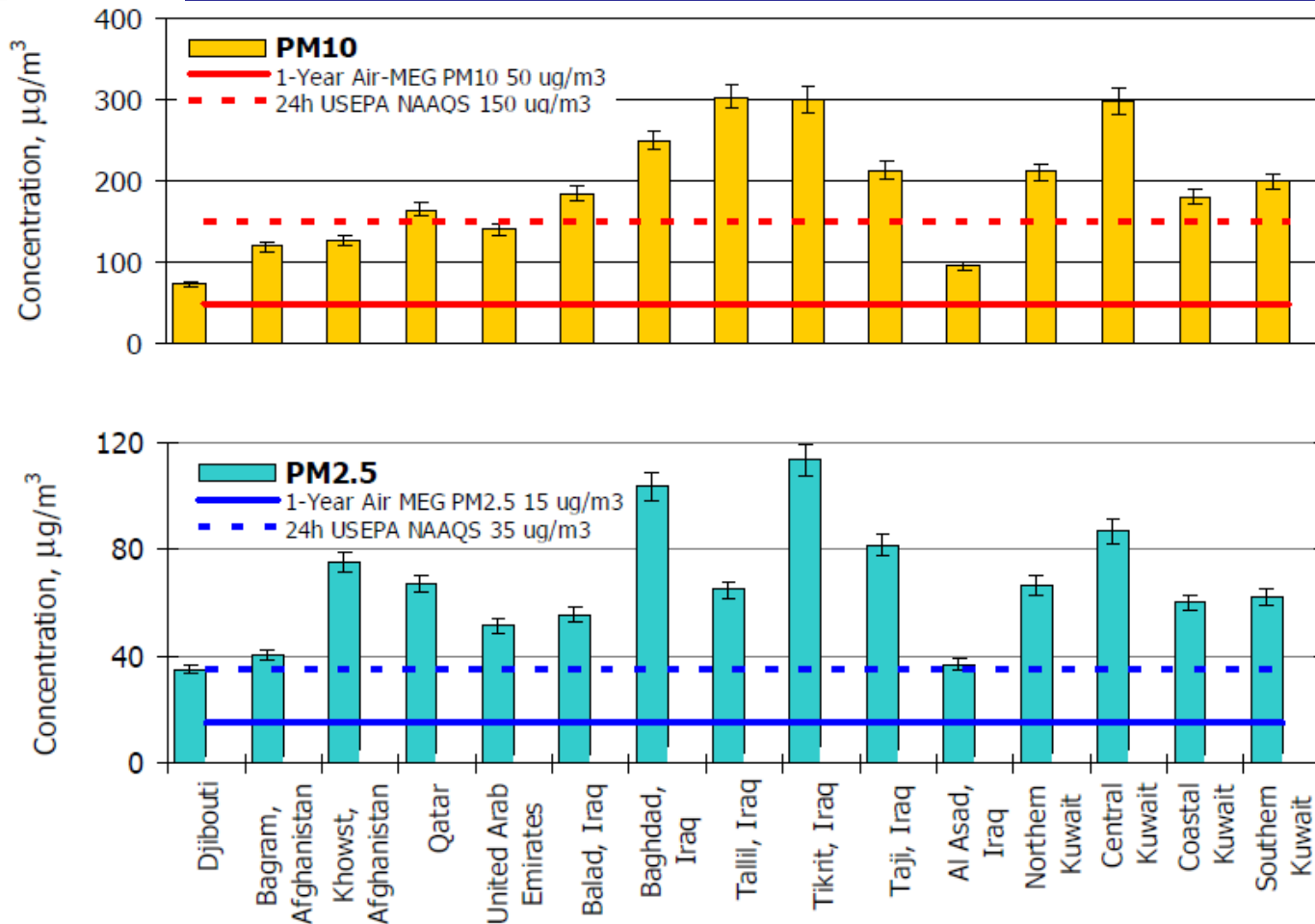


Figure 4-1. Averaged particulate mass concentrations and uncertainties for TSP, PM<sub>10</sub>, and PM<sub>2.5</sub> on Teflon® filters for each of the 15 sites. Averaging period is approximately one year.



# Surveillance

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- 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.
- A variety of DoD assets have this as part of their mission.
- Some of these efforts are compromised by a lack of **individual exposure and** location data for personnel.



# Location-Specific Environmental Exposures



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# Without Specific Coordinates, the Epidemiology is Insensitive to Location Specific Risks





# In Other Words

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- If a disease has a background incidence of  $1/10,000$ ; in a sample of 100,000 you would expect 10 cases = background incidence.
- If 1,000 of those individuals were assigned to a burn pit and had a 10-fold increased incidence ( $1/1,000$ ) they would only add 1 case to the background number of 10.
- There would be no statistical difference between a total of 10 cases and 11 cases.



