

4



THE ASSISTANT SECRETARY OF DEFENSE

**1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200**

MAY 12 2016

HEALTH AFFAIRS

MEMORANDUM FOR PRESIDENT, DEFENSE HEALTH BOARD

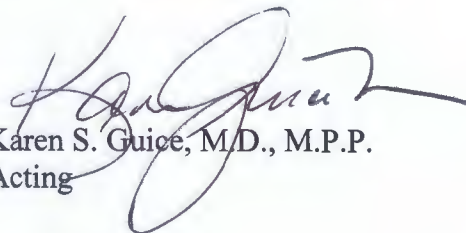
SUBJECT: Final Response to the Defense Health Board Report

Thank you for the Defense Health Board report summarizing the findings and recommendations regarding "Deployment Pulmonary Health." We greatly appreciate the in-depth information and recommendations to enable us to consider approaches to assessment, prevention, research, and surveillance of deployment-related pulmonary disease.

We provided an interim response on October 21, 2015, indicating we were working closely with the military Services to consider how best to revise our policies and adjust our procedures based on assessment of the recommendations within the report.

The enclosed response addresses each of the recommendations within the report. We concur with the majority of the recommendations and will proceed to implement policy and procedural changes, as necessary, to assess, enhance, and sustain the pulmonary health of our Service members and Department of Defense civilians.

We sincerely thank the Board members for an excellent report and their continued support to the mission to protect the health of our Service members and veterans.



Karen S. Guice, M.D., M.P.P.
Acting

Enclosure:
As stated

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

Defense Health Board (DHB) Recommendation 1: The Department of Defense (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.

DoD Response: Partially Concur. The DoD is implementing a new Periodic Health Assessment (PHA) program to standardize and optimize all annual and deployment-related health assessments. Service members will complete an annual, web-based PHA self-assessment which includes detailed questions on medical and behavioral health conditions, including questions related to respiratory health (wheezing, shortness of breath, difficulty breathing) and tobacco product usage (all types, duration and frequency of use, desire to quit). Deployed Service members will continue to complete deployment-related health assessments with similar questions depending on the date of the last completed PHA. The periodicity of these recurring Service member self-assessments and subsequent reviews and encounters with a health care provider will allow for individual comparison of symptoms and health conditions prior to and following a deployment.

DHB Recommendation 2: The DoD should work with the Department of Veterans Affairs (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.

DoD Response: Concur. The DoD will initiate collaboration with the VA to pursue development of a clinical practice guideline which will include a standardized pulmonary questionnaire.

DHB Recommendation 3(a): The DoD should:

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 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.

DoD Response: Concur. The DoD will assess spirometry quality assurance practices within a select number of Service occupational medicine and pulmonary health programs.

DHB Recommendation 3(b) and 3(c): 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.

DoD Response: Partially concur. The DoD will assess the feasibility of establishing a centralized database for occupational spirometry results within the functionality of the new electronic health record.

DHB Recommendation 3(d): The DoD should:

(d) Based on the results from Recommendation 3(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 help inform the feasibility of obtaining high-quality pre-deployment baseline spirometry on a wider scale.

DoD Response: Concur. The DoD recently completed the Study of Active Duty Military for Pulmonary Disease Related to Environmental Dust Exposure (STAMPEDE II) research at Fort Hood, Texas. The STAMPEDE II study focused on pre- and post-deployment spirometry and other pulmonary function diagnostics for a large cohort of deploying soldiers. The DoD will analyze the results of the STAMPEDE II study to determine whether additional studies would be useful in determining the feasibility of pre-deployment baseline spirometry on a wider scale.

DHB Recommendation 3(e): The DoD should:

(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.

DoD Response: Partially concur. The DoD does not support large-scale pre-deployment baseline spirometry based on the inherent difficulty of determining significant risks of exposure to potential pulmonary hazards prior to deployment. Furthermore, it is expected most individuals with abnormal pre-deployment spirometry results will be normal variants without significant pulmonary disease. The DoD will assess an approach which conducts pre-deployment baseline spirometry for Service members with known pre-existing pulmonary conditions and disease. This approach will focus on establishing baseline and monitoring for chronic changes in targeted (pre-disposed) Service members prior to and after deployment.

DIAGNOSIS OF PULMONARY DISEASE.

DHB 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.

DoD Response: Concur. The DoD generally agrees with the diagnostic approach provided with this recommendation.

DHB Recommendation 5: The 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 Diseases (ICD) coding.

DoD Response: Concur. The DoD will initiate collaboration with the VA to pursue development of a clinical practice guideline which will include a standardized pulmonary questionnaire.

SURVEILLANCE FOR DEPLOYMENT-RELATED DISEASE

DHB Recommendation 6(a): The 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.

DoD Response: Concur.

DHB Recommendation 6(b): The DoD should:

(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.

DoD Response: Concur. The DoD will develop a mechanism to declassify and provide individual deployment location data and other demographic information to facilitate determination of deployed populations at risk, exposure-related epidemiological studies and research, development of individual longitudinal exposure records

DHB Recommendation 7: The 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.

DoD Response: Concur. The DoD, through the Armed Forces Health Surveillance Branch of the Defense Health Agency Public Health Division, will begin routine analyses and reporting of pulmonary symptom data reported on post-deployment health assessment and reassessment forms.

Recommendation 8: The 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.