# Finding #6

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- a) Deployment-related epidemiologic studies are compromised by the 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 #6.1a

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## 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.**



# Recommendation #6.1b

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**DoD should:**

- b) Develop a mechanism to allow investigators to expeditiously **declassify** 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 declassification of individual location data to support epidemiologic research and surveillance.**





# Finding #7

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



# Recommendation #7.1

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**DoD should conduct routine analyses of aggregate **symptom** response data from pre-deployment health assessment, post-deployment 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

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Clinical and epidemiologic researchers have reported that inaccuracy **and inconsistency** in International Classification of Disease (ICD) coding of medical encounters has impeded efforts to conduct **deployment-related pulmonary health** surveillance and research.



# Recommendation #8.1

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**DoD should investigate **and implement** mechanisms to improve International Classification of Disease 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**

# **DEPLOYMENT PULMONARY HEALTH REGISTRIES**



# Registries

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- A registry can be 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.”
- There are currently several registries related to deployment pulmonary health.
- The Vision Center of Excellence has developed a joint DoD/VA registry which may provide development lessons.



# Finding #9

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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.



# Recommendation #9.1

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**DoD should implement an enterprise-wide clinical registry of deployment-related chronic pulmonary symptoms or disease. This registry should incorporate the Study of Active Duty Military for Pulmonary Disease related to Environmental Dust Exposure (STAMPEDE) registry, reach out to other registries, and provide a mechanism for including cases evaluated at the VA and civilian institutions. **The Defense and Veterans Eye Injury and Vision Registry might be used as a starting point in determining an appropriate model.****

**Evidence Level: III**



**DEPLOYMENT  
PULMONARY HEALTH  
RESEARCH ACTIVITIES**



# Research

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- An array of deployment pulmonary health research activities are taking place in the DoD and VA ranging from epidemiologic studies to basic research.
- Despite an impressive level of effort there are several key questions that are not being addressed and overall coordination was not clear.
- Multiple challenges to conducting research were reported to the Subcommittee.



# 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 loss 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. Loss to follow-up is also a concern with this study.



# Recommendation #10.1

(1 of 2)

## 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.



# Recommendation #10.1

(2 of 2)

## DoD should:

- 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 deployment-related chronic pulmonary symptoms and/or disease within the Millennium Health Cohort.**

**Evidence Level: III**

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# Finding #11

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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.



# Recommendation #11.1

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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

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- 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 IRB system does not allow investigators to review descriptions of ongoing research from outside of their own location.





# Recommendation #12.1

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## DoD should:

- a) **Designate a single office with the authority to determine priorities and allocate or re-allocate funding for the DoD deployment pulmonary health research portfolio.**
- b) **Hold, at a minimum, annual meetings with investigators to discuss 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 Institutional Review Board system so that any authorized investigator at any site can review, at a minimum, titles and abstracts of all submitted and approved research projects.**



# Finding #13

(1 of 3)

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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.



# Recommendation #13.1

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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 or 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 particulate matter such as Southwest Asia.

**Evidence Level: III**



# Finding #14

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Despite the substantial number of publications describing the elevated levels of particulate matter (PM) in Southwest Asia, there is limited research on personal respiratory protective equipment (PPE) specifically for PM for military field use.



# Recommendation #14.1

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**DoD should continue research to develop personal respiratory protective equipment appropriate for field or combat use to reduce particulate matter exposures.**

**Evidence Level: III**

# **DEPLOYMENT-RELATED PULMONARY DISEASE PREVENTION**



# Prevention

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- Prevention may be classified as:
  - Primary: Preventing initial development of disease
  - Secondary: Early detection of disease
  - Tertiary: Reducing the impact of disease
  
- While environmental pollutants may contribute to a decline in pulmonary status, the one clearly definable target for primary prevention is smoking cessation.



# 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.
- b) The percentage of Service members who smoke is higher than in the general population, thereby increasing their risk for development of these diseases.
- c) The MHS has a number of initiatives in this area and has prioritized supporting smoking cessation and prevention of initiation. **Effective, evidence-based** tobacco cessation efforts would help reduce preventable morbidities in Service members.





# Recommendation #15.1

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**DoD should provide evidence-based tobacco cessation programs, periodically review the effectiveness of those programs, and continue to reduce acceptance of tobacco use (e.g., 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. 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.



# Recommendation #16.1

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**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 personal protective equipment to reduce hazardous exposures, such as high particulate matter levels.**
- c) **Improve enforcement of existing regulations on the operation of open burn pits and improve overall waste management.**

**Evidence Level: III**

**PREDECISIONAL**



# Finding #17

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- 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.



# Recommendation #17.1

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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**



# Closing Remarks

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“Even if there is no association between deployment and a disease it does not mean that a soldier does not have a disease”

Daniel Sullivan

President and General Manager

Sergeant Thomas Joseph Sullivan Center

DoD/VA Workshop on Airborne Hazards

August 13, 2013