DoD Response: Concur. The conversion to ICD-10 coding provides additional codes for pulmonary symptomology and disease. The DoD will assess the capabilities of the new EHR under development to support improved ICD coding.

DEPLOYMENT PULMONARY HEALTH REGISTRIES

DHB Recommendation 9: The 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 Defense and Veterans Eye Injury and Vision Registry might be used as a starting point in determining an appropriate model.

DoD Response: Partially concur. The DoD will assess the feasibility of establishing an enterprise-wide clinical registry. In the near-term, the DoD will also consider incremental implementation of a broader clinical registry through the ongoing STAMPEDE III Comprehensive Evaluation study.

DEPLOYMENT PULMONARY HEALTH RESEARCH ACTIVITIES

Recommendation 10(a): The 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.

DoD Response: Concur. Data potentially linking disease and symptoms with exposure is still being analyzed in the STAMPEDE studies and the Millennium Cohort study. Once the data has been analyzed, it may be possible to develop testable hypotheses.

Recommendation 10(b): The DoD should:

(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.

DoD Response: Concur. A study is funded to begin in Fiscal Year (FY) 2016 at Walter Reed National Military Medical Center.

Recommendation 10(c): The 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.

DoD Response: Concur. The STAMPEDE studies will be funded at stable levels through FY 2017.

Recommendation 10(d): The DoD should:

(d) Provide resources necessary to conduct further studies of deployment-related chronic pulmonary symptoms and/or disease within the Millennium Health Cohort.

DoD Response: Concur. A three-year study of the Millennium Cohort to re-evaluate chronic respiratory symptoms/disease associated with deployment is underway.

DHB Recommendation 11: The 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.

DoD Response: Partially concur. The DoD will collaborate with the VA to assess the scope and requirements for the prospective study, then proceed forward in development of the research protocol if determined feasible.

DHB Recommendation 12(a): The 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.

DoD Response: Concur. The office with the authority to determine priorities and funding for deployment-related pulmonary health research is the Military Operational Medicine Research Program at (MOMRP) at the U.S Army Medical Research and Materiel Command. The MOMRP has oversight of the deployment-related pulmonary health research portfolio, and as such, manages the majority of DoD-funded research in this area.

DHB Recommendation 12(b): The DoD should:

(b) Hold, at minimum, annual meetings with investigators and other subject matter experts to discuss deployment pulmonary health research.

DoD Response: Concur. The DoD conducts, at a minimum, annual meetings within the DoD research community to discuss current and projected research projects related to deployment pulmonary health. In addition, the annual VA/DoD Airborne Hazard Symposium led to the establishment of the VA/DoD Airborne Hazards Joint Action Plan. The plan, which includes completed, current and planned deployment health studies, is updated periodically through meetings of VA and DoD researchers.

DHB Recommendation 12(c): The DoD should:

(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.

DoD Response: Concur. The DoD will assess the possibility of creating a web portal within the Military Operational Medicine Research Program which would list the relevant past, present and upcoming research projects related to deployment pulmonary health.

DHB Recommendation 12(d): The DoD should:

(d) Link DoD's electronic Institutional Review Board 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.

DoD Response: Non-concur. The establishment of a web portal (recommendation 12c) is the preferred mechanism for sharing information on deployment pulmonary health-related research activities.

DHB Recommendation 13: The 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 particulate matter (PM) such as Southwest Asia.

DoD Response: Concur. An initial retrospective study, titled "Pathological Diagnoses of Deployed Military Personnel with Pulmonary Disease," has been completed and is being submitted for publication. The study included 375 service members, of which 137 (36.5%) deployed to Southwest Asia prior to biopsy. Construction of a database of all pulmonary specimens at the Joint Pathology Center is nearly complete. The database will be analyzed for diagnoses among deployed, non-deployed, and non-military patients.

DHB Recommendation 14: The DoD should continue research to develop respiratory personal protective equipment (PPE) appropriate for field or combat use to reduce PM exposures.

DoD Response: Concur. The DoD is funding respiratory PPE research through the Small Business Innovation Research Program.

DEPLOYMENT-RELATED PULMONARY DISEASE PREVENTION

DHB Recommendation 15: The 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.

DoD Response: Concur. The DoD emphasizes tobacco cessation through a combination of policy, programs, command leadership, education and other practices.

DHB Recommendation 16(a): The DoD should:

(a) Continue efforts to better characterize (quantitatively and qualitatively) and minimize potentially harmful environmental and occupational exposures.

DoD Response: Concur.

DHB Recommendation 16(b): The DoD should:

(b) Continue efforts to develop better and more effective PPE to reduce hazardous exposures to things such as high PM levels.

DoD Response: Concur. The DoD is funding respiratory PPE research through the Small Business Innovation Research Program.

DHB Recommendation 16(c): The DoD should:

(c) Improve enforcement of existing regulations on the operation of open burn pits and improve overall waste management.

DoD Response: Concur. The Undersecretary of Defense for Acquisition, Technology, and Logistics is the DoD proponent for solid waste management and open burn pit policy. The Combatant Commands are responsible for enforcement of the policy within their operational areas.

DHB 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.

DoD Response: Concur. The DoD will continue collaboration with the VA through existing partnership offices to assess the delivery of services related to chronic pulmonary symptoms and disease, identify opportunities for improvement, and work closely together to implement required processes to improve overall outcomes.